

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and)	
KAI PHARMACEUTICALS, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
AUROBINDO PHARMA LIMITED and)	
AUROBINDO PHARMA USA INC.,)	
)	
Defendants.)	

COMPLAINT

Plaintiffs Amgen Inc. (“Amgen”) and KAI Pharmaceuticals, Inc. (“KAI”) (collectively “Plaintiffs”) by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendants Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. (collectively “Aurobindo”) of Abbreviated New Drug Application (“ANDA”) No. 215840 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of Parsabiv® (etelcalcetide) injection for intravenous use at strengths of 2.5 mg/0.5 mL, 5 mg/mL, and 10 mg/2 mL (“Aurobindo’s Proposed ANDA Product”) prior to the expiration of U.S. Patent Nos. 9,820,938 (“the ’938 patent”) and 10,344,765 (“the ’765 patent”) (collectively “the Asserted Patents”). Aurobindo notified Plaintiffs that it had submitted this ANDA by a letter received March 26, 2021 (“Notice Letter”). Upon information and belief, Aurobindo’s Proposed ANDA Product will be marketed as a competing product to Parsabiv® (etelcalcetide), a product developed by Plaintiffs for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

PARTIES

2. Plaintiff Amgen is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at One Amgen Center Drive, Thousand Oaks, CA 91320.

3. Plaintiff KAI is a corporation organized and existing under the laws of Delaware, having a place of business at One Amgen Center Drive, Thousand Oaks, CA 91320. KAI is a wholly owned subsidiary of Amgen.

4. Upon information and belief, Defendant Aurobindo Pharma Limited is a corporation organized and existing under the laws of the Republic of India, having a place of business at Plot No. 11, Water Mark Building, Hitech City Road, Whitefields, Kondapur, Hyderabad, Telangana 500084, India. Upon information and belief, Aurobindo Pharma Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Aurobindo Pharma USA Inc., throughout the United States, including in Delaware.

5. Upon information and belief, Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of Delaware, having its corporate offices and a principal place of business at 279 Princeton-Hightstown Road, East Windsor, NJ 08520. Upon information and belief, Aurobindo Pharma USA Inc. is a wholly owned subsidiary of Aurobindo Pharma Limited. Upon information and belief, Aurobindo Pharma USA Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drug products throughout the United States, including in Delaware.

6. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or

distribution of pharmaceutical products. Upon further information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. are agents of each other and/or operate in concert as integrated parts of the same business group.

7. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. acted in concert to develop Aurobindo's Proposed ANDA Product that is the subject of ANDA No. 215840 and to seek regulatory approval from the FDA to market and sell Aurobindo's Proposed ANDA Product throughout the United States, including in Delaware.

8. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. intend to act collaboratively to obtain approval for Aurobindo's ANDA No. 215840, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's Proposed ANDA Product in the United States, including in Delaware.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Aurobindo Pharma USA Inc. because, on information and belief, Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of the Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, Aurobindo Pharma USA Inc. has consented to general jurisdiction in Delaware.

11. This Court has personal jurisdiction over Aurobindo Pharma Limited because, *inter alia*, Aurobindo Pharma Limited, itself and through its subsidiary Aurobindo Pharma USA Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should

reasonably anticipate being haled into court here. On information and belief, Aurobindo Pharma Limited, itself and through its subsidiary Aurobindo Pharma USA Inc., develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

12. In addition, this Court has personal jurisdiction over Aurobindo Pharma Limited because, among other things, on information and belief: (1) Aurobindo Pharma Limited and its subsidiary Aurobindo Pharma USA Inc. filed Aurobindo's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of Aurobindo's Proposed ANDA Product in the United States, including in Delaware; and (2) upon approval of Aurobindo's ANDA, Aurobindo Pharma Limited and its subsidiary Aurobindo Pharma USA Inc. will market, distribute, offer for sale, sell, and/or import Aurobindo's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Aurobindo's Proposed ANDA Product in Delaware. On information and belief, upon approval of Aurobindo's ANDA, Aurobindo's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware.

13. In addition, this Court has personal jurisdiction over Aurobindo Pharma Limited because it has committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Amgen and KAI, both Delaware corporations.

14. In addition, this Court has personal jurisdiction over Aurobindo Pharma Limited because it regularly engages in patent litigation concerning Aurobindo's ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g., Pfizer Inc. v. Aurobindo Pharma, Ltd.*, C.A. No. 20-01528 (D. Del.); *Amgen Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 16-00853 (D. Del.).

15. In addition, to the extent personal jurisdiction does not exist over Aurobindo Pharma Limited in Delaware, this Court has personal jurisdiction over it under Federal Rule of Civil Procedure 4(k)(2) because Aurobindo Pharma Limited is not subject to jurisdiction in any state's courts of general jurisdiction and exercising jurisdiction over it is consistent with the United States Constitution and laws.

16. For at least the above reasons, it would not be unfair or unreasonable for Aurobindo Pharma Limited to litigate this action in this District, and Aurobindo Pharma Limited is subject to personal jurisdiction in this District.

17. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to Aurobindo Pharma USA Inc., at least because, on information and belief, Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of Delaware and therefore resides in Delaware for purposes of venue.

18. Venue is proper in this Court under 28 U.S.C. § 1391(c) with respect to Aurobindo Pharma Limited, at least because, on information and belief, Aurobindo Pharma Limited is a foreign corporation that may be sued in any judicial district.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.