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

ABBVIE INC., ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED, and MERCK SHARP & DOHME LLC, Plaintiffs, v. AUROBINDO PHARMA U.S.A., INC., AUROBINDO PHARMA LIMITED, and APITORIA PHARMA PRIVATE LIMITED, Defendants.	Civil Action No. 3:24-cv-04403-ZNQ-JBD

DEFENDANTS AUROBINDO PHARMA U.S.A., INC., AUROBINDO PHARMA LIMITED, AND APITORIA PHARMA PRIVATE LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' THIRD AMENDED COMPLAINT

Defendants Aurobindo Pharma U.S.A., Inc. ("Aurobindo USA"), Aurobindo Pharma Limited ("Aurobindo Pharma"), and Apitoria Pharma Private Limited ("Apitoria") (collectively, "Aurobindo"), by and through their undersigned counsel, file this Answer, Affirmative Defenses, and Counterclaims to Plaintiffs AbbVie Inc. ("AbbVie"), Allergan Pharmaceuticals International Limited ("Allergan"), and Merck Sharp & Dohme LLC's ("Merck") (collectively, "Plaintiffs") Third Amended Complaint, and state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Aurobindo denies all allegations in Plaintiffs' Third Amended Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 10,117,836 ("the '836 patent"), 11,717,515 ("the '515 patent"), 11,857,542 ("the '542 patent"), 11,925,709 ("the '709 patent"), 12,070,450 ("the '450 patent"), 12,168,004 ("the '004 patent"), 12,194,030 ("the '030 patent"), 12,220,408 ("the '408 patent"), 12,310,953 ("the '953 patent"), and 12,329,750 ("the '750 patent") (collectively, "the Patents-in-Suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et seq.*, and in particular under 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This action relates to Aurobindo's recent submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to market generic versions of Plaintiffs' commercial pharmaceutical product UBRELVY® (ubrogepant) oral tablets in 50 mg and 100 mg dosage forms ("UBRELVY® Tablets") submitted under New Drug Application ("NDA") No. 211765, prior to the expiration of patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for UBRELVY® Tablets. Aurobindo has submitted ANDA No. 219088 ("Aurobindo's ANDA"), which seeks approval to market its generic version of UBRELVY® Tablets, ubrogepant oral tablets, 50 mg, 100 mg ("Aurobindo's generic products"), prior to the expiration of the Patents-in-Suit.

ANSWER: Aurobindo admits that Plaintiffs filed a civil action alleging that Aurobindo infringed U.S. Patent Nos. 10,117,836 ("the '836 patent"), 11,717,515 ("the '515 patent"), 11,857,542 ("the '542 patent"), 11,925,709, ("the '709 patent"), 12,070,450 ("the '450 patent"), 12,168,004 ("the '004 patent"), 12,194,030 ("the '030 patent"), 12,220,408 ("the '408 patent"),

12,310,953 ("the '953 patent"), and 12,329,750 ("the '750 patent") (collectively, "the Patents-in-Suit") under the patent laws of the United States, Title 35, United States Code. Aurobindo admits that it had filed Abbreviated New Drug Application ("ANDA") No. 219088 with the U.S. Food and Drug Administration ("FDA"). Except as expressly admitted, Aurobindo is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 1, and on that basis denies these allegations.

> 2. Aurobindo has infringed one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 219088 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's generic products prior to the expiration of the Patents-in-Suit, or any extensions thereof. Aurobindo will infringe one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Aurobindo's generic products prior to the expiration of the Patents-in-Suit, or any extensions thereof.

ANSWER: Paragraph 2 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 2.

THE PARTIES

> 3. Plaintiff AbbVie is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie holds NDA No. 211765 for UBRELVY® Tablets.

ANSWER: Paragraph 3 contains legal conclusions to which no answer is required. To the extent that Aurobindo is required to answer, on information and belief, Aurobindo admits that AbbVie is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. Aurobindo admits that the FDA publication, the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), lists AbbVie as the holder of NDA No. 211765 for UBRELVY® Tablets. Except as expressly admitted, Aurobindo is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 3, and on that basis denies these allegations.

4. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including migraine treatment.

ANSWER: Aurobindo is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 4 and therefore denies the allegations.

5. AbbVie markets, distributes, and sells therapeutic drug products, including UBRELVY® Tablets, in this judicial district and throughout the United States.

ANSWER: Aurobindo is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 5 and therefore denies the allegations.

6. Plaintiff Allergan is a corporation organized and existing under the laws of Ireland, with a principal place of business at Clonshaugh Business & Technical Park, Dublin 17, Ireland D17 E400. Allergan is the assignee of the '515, '542, '450, '030, and '750 patents and the exclusive licensee of the '836, '709, '004, '408, and '953 patents. Allergan is an indirectly wholly owned subsidiary of AbbVie.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent that Aurobindo is required to answer, on information and belief, Aurobindo admits that Allergan is a corporation organized and existing under the laws of Ireland, with a principal place of business at Clonshaugh Business & Technical Park, Dublin 17, Ireland D17 E400. Aurobindo admits that the face of the '515, '542, '450, '030, and '750 patents indicate that Allergan is the assignee of the '515, '542, '450, '030, and '750 patents. Except as expressly admitted, Aurobindo is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 6, and on that basis denies these allegations.

7. Plaintiff Merck is a limited liability company organized and existing under the laws of the State of New Jersey, having a principal place of business at 126 Lincoln Avenue, Rahway, New Jersey 07065. Merck is the assignee of the '836, '709, '004, '408, and '953 patents.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent that Aurobindo is required to answer, on information and belief, Aurobindo admits that

Merck is a limited liability company organized and existing under the laws of the State of New Jersey, having a principal place of business at 126 Lincoln Avenue, Rahway, New Jersey 07065. Aurobindo admits that the face of the '836, '709, '004, '408, and '953 patents indicate that Merck is the assignee of the '836, '709, '004, '408, and '953 patents. Except as expressly admitted, Aurobindo is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 7, and on that basis denies these allegations.

8. Merck is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve health.

ANSWER: Aurobindo is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 8 and therefore denies the allegations.

9. Plaintiffs allege the following about Aurobindo on information and belief formed after a reasonable inquiry.

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

10. Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520. It is a wholly owned subsidiary of Aurobindo Pharma.

ANSWER: Aurobindo admits that Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520, and that Aurobindo USA is a wholly owned subsidiary of Aurobindo Pharma.

11. Aurobindo Pharma is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

ANSWER: Aurobindo admits that Aurobindo Pharma is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

12. Apitoria, formerly known as Auro Pharma India Private Limited, is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 1, Survey No. 83/1 Hyderabad Knowledge City, Panmaktha, Rai Durg, Hyderabad, 500032, India. It is a wholly owned subsidiary of Aurobindo Pharma.

ANSWER: Aurobindo admits that Apitoria, formerly known as Auro Pharma India Private Limited, is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 1, Survey No. 83/1 Hyderabad Knowledge City, Panmaktha, Rai Durg, Hyderabad, 500032, India, and that Apitoria is a wholly owned subsidiary of Aurobindo Pharma.

13. Aurobindo is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

ANSWER: Paragraph 13 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 remaining allegations of Paragraph 13.

14. Following any FDA approval of Aurobindo's ANDA, Aurobindo will distribute and sell the proposed Aurobindo generic products described in Aurobindo's ANDA throughout the United States, including in this judicial district.

ANSWER: Aurobindo's ANDA has not yet been tentatively or finally approved by the FDA and the allegations of Paragraph 14 are wholly speculative. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 14.

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 15.

16. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

17. This Court has personal jurisdiction over Defendant Aurobindo USA. On information and belief, Aurobindo USA is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Aurobindo USA directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Aurobindo USA has purposefully conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Aurobindo's generic products upon approval of Aurobindo's ANDA.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no 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 remaining allegations of Paragraph 17.

18. This Court has personal jurisdiction over Defendant Aurobindo Pharma. On information and belief, Aurobindo Pharma is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Aurobindo Pharma directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Aurobindo Pharma has purposefully conducted and continues to conduct business in this judicial

district, and this judicial district is a likely destination of Aurobindo's generic products upon approval of Aurobindo's ANDA.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no 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 remaining allegations of Paragraph 18.

19. This Court has personal jurisdiction over Defendant Apitoria. On information and belief, Apitoria is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Apitoria directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Apitoria has purposefully conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Aurobindo's generic products upon approval of Aurobindo's ANDA.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no 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 remaining allegations of Paragraph 19.

20. On information and belief, Aurobindo USA is a United States agent for Aurobindo Pharma. Aurobindo USA "is a wholly owned subsidiary of [Aurobindo Pharma]." Aurobindo Pharma, Financial Statements of Subsidiaries of Aurobindo Pharma Limited for the Financial Year 2022-23, 1423 (2023), https://www.aurobindo.com/api/uploads/FS-Subsidiaries%20of%20APL_2022-23.pdf ("Subsidiary 2023 Report") (last visited Mar. 29, 2024).

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. The Subsidiary 2023 Report speaks for itself. Aurobindo does not contest personal jurisdiction in this Court for the limited purposes of this action only. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 20.

21. On information and belief, Apitoria is the holder of FDA Drug Master File No. 38648 for ubrogepant.

ANSWER: Aurobindo admits that Apitoria is the holder of FDA Drug Master File No. 38648 for ubrogepant. Except as expressly admitted, Aurobindo is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 21, and on that basis denies these allegations.

