

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEWRON PHARMACEUTICALS S.p.A.,
ZAMBON S.p.A.,
MDD US OPERATIONS, LLC,

Plaintiffs,

v.

AUROBINDO PHARMA LIMITED,
AUROBINDO PHARMA USA INC.,
MSN LABORATORIES PRIVATE
LIMITED,
OPTIMUS PHARMA PVT LTD,
PRINSTON PHARMACEUTICAL, INC.,
RK PHARMA INC.,
ZENARA PHARMA PRIVATE LIMITED,

Defendants.

C.A. No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Newron Pharmaceuticals S.p.A. (“Newron”), Zambon S.p.A. (“Zambon”), and MDD US Operations, LLC (“MDD”, collectively, “Plaintiffs”), by their attorneys, hereby allege as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 8,076,515 (“the ’515 patent”), 8,278,485 (the “’485 patent”), and 8,283,380 (the “’380 patent”) (collectively, the Asserted Patents”) under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., including §§ 271(e)(2), 271(a)-(c), and for a declaratory judgment of infringement of the ’515, ’485, and ’380 patents under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 271(a)-(c). Plaintiffs institute this action to enforce their patent rights covering FDA-approved XADAGO[®] (safinamide) tablets.

THE PARTIES

A. Plaintiffs

2. Plaintiff Newron Pharmaceuticals S.p.A. is a joint stock company organized under the laws of the Republic of Italy with its principal place of business at Via Antonio Meucci 3, 20091 Bresso (MI) Italy.

3. Plaintiff Zambon S.p.A. is a company organized under the laws of Italy with its principal place of business at Via Lillo del Duca 10, 20091 Bresso (MI) Italy.

4. Plaintiff MDD US Operations, LLC is a company organized under the laws of Delaware with its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

B. Aurobindo

5. On information and belief, Defendant Aurobindo Pharma Limited (“Aurobindo Pharma”) is a corporation organized and existing under the laws of India with its principal place of business at Plot No. 11, Water Mark Building, Hightech City Rd, Whitefields, Kondapur, Hyderabad, Telangana 500084, India. On information and belief, Defendant Aurobindo Pharma USA Inc. (“Aurobindo Pharma USA”, collectively, “Aurobindo”) is a corporation organized and existing under the laws of Delaware with its principal place of business at 279 Princeton-Hightstown Rd, East Windsor, NJ 08520-1401.

C. MSN

6. On information and belief, Defendant MSN Laboratories Private Limited (“MSN”) is a corporation organized and existing under the laws of India with its principal place of business

at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad 500018 Telangana, India.

D. Optimus

7. On information and belief, Defendant Optimus Pharma Pvt Ltd (“Optimus”) is a corporation organized and existing under the laws of India with its principal place of business at 2nd Floor, Sy No. 37/A & 37/P, Plot No.6P, Signature Towers, Kothaguda, Kondapur, Hyderabad 500084, Telangana, India.

E. Princeton

8. On information and belief, Defendant Princeton Pharmaceutical, Inc. (“Princeton”) is a corporation organized and existing under the laws of Delaware with its principal place of business at 700 Atrium Drive, Somerset, NJ 08873.

F. RK Pharma

9. On information and belief, Defendant RK Pharma, Inc. (“RK Pharma”) is a corporation organized and existing under the laws of Delaware with its principal place of business at 401 N. Middletown Road, Building 215/215A, Pearl River, NY 10965.

G. Zenara

10. On information and belief, Defendant Zenara Pharma Private Limited (“Zenara”) is a corporation organized and existing under the laws of India with its principal place of business at Plot 87-95, Phase III, Industrial Development Area, Cherlapalli, Hyderabad, Telangana 500051, India.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) because the action concerns a federal question arising under the Patent Laws of the United States, including 35 U.S.C. § 271.

A. Aurobindo

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

13. This Court has personal jurisdiction over Defendant Aurobindo Pharma because, *inter alia*, Aurobindo Pharma, itself and through its subsidiaries, agents, and/or affiliates, including Aurobindo Pharma USA, 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, itself and through its subsidiaries, agents, and/or affiliates, including Aurobindo Pharma USA, 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.

14. In addition, this Court has personal jurisdiction over Aurobindo Pharma and Aurobindo Pharma USA because, among other things, on information and belief: (1) Aurobindo Pharma and its subsidiary Aurobindo Pharma USA, collectively and/or in concert with each other, developed Aurobindo's ANDA Product that is the subject of ANDA No. 215902 and 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 ANDA Product in the United States, including in Delaware; (2) upon approval of Aurobindo's ANDA, Aurobindo Pharma and its subsidiary

Aurobindo Pharma USA, collectively and/or in concert with each other, intend to market, distribute, offer for sale, sell, and/or import Aurobindo's ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Aurobindo's ANDA Product in Delaware; and (3) also upon approval of Aurobindo's ANDA, Aurobindo's 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. By filing Aurobindo's ANDA, Aurobindo Pharma and Aurobindo Pharma USA have made clear that they intend to use their distribution channels to direct sales of Aurobindo's ANDA Product into Delaware.

15. In addition, upon information and belief, this Court has personal jurisdiction over Aurobindo Pharma USA and Aurobindo Pharma because both regularly engage in patent litigation concerning Aurobindo's ANDA products in this District, have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and have filed counterclaims in such cases. *See, e.g., UCB Inc. et al. v. Annora Pharma Pvt. Ltd. et al.*, C.A. No. 20-0987-CFC, D.I. 37 (D. Del. July 24, 2020) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.); *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-0985-RGA, D.I. 10 (D. Del. Dec. 20, 2020) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.); *Taiho Pharm. Co. v. Eugia Pharma Specialities Ltd.*, C.A. No. 19-2309-CFC (D. Del. Mar. 23, 2020) (Aurobindo Pharma USA, Inc.); *Millennium Pharm. v. Aurobindo Pharma USA, Inc.*, C.A. No. 19-0471-CFC (D. Del. Dec. 26, 2019) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.); *Pfizer Inc. v. Aurobindo Pharma, Ltd.*, C.A. No. 19-0748-CFC (D. Del. July 8, 2019) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.).

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