

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

ASTRAZENECA AB and)	
ASTRAZENECA PHARMACEUTICALS LP,)	
)	
Plaintiffs,)	
)	Civil Action No. _____
v.)	
)	
ZYDUS PHARMACEUTICALS (USA), INC.,)	
AND CADILA HEALTHCARE LTD.,)	
)	
Defendants.)	
_____)	

COMPLAINT

Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively “AstraZeneca” or “Plaintiffs”), by their attorneys, for their Complaint, 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 filing by Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd. (collectively, “Zydus”) of an amendment to Abbreviated New Drug Application (“ANDA”) No. 214263 with the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Plaintiffs’ Tagrisso® (osimertinib mesylate) in tablet form in doses of 40 mg and 80 mg prior to the expiration of U.S. Patent No. 10,183,020 (“the ’020 patent”).

PARTIES

Plaintiffs

2. Plaintiff AstraZeneca AB is a public limited liability company organized under the laws of Sweden, with a principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with a principal place of business at 1800 Concord Pike, Wilmington, Delaware, 19850.

Defendants

4. On information and belief, defendant Zydus Pharmaceuticals (USA) Inc. (“Zydus Pharma”) is a corporation organized and existing under the laws of the State of New Jersey with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

5. On information and belief, defendant Cadila Healthcare Ltd. (“Cadila”) is a corporation organized and existing under the laws of India, with a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vasihnodevi Circle, S. G. Highway, Ahmedabad 382 481, India.

6. On information and belief, Zydus Pharma is a wholly owned subsidiary of Cadila, and is controlled and dominated by Cadila. On information and belief, Zydus Pharma is the U.S. agent for Cadila. Zydus has admitted in pending patent litigation concerning infringement of the '020 patent that Cadila is the manufacturer of Zydus Pharma's ANDA Products, and that Zydus Pharma is a wholly owned subsidiary of Cadila. *See AstraZeneca AB et al. v. Alembic Pharmaceuticals Limited et al.*, C.A. No. 20-202-RGA (D. Del. April 13, 2020) (“Pending Infringement Action”), D.I. 19 at ¶ 20.

7. On information and belief, Zydus Pharma is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Zydus Pharma, acting in concert with Cadila, files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Zydus Pharma, acting in concert with Cadila, files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

8. On information and belief, Zydus Pharma and Cadila acted in concert to prepare, submit, and amend ANDA No. 214263 for their 40 mg and 80 mg osimertinib mesylate tablets (“Zydus’s ANDA Products”), which was done at the direction of, under the control of, and for the direct benefit of Cadila.

JURISDICTION

9. Jurisdiction is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

10. This Court has personal jurisdiction over each of Cadila and Zydus Pharma.

11. Cadila is subject to personal jurisdiction in Delaware because, among other things, Cadila, itself and through its wholly owned subsidiary Zydus Pharma, 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, Cadila, itself and through its subsidiary Zydus Pharma, develops, manufactures, imports, markets, offers to sell, and/or sells

generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Cadila is subject to personal jurisdiction in Delaware because, upon information and belief, it controls and dominates Zydus Pharma and therefore the activities of Zydus Pharma in this jurisdiction are attributed to Cadila.

12. Zydus Pharma is subject to personal jurisdiction in Delaware because, among other things, it has purposely 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, Zydus Pharma, itself and in concert with Cadila, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

13. On information and belief, Zydus knows and intends that following any approval of Zydus's ANDA No. 214263 as amended, Zydus will manufacture and import into the United States Zydus's ANDA Products and directly or indirectly market, sell, and distribute Zydus's ANDA Products throughout the United States, including in Delaware. On information and belief, following any FDA approval of ANDA No. 214263 as amended, Zydus knows and intends that Zydus's ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

14. On information and belief, Cadila and Zydus Pharma are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic

pharmaceutical products throughout the United States, including into Delaware, and including with respect to Zydus's ANDA Products at issue. On information and belief, Zydus Pharma participated in, assisted, and cooperated with Cadila in the acts complained of herein.

15. Zydus has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

16. On information and belief, Zydus, with knowledge of the Hatch-Waxman Act process, directed Zydus's Second Notice Letter (defined below) to, *inter alia*, AstraZeneca Pharmaceuticals LP, to an address in Delaware, and alleged in Zydus's Second Notice Letter that the '020 patent will not be infringed by the commercial manufacture, use or sale of Zydus's ANDA Products. On information and belief, Zydus knowingly and deliberately challenged the '020 patent in its Second Notice Letter knowing that each time it did so it was triggering a forty-five day period for Plaintiffs to bring an action for patent infringement under the Hatch-Waxman Act.

17. Because AstraZeneca Pharmaceuticals LP is a limited partnership organized in Delaware, it suffers injury and consequences from Zydus's submission of an amendment to Zydus's ANDA No. 214263, and challenging the '020 patent in Delaware.

18. Zydus Pharma has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Zydus's Second Notice Letter to a Delaware entity, it would be sued in Delaware for patent infringement.

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