> 22. On information and belief, Aurobindo USA, Aurobindo Pharma, and Apitoria hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

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

> 23. Aurobindo USA, Aurobindo Pharma, and Apitoria each directly or indirectly currently sells significant quantities of generic drug products and derives substantial revenue from the sale of those products in the United States and in this judicial district. According to its Subsidiary 2023 Report, "[Aurobindo Pharma] and its subsidiaries develop, manufacture, market and distribute generic and branded prescription and over-the-counter pharmaceuticals to a wide range of wholesalers, distributors and retailers throughout the United States." *Id.*

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. The Subsidiary 2023 Report speaks for itself. Aurobindo does not contest personal jurisdiction in this Court for the limited purposes of this action only. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 23.

> 24. According to the Aurobindo 2023 Report, Aurobindo Pharma "ranks #1 in terms of prescription share and has a presence across orals, injectables, OTC and branded Oncology segments" in the United States. Aurobindo Pharma, Integrated Annual Report 2022-23, 14 (2023), https://www.aurobindo.com/api/uploads/annualreports/AurobindoIR22-23_IR_Final_Web.pdf ("Aurobindo 2023 Report") (last visited Mar. 29, 2024). During the 2022-23 fiscal year, Aurobindo Pharma claims to have "launched 34 products within the US formulations segment, including 17 injectable products." *Id.* at 130. Aurobindo Pharma also claims that the "US market

is the dominant market globally for [Aurobindo Pharma] with around 45-50% of the revenue coming from the US." *Id.* at 137.

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. The Aurobindo 2023 Report speaks for itself. Aurobindo does not contest personal jurisdiction in this Court for the limited purposes of this action only. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 24.

25. Aurobindo Pharma is engaged in the submission and approval of ANDAs for the United States market, claiming that it is "one of the most frequent filers of . . . ANDA[s] in the United States." *Id.* at 13. Aurobindo Pharma claims to have "774 ANDA filings as [of] 31st March '23, including 565 final approvals." *Id.* at 14. Aurobindo Pharma claims to have "[f]iled 49 ANDAs with USFDA" and "[r]eceived final approval for 59 ANDAs from USFDA" during its 2022-23 fiscal year. *Id.* at 129.

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. The Aurobindo 2023 Report speaks for itself. Aurobindo does not contest personal jurisdiction in this Court for the limited purposes of this action only. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 25.

26. On information and belief, the acts of Aurobindo USA and Apitoria complained of herein were done with the cooperation, participation, and assistance of Aurobindo Pharma.

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. Aurobindo does not contest personal jurisdiction in this Court for the limited purposes of this action only. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 26.

27. Aurobindo's ANDA filing regarding the Patent-in-Suit relates to this litigation and is substantially connected with this judicial district because it predicts Aurobindo's intent to market and sell Aurobindo's generic products in this judicial district.

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. Aurobindo's ANDA has not yet been tentatively or finally approved by the FDA and

the allegations of Paragraph 27 are wholly speculative. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 27.

28. On information and belief, Aurobindo USA, Aurobindo Pharma, and Apitoria have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 219088.

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 28.

29. Following FDA approval of ANDA No. 219088, Aurobindo will act in concert to import, market, distribute, offer for sale, and/or sell Aurobindo's generic products described in ANDA No. 219088 throughout the United States, including in New Jersey and will derive substantial revenue from the use, consumption, or sale of Aurobindo's generic products in the state of New Jersey.

ANSWER: Aurobindo's ANDA has not yet been tentatively or finally approved by the FDA and the allegations of Paragraph 29 are wholly speculative. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 29.

30. If ANDA No. 219088 is approved, Aurobindo's generic products will be marketed, distributed, offered for sale, and/or sold in New Jersey; prescribed by healthcare providers practicing in New Jersey; administered by healthcare providers located within New Jersey; and/or used by patients in New Jersey, all of which will have a substantial effect on New Jersey.

ANSWER: Aurobindo's ANDA has not yet been tentatively or finally approved by the FDA and the allegations of Paragraph 30 are wholly speculative. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 30.

31. If ANDA No. 219088 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Aurobindo's generic products, including in New Jersey.

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 31.

32. This Court also has personal jurisdiction over Aurobindo because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. Aurobindo has been sued multiple times in this district without

challenging personal jurisdiction. *See, e.g.*, Defs.' Answer to Pls.' Compl., *Axsome Malta Ltd. v. Alkem Lab'ys Ltd.*, No. 2:23-cv-20354-MCA-LDW (D.N.J. Nov. 13, 2023); Defs.' Answer to Pls.' Compl., *Theravance Biopharma R&D IP, LLC v. Eugia Pharma Specialities Ltd.*, No. 1:23-cv-06667-KMW-AMD (D.N.J. Sept. 21, 2023); Answer to Pls.' Compl., *Bausch Health Ir. Ltd. v. Aurobindo Pharma Ltd.*, No. 2:23-cv-00170-SRC-JSA (D.N.J. July 5, 2023); Answer to Pls.' Compl., *Eisai Co. v. Aurobindo Pharma Ltd.*, No. 1:22-cv- 03610-CPO-AMD (D.N.J. Sept. 23, 2022).

ANSWER: Paragraph 32 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. Prior consent to personal jurisdiction in this Court has no bearing on this action. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 32.

33. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Aurobindo.

ANSWER: Paragraph 33 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 remaining allegations of Paragraph 33.

34. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Aurobindo USA has a principal place of business in New Jersey.

ANSWER: Paragraph 34 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 remaining allegations of Paragraph 34.

35. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Aurobindo Pharma is incorporated in the Republic of India and may be sued in any judicial district in the United States.

ANSWER: Paragraph 35 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 remaining allegations of Paragraph 35.

36. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Apitoria is incorporated in the Republic of India and may be sued in any judicial district in the United States.

ANSWER: Paragraph 36 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 remaining allegations of Paragraph 36.

FACTUAL BACKGROUND

UBRELVY® and the NDA

37. AbbVie is the holder of the New Drug Application ("NDA") No. 211765 for UBRELVY® (ubrogepant) tablets in 50 mg and 100 mg dosages forms.

ANSWER: Aurobindo admits that the Orange Book lists AbbVie as the holder of NDA No. 211765 for UBRELVY® (ubrogepant) tablets in 50 mg and 100 mg dosages forms. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 37.

38. The FDA approved NDA No. 211765 on December 23, 2019.

ANSWER: Upon information and belief, according to publicly available information, Aurobindo admits that the FDA approved NDA No. 211765 on December 23, 2019. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 38.

39. The FDA Orange Book for NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg, lists U.S. Patent No. 8,754,096 ("the '096 patent"); U.S. Patent No. 8,912,210 ("the '210 patent"); U.S. Patent No. 9,499,545 ("the '545 patent"); U.S. Patent No. 9,833,448 ("the '448 patent"); the '836 patent; the '515 patent; the '542 patent; the '709 patent; the '450 patent; the '004 patent; and the '030 patent.

ANSWER: Aurobindo admits that the Orange Book for NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg, lists U.S. Patent No. 8,754,096 ("the '096 patent"); U.S. Patent No. 8,912,210 ("the '210 patent"); U.S. Patent No. 9,499,545 ("the '545 patent"); U.S. Patent No. 9,833,448 ("the '448 patent"); the '836 patent; the '515 patent; the '542 patent; the '709 patent; the '450 patent; the '004 patent; and the '030 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 39.

> 40. UBRELVY® Tablets are approved for the acute treatment of migraine attacks with or without aura in adults. Ubrogepant is the active ingredient of UBRELVY® Tablets. Ubrogepant is a calcitonin gene-related (CGRP) receptor antagonist.

ANSWER: Aurobindo admits that the FDA-approved label for UBRELVY® Tablets states that UBRELVY® is a calcitonin gene-related peptide receptor antagonist indicated for the acute treatment of migraine with or without aura in adults. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 40.

> 41. Migraine is a debilitating disease. Migraine impacts more than 37 million men, women, and children in the United States. Migraine costs millions of dollars each year in the United States due to direct medical expenses and lost productivity. Migraine is also associated with other illnesses.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 41.

> 42. The recommended dose of UBRELVY® Tablets is 50 mg or 100 mg taken orally with or without food. If needed, a second dose may be administered at least 2 hours after the initial dose. For patients with severe hepatic impairment or severe renal impairment, the recommended dose is 50 mg. If needed, a second 50 mg dose may be taken at least 2 hours after the initial dose. The FDA approved the inclusion of this safe and effective dosing regimen for UBRELVY® for patients with severe hepatic impairment or severe renal impairment, and information concerning these patients is included in the UBRELVY® Label.

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent that Aurobindo is required to answer, on information and belief,

Aurobindo admits that the FDA-approved label for UBRELVY® states that the recommended dose is 50 mg or 100 mg taken orally with or without food. The FDA-approved label for UBRELVY® also states if needed, a second dose may be administered at least 2 hours after the initial dose. The FDA-approved label for UBRELVY® states for patients with severe hepatic impairment or severe renal impairment, the recommended dose is 50 mg. The FDA-approved label for UBRELVY® also states if needed, a second 50 mg dose may be taken at least 2 hours after the initial dose. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 42.

> 43. For patients who concomitantly use weak or moderate CYP3A4 inducers, the recommended dose is 100 mg. If needed, a second 100 mg dose may be taken at least 2 hours after the initial dose. The FDA approved the inclusion of this safe and effective dosing regimen for UBRELVY® for patients who concomitantly use weak or moderate CYP3A4 inducers, and information concerning these patients is included in the UBRELVY® Label. For patients who concomitantly use weak CYP3A4 inhibitors, the recommended dose is 50 mg. If needed, a second 50 mg dose may be taken at least 2 hours after the initial dose. For patients who concomitantly use moderate CYP3A4 inhibitors, the recommended dose is 50 mg. The UBRELVY® Label states that those patients should avoid taking a second dose within 24 hours after the initial dose. The FDA approved the inclusion of this safe and effective dosing regimen for UBRELVY® for patients who concomitantly use weak or moderate CYP3A4 inhibitors, and information concerning these patients is included in the UBRELVY® Label. For patients who concomitantly use BCRP and/or P-gp only inhibitors, the recommended dose is 50 mg. If needed, a second 50 mg dose may be taken at least 2 hours after the initial dose. The FDA approved the inclusion of this safe and effective dosing regimen for UBRELVY® for patients who concomitantly use BCRP and/or P-gp only inhibitors, and information concerning these patients is included in the UBRELVY® Label.

