IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., ARBOR PHARMACEUTICALS, LLC, and TAKEDA PHARMACEUTICAL COMPANY LIMITED, Plaintiffs, v. GLENMARK PHARMACEUTICALS LIMITED and GLENMARK PHARMACEUTICALS INC., USA, Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Azurity Pharmaceuticals, Inc., Arbor Pharmaceuticals, LLC (together with Azurity Pharmaceuticals, Inc., "Azurity"), and Takeda Pharmaceutical Company Limited ("Takeda") (collectively, "Plaintiffs"), for their Complaint against Defendants Glenmark Pharmaceuticals Limited ("Glenmark Ltd.") and Glenmark Pharmaceuticals Inc., USA ("Glenmark USA") (collectively "Defendants" or "Glenmark"), hereby allege as follows:

THE PARTIES

1. Azurity Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801.

2. Arbor Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.

3. Takeda is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan.

4. Upon information and belief, Defendant Glenmark Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Glenmark House, HDO-Corporate Building, Wing-A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India. Upon information and belief, Defendant Glenmark Ltd., itself and through its wholly owned subsidiary Glenmark USA, develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this judicial district.

5. Upon information and belief, Defendant Glenmark USA is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 759 Corporate Drive, Mahwah, New Jersey 07430. Upon information and belief, Glenmark USA is a wholly owned subsidiary of Glenmark Ltd. and acts as its authorized agent in the United States. Upon information and belief, Glenmark USA develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this judicial district.

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent No. 9,066,936 ("the '936 patent"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

JURISDICTION & VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, the incorporation of Glenmark USA in the State of Delaware and the fact that they have availed themselves of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware and because they intend to market, sell, and/or distribute generic pharmaceutical drug products within this State and to residents of this State, including the generic drug product that is the subject of Abbreviated New Drug Application ("ANDA") No. 216378. This Court has personal jurisdiction over Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

9. This Court also has personal jurisdiction over Defendants by virtue of, *inter alia*, the fact that they have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to and/or will lead to foreseeable harm and injury to Plaintiffs, including Azurity Pharmaceuticals, Inc. and Arbor Pharmaceuticals, LLC, both Delaware corporations.

10. This Court also has personal jurisdiction over Defendants because they have previously been sued in this district and have not challenged personal jurisdiction, and they have purposefully availed themselves of the rights and benefits of the jurisdiction of this Court by filing claims and counterclaims in this district. *See, e.g.*, *Novartis Pharm. Corp. v. HEC Pharm. Co., Ltd. et al*, C.A. No. 20-133-MN, D.I.11 (D. Del. Feb. 18, 2020); *Pfizer Inc. et al v. Glenmark Pharma. Ltd. et al*, C.A. No. 19-1209-RGA, D.I. 15 (D. Del. Sep. 3, 2019); *Novartis Pharm. Corp. v. Accord Healthcare Inc. et al.*, C.A. No. 18-1043-LPS, D.I. 146 (D. Del. Sep. 17, 2018); *Delcor Asset Corp. v. Glenmark Pharm. Ltd. et al*, C.A. No. 18-460-SRF, D.I. 18 (D. Del. May 29, 2018); *Biogen Int'l GMBH et al v. Glenmark Pharm. Ltd et al*, C.A. No. 17-852, D.I. 9 (D. Del. Oct. 16, 2017).

11. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Glenmark Ltd. in this action, this Court may exercise jurisdiction over Glenmark Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Glenmark Limited is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Glenmark Limited has sufficient contacts with the United States as a whole, including, but not limited to, submitting ANDA No. 216378 to the FDA with the intent to develop, manufacture, market, sell, distribute, and/or import the generic drug product that is the subject of ANDA No. 216378 throughout the United States, such that this Court's exercise of jurisdiction over Glenmark Ltd. satisfies due process.

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

THE '936 PATENT

13. On June 30, 2015, the '936 patent, entitled "Solid pharmaceutical composition comprising a benzimidazole-7-carboxylate derivative and a pH control agent" was duly and legally issued. A copy of the '936 patent is attached as Exhibit A.

