IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VERTEX PHARMACEUTICALS INCORPORATED, *Plaintiff*, v. SUN PHARMACEUTICAL INDUSTRIES LIMITED, *Defendant.*	C.A. No. 1:20-cv-00988-RGA-CJB (CONSOLIDATED)
VERTEX PHARMACEUTICALS INCORPORATED, *Plaintiff,* v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA U.S.A., INC., *Defendants.*	C.A. No. 1:23-cv-00582-RGA

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

Defendants, Aurobindo Pharma Limited ("APL") and Aurobindo Pharma U.S.A., Inc. ("APUI")(collectively for identification purposes only, "Aurobindo"), by and through their undersigned counsel, respectfully submit their Answer to Plaintiff's Complaint, stating as follows:

RESPONSE TO ALLEGATIONS CONCERNING THE 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 Defendant Aurobindo Pharma Limited's submission of Abbreviated New Drug Application ("ANDA") No. 217086 to the United States Food and Drug Administration

("FDA"), seeking approval to market a generic version of Vertex's KALYDECO® (ivacaftor) tablets prior to the expiration of patents that cover, *inter alia*, KALYDECO® and its use.

RESPONSE: Aurobindo admits Plaintiffs purport to bring an action for alleged patent infringement pursuant to the patent laws of the United States, 35 U.S.C. § 1, et seq. Aurobindo lacks information sufficient to form a belief about the truth of the allegations pertaining to parties other than APL or APUI and, therefore, denies the same. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

2. In ANDA No. 217086, Defendant Aurobindo Pharma Limited seeks approval to commercially market a generic version of Vertex's KALYDECO® tablets prior to the expiration of United States Patent Nos. 10,646,481 (the "'481 patent") and 11,564,916 (the "'916 patent"), which are owned by Vertex.

RESPONSE: Aurobindo admits APL submitted APL's ANDA to the FDA. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

3. On June 2, 2022, Vertex brought an action against Aurobindo for infringement of the '481 patent (C.A. No. 1:22-cv-00728-RGA). The case was consolidated on July 29, 2022 (C.A. No. 20-988-RGA-CJB).

RESPONSE: Aurobindo admits Vertex alleges infringement of the '481 patent and the cases have been consolidated. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO THE ALLEGATIONS CONCERNING THE PARTIES

4. Plaintiff Vertex is a corporation organized and existing under the laws of Massachusetts with its principal place of business at 50 Northern Avenue, Boston, MA 02210. Vertex is a biopharmaceutical company committed to improving the lives of patients worldwide. Vertex focuses on the pursuit of medical research to create transformative medicines for people with serious and life-threatening diseases, such as cystic fibrosis.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

5. Upon information and belief, Defendant Aurobindo Pharma Limited is a company organized and existing under the laws of India, with its principal place of business at Plot No. 2, Maitrivihar, Amerpeet, Hyderabad-500038, Telangana, India. Upon information and belief, Defendant Aurobindo Pharma Limited is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the United States market, alone and/or through its wholly owned subsidiaries and agents, including Defendant Aurobindo Pharma U.S.A., Inc.

RESPONSE: Aurobindo admits APL is an Indian company with a place of business at Water Mark Building, Plot No. 11, Survey no. 9, Kondapur, Hitech City, Hyderabad – 500 084, Telangana, India. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

6. Upon information and belief, Defendant Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 085220. Upon information and belief, Defendant Aurobindo Pharma U.S.A., Inc. is a wholly-owned subsidiary of Aurobindo Pharma Limited.

RESPONSE: Aurobindo admits APUI is incorporated in Delaware with a place of business located at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO THE ALLEGATIONS PERTAINING TO THE PATENT-IN-SUIT

7. On January 31, 2023, the United States Patent and Trademark Office duly and legally issued the ’916 patent, entitled “Pharmaceutical Composition and Administrations Thereof,” to Vertex as assignee. A copy of the ’916 patent is attached to this Complaint as Exhibit A.

RESPONSE: Upon information and belief, Aurobindo admits Exhibit A appears to be a copy of the ’916 patent, which is titled “Pharmaceutical Composition and Administrations Thereof” and is the best evidence of its contents. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

8. Vertex is the lawful owner of and holds all right, title, and interest in the patent-in-suit.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

RESPONSE TO THE ALLEGATIONS PERTAINING TO KALYDECO®

9. Vertex holds approved New Drug Application ("NDA") No. 203188 ("Vertex's NDA") for the use of ivacaftor 150 mg tablets ("Vertex's NDA Product") for the treatment of cystic fibrosis ("CF") in patients age six and older who have one mutation in the cystic fibrosis transmembrane conductance regulator ("CFTR") gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. Vertex sells the ivacaftor tablets under the trade name KALYDECO®.

RESPONSE: Upon information and belief, Aurobindo admits Vertex holds NDA No. 203188. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

10. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the '916 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Vertex's NDA.