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 43.

> 44. To date, only two orally available CGRP receptor antagonists have been approved by FDA for acute treatment of migraine. UBRELVY® Tablets were the first. The prescribing information for the other, NURTEC® ODT, states that use of the drug should be avoided in patients with severe hepatic impairment. The prescribing information for NURTEC® ODT further states that use of the drug should be avoided in patients who concomitantly use moderate CYP3A inducers. Thus, UBRELVY® Tablets are the only orally available CGRP receptor antagonist in the United States indicated for acute treatment of migraine in patients with severe

hepatic impairment and patients who concomitantly use moderate CYP3A inducers.

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 44.

45. UBRELVY® Tablets are marketed and sold in the United States by AbbVie.

ANSWER: Aurobindo admits that UBRELVY® Tablets are marketed and sold in the United States by AbbVie. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 45.

The Patents-in-Suit

46. The '836 patent, titled "Tablet Formulation for CGRP Active Compounds," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on November 6, 2018. A true and correct copy of the '836 patent is attached as Exhibit A.

ANSWER: Aurobindo admits that the '836 patent is titled "Tablet Formulation for CGRP Active Compounds," and that the '836 patent was issued by the USTPO on or about November 6, 2018. What appears to be an uncertified copy of the '836 patent was attached to Plaintiffs' Third Amended Complaint as Exhibit A. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 46.

47. Merck is the assignee of the '836 patent through assignment as recorded by the USPTO at Reel 041662, Frame 0851; Reel 041829, Frame 0001; and Reel 061102, Frame 0145.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, Merck is the assignee of the '836 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 47.

48. The '836 patent currently expires on January 30, 2035.

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. Aurobindo admits that the Orange Book lists the expiration date of the '836 patent as

January 30, 2035. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 48.

49. Allergan is the exclusive licensee of the '836 patent.

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 49.

50. The '836 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg.

ANSWER: Aurobindo admits that the Orange Book lists the '836 patent in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 50.

51. The '515 patent, titled "Treatment of Migraine," was duly and legally issued by the USPTO on August 8, 2023. A true and correct copy of the '515 patent is attached as Exhibit B.

ANSWER: Aurobindo admits that the '515 patent is titled "Treatment of Migraine," and that the '515 patent was issued by the USTPO on or about August 8, 2023. What appears to be an uncertified copy of the '515 patent was attached to Plaintiffs' Third Amended Complaint as Exhibit B. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 51.

52. Allergan is the assignee of the '515 patent through assignment as recorded by the USPTO at Reel 063519, Frame 0307.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, Allergan is the assignee of the '515 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 52.

53. The '515 patent currently expires on December 22, 2041.

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. Aurobindo admits that the Orange Book lists the expiration date of the '515 patent as

December 22, 2041. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 53.

54. The '515 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg.

ANSWER: Aurobindo admits that the Orange Book lists the '515 patent in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 54.

55. The '542 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on January 2, 2024. A true and correct copy of the '542 patent is attached as Exhibit C.

ANSWER: Aurobindo admits that the '542 patent is titled "Treatment of Migraine," and that the '542 patent was issued by the USTPO on or about January 2, 2024. What appears to be an uncertified copy of the '542 patent was attached to Plaintiffs' Third Amended Complaint as Exhibit C. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 55.

56. Allergan is the assignee of the '542 patent through assignment as recorded by the USPTO at Reel 064076, Frame 0407.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, Allergan is the assignee of the '542 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 56.

57. The '542 patent currently expires on December 22, 2041.

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. Aurobindo admits that the Orange Book lists the expiration date of the '542 patent as December 22, 2041. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 57.

58. The ’542 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg.

ANSWER: Aurobindo admits that the Orange Book lists the ’542 patent in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 58.

59. The ’709 patent, titled “Tablet Formulation for CGRP Active Compounds,” was duly and legally issued by the United States Patent and Trademark Office on March 12, 2024. A true and correct copy of the ’709 patent is attached as Exhibit D.

ANSWER: Aurobindo admits that the ’709 patent is titled “Tablet Formulation for CGRP Active Compounds,” and that the ’709 patent was issued by the USPTO on or about March 12, 2024. What appears to be an uncertified copy of the ’709 patent was attached to Plaintiffs’ Third Amended Complaint as Exhibit D. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 59.

60. Merck is the assignee of the ’709 patent through assignment as recorded by the USPTO at Reel 061200, Frame 0836.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, Merck is the assignee of the ’709 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 60.

61. The ’709 patent currently expires on January 30, 2035.

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. Aurobindo admits that the Orange Book lists the expiration date of the ’709 patent as January 30, 2035. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 61.

62. Allergan is the exclusive licensee of the ’709 patent.

ANSWER: Paragraph 62 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 62.

63. The '709 patent will be submitted for listing in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg, 100 mg.

ANSWER: Aurobindo admits that the Orange Book lists the '709 patent in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg, 100 mg. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 63.

64. The '450 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on August 27, 2024. A true and correct copy of the '450 patent is attached as Exhibit E.

ANSWER: Aurobindo admits that the '450 patent is titled "Treatment of Migraine," and that the '450 patent was issued by the USPTO on or about August 27, 2024. What appears to be an uncertified copy of the '450 patent was attached to Plaintiffs' Third Amended Complaint as Exhibit E. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 64.

65. Allergan is the assignee of the '450 patent through assignment as recorded by the USPTO at Reel 065814, Frame 0254.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, Allergan is the assignee of the '450 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 65.

66. The '450 patent currently expires on December 22, 2041.

ANSWER: Paragraph 66 contains legal conclusions and allegations to which no answer is required. Aurobindo admits that the Orange Book lists the expiration date of the '450 patent as December 22, 2041. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 66.

67. The ’450 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 100 mg.

ANSWER: Aurobindo admits that the Orange Book lists the ’450 patent in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 100 mg. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 67.

68. The ’004 patent, titled “Treatment of Migraine,” was duly and legally issued by the United States Patent and Trademark Office on December 17, 2024. A true and correct copy of the ’004 patent is attached as Exhibit F.

ANSWER: Aurobindo admits that the ’004 patent is titled “Treatment of Migraine,” and that the ’004 patent was issued by the USPTO on or about December 17, 2024. What appears to be an uncertified copy of the ’004 patent was attached to Plaintiffs’ Third Amended Complaint as Exhibit F. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 68.

69. Merck is the assignee of the ’004 patent through assignment as recorded by the USPTO at Reel 069116, Frame 0667.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, Merck is the assignee of the ’004 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 69.

70. The ’004 patent currently expires on January 30, 2035.

ANSWER: Paragraph 70 contains legal conclusions and allegations to which no answer is required. Aurobindo admits that the Orange Book lists the expiration date of the ’004 patent as January 30, 2035. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 70.

71. Allergan is the exclusive licensee of the ’004 patent.

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 71.

72. The ’004 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg, 100 mg.

ANSWER: Aurobindo admits that the Orange Book lists the ‘004 patent in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg, 100 mg. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 72.

73. The ’030 patent, titled “Treatment of Migraine,” was duly and legally issued by the United States Patent and Trademark Office on January 14, 2025. A true and correct copy of the ’030 patent is attached as Exhibit G.

ANSWER: Aurobindo admits that the ’030 patent is titled “Treatment of Migraine,” and that the ’030 patent was issued by the USPTO on or about January 14, 2025. What appears to be an uncertified copy of the ’030 patent was attached to Plaintiffs’ Third Amended Complaint as Exhibit G. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 73.

74. Allergan is the assignee of the ’030 patent through assignment as recorded by the USPTO at Reel 068953, Frame 0640.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, Allergan is the assignee of the ’030 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 74.

75. The ’030 patent currently expires on December 22, 2041.

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. Aurobindo admits that the Orange Book lists the expiration date of the ’030 patent as December 22, 2041. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 75.

76. The ’030 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg.

ANSWER: Aurobindo admits that the Orange Book lists the '030 patent in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 76.

77. The '408 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on February 11, 2025. A true and correct copy of the '408 patent is attached as Exhibit H.

ANSWER: Aurobindo admits that the '408 patent is titled "Treatment of Migraine," and that the '408 patent was issued by the USPTO on or about February 11, 2025. What appears to be an uncertified copy of the '408 patent was attached to Plaintiffs' Third Amended Complaint as Exhibit H. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 77.

78. Merck is the assignee of the '408 patent through assignment as recorded by the USPTO at Reel 069185, Frame 0001.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, Merck is the assignee of the '408 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 78.

79. The '408 patent currently expires on January 30, 2035.

ANSWER: Paragraph 79 contains legal conclusions and allegations to which no answer is required. Aurobindo admits that the Orange Book lists the expiration date of the '408 patent as January 30, 2035. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 79.

80. The '408 patent covers the UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg product, NDA No. 211765, in the FDA Orange Book.

ANSWER: Aurobindo admits that the Orange Book lists the '408 patent in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 80.

81. The ’953 patent, titled “Pharmaceutical Formulations for the Treatment of Migraine,” was duly and legally issued by the United States Patent and Trademark Office on May 27, 2025. A true and correct copy of the ’953 patent is attached as Exhibit I.

ANSWER: Aurobindo admits that the ’953 patent is titled “Pharmaceutical Formulations for the Treatment of Migraine,” and that the ’953 patent was issued by the USPTO on or about May 27, 2025. What appears to be an uncertified copy of the ’953 patent was attached to Plaintiffs’ Third Amended Complaint as Exhibit I. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 81.

