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

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. Upon information and belief, AstraZeneca AB 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.

20. On information and belief, AstraZeneca AB has consented to jurisdiction in Delaware in one or more prior cases arising out of its filing of an action for patent infringement under the provisions of § 271 related to the filing of Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") and/or it has filed counterclaims in such cases. These actions include cases specifically related to enforcement actions concerning ANDAs concerning generic alternatives to Tagrisso®. *See*, *e.g.*, *AstraZeneca AB and AstraZeneca Pharmaceuticals LP v. Alembic Pharmaceuticals Limited et al.*, C.A. No: 20-202-RGA (D. Del. Feb. 11, 2020).

21. Additionally, this Court has personal jurisdiction over AstraZeneca AB because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met since (a) Plaintiffs' claims arise under federal law; (b) AstraZeneca AB is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) AstraZeneca AB has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation of AstraZeneca Pharmaceuticals LP's NDA No. 208065, including drug product manufacturing, quality control testing, drug product release, and stability testing, and/or manufacturing and/or selling pharmaceutical products, including Tagrisso® Products, distributed throughout the United

States, including in this Judicial District, such that this Court's exercise of jurisdiction over AstraZeneca AB satisfies due process.

22. AstraZeneca PLC is subject to personal jurisdiction in Delaware because, among other things, AstraZeneca PLC itself, and through its wholly owned subsidiaries AstraZeneca Pharmaceuticals LP and/or 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 PLC itself, and through its wholly owned subsidiaries AstraZeneca Pharmaceuticals LP and/or AstraZeneca AB, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells pharmaceutical products, including Tagrisso® Products, throughout the United States, including in the State of Delaware, 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.

23. In addition, AstraZeneca PLC is subject to personal jurisdiction in Delaware because, on information and belief, it controls, either directly or indirectly, and dominates AstraZeneca Pharmaceuticals LP and/or AstraZeneca AB, and therefore, the activities of AstraZeneca Pharmaceuticals LP and/or AstraZeneca AB in this jurisdiction are attributed to AstraZeneca PLC. *See* 2020 Annual Report at 236. The AstraZeneca global website presents the company as a single entity and presents the AstraZeneca PLC Board as responsible for setting strategy and policies and monitoring progress toward meeting annual plans of the company, further indicating central control of AstraZeneca PLC over its wholly owned subsidiaries AstraZeneca Pharmaceuticals LP and/or AstraZeneca AB. *See, e.g.*, https://www.astrazeneca.com/our-company/leadership.html.

24. On information and belief, Defendants regularly do business in Delaware, and their practices have involved placing pharmaceutical products, including Tagrisso® Products, into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Defendants' pharmaceutical products, including Tagrisso® Products, are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Tagrisso® Products are prescribed by physicians practicing within Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities has a substantial effect within Delaware and constitutes infringement of the patents-in-suit before their expiration.

25. AstraZeneca PLC's annual report states that their largest selling product in 2020 was Tagrisso®, of which sales revenue from the United States accounted for $1.566 billion USD, which includes sales in this Judicial District.

26. Additionally, this Court has personal jurisdiction over AstraZeneca PLC because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met since (a) Plaintiffs' claims arise under federal law; (b) AstraZeneca PLC is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) AstraZeneca PLC itself, through its wholly owned subsidiaries AstraZeneca Pharmaceuticals LP and/or AstraZeneca AB, has sufficient contacts in the United States as a whole, including, but not limited to, either directly or indirectly, participating in the preparation of AstraZeneca Pharmaceuticals LP's NDA No. 208065, and/or manufacturing and/or selling pharmaceutical products, including Tagrisso® Products, distributed throughout the United States, including in this Judicial District, such that this Court's exercise of jurisdiction over AstraZeneca PLC satisfies due process.

27. On information and belief, Defendants have systematic and continuous contacts with Delaware; have established distribution channels for Tagrisso® Products in Delaware; regularly and continuously conduct business in Delaware, including by selling Tagrisso® Products in Delaware, either directly or indirectly through their subsidiaries, agents, or affiliates; have purposefully availed themselves of the privilege of doing business in Delaware; and derive substantial revenue from the sale of Tagrisso® Products in Delaware.

28. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) as to AstraZeneca Pharmaceuticals LP because AstraZeneca Pharmaceuticals LP resides in Delaware and has a regular and established place of business in Delaware.

29. Venue is proper in this Court as to AstraZeneca AB because AstraZeneca AB is a foreign entity that may be sued in any judicial district, including in the District of Delaware. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

30. Venue is proper in this Court as to AstraZeneca PLC because AstraZeneca PLC is a foreign entity that may be sued in any judicial district, including in the District of Delaware. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

FACTUAL BACKGROUND

31. Non-Small Cell Lung Cancer ("NSCLC") is an epithelial lung cancer and the leading cause of cancer death in the United States, Japan, and Western Europe. Approximately 75 percent of lung cancer cases are categorized as NSCLC.

32. In 2003, the FDA approved the compound known as gefitinib (marketed under the tradename IRESSA®) for the treatment of epidermal growth factor receptor (EGFR)-mediated NSCLC in the United States. Soon after, the FDA also approved the compound known as erlotinib (marketed under the tradename TARCEVA®) for treating EGFR-mediated NSCLC in the United States. Both gefitinib and erlotinib are small molecule EGFR Tyrosine Kinase

Inhibitors ("TKIs"). Unfortunately, some NSCLC patients treated with gefitinib or erlotinib later were recognized as desensitized or resistant, or never initially responsive to these treatments (together categorized as "gefitinib and/or erlotinib resistant NSCLC").

33. The inventors of the patents-in-suit determined that small molecule inhibitors that irreversibly bind to the EGFR tyrosine kinase domain via a covalent bond to cysteine 773 of the EGFR catalytic domain in EGFR ("irreversible EGFR TKIs") are effective in treating cancers like NSCLC that are resistant to gefitinib and/or erlotinib therapy. The inventions arising out of this research are described and claimed in the patents-in-suit: the '314 patent and the '162 patent.

34. Puma is a biopharmaceutical company that focuses on the development and commercialization of products for the treatment of cancer. In 2011, Puma licensed the patent rights for the patents-in-suit from Pfizer and Wyeth to fully develop treatments for cancer, bring approved therapies to market, and deliver them to patients in need. Puma has invested millions of dollars in this endeavor.

35. Pursuant to the licensing agreement, Puma is the holder of NDA 208051 for NERLYNX® (neratinib), an intracellular kinase inhibitor that irreversibly binds to EGFR, human epidermal growth factor receptor 2 ("HER2"), and human epidermal growth factor receptor 4 ("HER4"). NERLYNX® was approved on July 17, 2017, by the FDA for use (1) as a single agent for extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, to follow adjuvant trastuzumab based therapy and (2) in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.

36. Additionally, Puma is currently in phase 2 clinical trials investigating the use of neratinib in treating EGFR-mutant mediated lung cancers.

THE PATENTS-IN-SUIT

37. The '314 patent, titled "Method For Treating Gefitinib Resistant Cancer" was duly and lawfully issued on March 31, 2020. Plaintiff Wyeth co-owns, and Plaintiffs Wyeth and Puma are the exclusive licensees of, and together have all the rights to enforce, the '314 patent. The '314 patent is the U.S. national entry of corresponding international application PCT/US2006/003717, filed February 2, 2006. A true and correct copy of the '314 patent is attached hereto as Exhibit A.

38. The patents-in-suit are assigned to Wyeth LLC and The General Hospital Corporation ("GHC").

39. GHC is a corporation organized and existing under the laws of the State of Massachusetts with its principal office at 55 Fruit Street, Boston, MA 02114. Wyeth LLC is the exclusive licensee of the patents-in-suit under a license agreement with GHC. Under the license, GHC transferred all substantial rights to the patents-in-suit, including the exclusive right to enforce and sub-license those patents, to Wyeth LLC, and the only limited rights retained by GHC relate to their retained research rights to the patents-in-suit.

40. The '314 patent claims methods for treating patients with NSCLC that are resistant to gefitinib and/or erlotinib using an irreversible EGFR inhibitor that covalently binds to cysteine 773 residue in the ligand-binding pocket of EGFR. According to the claimed method, the irreversible EGFR inhibitor is administered daily and can be delivered orally. NSCLCs with a T790M EGFR mutation, including those treated with Tagrisso®, are resistant to gefitinib and/or erlotinib treatment.

