IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACADIA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
	)	
AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA, INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff ACADIA Pharmaceuticals Inc. ("ACADIA" or "Plaintiff"), for its Complaint against Defendants Aurobindo Pharma Limited ("Aurobindo Limited") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") (collectively, "Aurobindo" or "Defendants"), hereby alleges as follows:

THE PARTIES

1. ACADIA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12830 El Camino Real, Suite 400, San Diego, California 92130.

2. Upon information and belief, Aurobindo Limited is an entity organized and existing under the laws of India, having a principal place of business at Plot no. 2, Maitrivihar, Ameerpet, Hyderabad-500038, Telangana, India.

3. Upon information and belief, 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.

4. Upon information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Limited.

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

6. Upon information and belief, Aurobindo Limited and Aurobindo USA work in concert, either directly or indirectly, with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in the State of Delaware.

7. Upon information and belief, Aurobindo Limited and Aurobindo USA have participated and collaborated in the preparation, filing, and seeking FDA approval of Abbreviated New Drug Application ("ANDA") No. 214782 for pimavanserin tartrate oral capsules, EQ 34 mg ("the Aurobindo Generic Product"); continue to participate and collaborate in seeking FDA approval of ANDA No. 214782; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and/or sale of the Aurobindo Generic Product throughout the United States including in the State of Delaware.

NATURE OF THE ACTION

8. This is a civil action for infringement of United States Patent No. 11,452,721 ("the '721 patent" or "the patent-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

PROCEEDINGS CONCERNING RELATED PATENTS

9. The '721 patent is related to U.S. Patent Nos. 10,646,480 ("the '480 patent") and 10,849,891 ("the '891 patent").

10. The '480 patent and the '891 patent were asserted against Aurobindo in consolidated Civil Action No. 20-985-GBW.

11. On April 22, 2022, subject to all of ACADIA's rights to appeal, ACADIA and Aurobindo stipulated to noninfringement of the asserted claims of the '480 patent and the '891 patent under the Court's construction of various terms.

12. ACADIA and Aurobindo also stipulated that Aurobindo's unadjudicated defenses with respect to the '480 and '891 patents are dismissed without prejudice, and that Aurobindo reserves and retains the right to reassert any such defenses in the future, including in the event of a reversal and remand to this Court following an appeal from final judgment entered in this case.

JURISDICTION AND VENUE

13. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 2201, 2202, and 35 U.S.C. § 271. The Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

14. In consolidated Civil Action No. 20-985-GBW, Aurobindo did not contest subject matter jurisdiction in this Court.

15. Upon information and belief, Aurobindo USA is a Delaware corporation and has a registered agent in the State of Delaware, the Corporation Service Company located at 251 Little Falls Drive, Wilmington, Delaware 19808.

16. Venue is proper in this Court as to Aurobindo USA under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because, *inter alia*, Aurobindo USA has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

17. The Court has personal jurisdiction over Aurobindo USA and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, Aurobindo USA is a Delaware corporation and thus resides in Delaware and has committed, aided, abetted, contributed to, and/or

participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware. Upon information and belief, Aurobindo USA intends to engage in the commercial manufacture, use, or sale of the Aurobindo Generic Product under ANDA No. 214782 before the expiration of the patent-in-suit, throughout the United States, including in the State of Delaware.

18. Upon information and belief, Aurobindo USA is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions and through the actions of its agents and affiliates.

19. Upon information and belief, Aurobindo USA has purposely availed itself of the privilege of doing business in Delaware, including by, *inter alia*, holding a Distributor/Manufacturer License for Controlled Substances from the State of Delaware under License No. DM-0006550 and a Pharmacy Wholesale License from the State of Delaware under License No. A4-0001270.

20. The Court also has personal jurisdiction over Aurobindo USA, and venue is proper in this Judicial District, by virtue of the fact that, upon information and belief, Aurobindo USA maintains pervasive, continuous, and systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of Delaware, through its own actions and through the actions of its agents and affiliates.

21. Venue is proper in this Court as to Aurobindo Limited under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because, *inter alia*, Aurobindo Limited, directly or indirectly through its subsidiaries, agents, and/or alter egos, has a regular and established place of business in Delaware,

including, at least, Aurobindo USA, a wholly owned subsidiary incorporated in the State of Delaware, and has also committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

22. The Court has personal jurisdiction over Aurobindo Limited, and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, Aurobindo Limited wholly owns a subsidiary that is incorporated in the State of Delaware and has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware. Aurobindo Limited has indicated that it intends, directly or indirectly through its subsidiaries, agents, and/or alter egos, to engage in the commercial manufacture, use, or sale of the Aurobindo Generic Product under ANDA No. 214782 before the expiration of the patent-in-suit, throughout the United States, including in the State of Delaware.

23. Upon information and belief, Aurobindo Limited is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions and through the actions of its agents and affiliates, including, at least, Aurobindo USA.