82. Merck is the assignee of the ’953 patent through assignment as recorded by the USPTO at Reel 069494, Frame 0051.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, Merck is the assignee of the ’953 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 82.

83. The ’953 patent currently expires on January 30, 2035.

ANSWER: Paragraph 83 contains legal conclusions and allegations to which no answer is required. Aurobindo admits that the Orange Book lists the expiration date of the ’953 patent as January 30, 2035. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 83.

84. The ’953 patent covers the UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg product, NDA No. 211765, in the FDA Orange Book.

ANSWER: Aurobindo admits that the Orange Book lists the ‘953 patent in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 84.

85. The ’750 patent, titled “Treatment of Migraine,” was duly and legally issued by the United States Patent and Trademark Office on June 17, 2025. A true and correct copy of the ’750 patent is attached as Exhibit J.

ANSWER: Aurobindo admits that the '750 patent is titled "Treatment of Migraine," and that the '750 patent was issued by the USPTO on or about June 17, 2025. What appears to be an uncertified copy of the '750 patent was attached to Plaintiffs' Third Amended Complaint as Exhibit J. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 85.

86. Allergan is the assignee of the '750 patent through assignment as recorded by the USPTO at Reel 070679, Frame 0475.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, Allergan is the assignee of the '750 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 86.

87. The '750 patent currently expires on December 22, 2041.

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. The '750 patent covers the UBRELVY® (ubrogepant) oral tablets, 50 mg product, NDA No. 211765, in the FDA Orange Book.

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.

Aurobindo's ANDA No. 219088

89. On information and belief, Aurobindo filed ANDA No. 219088 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of ubrogepant oral tablets, 50 mg, 100 mg, which are generic versions of AbbVie's UBRELVY® Tablets.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 89.

90. AbbVie received a letter sent by Aurobindo ("Aurobindo's Notice Letter I"), dated February 13, 2024, purporting to be a notice letter "[p]ursuant to subsection 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act."

ANSWER: Aurobindo admits that it sent a Notice Letter to Plaintiffs. The content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 90.

91. Aurobindo's Notice Letter I represents that Aurobindo's ANDA No. 219088 contains a Paragraph IV certification, alleging that the claims of the '836 patent are invalid, unenforceable, and/or will not be infringed by Aurobindo's generic products.

ANSWER: Aurobindo admits that it had provided a Paragraph IV certification to the FDA in connection with the submission of its ANDA No. 219088. The content of Aurobindo's Notice Letter and Aurobindo's Paragraph IV certification speak for themselves. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 91.

92. AbbVie received a letter sent by Aurobindo ("Aurobindo's Notice Letter II"), dated April 30, 2024, purporting to be a notice letter "[p]ursuant to subsection 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act."

ANSWER: Aurobindo admits that it sent a Notice Letter to Plaintiffs. The content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 92.

93. Aurobindo's Notice Letter II represents that Aurobindo's ANDA No. 219088 contains a Paragraph IV certification, alleging that the claims of the '709 patent are invalid, unenforceable, and/or will not be infringed by Aurobindo's generic products.

ANSWER: Aurobindo admits that it had provided a Paragraph IV certification to the FDA in connection with the submission of its ANDA No. 219088. The content of Aurobindo's Notice Letter and Aurobindo's Paragraph IV certification speak for themselves. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 93.

94. AbbVie received a letter sent by Aurobindo ("Aurobindo's Notice Letter III"), dated August 22, 2024, purporting to be a notice letter "[p]ursuant to subsection 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act."

ANSWER: Aurobindo admits that it sent a Notice Letter to Plaintiffs. The content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 94.

95. Aurobindo's Notice Letter III represents that Aurobindo's ANDA No. 219088 contains a Paragraph IV certification, alleging that the claims of the '515 and '542 patents are invalid, unenforceable, and/or will not be infringed by Aurobindo's generic products.

ANSWER: Aurobindo admits that it had provided a Paragraph IV certification to the FDA in connection with the submission of its ANDA No. 219088. The content of Aurobindo's Notice Letter and Aurobindo's Paragraph IV certification speak for themselves. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 95.

96. AbbVie received a letter sent by Aurobindo ("Aurobindo's Notice Letter IV"), dated April 25, 2025, purporting to be a notice letter "[p]ursuant to subsection 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act."

ANSWER: Aurobindo admits that it sent a Notice Letter to Plaintiffs. The content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 96.

97. Aurobindo's Notice Letter IV represents that Aurobindo's ANDA No. 219088 contains a Paragraph IV certification, alleging that the claims of the '450, '004, '030, and '408 patents are invalid, unenforceable, and/or will not be infringed by Aurobindo's generic products.

ANSWER: Aurobindo admits that it had provided a Paragraph IV certification to the FDA in connection with the submission of its ANDA No. 219088. The content of Aurobindo's Notice Letter and Aurobindo's Paragraph IV certification speak for themselves. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 97.

98. Plaintiffs have not yet received a Notice of Paragraph IV Certification regarding AbbVie's ANDA No. 219088 for the '953 patent and the '750 patent under Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95.

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. On information and belief, Aurobindo's Notice Letters I, II, III, and IV and the information contained therein, coupled with regulatory requirements, demonstrate Aurobindo's infringement of the '953 and '750 patents.

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. Aurobindo's Notice Letters I, II, III, or IV do not state or otherwise indicate that Aurobindo submitted a Paragraph IV certification for the '096, '210, '545, and '448 patents, each of which is listed in the FDA Orange Book for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg. Accordingly, on information and belief, Aurobindo submitted a Paragraph III certification for the '096, '210, '545, and '448 patents, and informed the FDA that it would not launch at least before December 23, 2033.

ANSWER: Paragraph 100 contains legal conclusions and allegations to which no answer is required. Aurobindo admits that it sent Notice Letters to Plaintiffs. The content of Aurobindo's Notice Letters speak for themselves. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 100.

101. Aurobindo's purpose in submitting ANDA No. 219088 and a Paragraph IV certification is to market Aurobindo's generic products before the expiration of the '836, '709, '515, '542, '450, '004, '030, and '408 patents. Aurobindo intends to market Aurobindo's generic products before the expiration of the '953 and '750 patents.

ANSWER: Aurobindo admits that it sent Notice Letters to Plaintiffs, which included notice that Aurobindo is seeking approval for Aurobindo's proposed generic products before the expiration of the '836, '709, '515, '542, '450, '004, '030, and '408 patents. The content of

Aurobindo's Notice Letters speak for themselves. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 101.

> 102. To obtain approval of an ANDA for a generic drug, an ANDA applicant must show, *inter alia*, that the generic drug is bioequivalent to its reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv). If approved, Aurobindo's generic products will be bioequivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 102 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that if approved, its generic products will be bioequivalent to AbbVie's UBRELVY® Tablets. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 102.

> 103. To obtain approval of an ANDA for a generic drug, an ANDA applicant must also show, *inter alia*, that the conditions of use prescribed, recommended, or suggested in the proposed labeling have been previously approved for its reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(i). Further, the FDA will refuse to approve an ANDA if the labeling proposed for a generic drug product differs from the labeling approved for its reference listed drug product and such differences make the proposed generic drug product less safe or effective. *See* 21 C.F.R. § 314.127(a)(7). On information and belief, if approved, Aurobindo's generic products will have the same indication and safety and efficacy information as AbbVie's UBRELVY® Tablets.

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. Following FDA approval of Aurobindo's ANDA No. 219088, Aurobindo will make, use, sell, and/or offer to sell Aurobindo's generic products throughout the United States, or import such generic products into the United States before the Patents-in-Suit expire. The manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic products will directly infringe the Patents-in-Suit.

ANSWER: Aurobindo's ANDA has not yet been tentatively or finally approved by the FDA and the allegations of Paragraph 104 are wholly speculative. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 104.

105. Following FDA approval of Aurobindo's ANDA No. 219088, Aurobindo will actively induce or contribute to the manufacture, use, offer for sale, and/or sale of Aurobindo's generic products in a manner that infringes the Patents-in-Suit.

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.

106. Plaintiffs commenced this action within 45 days of receiving Aurobindo's Notice Letter.

ANSWER: Paragraph 106 contains legal conclusions to which no answer is required. To the extent that Aurobindo is required to answer, on information and belief, Aurobindo admits that Plaintiffs commenced this action within 45 days of receiving Aurobindo's Notice Letter. Except as expressly admitted, Aurobindo is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 106, and on that basis denies these allegations.

COUNT I
INFRINGEMENT BY AUROBINDO OF THE '836 PATENT

107. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

108. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '836 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 108.

109. Aurobindo's Notice Letter states that Aurobindo submitted to the FDA, a certification that the claims of the '836 patent are purportedly invalid, unenforceable, and/or will not be infringed.

ANSWER: Aurobindo admits that its Notice Letter included a certification regarding the '836 patent. The content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 109.

110. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

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. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Aurobindo's ANDA seeking approval for the commercial manufacture, use, or sale of Aurobindo's generic products before the expiration date of the '836 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 111 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 111.

112. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '836 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '836 patent and any additional periods of exclusivity.

ANSWER: Paragraph 112 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 112.

113. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '836 patent.

ANSWER: Paragraph 113 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 113.

114. Aurobindo had knowledge of the '836 patent, as evidenced by Aurobindo's Notice Letter, and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents.

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. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '836 patent.

ANSWER: Paragraph 115 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 115.

116. The offering to sell, sale, making, and/or importation of Aurobindo's generic products will actively induce infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of the '836 patent, as evidenced by Aurobindo's Notice Letter.

