

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MERZ PHARMACEUTICALS, LLC and
MERZ NORTH AMERICA, INC.,

Plaintiffs,

v.

AUROBINDO PHARMA LTD, and
AUROBINDO PHARMA USA INC.

Defendants.

C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merz Pharmaceuticals, LLC (“Merz LLC”) and Merz North America, Inc. (“Merz N.A.”) (together, “Merz” or “Plaintiffs”) bring this action against Defendant Aurobindo Pharma Ltd., (“APL”) and Aurobindo Pharma USA Inc. (“APUI,” collectively, “Aurobindo” or “Defendants”), and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 7,638,552 (“the ’552 Patent”) and 7,816,396 (“the ’396 Patent,” collectively, the “patents-in-suit”), arising under the United States patent laws, Title 35, United States Code. This action relates to Aurobindo’s filing of Abbreviated New Drug Application (“ANDA”) No. 214847 under section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking United States Food and Drug Administration (“FDA”) approval to manufacture and sell a generic version of Plaintiffs’ CUVPOSA® (glycopyrrolate), 1mg/5mL oral solution (“CUVPOSA®”) prior to the expiration of the ’552 and the ’396 Patents.

2. By letter dated November 16, 2020, Defendant Aurobindo notified Plaintiff Merz LLC that it had filed ANDA No. 214847, seeking FDA approval to manufacture and sell a generic version of Plaintiffs' CUVPOSA®.

THE PARTIES

3. Plaintiff Merz LLC is a limited liability company organized and existing under the laws of North Carolina, with a principal place of business at 6501 Six Forks Road, Raleigh, North Carolina 27615. Plaintiff Merz LLC is in the business of, *inter alia*, holding intellectual property and regulatory approval rights to innovative pharmaceutical products.

4. Plaintiff Merz N.A. is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 6501 Six Forks Road, Raleigh, North Carolina 27615. Plaintiff Merz N.A. is in the business of, *inter alia*, researching, developing, manufacturing, marketing, promoting, selling, distributing, and/or obtaining regulatory approval for innovative pharmaceutical products throughout the United States, including in this judicial district.

5. On information and belief, Defendant APL is a corporation that is incorporated in India, having a principal place of business at Plot No 2, Maitrivihar, Behind Maitrivanam, Ameerpet, Hyderabad, Telangana TS 500038 IN.

6. On information and belief, Defendant APUI is a corporation that is incorporated in Delaware, having a principal place of business at 279 Princeton-Hightstown Rd, East Windsor, NJ 08520-1401.

7. On information and belief, Defendant APUI is a wholly owned subsidiary of APL.

8. On information and belief, Aurobindo, by itself and/or through its affiliates and agents, is in the business of, *inter alia*, developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within the State of Delaware.

9. On information and belief, Aurobindo has filed ANDA No. 214847 and will be involved in the manufacture, importation, marketing and sale of the drug that is subject to ANDA No. 214847 if it is approved.

10. On information and belief, and consistent with their past practices, APL and APUI acted collaboratively in the preparation and submission of ANDA No. 214847.

11. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 214847, APL and APUI will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 214847 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

13. This Court has personal jurisdiction over APL because APL, through its wholly-owned subsidiary APUI, has purposely availed itself of the benefits and protections of Delaware's laws, as it develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including the State of Delaware.

Therefore, APL transacts business related to Merz's claims and/or has engaged in systematic and continuous business contacts within the State of Delaware.

14. Alternatively, to the extent the above facts do not establish personal jurisdiction over APL, this Court may exercise jurisdiction over APL pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) APL is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) APL has sufficient contacts within the United States as a whole, including but not limited to preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over APL satisfies due process.

15. This Court has personal jurisdiction over APUI for purposes of this civil action because, *inter alia*, APUI, on information and belief, is incorporated in the State of Delaware.

16. This Court also has personal jurisdiction over APUI for purposes of this civil action because, *inter alia*, APUI has purposely availed itself of the benefits and protections of Delaware's laws, as it develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including the State of Delaware. Therefore, APL transacts business related to Merz's claims and/or has engaged in systematic and continuous business contacts within the State of Delaware.

17. This Court has personal jurisdiction over Aurobindo for purposes of this civil action because, *inter alia*, Aurobindo has filed ANDA No. 214847 and intends to make, use, offer for sale, sell and/or import its proposed ANDA product in the United States, including Delaware, prior to the expiration of the patents-in-suit if ANDA No. 214847 is approved. Such acts will lead to foreseeable harm to Plaintiffs in Delaware.

18. On information and belief, Aurobindo has not challenged personal jurisdiction in this Court in one or more prior cases arising out of the filing of its ANDAs. *See, e.g., Merck*

Sharp & Dohme Corp. v. Aurobindo Pharma Ltd et al., C.A. No. 20-1099 (D. Del.); *Novartis Pharmaceuticals Corp. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-1426 (D. Del.); *Pfizer Inc. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-1528 (D. Del.).

19. On information and belief, Aurobindo has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted counterclaims in this jurisdiction. *See, e.g., Merck Sharp & Dohme Corp. v. Aurobindo Pharma Ltd et al.*, C.A. No. 20-1099 (D. Del.); *Novartis Pharmaceuticals Corp. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-1426 (D. Del.); *Pfizer Inc. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-1528 (D. Del.).

20. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT AND CUVPOSA®

21. On December 29, 2009, the United States Patent and Trademark Office (“PTO”) issued the ’552 Patent, entitled “Method for Increasing The Bioavailability of Glycopyrrolate,” to Sciele Pharma, Inc., the initial assignee of the named inventors, Alan Roberts and Balaji Venkataraman. The ’552 Patent was subsequently assigned to Shiongi Pharma, Inc. on January 11, 2010; to Shionogi Inc. on March 31, 2011; and then to Plaintiff Merz LLC on August 24, 2012. Plaintiff Merz LLC is the current record owner of the ’552 Patent. A copy of the ’552 Patent is attached hereto as Exhibit A.

22. On October 19, 2010, the PTO issued the ’396 Patent, entitled “Method for Increasing The Bioavailability of Glycopyrrolate,” to Sciele Pharma, Inc., the initial assignee of the named inventors, Alan Roberts and Balaji Venkataraman. The ’396 Patent was subsequently assigned to Shionogi Pharma, Inc. on January 11, 2010; to Shionogi Inc. on March 31, 2011; and

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