24. Aurobindo's website states that it "exports to over 150 countries across the globe with around 90% of revenues derived from international operations" and has "multiple facilities approved by leading regulatory agencies such as USFDA." *Business Overview*, https://www.aurobindo.com/investors/disclosures-under-regulation-46/business-overview/ (last visited October 21, 2022). The website further states that it "also has 3 R&D centres in USA" and

a "large manufacturing infrastructure for APIs and formulations" with "11 units for APIs / intermediates and 15 units (10 in India, 3 in USA, 1 in Brazil, and 1 in Portugal) for formulations [that] are designed to meet the requirements of both advanced as well as emerging market opportunities." *Id.* "The R&D Centre has developed products and filed more than 200 ANDA's" with the "focus [being] to develop products for the US and EU." *Research and Development (R&D)*, https://www.aurobindo.com/about-us/business-units/rd/ (last visited October 21, 2022).

25. The Court also has personal jurisdiction over Aurobindo Limited, and venue is proper in this Judicial District, by virtue of the fact that, upon information and belief, Aurobindo Limited maintains pervasive, continuous, and systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of Delaware, through its own actions and through the actions of its agents and affiliates, including, at least, Aurobindo USA. Upon information and belief, Aurobindo Limited derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in the State of Delaware.

26. Aurobindo's infringing actions with respect to the filing of ANDA No. 214782 and intent to commercialize the Aurobindo Generic Product have led and/or will lead to foreseeable harm and injury to ACADIA.

27. The Court also has personal jurisdiction over Aurobindo Limited and Aurobindo USA, and venue is proper in this Court because, *inter alia*, they have previously been sued together in this Judicial District and have not challenged personal jurisdiction or venue, and have purposefully availed themselves of the rights and benefits of the jurisdiction of the Court by filing counterclaims in this Judicial District. *See*, *e.g.*, *Millennium Pharm. v. Aurobindo Pharma USA, Inc.*, C.A. No. 19-471-CFC (D. Del.) (Aurobindo Limited and Aurobindo USA did not contest

jurisdiction and filed counterclaims); *Allergan Sales, LLC v. Aurobindo Pharma USA, Inc.*, C.A. No. 18-118-GMS (D. Del.) (same); *Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd.*, C.A. No. 19-1965-LPS (D. Del.) (Aurobindo Limited and Aurobindo USA did not contest jurisdiction); *Pfizer Inc. v. Aziant Drug Research Sols. Pvt. Ltd.*, C.A. No. 19-743-CFC (D. Del.) (same); *Pfizer Inc. v. Aurobindo Pharma, Ltd.*, C.A. No. 19-748-CFC (D. Del.) (same); *ACADIA Pharmaceuticals Inc. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-985-GBW (D. Del.) (same).

28. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Aurobindo Limited in this action, this Court may exercise jurisdiction over Aurobindo Limited pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) ACADIA's claims arise under federal law; (b) Aurobindo Limited is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Aurobindo Limited has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA, and manufacturing and selling active pharmaceutical ingredients that are used in the products distributed throughout the United States, such that this Court's exercise of jurisdiction over Aurobindo Limited satisfies due process.

29. In consolidated Civil Action No. 20-985-GBW, Aurobindo did not contest venue in this Court.

30. In consolidated Civil Action No. 20-985-GBW, Aurobindo did not contest personal jurisdiction in this Court.

ACADIA'S NDA AND THE '721 PATENT

31. ACADIA holds New Drug Application ("NDA") No. 210793 for oral capsules containing pimavanserin tartrate, Eq. 34 mg base as the active ingredient. ACADIA exclusively manufactures, markets and sells these oral capsules in the United States under the brand name NUPLAZID®.

32. On September 27, 2022, the '721 patent, entitled "Formulations of pimavanserin" was duly and legally issued. A copy of the '721 patent is attached as Exhibit A.

33. ACADIA owns the '721 patent.

34. Pursuant to 21 U.S.C. § 355(b)(1), the '721 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering NUPLAZID® Eq. 34 mg base or its use.

AUROBINDO'S ANDA

35. Upon information and belief, Aurobindo submitted ANDA No. 214782 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Aurobindo's ANDA No. 214782 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the Aurobindo Generic Product prior to the expiration of the '721 patent.

36. Upon information and belief, by filing ANDA No. 214782, Aurobindo has certified to the FDA that the Aurobindo Generic Product has the same active ingredient as NUPLAZID® Eq. 34 mg base and the same or substantially the same proposed labeling as NUPLAZID® Eq. 34 mg base.

37. ACADIA received written notification of Aurobindo's ANDA No. 214782 and its accompanying § 505(j)(2)(A)(vii)(IV) certifications by two letters, one dated June 10, 2020 and sent by FedEx® Priority Overnight ("Aurobindo's 6/10/20 Notice Letter") and one dated January 13, 2021 ("Aurobindo's 1/13/21 Notice Letter") (collectively, "Aurobindo's Notice Letters").