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. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

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. Aurobindo should have had and/or has had and continues to have knowledge that Aurobindo's generic products are especially adapted for a use that infringes the '836 patent.

ANSWER: Paragraph 118 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 118.

119. Aurobindo should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Aurobindo's generic products.

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. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

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. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '836 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. Plaintiffs do not have an adequate remedy at law.

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.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT BY AUROBINDO OF THE '836 PATENT

123. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

124. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

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. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '836 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 125.

126. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

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. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '836 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '836 patent and any additional periods of exclusivity.

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.

128. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '836 patent.

ANSWER: Paragraph 128 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 128.

129. Aurobindo had knowledge of the '836 patent, as evidenced by Aurobindo's Notice Letter, and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 129 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 129.

130. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to

the instructions in the proposed package insert in a way that directly infringes the '836 patent.

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. The offering to sell, sale, making, and/or importation of Aurobindo's generic products would actively induce infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of the '836 patent, as evidenced by Aurobindo's Notice Letter.

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. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

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. Aurobindo should have had and/or has had and continues to have knowledge that Aurobindo's generic products are especially adapted for a use that infringes the '836 patent.

ANSWER: Paragraph 133 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 133.

134. Aurobindo should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Aurobindo's generic products.

ANSWER: Paragraph 134 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 134.

135. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 135 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 135.

136. On information and belief, Aurobindo's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Aurobindo's generic products in the United States, will begin immediately after FDA approves Aurobindo's generic products. Such activity before the expiration of the '836 patent will constitute infringement of one or more claims of the '836 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement of the '836 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Paragraph 137 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 137.

138. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '836 patent.

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. Plaintiffs do not have an adequate remedy at law.

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.

COUNT III
INFRINGEMENT BY AUROBINDO OF THE '515 PATENT

140. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

141. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '515 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 141.

142. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

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. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Aurobindo's ANDA seeking approval for the commercial manufacture, use, or sale of Aurobindo's generic products before the expiration date of the '515 patent, constitutes infringement, either literally or under the doctrine of equivalents.

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. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '515 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '515 patent and any additional periods of exclusivity.

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. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '515 patent.

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. Aurobindo had knowledge of the '515 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents.

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. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '515 patent.

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. The offering to sell, sale, making, and/or importation of Aurobindo's generic products will actively induce infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '515 patent.

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. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

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.

150. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 150 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 150.

151. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '515 patent.

ANSWER: Paragraph 151 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 151.

152. Plaintiffs do not have an adequate remedy at law.

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.

COUNT IV
DECLARATORY JUDGMENT OF
INFRINGEMENT BY AUROBINDO OF THE '515 PATENT

153. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

154. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

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. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '515 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 155.

156. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 156 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 156.

157. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '515 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '515 patent and any additional periods of exclusivity.

ANSWER: Paragraph 157 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 157.

158. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '515 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. Aurobindo had knowledge of the '515 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 159 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 159.

160. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '515 patent.

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. The offering to sell, sale, making, and/or importation of Aurobindo's generic products would actively induce infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '515 patent.

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. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 162 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 162.

163. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

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. On information and belief, Aurobindo's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Aurobindo's generic products in the United States, will begin immediately after FDA approves Aurobindo's generic products. Such activity before the expiration of the '515 patent will constitute infringement of one or more claims of the '515 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement of the '515 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

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. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '515 patent.

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. Plaintiffs do not have an adequate remedy at law.

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.

COUNT V
INFRINGEMENT BY AUROBINDO OF THE '542 PATENT

168. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

169. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '542 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 169.

170. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

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. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Aurobindo's ANDA seeking approval for the commercial manufacture, use, or sale of Aurobindo's generic products before the expiration date of the '542 patent, constitutes infringement, either literally or under the doctrine of equivalents.

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.

172. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '542 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '542 patent and any additional periods of exclusivity.

ANSWER: Paragraph 172 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 172.

173. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '542 patent.

ANSWER: Paragraph 173 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 173.

174. Aurobindo had knowledge of the '542 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents.

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. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '542 patent.

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. The offering to sell, sale, making, and/or importation of Aurobindo's generic products would actively induce infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '542 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. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 177 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 177.

178. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 178 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 178.

179. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '542 patent.

ANSWER: Paragraph 179 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 179.

180. Plaintiffs do not have an adequate remedy at law.

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.

COUNT VI
DECLARATORY JUDGMENT OF
INFRINGEMENT BY AUROBINDO OF THE '542 PATENT

181. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

182. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

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. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '542 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 183.

184. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 184 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 184.

185. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '542 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '542 patent and any additional periods of exclusivity.

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. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '542 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. Aurobindo had knowledge of the '542 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents.

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. Aurobindo is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '542 patent.

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. The offering to sell, sale, making, and/or importation of Aurobindo's generic products would actively induce infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '542 patent.

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. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

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. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

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. On information and belief, Aurobindo's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Aurobindo's generic products in the United States, will begin immediately after FDA approves Aurobindo's generic products. Such activity before the expiration of the '542 patent will constitute infringement of one or more claims of the '542 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement of the '542 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

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.

194. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '542 patent.

ANSWER: Paragraph 194 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 194.

195. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 195 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 195.

COUNT VII
INFRINGEMENT BY AUROBINDO OF THE '709 PATENT

196. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

197. This Complaint provides notice of the '709 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 197 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 197.

198. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '709 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 198.

199. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 199 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 199.

200. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Aurobindo's ANDA seeking approval for the commercial manufacture, use, or sale of Aurobindo's generic products before the expiration date of the '709 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 200 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 200.

201. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '709 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '709 patent and any additional periods of exclusivity.

ANSWER: Paragraph 201 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 201.

202. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '709 patent.

ANSWER: Paragraph 202 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 202.

203. Aurobindo had knowledge of the '709 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 203 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 203.

204. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '709 patent.

ANSWER: Paragraph 204 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 204.

205. The offering to sell, sale, making, and/or importation of Aurobindo's generic products would actively induce infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '709 patent.

ANSWER: Paragraph 205 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 205.

206. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 206 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 206.

207. Aurobindo should have had and/or has had and continues to have knowledge that Aurobindo's generic products are especially adapted for a use that infringes the '709 patent.

ANSWER: Paragraph 207 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 207.

208. Aurobindo should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Aurobindo's generic products.

ANSWER: Paragraph 208 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 208.

209. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 209 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 209.

210. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '709 patent.

ANSWER: Paragraph 210 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 210.

211. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 211 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 211.

COUNT VIII
DECLARATORY JUDGMENT OF
INFRINGEMENT BY AUROBINDO OF THE '709 PATENT

212. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

213. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: Paragraph 213 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 213.

214. This Complaint provides notice of the '709 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 214 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 214.

215. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '709 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 215.

216. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 216 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 216.

217. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '709 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '709 patent and any additional periods of exclusivity.

ANSWER: Paragraph 217 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 217.

218. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '709 patent.

ANSWER: Paragraph 218 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 218.

219. Aurobindo had knowledge of the '709 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 219 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 219.

220. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to

the instructions in the proposed package insert in a way that directly infringes the '709 patent.

ANSWER: Paragraph 220 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 220.

221. The offering to sell, sale, making, and/or importation of Aurobindo's generic products would actively induce infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '709 patent.

ANSWER: Paragraph 221 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 221.

222 If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 222 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 222.

223. Aurobindo should have had and/or has had and continues to have knowledge that Aurobindo's generic products are especially adapted for a use that infringes the '709 patent.

ANSWER: Paragraph 223 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 223.

224. Aurobindo should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Aurobindo's generic products.

ANSWER: Paragraph 224 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 224.

225. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 225 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 225.

226. On information and belief, Aurobindo's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Aurobindo's generic products in the United States, will begin immediately after FDA approves Aurobindo's generic products. Such activity before the expiration of the '709 patent will constitute infringement of one or more claims of the '709 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 226 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 226.

227. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement of the '709 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Paragraph 227 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 227.

228. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '709 patent.

ANSWER: Paragraph 228 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 228.

229. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 229 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 229.

COUNT IX
INFRINGEMENT BY AUROBINDO OF THE '450 PATENT

230. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

231. This Complaint provides notice of the '450 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 231 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 231.

232. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '450 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 232.

233. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 233 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 233.

234. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Aurobindo's ANDA seeking approval for the commercial manufacture, use, or sale of Aurobindo's generic products before the expiration date of the '450 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 234 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 234.

235. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '450 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '450 patent and any additional periods of exclusivity.

ANSWER: Paragraph 235 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 235.

236. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '450 patent.

ANSWER: Paragraph 236 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 236.

237. Aurobindo had knowledge of the '450 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '450 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 237 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 237.

238. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '450 patent.

ANSWER: Paragraph 238 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 238.

239. The offering to sell, sale, making, and/or importation of Aurobindo's generic products would actively induce infringement of at least one of the claims of the '450 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '450 patent.

ANSWER: Paragraph 239 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 239.

240. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 240 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 240.

241. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 241 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 241.

242. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '450 patent.

ANSWER: Paragraph 242 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 242.

243. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 243 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 243.

COUNT X
DECLARATORY JUDGMENT OF
INFRINGEMENT BY AUROBINDO OF THE '450 PATENT

244. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

245. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: Paragraph 245 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 245.

246. This Complaint provides notice of the '450 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 246 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 246.

247. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '450 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 247.

248. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 248 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 248.

249. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '450 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '450 patent and any additional periods of exclusivity.

ANSWER: Paragraph 249 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 249.

250. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '450 patent.

ANSWER: Paragraph 250 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 250.

251. Aurobindo had knowledge of the '450 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '450 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 251 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 251.

252. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '450 patent.

ANSWER: Paragraph 252 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 252.

