IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC. and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs, v. AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA U.S.A., INC., and APITORIA PHARMA PRIVATE LIMITED, Defendants.	)	C.A. No. 24-622 (CFC)

DEFENDANTS AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA U.S.A., INC., AND APITORIA PHARMA PRIVATE LIMITED'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS PFIZER INC. AND PFIZER IRELAND PHARMACEUTICALS' COMPLAINT

Defendants Aurobindo Pharma Limited ("Aurobindo Pharma"), Aurobindo Pharma U.S.A., Inc. ("Aurobindo USA"), and Apitoria Pharma Private Limited ("Apitoria") (collectively, "Aurobindo" or "Defendants"), by and through their undersigned counsel, file this Answer and Affirmative Defenses to Plaintiffs Pfizer Inc. and Pfizer Ireland Pharmaceuticals' (collectively, "Pfizer" or "Plaintiffs") Complaint, and state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Aurobindo denies all allegations and characterizations in Pfizer's Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Aurobindo's submission of Abbreviated New Drug Application ("ANDA") No. 219328 (the "Aurobindo ANDA") to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Pfizer's NURTEC ODT® (rimegepant sulfate) tablet before the expiration of U.S. Patent No. 11,083,724 ("the '724 patent" or "the patent-in-suit").

ANSWER: Aurobindo admits that Pfizer filed a civil action alleging that Aurobindo infringed U.S. Patent No. 11,083,724 ("the '724 patent" or "the patent-in-suit") under the patent laws of the United States, Title 35 of the United States Code. Aurobindo admits that it had filed Abbreviated New Drug Application ("ANDA") No. 219328 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.

THE PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

ANSWER: Aurobindo is without knowledge or information to form a belief about the truth of the allegations of Paragraph 2, and on that basis denies these allegations.

3. Plaintiff Pfizer Ireland Pharmaceuticals is a private unlimited liability company organized under the laws of Ireland and has its registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

ANSWER: Aurobindo is without knowledge or information to form a belief about the truth of the allegations of Paragraph 3, and on that basis denies these allegations.

4. Upon information and belief, Defendant Aurobindo Pharma is a company organized and existing under the laws of India, having a principal place of business at Plot No. 2, Maitrivihar, Amerpeet, Hyderabad-50038, Telangana, India.

ANSWER: Aurobindo admits that Aurobindo Pharma is a corporation organized and existing under the laws of India, having a register office at Plot No. 2, Maitrivihar, Amerpeet, Hyderabad-50038, Telangana, India. Except as expressly admitted, Aurobindo denies the remaining allegations in Paragraph 4.

5. Upon information and belief, Defendant Aurobindo USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

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, New Jersey 08520.

6. Upon information and belief, Defendant 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.

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.

7. Upon information and belief, Aurobindo USA and Apitoria are wholly owned subsidiaries of Aurobindo Pharma.

ANSWER: Aurobindo admits that Aurobindo USA and Apitoria are wholly owned subsidiaries of Aurobindo Pharma.

8. Upon information and belief, Aurobindo Pharma, Aurobindo USA, and Apitoria are generic pharmaceutical companies that, in coordination with each other or at the direction of Aurobindo Pharma, develop, manufacture, market, and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

ANSWER: Paragraph 8 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 8.

THE PATENT-IN-SUIT

9. On August 10, 2021, the USPTO duly and legally issued the '724 patent, entitled "Rimegepant for CGRP Related Disorders." The '724 patent is assigned to Pfizer Ireland Pharmaceuticals. A copy of the '724 patent is attached to this Complaint as Exhibit A.

ANSWER: Aurobindo admits that the '724 patent is titled "Rimegepant for CGRP Related Disorders," and that the '724 patent was issued by the USPTO on or about August 10, 2021. What appears to be an uncertified copy of the '724 patent was attached to Pfizer's Complaint as Exhibit A. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 9.

NURTEC ODT®

10. Pfizer Inc. holds approved New Drug Application No. 212728 for rimegepant sulfate orally disintegrating tablets (trade name NURTEC ODT®) for the acute treatment of migraine with or without aura in adults and the preventive treatment of episodic migraine in adults.

ANSWER: Aurobindo admits that the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), lists Pfizer Inc. as the holder of New Drug Application No. 212728 for rimegepant sulfate orally disintegrating tablets (trade name NURTEC ODT®), which is approved for the acute treatment of migraine with or without aura in adults and the preventive treatment of episodic migraine in adults. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 10.

11. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the patent-in-suit is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to NURTEC ODT®.

ANSWER: Aurobindo admits that the patent-in-suit is listed in the Orange Book. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 11.

THE AUROBINDO ANDA

12. Upon information and belief, Aurobindo Pharma prepared and submitted, through Aurobindo USA, the Aurobindo ANDA to the FDA in accordance with 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of rimegepant orally disintegrating tablets ("Aurobindo's ANDA Product") before the expiration of the patent-in-suit.

ANSWER: Aurobindo admits that it had filed ANDA No. 219328 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 12.

13. Upon information and belief, Aurobindo Pharma acted in concert with Aurobindo USA and Apitoria, or at the direction of one or both, to prepare and submit the Aurobindo ANDA.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 13.