38. Aurobindo's 6/10/20 Notice Letter represented that Aurobindo certified in ANDA No. 214782 that the claims of the '480 patent, which is related to the patent-in-suit, are invalid or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Aurobindo Generic Product.

39. Aurobindo's 1/13/21 Notice Letter represented that Aurobindo certified in ANDA No. 214782 that the claims of the '891 patent, which is related to the patent-in-suit, are invalid or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Aurobindo Generic Product.

40. According to applicable regulations, Notice Letters such as Aurobindo's Notice Letters must contain a detailed statement of the factual and legal bases for the applicant's opinion that the patent is invalid, unenforceable, or not infringed, which includes a claim-by-claim analysis, describing "[f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

41. On information and belief, Aurobindo has not submitted any § 505(j)(2)(A)(vii)(IV) certifications ("Paragraph IV Notice Letter") concerning the '721 patent.

42. This action is being commenced by ACADIA prior to receipt of any Paragraph IV Notice Letter from Aurobindo concerning the '721 patent.

COUNT I - INFRINGEMENT
BY AUROBINDO LIMITED AND AUROBINDO USA

43. ACADIA re-alleges paragraphs 1-42 as if fully set forth herein.

44. Aurobindo's submission of ANDA No. 214782 to the FDA constituted infringement of the '721 patent under 35 U.S.C. § 271(e)(2)(A).

45. Upon information and belief, Aurobindo intends to and will engage in the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Aurobindo Generic Product if it receives FDA approval of ANDA No. 214782.

46. Upon information and belief, the commercial manufacture, use, sale and/or offer for sale, within the United States, and/or import into the United States of the Aurobindo Generic Product prior to the expiration of the '721 patent will infringe and/or induce and/or contribute to the infringement of the '721 patent under 35 U.S.C. § 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

47. Aurobindo Limited and Aurobindo USA are jointly and severally liable for infringement of the '721 patent under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Aurobindo Limited and Aurobindo USA actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 214782 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the Aurobindo Generic Product prior to the expiration of the '721 patent.

48. Aurobindo filed ANDA No. 214782 without adequate justification for asserting that the '721 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Aurobindo Generic Product.

49. Moreover, if Aurobindo manufactures, uses, offers for sale, or imports into the United States any of the Aurobindo Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '721 patent, including any applicable exclusivities or extensions, Aurobindo would infringe one or more claims of the '721 patent under 35 U.S.C. § 271(a), (b), and/or (c).

50. ACADIA is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Aurobindo's ANDA No. 214782 be a date

that is not earlier than the expiration of the '721 patent, or any later expiration of exclusivity for the '721 patent to which ACADIA is or becomes entitled.

51. ACADIA is entitled to a declaration that, if Aurobindo commercially manufactures, uses, offers for sale, imports, and/or sells the proposed Aurobindo Generic Product within the United States, imports the proposed Aurobindo Generic Product into the United States, and/or induces and/or contributes to such conduct, Aurobindo will infringe one or more claims of the '721 patent under 35 U.S.C. § 271(a), (b), and/or (c).

52. ACADIA will be irreparably harmed by Aurobindo's infringing activities unless those activities are enjoined by this Court. ACADIA does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, ACADIA requests that the Court grant the following relief:

A. A Judgment that Aurobindo has infringed the '721 patent by submitting ANDA No. 214782 to the FDA;

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Aurobindo's ANDA No. 214782 will not be earlier than the expiration date of the '721 patent, or any later expiration of any patent term extension or exclusivity for the '721 patent to which ACADIA is or becomes entitled;

C. A declaration and judgment that the '721 patent has or will be infringed by Aurobindo's commercial manufacture, use, offer for sale, sale, and/or import of the proposed Aurobindo Generic Product within the United States;

D. An Order permanently enjoining Aurobindo, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with Aurobindo, from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing the Aurobindo Generic Product identified in this Complaint, or any

product that infringes or induces or contributes to the infringement of the '721 patent, prior to the expiration of the '721 patent, including any exclusivities or extensions to which ACADIA is or becomes entitled;

E. That ACADIA be awarded monetary relief to the extent Aurobindo commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any product that infringes or induces or contributes to the infringement of the '721 patent, within the United States prior to the expiration of the '721 patent, including any later expiration of any patent term extensions or exclusivities for the '721 patent to which ACADIA is or will become entitled, and that any such monetary relief be awarded to ACADIA with prejudgment interest;

F. A finding that this case is an exceptional case and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

G. That ACADIA be awarded the costs and expenses that it incurs in prosecuting this action; and

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

DATED: October 21, 2022

SAUL EWING ARNSTEIN & LEHR LLP

/s/ Michelle C. Streifthau-Livizos

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