

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PUMA BIOTECHNOLOGY, INC. and
WYETH LLC,

Plaintiffs,

v.

ASTRAZENECA PHARMACEUTICALS
LP, ASTRAZENECA AB, and
ASTRAZENECA PLC,

Defendants.

C.A. No. _____

DEMAND FOR JURY TRIAL

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Puma Biotechnology, Inc. (“Puma”) and Wyeth LLC (collectively, “Plaintiffs”), by their attorneys, bring this complaint against Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and AstraZeneca PLC (collectively, “AstraZeneca” or “Defendants”), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code § 100 *et seq.*, including 35 U.S.C. § 271, for infringement of United States Patent Nos. 10,603,314 (“the ’314 patent”) and 10,596,162 (“the ’162 patent”) (collectively, “the patents-in-suit”) directed to the treatment of non-small cell lung cancer.

2. Plaintiffs seek judgment that Defendants have infringed, and continue to infringe, the patents-in-suit arising out of Defendants’ commercial manufacture, use, offer for sale, sale, distribution, and/or importation of osimertinib and Tagrisso[®] (osimertinib) dosage forms (“Tagrisso[®] Products”) in the United States prior to the expiration of the patents-in-suit.

THE PARTIES

3. Plaintiff Puma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10880 Wilshire Boulevard, Suite 2150, Los Angeles, California 90024. Puma is the exclusive licensee of the patents-in-suit under a license agreement with Wyeth LLC (“Wyeth”).

4. Plaintiff Wyeth is a limited liability company organized and existing under the laws of the State of Delaware with offices at 235 East 42nd Street, New York, NY 10017. Wyeth LLC is a wholly owned subsidiary of Pfizer, Inc. Wyeth is a co-owner of the patents-in-suit.

5. On information and belief, Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with a principal place of business at 1800 Concord Pike, P.O. Box 15437, Wilmington, Delaware 19850. On information and belief, AstraZeneca Pharmaceuticals LP is a wholly owned subsidiary of Defendant AstraZeneca PLC, wherein the ownership is held as a partnership interest. *See* AstraZeneca Annual Report and Form 20-F Information 2020 (“2020 Annual Report”) at 236–37, available at https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf.

6. On information and belief, Defendant AstraZeneca Pharmaceuticals LP is the holder of New Drug Application (“NDA”) No. 208065 for Defendants’ Tagrisso[®] Products, including tablets of 40 mg and 80 mg dosage strength, and is a distributor of Defendants’ Tagrisso[®] Products throughout the United States, including in the State of Delaware. *See* Tagrisso[®] Product Label.

7. On information and belief, Defendant AstraZeneca Pharmaceuticals LP is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for

sale, using, distributing, and/or importing pharmaceutical products, including the Defendants' Tagrisso[®] Products, throughout the United States, including in this Judicial District, through its own actions and through the actions of its agents.

8. On information and belief, Defendant AstraZeneca AB is a public limited liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden. On information and belief, AstraZeneca AB is a wholly owned subsidiary of Defendant AstraZeneca PLC. On information and belief, the President of AstraZeneca AB serves on the AstraZeneca PLC Senior Executive Team. *See* 2020 Annual Report at 106.

9. On information and belief, Defendant AstraZeneca AB is the European Marketing Authorization Holder for Defendants' Tagrisso[®] Product, including tablets of 40 mg and 80 mg dosage strength. On information and belief, AstraZeneca AB is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, and/or distributing pharmaceutical products, including the Defendants' Tagrisso[®] Products, throughout the world, including in Europe and in the United States, through its own actions and through the actions of its agents. *See* Center For Drug Evaluation And Research, Application Number 208065Orig1s000, Chemistry Review(s), effective date March 13, 2015, at 10–13, 50–52, 136–138, and 164, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/208065Orig1s000ChemR.pdf.

10. On information and belief, Defendant AstraZeneca PLC is a public limited company domiciled in the United Kingdom and having a location at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom. *See* 2020 Annual Report at 288. On information and belief, AstraZeneca PLC, through its 100% ownership of

subsidiaries Defendant AstraZeneca Pharmaceuticals LP and Defendant AstraZeneca AB, derived and reported substantial revenue in 2020 from the worldwide sales (\$4.328 billion USD) associated with Defendants' Tagrisso[®] Products, and particularly sales revenue from within the United States (\$1.566 billion USD), including in this Judicial District. *See* 2020 Annual Report at 87 and 187.

JURISDICTION AND VENUE

11. Plaintiffs incorporate each of the preceding paragraphs 1–10 as if fully set forth herein.

12. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, including 35 U.S.C. § 271, for infringement of the asserted patents-in-suit.

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

14. This Court has personal jurisdiction over AstraZeneca Pharmaceuticals LP because AstraZeneca Pharmaceuticals LP is a corporation with a principal place of business in Delaware and has at least one other regular and established place of business in Delaware.

15. AstraZeneca Pharmaceuticals LP is also subject to personal jurisdiction in Delaware because, among other things, upon information and belief, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being sued in this Court. On information and belief, AstraZeneca Pharmaceuticals LP develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells, or causes others to use, promote, market, offer to sell, or sell pharmaceutical products, including Tagrisso[®] Products, throughout the United States, including in the State of Delaware related to Plaintiffs' claims, and therefore, transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

16. Upon information and belief, AstraZeneca Pharmaceuticals LP, as the holder of NDA No. 208065 and distributor of Defendants' Tagrisso[®] Products throughout the United States, including in the State of Delaware, also derives substantial revenue from interstate and/or international commerce, including substantial revenue from pharmaceutical products, including Tagrisso[®] Products, used and/or consumed or services rendered in the State of Delaware and this Judicial District and that are manufactured and/or distributed by Defendants.

17. On information and belief, AstraZeneca Pharmaceuticals LP is one of AstraZeneca PLC's principal U.S. trading entities. *See* AstraZeneca Annual Report and Form 20-F Information 2014 ("2014 Annual Report") at 98, available at https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-reports-homepage/2014-Annual-report-English.pdf.

18. AstraZeneca Pharmaceuticals LP, in concert with AstraZeneca AB, and under the direct or indirect control of AstraZeneca PLC, has committed acts of infringement and continues to commit such acts in this Judicial District by developing, manufacturing, importing, marketing, distributing, using, offering to sell, and/or selling pharmaceutical products, including Tagrisso[®] Products, under its NDA No. 208065 in or into this Judicial District, prior to the expiration of the patents-in-suit.

19. AstraZeneca AB is subject to personal jurisdiction in Delaware because, among other things, AstraZeneca AB purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being sued in this Court. On information and belief, AstraZeneca AB itself, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells, or causes others to use, offer to sell, or sell pharmaceutical products, including Tagrisso[®] Products, throughout the United States, including in the State of Delaware

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