14. Upon information and belief, Aurobindo's ANDA Product is a generic copy of NURTEC ODT®.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 14.

15. Upon information and belief, the Aurobindo ANDA refers to and relies upon Pfizer's New Drug Application No. 212728 and purports to contain data on the bioequivalence of Aurobindo's ANDA Product to NURTEC ODT®.

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. By a letter to Pfizer Inc. and Pfizer Ireland Pharmaceuticals dated April 17, 2024 ("Aurobindo's Paragraph IV Notice Letter"), Aurobindo stated that the Aurobindo ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid and enforceable claim of the patent-in-suit will be infringed by the manufacture, use, or sale of Aurobindo's ANDA Product (the "Paragraph IV Certification"). Aurobindo's Paragraph IV Notice Letter included a statement purporting to allege the factual and legal bases for the Paragraph IV Certification.

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 16.

17. Upon information and belief, if the FDA approves the Aurobindo ANDA, Aurobindo will manufacture, distribute, import, offer for sale and/or sell Aurobindo's ANDA Product throughout the United States, including within the State of Delaware.

ANSWER: Aurobindo's ANDA has not yet been tentatively or finally approved by the FDA, and the allegations of Paragraph 17 are wholly speculative. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 17.

18. This action is being filed within 45 days of Pfizer's receipt of Aurobindo's Paragraph IV Notice Letter.

ANSWER: Paragraph 18 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 18, and on that basis denies these allegations.

JURISDICTION AND VENUE

19. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

20. This Court has personal jurisdiction over Aurobindo Pharma because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Aurobindo Pharma is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Aurobindo Pharma directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the

United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, Aurobindo's contacts with Delaware have been systematic and continuous, and this judicial district is a likely destination of Aurobindo's ANDA Product.

ANSWER: Paragraph 20 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 20.

21. Upon information and belief, Aurobindo Pharma is the holder of the Aurobindo ANDA.

ANSWER: Aurobindo admits that Aurobindo Pharma is the holder of the Aurobindo ANDA. 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. This Court has personal jurisdiction over Apitoria because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Apitoria is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Apitoria directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, Apitoria's contacts with Delaware have been systematic and continuous, and this judicial district is a likely destination of Aurobindo's ANDA Product.

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

23. Upon information and belief, Apitoria acted in concert with or directed Aurobindo Pharma and/or Aurobindo USA to prepare and submit the Aurobindo

ANDA, with the intention of receiving a significant financial benefit from the FDA's approval of the Aurobindo ANDA.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 23.

24. This Court has personal jurisdiction over Aurobindo USA because its affiliations with the State of Delaware, including by virtue of its incorporation in Delaware, are so continuous and systematic that Aurobindo USA resides in Delaware.

ANSWER: Paragraph 24 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 24.

25. This Court also has personal jurisdiction over Aurobindo USA because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Aurobindo USA is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Aurobindo USA directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, Aurobindo USA's contacts with the State of Delaware have been systematic and continuous, and this judicial district is a likely destination of Aurobindo's ANDA Product.

ANSWER: Paragraph 25 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 25.

26. Upon information and belief, Aurobindo USA acted in concert with Aurobindo Pharma and Apitoria, or at the direction of one or both, to prepare and submit the Aurobindo ANDA, with the intention of receiving a significant financial benefit from the marketing and distribution of Aurobindo's ANDA Product throughout the United States, including in Delaware.

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 26.

27. Upon information and belief, Aurobindo Pharma, Apitoria, and Aurobindo USA have thus been, and continue to be, agents of each other and/or operate in concert with respect to the drafting, submission, approval, and maintenance of the Aurobindo ANDA.

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 27.

28. Upon information and belief, Aurobindo Pharma, Apitoria, and Aurobindo USA are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Aurobindo's ANDA Product.

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. This Court also has personal jurisdiction over Aurobindo Pharma and Aurobindo USA because they have availed themselves of the legal protections of the State of Delaware by previously consenting to personal jurisdiction in this judicial district and by asserting counterclaims against plaintiffs. *See, e.g., Bayer Pharma AG v. Aurobindo Pharma Ltd. & Aurobindo Pharma USA, Inc.*, C.A. No. 23-1372 (D. Del.); *Abbvie Inc. v. Aurobindo Pharma Ltd. & Aurobindo Pharma USA, Inc. et al.*, C.A. No. 23-1332 (D. Del.); *Taiho Pharm. Co. Ltd. v. Aurobindo Pharma Ltd. & Aurobindo Pharma USA, Inc. et al.*, C.A. No. 23-1193 (D. Del.); *Vifor Fresenius Med. Care Renal Pharma Ltd v. Aurobindo Pharma Ltd. & Aurobindo Pharma USA, Inc.*, C.A. No. 23-877 (D. Del.); *Pfizer Inc. v. Aurobindo Pharma Ltd. & Aurobindo Pharma USA, Inc.*, C.A. No. 23-717 (D. Del.).

ANSWER: Paragraph 29 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 29.

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

ANSWER: Paragraph 30 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 30.