RESPONSE: Upon information and belief, Aurobindo admits the '916 patent is listed in the Orange Book in connection with Vertex's NDA No. 203188. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO AUROBINDO'S ANDA

11. Upon information and belief, Defendant Aurobindo Pharma Limited acted in concert with Defendant Aurobindo Pharma U.S.A. Inc. to prepare and submit Abbreviated New Drug Application ("ANDA") No. 217086 ("Aurobindo's ANDA") to the FDA. Defendants submitted Aurobindo's ANDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of 150 mg ivacaftor tablets ("Aurobindo's ANDA Product"), which are based on Vertex's NDA Product, before the expiration of the '481 and '916 patents.

RESPONSE: Aurobindo admits that APL submitted APL's ANDA No. 217086 ("APL's AND") to the FDA under 21 U.S.C. § 355(j) and that APL's ANDA seeks FDA approval of APL's ANDA

prior to the expiration of the '481 and '916 patents. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

12. Upon information and belief, Aurobindo's ANDA refers to and relies upon Vertex's NDA and contains data that, according to Defendants, demonstrates the bioequivalence of Aurobindo's ANDA Product to Vertex's NDA Product.

RESPONSE: Aurobindo admits that APL's ANDA references Vertex's ANDA and includes data meeting the necessary requirements for FDA approval. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

13. By letter to Vertex dated April 20, 2022 ("Aurobindo's April 20, 2022 Paragraph IV Notice Letter"), Defendant Aurobindo Limited stated that Aurobindo's ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid claim of the '481 patent will be infringed by the manufacture, importation, use, or sale of Aurobindo's ANDA Products (the "April 20, 2022 Paragraph IV Certification"). Defendant Aurobindo Limited attached an exhibit to its April 20, 2022 letter, in which it purported to allege the factual and legal bases for its April 20, 2022 Paragraph IV Certification.

RESPONSE: Aurobindo admits APL notified Plaintiff of the filing of its ANDA and its certification pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(IV) and that APL's notification was dated April 20, 2022. Aurobindo admits that its Paragraph IV Notice Letter included a detailed statement of the factual and legal bases for Aurobindo's Paragraph IV certification that asserted that no valid claim of the '481 patent was or would be infringed by Aurobindo's ANDA or ANDA product. Aurobindo denies all further allegations in this paragraph. Allegations not admitted are denied.

14. By letter to Vertex dated April 12, 2022 [sic] ("Aurobindo's April 12, 2023 Paragraph IV Notice Letter"), Defendant Aurobindo Limited stated that Aurobindo's ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid claim of the '916 patent will be infringed by the manufacture, importation, use, or sale of Aurobindo's ANDA Product (the "April 12, 2023 Paragraph IV Certification"). Defendant Aurobindo Limited attached an exhibit to its April 12, 2023 letter, in which it purported to allege the factual and legal bases for its April 12, 2023 Paragraph IV Certification.

RESPONSE: Aurobindo admits APL notified Plaintiff of the filing of its ANDA and its certification pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(IV) and that APL's notification was dated

April 20, 2022. Aurobindo Admits that Aurobindo's April 12, 2023, Paragraph IV Notice Letter included a detailed statement of the factual and legal bases for Aurobindo's Paragraph IV certification that asserted that no valid claim of the '916 patent was or would be infringed by Aurobindo's ANDA or ANDA product. Aurobindo denies all further allegations in this paragraph. Allegations not admitted are denied.

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

RESPONSE: Aurobindo admits that APL's ANDA seeks FDA approval. To the extent this paragraph alleges uncertain future events, the allegations are hypothetical in nature and, therefore, Aurobindo denies such allegations. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

16. This action is being filed within 45 days of Vertex's receipt of Aurobindo's April 12, 2023 Paragraph IV Notice Letter.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

RESPONSE TO THE ALLEGATIONS PERTAINING TO JURISDICTION AND VENUE

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

RESPONSE: Aurobindo admits the Court has subject matter jurisdiction. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

18. This Court has personal jurisdiction over Defendant Aurobindo Pharma Limited because of its regular transaction and/or solicitation of business in this State. Furthermore, by continuously placing its products into the stream of commerce for distribution and consumption in Delaware, and throughout the United States, Defendant Aurobindo Pharma Limited has engaged in the regular conduct of business within this judicial district.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest venue in this District or the Court's exercise of personal jurisdiction over Aurobindo. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

19. In addition, this Court has personal jurisdiction over Defendant Aurobindo Pharma Limited by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Upon information and belief, Defendant Aurobindo Pharma U.S.A., Inc., a wholly-owned subsidiary of Aurobindo Pharma Limited, is incorporated in Delaware.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest venue in this District or the Court's exercise of personal jurisdiction over Aurobindo. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

20. Defendant Aurobindo Pharma Limited filed ANDA No. 217086 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Product in the United States, including in Delaware. Upon information and belief, upon approval of ANDA No. 217086, Defendant Aurobindo Pharma Limited will market, distribute, offer for sale, and/or sell Aurobindo's Product in the United States, including in Delaware.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest venue in this District or the Court's exercise of personal jurisdiction over Aurobindo. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