14. Takeda owns the '936 patent. Azurity holds an exclusive license to the '936 patent in the United States.

ACTS GIVING RISE TO THIS ACTION

15. Azurity holds New Drug Application ("NDA") No. 200796 for oral tablets containing 40/80 mg azilsartan medoxomil as the active ingredient. Azurity markets and sells these oral tablets in the United States under the brand name EDARBI®.

16. Pursuant to 21 U.S.C. § 355(b)(1), the '936 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering EDARBI® or its use. United States Patent Nos. 7,157,584 ("the '584 patent") and 7,572,920 ("the '920 patent") are further listed in the Orange Book as covering EDARBI® or its use.

17. Upon information and belief, Glenmark submitted ANDA No. 216378 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Glenmark's ANDA No. 216378 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 an oral tablet containing 40 mg or 80 mg of azilsartan medoxomil ("the Glenmark Generic Product") prior to the expiration of the '936 patent.

18. Upon information and belief, by filing ANDA No. 216378, Glenmark has certified to the FDA that the Glenmark Generic Product has the same active ingredients as EDARBI® and the same or substantially the same proposed labeling as EDARBI®.

19. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Glenmark certified in ANDA No. 216378 that the claims of the '936 patent are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Glenmark Generic Product.

20. Upon information and belief, Glenmark did not certify the claims of the '584 patent and the '920 patent to be invalid, unenforceable, or not to be infringed by the commercial manufacture, use, sale, or offer for sale of the Glenmark Generic Product in ANDA No. 216378.

21. Plaintiffs received written notification of Glenmark's ANDA No. 216378 and its accompanying § 505(j)(2)(A)(vii)(IV) certifications by Federal Express, dated November 17, 2022 ("Glenmark's Notice Letter").

22. To date, Glenmark has not provided Plaintiffs with a copy of any portions of ANDA No. 216378 or any information regarding the Glenmark Generic Product, beyond the information set forth in Glenmark's Notice Letter.

23. The limited information relating to the Glenmark Generic Product that was provided in Glenmark's Notice Letter does not demonstrate that the Glenmark Generic Product, which Glenmark has asked the FDA to approve for sale in the U.S., will not fall within the scope of issued claims of the '936 patent.

24. This action was commenced within 45 days of Plaintiffs receiving Glenmark's Notice Letter.

COUNT I
INFRINGEMENT BY GLENMARK OF U.S. PATENT NO. 9,066,936

25. Plaintiffs re-allege paragraphs 1-24 as if fully set forth herein.

26. Glenmark's submission of ANDA No. 216378 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '936 patent under 35 U.S.C. § 271(e)(2)(A).

27. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the Glenmark Generic Product—if approved by the FDA, prior to the expiration of the '936 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '936 patent.

28. Plaintiffs are 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 or Glenmark's ANDA No. 216378 be a date that is not earlier than the expiration of the '936 patent, or any later expiration of patent term extension, adjustment, or exclusivity for the '936 patent to which Plaintiffs are or become entitled.

29. Plaintiffs will be irreparably harmed by Glenmark's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

30. Upon information and belief, Defendants were aware of the existence of the '936 patent and were aware that the filing of ANDA No. 216378 and the certification with respect to the '936 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment that:

A. Glenmark has infringed one or more claims of the '936 patent;

B. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Glenmark's ANDA No. 216378 will not be earlier than the expiration date of the '936 patent, or any later expiration of any patent term extension, adjustment, or exclusivity for the '936 patent to which Plaintiffs are or become entitled;

C. Glenmark, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing the Glenmark Generic Product and any other product that infringes or induces or contributes to the infringement of the '936 patent, prior to the expiration of the '936 patent, including any exclusivity, adjustment, or extension to which Plaintiffs are or become entitled;

D. Plaintiffs be awarded monetary relief to the extent Glenmark 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 '936 patent within the United States prior to its expiration, including any later expiration of any patent term extension, adjustment, or exclusivity for the '936 patent to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

E. Plaintiffs be awarded the attorneys' fees, costs, and expenses that they incur in litigating this action; and

F. Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: December 16, 2022

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