253. The offering to sell, sale, making, and/or importation of Aurobindo's generic products would actively induce infringement of at least one of the claims of the '450 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '450 patent.

ANSWER: Paragraph 253 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 253.

254. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 254 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 254.

255. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 255 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 255.

256. On information and belief, Aurobindo's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Aurobindo's generic products in the United States, will begin immediately after FDA approves Aurobindo's generic products. Such activity before the expiration of the '450 patent will constitute infringement of one or more claims of the '450 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 256 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 256.

257. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement of the '450 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Paragraph 257 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 257.

258. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '450 patent.

ANSWER: Paragraph 258 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 258.

259. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 259 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 259.

COUNT XI
INFRINGEMENT BY AUROBINDO OF THE '004 PATENT

260. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

261. This Complaint provides notice of the '004 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 261 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 261.

262. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '004 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 262.

263. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 263 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 263.

264. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Aurobindo's ANDA seeking approval for the commercial manufacture, use, or sale of Aurobindo's generic products before the expiration date of the '004 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 264 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 264.

265. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '004 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '004 patent and any additional periods of exclusivity.

ANSWER: Paragraph 265 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 265.

266. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '004 patent.

ANSWER: Paragraph 266 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 266.

267. Aurobindo had knowledge of the '004 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '004 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 267 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 267.

268. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '004 patent.

ANSWER: Paragraph 268 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 268.

269. The offering to sell, sale, making, and/or importation of Aurobindo's generic products would actively induce infringement of at least one of the claims of the '004 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '004 patent.

ANSWER: Paragraph 269 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 269.

270. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 270 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 270.

271. Aurobindo should have had and/or has had and continues to have knowledge that Aurobindo's generic products are especially adapted for a use that infringes the '004 patent.

ANSWER: Paragraph 271 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 271.

272. Aurobindo should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Aurobindo's generic products.

ANSWER: Paragraph 272 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 272.

273. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 273 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 273.

274. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '004 patent.

ANSWER: Paragraph 274 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 274.

275. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 275 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 275.

COUNT XII
DECLARATORY JUDGMENT OF
INFRINGEMENT BY AUROBINDO OF THE '004 PATENT

276. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

277. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: Paragraph 277 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 277.

278. This Complaint provides notice of the '004 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 278 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 278.

279. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '004 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 279.

280. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 280 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 280.

281. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '004 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '004 patent and any additional periods of exclusivity.

ANSWER: Paragraph 281 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 281.

282. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '004 patent.

ANSWER: Paragraph 282 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 282.

283. Aurobindo had knowledge of the '004 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '004 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 283 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 283.

284. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to

the instructions in the proposed package insert in a way that directly infringes the '004 patent.

ANSWER: Paragraph 284 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 284.

285. The offering to sell, sale, making, and/or importation of Aurobindo's generic products would actively induce infringement of at least one of the claims of the '004 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '004 patent.

ANSWER: Paragraph 285 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 285.

286. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 286 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 286.

287. Aurobindo should have had and/or has had and continues to have knowledge that Aurobindo's generic products are especially adapted for a use that infringes the '004 patent.

ANSWER: Paragraph 287 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 287.

288. Aurobindo should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Aurobindo's generic products.

ANSWER: Paragraph 288 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 288.

289. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 289 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 289.

290. On information and belief, Aurobindo's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Aurobindo's generic products in the United States, will begin immediately after FDA approves Aurobindo's generic products. Such activity before the expiration of the '004 patent will constitute infringement of one or more claims of the '004 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 290 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 290.

291. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement of the '004 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Paragraph 291 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 291.

292. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '004 patent.

ANSWER: Paragraph 292 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 292.

293. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 293 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 293.

COUNT XIII
INFRINGEMENT BY AUROBINDO OF THE '030 PATENT

294. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

295. This Complaint provides notice of the '030 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 295 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 295.

296. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '030 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 296.

297. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 297 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 297.

298. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Aurobindo's ANDA seeking approval for the commercial manufacture, use, or sale of Aurobindo's generic products before the expiration date of the '030 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 298 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 298.

299. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '030 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '030 patent and any additional periods of exclusivity.

ANSWER: Paragraph 299 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 299.

300. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '030 patent.

ANSWER: Paragraph 300 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 300.

301. Aurobindo had knowledge of the '030 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 301 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 301.

302. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '030 patent.

ANSWER: Paragraph 302 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 302.

303. The offering to sell, sale, making, and/or importation of Aurobindo's generic products will actively induce infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '030 patent.

ANSWER: Paragraph 303 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 303.

304. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 304 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 304.

305. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 305 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 305.

306. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '030 patent.

ANSWER: Paragraph 306 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 306.

307. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 307 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 307.

COUNT XIV
DECLARATORY JUDGMENT OF
INFRINGEMENT BY AUROBINDO OF THE '030 PATENT

308. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

309. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: Paragraph 309 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 309.

310. This Complaint provides notice of the '030 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 310 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 310.

311. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '030 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 311.

312. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 312 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 312.

313. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '030 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '030 patent and any additional periods of exclusivity.

ANSWER: Paragraph 313 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 313.

314. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '030 patent.

ANSWER: Paragraph 314 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 314.

315. Aurobindo had knowledge of the '030 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 315 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 315.

316. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '030 patent.

ANSWER: Paragraph 316 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 316.

317. The offering to sell, sale, making, and/or importation of Aurobindo's generic products will actively induce infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '030 patent.

ANSWER: Paragraph 317 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 317.

318. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 318 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 318.

319. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 319 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 319.

320. On information and belief, Aurobindo's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Aurobindo's generic products in the United States, will begin immediately after FDA approves Aurobindo's generic products. Such activity before the expiration of the '030 patent will constitute infringement of one or more claims of the '030 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 320 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 320.

321. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement of the '030 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Paragraph 321 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 321.

322. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '030 patent.

ANSWER: Paragraph 322 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 322.

323. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 323 contains legal conclusions and allegations to which no answer of required. To the extent an answer is required, Aurobindo denies the allegations in Paragraph 323.

COUNT XV
INFRINGEMENT BY AUROBINDO OF THE '408 PATENT

324. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

325. This Complaint provides notice of the '408 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 325 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 325.

326. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '408 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 326.

327. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 327 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 327.

328. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Aurobindo's ANDA seeking approval for the commercial manufacture, use, or sale of Aurobindo's generic products before the expiration date of the '408 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 328 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 328.

329. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '408 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '408 patent and any additional periods of exclusivity.

ANSWER: Paragraph 329 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 329.

330. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '408 patent.

ANSWER: Paragraph 330 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 330.

331. Aurobindo had knowledge of the '408 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '408 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 331 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 331.

332. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '408 patent.

ANSWER: Paragraph 332 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 332.

333. The offering to sell, sale, making, and/or importation of Aurobindo's generic products will actively induce infringement of at least one of the claims of the '408 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '408 patent.

ANSWER: Paragraph 333 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 333.

334. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 334 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 334.

335. Aurobindo should have had and/or has had and continues to have knowledge that Aurobindo's generic products are especially adapted for a use that infringes the '408 patent.

ANSWER: Paragraph 335 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 335.

336. Aurobindo should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Aurobindo's generic products.

ANSWER: Paragraph 336 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 336.

337. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 337 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 337.

338. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '408 patent.

ANSWER: Paragraph 338 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 338.

339. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 339 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 339.

COUNT XVI
DECLARATORY JUDGMENT OF
INFRINGEMENT BY AUROBINDO OF THE '408 PATENT

340. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

341. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: Paragraph 341 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 341.

342. This Complaint provides notice of the '408 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 342 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 342.

343. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '408 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 343.

344. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 344 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 344.

345. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '408 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's

ANDA shall be no earlier than the expiration of the '408 patent and any additional periods of exclusivity.

ANSWER: Paragraph 345 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 345.

346. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '408 patent.

ANSWER: Paragraph 346 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 346.

347. Aurobindo had knowledge of the '408 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '408 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 347 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 347.

348. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '408 patent.

ANSWER: Paragraph 348 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 348.

349. The offering to sell, sale, making, and/or importation of Aurobindo's generic products will actively induce infringement of at least one of the claims of the '408 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '408 patent.

ANSWER: Paragraph 349 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 349.

350. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 350 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 350.

351. Aurobindo should have had and/or has had and continues to have knowledge that Aurobindo's generic products are especially adapted for a use that infringes the '408 patent.

ANSWER: Paragraph 351 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 351.

352. Aurobindo should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Aurobindo's generic products.

ANSWER: Paragraph 352 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 352.

353. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 353 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 353.

354. On information and belief, Aurobindo's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Aurobindo's generic products in the United States, will begin immediately after FDA approves Aurobindo's

generic products. Such activity before the expiration of the '408 patent will constitute infringement of one or more claims of the '408 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 354 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 354.

355. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement of the '408 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Paragraph 355 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 355.

356. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '408 patent.

ANSWER: Paragraph 356 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 356.

357. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 357 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 357.

COUNT XVII
INFRINGEMENT BY AUROBINDO OF THE '953 PATENT

358. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

359. This Complaint provides notice of the '953 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 359 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 359.

360. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '953 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 360.

361. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 361 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 361.

362. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Aurobindo's ANDA seeking approval for the commercial manufacture, use, or sale of Aurobindo's generic products before the expiration date of the '953 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 362 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 362.

363. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '953 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '953 patent and any additional periods of exclusivity.

ANSWER: Paragraph 363 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 363.

364. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '953 patent.

ANSWER: Paragraph 364 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 364.

365. Aurobindo had knowledge of the '953 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '953 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 365 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 365.

366. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '953 patent.

ANSWER: Paragraph 366 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 366.

367. The offering to sell, sale, making, and/or importation of Aurobindo's generic products will actively induce infringement of at least one of the claims of the '953 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '953 patent.