31. Venue is proper in this Court for Aurobindo Pharma under 28 U.S.C. § 1391 because, upon information and belief, Aurobindo Pharma is not a resident of the United States and may thus be sued in any judicial district.

ANSWER: Paragraph 31 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 31.

32. Venue is proper in this Court for Apitoria under 28 U.S.C. § 1391 because, upon information and belief, Apitoria is not a resident of the United States and may thus be sued in any judicial district.

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 venue in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 32.

33. Venue is proper in this Court for Aurobindo USA under 28 U.S.C. §§ 1391 and 1400(b) because Aurobindo USA is a corporation organized and existing under the laws of Delaware.

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 venue in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 33.

COUNT I
(Infringement of the '724 Patent)

34. Pfizer realleges, and incorporates fully herein, each preceding paragraph.

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

35. Defendants have infringed one or more claims of the '724 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the Aurobindo ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Aurobindo's ANDA Product before the expiration of the '724 patent.

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

36. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product within the United States, or importation of Aurobindo's ANDA Product into the United States, during the term of the '724 patent would infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 36.

37. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product within the United States, or importation of Aurobindo's ANDA Product into the United States, during the term of the '724 patent would induce and/or contribute to the infringement of one or more claims of the '724 patent under 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 37.

38. For example, claim 1 of the '724 patent recites:

> A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: Aurobindo admits that Paragraph 38 contains an accurate recitation of claim 1 of the '724 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 38.

39. Upon information and belief, Aurobindo's ANDA Product will contain a pharmaceutical composition comprising a therapeutically effective amount of rimegepant sulfate, which is a pharmaceutically acceptable salt of the CGRP receptor antagonist rimegepant. Upon information and belief, the pharmaceutical composition of Aurobindo's ANDA Product will be in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 39.

40. Upon information and belief, Defendants have acted with full knowledge of the '724 patent and without a reasonable basis for believing that they would not be liable for infringement of the '724 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product with its proposed labeling immediately and imminently upon approval of the Aurobindo ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '724 patent.

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 40.

41. Upon information and belief, if the FDA approves the Aurobindo ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent, and will do so immediately and imminently upon approval.

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. Upon information and belief, Defendants know that Aurobindo's ANDA Product is especially made or adapted for use in infringing the '724 patent, and that Aurobindo's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '724 patent immediately and imminently upon approval of the Aurobindo ANDA.

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 42.

43. Pfizer will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '724 patent.

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. Pfizer has no adequate remedy at law.

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. Pfizer is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 45.

COUNT II
(Declaratory Judgment of Infringement of the '724 Patent)

46. Pfizer realleges, and incorporates fully herein, each preceding paragraph.

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

47. There is a substantial and immediate controversy between Pfizer and Aurobindo concerning the '724 patent. Pfizer is entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Aurobindo will infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent upon approval of the Aurobindo ANDA.

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 47.

48. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product within the United States, or importation of Aurobindo's ANDA Product into the United States, during the term

of the '724 patent would infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 48.

49. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product within the United States, or importation of Aurobindo's ANDA Product into the United States, during the term of the '724 patent would induce and/or contribute to the infringement of one or more claims of the '724 patent under 35 U.S.C. §§ 271(b) and/or (c).

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. For example, claim 1 of the '724 patent recites:

> A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: Aurobindo admits that Paragraph 50 contains an accurate recitation of claim 1 of the '724 patent. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 50.

51. Upon information and belief, Aurobindo's ANDA Product will contain a pharmaceutical composition comprising a therapeutically effective amount of rimegepant sulfate, which is a pharmaceutically acceptable salt of the CGRP receptor antagonist rimegepant. Upon information and belief, the pharmaceutical composition of Aurobindo's ANDA product will be in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 51.

52. Upon information and belief, Defendants have acted with full knowledge of the '724 patent and without a reasonable basis for believing that they would not be liable for infringement of the '724 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of

Aurobindo's ANDA Product with its proposed labeling immediately and imminently upon approval of the Aurobindo ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '724 patent.

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 52.

53. Upon information and belief, if the FDA approves the Aurobindo ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent, and will do so immediately and imminently upon approval.

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 53.

54. Upon information and belief, Defendants know that Aurobindo's ANDA Product is especially made or adapted for use in infringing the '724 patent, and that Aurobindo's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '724 patent immediately and imminently upon approval of the Aurobindo ANDA.

ANSWER: Paragraph 54 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 54.

55. Pfizer will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '724 patent.

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

56. Pfizer has no adequate remedy at law.

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 56.

57. Pfizer is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 57.

58. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product with its proposed labeling will infringe the '724 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 58.

PLAINTIFFS' REQUEST FOR RELIEF

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

AUROBINDO'S AFFIRMATIVE DEFENSES

Without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not expressly admitted, Aurobindo asserts the following Affirmative Defenses to Pfizer's Complaint without assuming the burden of proof on any defense that would otherwise rest on Pfizer. 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. 219328 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 patent-in-suit.

SECOND DEFENSE

Each of the claims of the patent-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

Pfizer's 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.

Dated: July 23, 2024

Respectfully submitted,

/s/ Kaan Ekiner

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