21. This Court has personal jurisdiction over Defendant Aurobindo Pharma U.S.A., Inc. because, among other things, Aurobindo Pharma U.S.A., Inc. is a corporation formed under the laws of the state of Delaware and has appointed a registered agent in Delaware to accept service of process. Defendant Aurobindo Pharma U.S.A., Inc. has therefore purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest venue in this District or the Court's exercise of personal jurisdiction over Aurobindo. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

22. Upon information and belief, Defendant Aurobindo Pharma U.S.A., Inc., acting as the agent of Defendant Aurobindo Pharma Limited, markets, distributes, offers for sale, and/or sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Defendant Aurobindo Pharma Limited or for which Defendant Aurobindo Pharma Limited is the named

applicant on approved ANDAs. Upon information and belief, upon approval of ANDA No. 217086, Defendant Aurobindo Pharma U.S.A., Inc. will market, distribute, offer for sale, and/or sell Aurobindo's Product in the United States, including in Delaware.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest venue in this District or the Court's exercise of personal jurisdiction over Aurobindo. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

23. Upon information and belief, Defendants have previously consented to suit in this judicial district and have not challenged personal jurisdiction. Defendants have further availed themselves of the jurisdiction of this Court by previously asserting counterclaims in this jurisdiction. *See, e.g., ACADIA Pharmaceuticals Inc. v. Aurobindo Pharma Limited et al.*, No. 20-985, D.I. 10 (D. Del. Sep. 1, 2020); *Amgen Inc. v. Aurobindo Pharma Ltd. et al.*, No. 16-853, D.I. 10 (D. Del. Nov. 28, 2016).

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest venue in this District or the Court's exercise of personal jurisdiction over Aurobindo. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

24. Venue is proper in this Court for Defendant Aurobindo Pharma Limited under 28 U.S.C. § 1391(c)(3) because Aurobindo Pharma Limited, on information and belief, is not a resident of the United States and may thus be sued in any judicial district.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest venue in this District or the Court's exercise of personal jurisdiction over Aurobindo. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

25. Venue is proper in this Court for Defendant Aurobindo Pharma U.S.A., Inc. under 28 U.S.C. § 1400(b) because, *inter alia*, Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not contest venue in this District or the Court's exercise of personal jurisdiction over Aurobindo. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO REQUEST FOR RELIEF
ALLEGED INFRINGEMENT OF U.S. PATENT NO. 11,564,916

26. Vertex hereby realleges and incorporates by reference the allegations of paragraphs 1 to 25 of this Complaint.

RESPONSE: Aurobindo hereby restates and incorporates by reference its responses to the allegations of paragraph 1 to 25 of the Complaint.

27. Defendants have infringed one or more claims of the '916 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining Aurobindo's 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 prior to the expiration of the '916 patent.

RESPONSE: Denied.

28. 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 '916 patent would infringe, induce the infringement, and/or contribute to the infringement of one or more claims of the '916 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

RESPONSE: Denied.

29. Upon information and belief, Defendants have acted with full knowledge of the '916 patent and without a reasonable basis for believing that they would not be liable for infringement of the '916 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 Aurobindo's ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '916 patent.

RESPONSE: Denied.

30. Upon information and belief, if the FDA approves Aurobindo's ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '916 patent, and will do so immediately and imminently upon approval.

RESPONSE: Denied.

31. Upon information and belief, Defendants know that Aurobindo's ANDA Product is especially made or adapted for use in infringing the '916 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 '916 patent immediately and imminently upon approval of Aurobindo's ANDA.

RESPONSE: Denied.

32. Vertex will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '916 patent.

RESPONSE: Denied.

33. Vertex has no adequate remedy at law.

RESPONSE: Denied.

34. Vertex is entitled to a permanent injunction against further infringement under 35 U.S.C. § 283.

RESPONSE: Denied.

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

RESPONSE: Denied.

GENERAL DENIAL AND RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

All allegations in Plaintiff's Complaint not expressly admitted by Aurobindo are hereby denied. Having answered Plaintiff's Complaint, Aurobindo denies Plaintiff is entitled to any of the relief requested in the Complaint or any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Aurobindo asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiff.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of APL's ANDA 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 asserted patent.

SECOND SEPARATE DEFENSE

Each of the claims of the asserted patent are invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or for satisfying other bases (including judicially-created bases) for invalidation or unenforceability, for example, for at least the reasons set forth in APL's Notice Letters.

THIRD SEPARATE DEFENSE

Each of the claims of the asserted patent are invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102 or 103, for example, for at least the reasons set forth in APL's Notice Letters.

FOURTH SEPARATE DEFENSE

Each of the claims of the asserted patent are invalid, pursuant to 35 U.S.C. § 112, as, for example, indefinite, not enabled and/or failing to provide adequate written description.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the asserted patent, Plaintiff is estopped from maintaining that any valid or enforceable claims of the asserted patents are infringed by the product that is the subject of APL's ANDA.

SIXTH SEPARATE DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted.

SEVENTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

WHEREFORE, Aurobindo hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the Asserted patent, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

Dated: July 18, 2023

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