ANSWER: Paragraph 367 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 367.

368. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 368 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 368.

369. Aurobindo should have had and/or has had and continues to have knowledge that Aurobindo's generic products are especially adapted for a use that infringes the '953 patent.

ANSWER: Paragraph 369 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 369.

370. Aurobindo should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Aurobindo's generic products.

ANSWER: Paragraph 370 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 370.

371. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 371 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 371.

372. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '953 patent.

ANSWER: Paragraph 372 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 372.

373. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 373 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 373.

COUNT XVIII
DECLARATORY JUDGMENT OF
INFRINGEMENT BY AUROBINDO OF THE '953 PATENT

374. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

375. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: Paragraph 375 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 375.

376. This Complaint provides notice of the '953 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 376 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 376.

377. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '953 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 377.

378. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 378 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 378.

379. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '953 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '953 patent and any additional periods of exclusivity.

ANSWER: Paragraph 379 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 379.

380. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '953 patent.

ANSWER: Paragraph 380 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 380.

381. Aurobindo had knowledge of the '953 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '953 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 381 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 381.

382. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '953 patent.

ANSWER: Paragraph 382 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 382.

383. The offering to sell, sale, making, and/or importation of Aurobindo's generic products will actively induce infringement of at least one of the claims of the '953 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '953 patent.

ANSWER: Paragraph 383 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 383.

384. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 384 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 384.

385. Aurobindo should have had and/or has had and continues to have knowledge that Aurobindo's generic products are especially adapted for a use that infringes the '953 patent.

ANSWER: Paragraph 385 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 385.

386. Aurobindo should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Aurobindo's generic products.

ANSWER: Paragraph 386 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 386.

387. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 387 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 387.

388. On information and belief, Aurobindo's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Aurobindo's generic products in the United States, will begin immediately after FDA approves Aurobindo's generic products. Such activity before the expiration of the '953 patent will constitute infringement of one or more claims of the '953 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 388 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 388.

389. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement of the '953 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Paragraph 389 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 389.

390. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '953 patent.

ANSWER: Paragraph 390 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 390.

391. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 391 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 391.

COUNT XIX
INFRINGEMENT BY AUROBINDO OF THE '750 PATENT

392. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

393. This Complaint provides notice of the '750 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 393 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 393.

394. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '750 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 394.

395. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 395 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 395.

396. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Aurobindo's ANDA seeking approval for the commercial manufacture, use, or sale of Aurobindo's generic products before the expiration date of the '750 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 396 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 396.

397. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '750 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '750 patent and any additional periods of exclusivity.

ANSWER: Paragraph 397 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 397.

398. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '750 patent.

ANSWER: Paragraph 398 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 398.

399. Aurobindo had knowledge of the '750 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 399 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 399.

400. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '750 patent.

ANSWER: Paragraph 400 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 400.

401. The offering to sell, sale, making, and/or importation of Aurobindo's generic products will actively induce infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '750 patent.

ANSWER: Paragraph 401 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 401.

402. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 402 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 402.

403. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 403 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 403.

404. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '750 patent.

ANSWER: Paragraph 404 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 404.

405. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 405 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 405.

COUNT XX
DECLARATORY JUDGMENT OF
INFRINGEMENT BY AUROBINDO OF THE '750 PATENT

406. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Aurobindo incorporates by reference each of its responses to the prior paragraphs of this Complaint as if fully set forth herein.

407. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: Paragraph 407 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 407.

408. This Complaint provides notice of the '750 patent to the extent that Aurobindo did not already have notice of this patent.

ANSWER: Paragraph 408 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 408.

409. Aurobindo filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's generic products in the United States before the expiration of the '750 patent.

ANSWER: Aurobindo admits that it had filed ANDA No. 219088 with the FDA. Aurobindo admits that it 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 remaining allegations of Paragraph 409.

410. On information and belief, Aurobindo represented to the FDA that Aurobindo's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 410 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 410.

411. After FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '750 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's generic products, and by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the expiration of the '750 patent and any additional periods of exclusivity.

ANSWER: Paragraph 411 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 411.

412. Aurobindo knows or should know, and intends that healthcare providers will prescribe and patients will take Aurobindo's generic products for which approval is sought in Aurobindo's ANDA, and therefore will infringe at least one claim in the '750 patent.

ANSWER: Paragraph 412 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 412.

413. Aurobindo had knowledge of the '750 patent and, by its promotional activities and proposed package insert for Aurobindo's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 413 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 413.

414. Aurobindo is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's generic products according to the instructions in the proposed package insert in a way that directly infringes the '750 patent.

ANSWER: Paragraph 414 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 414.

415. The offering to sell, sale, making, and/or importation of Aurobindo's generic products will actively induce infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents. On information and belief, Aurobindo has knowledge and is aware of the '750 patent.

ANSWER: Paragraph 415 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 415.

416. If Aurobindo's ANDA is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's generic products.

ANSWER: Paragraph 416 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 416.

417. Aurobindo's actions relating to Aurobindo's ANDA complained of herein were done by and for the benefit of Aurobindo.

ANSWER: Paragraph 417 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 417.

418. On information and belief, Aurobindo's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Aurobindo's generic products in the United States, will begin immediately after FDA approves Aurobindo's generic products. Such activity before the expiration of the '750 patent will constitute infringement of one or more claims of the '750 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 418 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 418.

419. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement of the '750 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Paragraph 419 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 419.

420. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '750 patent.

ANSWER: Paragraph 420 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 420.

421. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 421 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 421.

PLAINTIFFS' REQUEST FOR RELIEF

All allegations in Plaintiffs' Third Amended Complaint that are not expressly admitted by Aurobindo are denied. Aurobindo denies that Plaintiffs are entitled to any of the relief sought in their Request for Relief.

AUROBINDO'S AFFIRMATIVE DEFENSES

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

FIRST DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 219088 has not infringed, does 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 Patents-in-Suit.

SECOND DEFENSE

Each of the claims of each of the Patents-in-Suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, or for failure to satisfy other judicially created bases for invalidation or unenforceability.

THIRD DEFENSE

Plaintiffs' Third Amended Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or willful infringement. Aurobindo's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

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.

AUROBINDO'S COUNTERCLAIMS

Defendants/Counterclaim Plaintiffs Aurobindo Pharma U.S.A., Inc. ("Aurobindo USA"), Aurobindo Pharma Limited ("Aurobindo Pharma"), and Apitoria Pharma Private Limited ("Apitoria") (collectively, "Aurobindo"), by and through their undersigned counsel, plead the following counterclaims against Plaintiffs/Counterclaim Defendants AbbVie Inc. ("AbbVie"), Allergan Pharmaceuticals International Limited ("Allergan"), and Merck Sharp & Dohme LLC ("Merck") (collectively, "Plaintiffs/Counterclaim Defendants"):

PARTIES

1. Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520.

2. Aurobindo Pharma is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

3. Apitoria, is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 1, Survey No. 83/1 Hyderabad Knowledge City, Panmaktha, Rai Durg, Hyderabad, 500032, India.

4. On information and belief, AbbVie is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

5. On information and belief, Allergan is a corporation organized and existing under the laws of Ireland, with a principal place of business at Clonshaugh Business & Technical Park, Dublin 17, Ireland D17 E400.

6. On information and belief, Merck is a limited liability company organized and existing under the laws of the State of New Jersey, having a principal place of business at 126 Lincoln Avenue, Rahway, New Jersey 07065.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; based on an actual controversy between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

8. This Court has personal jurisdiction over Plaintiffs/Counterclaim Defendants because, *inter alia*, Plaintiffs/Counterclaim Defendants subjected themselves to the jurisdiction of this Court by filing their Complaint here.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b), and/or by Plaintiffs/Counterclaim Defendants' choice of forum.

FACTUAL BACKGROUND

10. On information and belief, and based on the allegations in the Third Amended Complaint, AbbVie is the holder of the New Drug Application ("NDA") No. 211765 for UBRELVY® (ubrogepant) tablets in 50 mg and 100 mg dosages forms.

11. On information and belief, and based on the allegations in the First Amended Complaint, Plaintiffs/Counterclaim Defendants caused the Food and Drug Administration ("FDA") to list U.S. Patent Nos. 10,117,836 ("the '836 patent"), 11,717,515 ("the '515 patent"), 11,857,542 ("the '542 patent"), 11,925,709, ("the '709 patent"), 12,070,450 ("the '450 patent"), 12,168,004 ("the '004 patent"), 12,194,030 ("the '030 patent"), 12,220,408 ("the '408 patent"), 12,310,953 ("the '953 patent"), and 12,329,750 ("the '750 patent") (collectively, "the Asserted Patents") in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 211765.

12. The '836 patent lists the title as "Tablet Formulation for CGRP Active Compounds," and the issue date as November 6, 2018.

13. The '515 patent lists the title as "Treatment of Migraine," and the issue date as August 8, 2023.

14. The '542 patent lists the title as "Treatment of Migraine," and the issue date as January 2, 2024.

15. The '709 patent lists the title as "Tablet Formulation for CGRP Active Compounds," and the issue date as March 12, 2024.

16. The ’450 patent lists the title as “Treatment of Migraine,” and the issue date as August 27, 2024.

17. The ’004 patent lists the title as “Treatment of Migraine,” and the issue date as December 17, 2024.

18. The ’030 patent lists the title as “Treatment of Migraine,” and the issue date as January 14, 2025.

19. The ’408 patent lists the title as “Treatment of Migraine,” and the issue date as February 11, 2025.

20. The ’953 patent lists the title as “Pharmaceutical Formulations for the Treatment of Migraine,” and the issue date as May 27, 2025.

