IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VERTEX PHARMACEUTICALS INCORPORATED,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA U.S.A., INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiff Vertex Pharmaceuticals Incorporated ("Vertex"), by its undersigned attorneys, for its Complaint against Defendants Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc. (collectively, "Aurobindo" or "Defendants"), alleges as follows:

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.

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.

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).

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.

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.

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.

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.

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

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®.

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.

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.

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.

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.

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.

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.

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

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.

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.

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.

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.

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.

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.

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).

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.

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.

CLAIM FOR RELIEF
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.

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.

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).

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.

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.

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.

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

33. Vertex has no adequate remedy at law.

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

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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Vertex prays for a judgment in its favor and against Defendants and respectfully requests the following relief:

A. A judgment that Defendants have infringed the '916 patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA and maintaining ANDA No. 217086;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of approval of ANDA No. 217086 shall be a date not earlier than the expiration of the '916 patent, or any later expiration of exclusivity to which Vertex is or becomes entitled;

C. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo's ANDA Product will directly infringe, induce and/or contribute to infringement of the '916 patent;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons acting in privity or concert with them, from manufacturing, using, offering to sell, or selling Aurobindo's ANDA Product within the United States, or importing Aurobindo's ANDA Product into the United States, prior to the expiration of the '916 patent, or any later expiration of exclusivity to which Vertex is or becomes entitled;

E. A permanent injunction, pursuant to 35 U.S.C. § 283, enjoining Defendants, their officers, agents, servants, and employees, and those persons acting in privity or concert with them, from manufacturing, using offering to sell, or selling Aurobindo's ANDA Products within the United States, or importing Aurobindo's ANDA Products into the United States, before the expiration or the '916 patent, including any extensions;

F. If Defendants commercially manufacture, use, offer to sell, or sell Aurobindo's ANDA Product within the United States, or import Aurobindo's ANDA Product into the United States, prior to the expiration of the '916 patent, including any extensions, a judgment awarding damages to Vertex resulting from such infringement, together with interest;

G. A judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Vertex its attorneys' fees incurred in this action;

H. A judgment awarding Vertex costs and expenses incurred in this action; and

I. Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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