21. The ’750 patent lists the title as “Treatment of Migraine,” and the issue date as June 17, 2025.

22. Plaintiffs/Counterclaim Defendants purport and claim to be the owner of or exclusive licensee for, and to have the right to enforce, the Asserted Patents.

23. Aurobindo submitted Abbreviated New Drug Application (“ANDA”) No. 219088 to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Aurobindo’s proposed drug product containing ubrogepant oral tablets, 50 mg, 100 mg (“Aurobindo’s ANDA product”). For ANDA No. 219088, Aurobindo submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA with respect to the ’836, ‘515, ‘542, ‘709, ’450, ’004, ’030, and ’408 patents.

24. Aurobindo sent notice of the certification with respect to the ’836 patent to Plaintiffs/Counterclaim Defendants on or about February 13, 2024 (“the First Notice Letter”). On

information and belief, and as Plaintiffs/Counterclaim Defendants allege in their Complaint, Plaintiffs/Counterclaim Defendants received the Notice Letter.

25. On March 29, 2024, Plaintiffs/Counterclaim Defendants filed suit in this Judicial District against Aurobindo in connection with ANDA No. 219088 alleging infringement of the '836, '515, '542 and '709 patents.

26. Aurobindo sent notice of the certification with respect to the '709 patent to Plaintiffs/Counterclaim Defendants on or about April 30, 2024 ("the Second Notice Letter"). On information and belief, and as Plaintiffs/Counterclaim Defendants allege in their First Amended Complaint, Plaintiffs/Counterclaim Defendants received the Second Notice Letter.

27. Aurobindo sent notice of the certification with respect to the '515 and '542 patents to Plaintiffs/Counterclaim Defendants on or about August 22, 2024 ("the Third Notice Letter"). On information and belief, and as Plaintiffs/Counterclaim Defendants allege in their First Amended Complaint, Plaintiffs/Counterclaim Defendants received the Third Notice Letter.

28. On January 24, 2025, Plaintiffs/Counterclaim Defendants filed their First Amended Complaint against Aurobindo in connection with ANDA No. 219088 alleging infringement of the '836, '515, '542, '709, '450, and '004 patents.

29. On March 3, 2025, Plaintiffs/Counterclaim Defendants filed their Second Amended Complaint against Aurobindo in connection with ANDA No. 219088 alleging infringement of the '836, '515, '542, '709, '450, and '004, '030, and '408 patents.

30. Aurobindo sent notice of the certification with respect to the '450, and '004, '030, and '408 patents to Plaintiffs/Counterclaim Defendants on or about April 25, 2025 ("the Fourth Notice Letter"). On information and belief, and as Plaintiffs/Counterclaim Defendants allege in

their First Amended Complaint, Plaintiffs/Counterclaim Defendants received the Third Notice Letter.

31. On June 27, 2025, Plaintiffs/Counterclaim Defendants filed their Third Amended Complaint against Aurobindo in connection with ANDA No. 219088 alleging infringement of the Asserted Patents.

32. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the Asserted Patents, and as to Aurobindo's right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA product.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,117,836)

33. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

34. Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '836 patent.

35. A present, genuine, and justiciable controversy exists between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aurobindo's ANDA Product would infringe any valid or enforceable claim of the '836 patent.

36. The Court should declare that Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '836 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,117,836)

37. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

38. Upon information and belief, the claims of the '836 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

39. There is a real, substantial, and justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants concerning whether the claims of the '836 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

40. The Court should declare that the claims of the '836 patent are invalid and/or unenforceable.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,717,515)

41. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

42. Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '515 patent.

43. A present, genuine, and justiciable controversy exists between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aurobindo's ANDA Product would infringe any valid or enforceable claim of the '515 patent.

44. The Court should declare that Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '515 patent.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,717,515)

45. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

46. Upon information and belief, the claims of the '515 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

47. There is a real, substantial, and justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants concerning whether the claims of the '515 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

48. The Court should declare that the claims of the ’515 patent are invalid and/or unenforceable.

COUNT V
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,857,542)

49. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo’s Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

50. Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’542 patent.

51. A present, genuine, and justiciable controversy exists between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aurobindo’s ANDA Product would infringe any valid or enforceable claim of the ’542 patent.

52. The Court should declare that Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’542 patent.

COUNT VI
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,857,542)

53. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo’s Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

54. Upon information and belief, the claims of the ’542 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or

251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

55. There is a real, substantial, and justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants concerning whether the claims of the '542 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

56. The Court should declare that the claims of the '542 patent are invalid and/or unenforceable.

COUNT VII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,925,709)

57. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

58. Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '709 patent.

59. A present, genuine, and justiciable controversy exists between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aurobindo's ANDA Product would infringe any valid or enforceable claim of the '709 patent.

60. The Court should declare that Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '709 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,925,709)

61. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

62. Upon information and belief, the claims of the '709 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

63. There is a real, substantial, and justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants concerning whether the claims of the '709 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

64. The Court should declare that the claims of the '709 patent are invalid and/or unenforceable.

COUNT IX
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,070,450)

65. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

66. Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '450 patent.

67. A present, genuine, and justiciable controversy exists between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aurobindo's ANDA Product would infringe any valid or enforceable claim of the '450 patent.

68. The Court should declare that Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '450 patent.

COUNT X
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,070,450)

69. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

70. Upon information and belief, the claims of the '450 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

71. There is a real, substantial, and justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants concerning whether the claims of the '450 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

72. The Court should declare that the claims of the '450 patent are invalid and/or unenforceable.

COUNT XI
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,168,004)

73. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

74. Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '004 patent.

75. A present, genuine, and justiciable controversy exists between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aurobindo's ANDA Product would infringe any valid or enforceable claim of the '004 patent.

76. The Court should declare that Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '004 patent.

COUNT XII
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,168,004)

77. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

78. Upon information and belief, the claims of the '004 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

79. There is a real, substantial, and justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants concerning whether the claims of the ’004 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

80. The Court should declare that the claims of the ’004 patent are invalid and/or unenforceable.

COUNT XIII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,194,030)

81. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo’s Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

82. Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’030 patent.

83. A present, genuine, and justiciable controversy exists between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, inter alia, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aurobindo’s ANDA Product would infringe any valid or enforceable claim of the ’030 patent.

84. The Court should declare that Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’030 patent.

COUNT XIV
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,194,030)

85. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

86. Upon information and belief, the claims of the '030 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

87. There is a real, substantial, and justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants concerning whether the claims of the '030 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

88. The Court should declare that the claims of the '030 patent are invalid and/or unenforceable.

COUNT XV
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,220,408)

89. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

90. Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '408 patent.

91. A present, genuine, and justiciable controversy exists between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, inter alia, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aurobindo's ANDA Product would infringe any valid or enforceable claim of the '408 patent.

92. The Court should declare that Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '408 patent.

COUNT XVI
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,220,408)

93. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

94. Upon information and belief, the claims of the '408 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

95. There is a real, substantial, and justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants concerning whether the claims of the '408 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

96. The Court should declare that the claims of the '408 patent are invalid and/or unenforceable.

COUNT XVII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,310,953)

97. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

98. Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '953 patent.

99. A present, genuine, and justiciable controversy exists between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aurobindo's ANDA Product would infringe any valid or enforceable claim of the '953 patent.

100. The Court should declare that Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '953 patent.

COUNT XVIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,310,953)

101. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

102. Upon information and belief, the claims of the '953 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

103. There is a real, substantial, and justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants concerning whether the claims of the ’953 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

104. The Court should declare that the claims of the ’953 patent are invalid and/or unenforceable.

COUNT XIX
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,329,750)

105. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo’s Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

106. Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’750 patent.

107. A present, genuine, and justiciable controversy exists between Aurobindo, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aurobindo’s ANDA Product would infringe any valid or enforceable claim of the ’750 patent.

108. The Court should declare that Aurobindo has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’750 patent.

COUNT XX
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,329,750)

109. Aurobindo incorporates by reference and re-alleges each of the foregoing paragraphs of Aurobindo's Answer and Affirmative Defenses to the Third Amended Complaint and these Counterclaims as if fully set forth herein.

110. Upon information and belief, the claims of the '750 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

111. There is a real, substantial, and justiciable controversy between Aurobindo and Plaintiffs/Counterclaim Defendants concerning whether the claims of the '750 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

112. The Court should declare that the claims of the '750 patent are invalid and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Aurobindo prays that the Court enter judgment in its favor and against Plaintiffs/Counterclaim Defendants as follows:

A. Declaring that the filing of Aurobindo's ANDA No. 219088 has not and does not directly or indirectly infringe any valid claim of any of the Asserted Patents;

B. Declaring that the commercial manufacture, use, offer to sell, sale within the United States, and/or importation into the United States of Aurobindo's ubrogepant oral tablets, 50 mg,

100 mg described in ANDA No. 219088 does not, and would not, if marketed, directly or indirectly infringe any valid claim of the Asserted Patents;

C. Declaring that the claims of the Asserted Patents are invalid;

D. Ordering that judgment be entered in favor of Aurobindo and that Plaintiffs/Counterclaim Defendants' Third Amended Complaint be dismissed with prejudice;

E. Declaring this case exceptional and awarding Aurobindo its reasonable attorney fees and costs of defending this action and prosecuting its counterclaims under 35 U.S.C. § 285; and

F. Awarding Aurobindo such other and further relief as this Court deems just and proper.

Dated: July 11, 2025

Respectfully submitted,

s/ Kaan Ekiner

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CERTIFICATE OF SERVICE

I, Kaan Ekiner, hereby certify that on July 11, 2025, a true and correct copy of the foregoing **DEFENDANTS AUROBINDO PHARMA U.S.A., INC., AUROBINDO PHARMA LIMITED, AND APITORIA PHARMA PRIVATE LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' THIRD AMENDED 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.

Dated: July 11, 2025

s/ Kaan Ekiner
Kaan Ekiner