41. The '162 patent, titled "Method For Treating Gefitinib Resistant Cancer" was duly and lawfully issued on March 24, 2020. Plaintiff Wyeth co-owns, and Plaintiffs Wyeth and Puma are the exclusive licensees of, and together have the right to enforce, the '162 patent. A true and correct copy of the '162 patent is attached hereto as Exhibit B.

42. The '162 patent claims methods for treating gefitinib and/or erlotinib resistant NSCLC having a T790M EGFR mutation using an irreversible EGFR inhibitor that covalently binds to cysteine 773 of the catalytic domain within the EGFR T790M mutant. According to the claimed method, the irreversible EGFR inhibitor is administered daily with a unit dosage of 2–500 mg. NSCLCs with a T790M EGFR mutation, including those treated with Tagrisso®, are resistant to gefitinib and/or erlotinib treatment.

TAGRISSO® PRODUCT

43. A decade after publication of the provisional applications that led to the patents-in-suit and disclosure to the public of the inventors' contribution to the relevant field of medicine, on November 13, 2015, the FDA approved Tagrisso® (osimertinib), as an irreversible EGFR inhibitor. Tagrisso® was approved by the FDA under NDA No. 208065 held by Defendant AstraZeneca Pharmaceuticals LP, for the indication of treating patients with metastatic EGFR T790M mutation-positive NSCLC who have progressed on or after EGFR TKI therapy. A copy of the current prescribing information for Tagrisso® (the "Tagrisso® Product Label") is attached hereto as Exhibit C.

44. Since November 13, 2015, the Tagrisso® Product has been approved by the FDA to treat metastatic EGFR T790M mutation-positive NSCLC, and AstraZeneca through this Label knowingly and intentionally instructs end users to administer Tagrisso® Products to humans to treat EGFR T790M mutation-positive NSCLC.

45. On April 18, 2018, the FDA granted the supplemental approval of Tagrisso® (osimertinib), under NDA No. 208065/S-008 held by Defendant AstraZeneca Pharmaceuticals LP, and the Tagrisso® Product Label was amended to include an indication for first-line treatment of patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

46. On December 18, 2020, the FDA granted the supplemental approval of Tagrisso® (osimertinib), under NDA No. NDA 208065/S-21 held by Defendant AstraZeneca Pharmaceuticals LP, and the Tagrisso® Product Label was amended to include an indication for an adjuvant therapy after tumor resection in adult patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

47. Use of AstraZeneca's Tagrisso® Products according to the Tagrisso® Product Label infringes at least claim 1 of each of the patents-in-suit.

COUNT I: INFRINGEMENT OF THE '314 PATENT

48. Plaintiffs re-allege and incorporate by reference each of the allegations set forth in Paragraphs 1–47.

49. The use of Tagrisso® Products to treat patients according to the Tagrisso® Product Label is covered by one or more claims of the '314 patent, including at least claim 1 of the '314 patent, because claim 1 of the '314 patent encompasses treating patients with gefitinib and/or erlotinib resistant NSCLC using an irreversible EGFR TKI.

50. AstraZeneca's commercial manufacture, use, importation, marketing, sale, and/or offer for sale of the Tagrisso® Products, including tablets of 40 mg and 80 mg dosage strength, in or into the United States directly infringes, contributes to the infringement of, and/or actively induces the infringement by others of one or more claims of the '314 patent under 35 U.S.C. § 271(a)–(c).

51. The use of AstraZeneca's Tagrisso® Products by pharmacies, hospitals, clinics, healthcare professionals, and other end users to treat NSCLC patients under the indications specified in the Tagrisso® Product Label directly infringes one or more claims of the '314 patent under 35 U.S.C. § 271(a).

52. On information and belief, AstraZeneca, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute Tagrisso® Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, AstraZeneca knowingly and intentionally accompany the Tagrisso® Products with a product label or product insert that includes instructions for using or administering the Tagrisso® Products to treat NSCLC patients which infringes the '314 patent. Accordingly, AstraZeneca induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the Tagrisso® Products to directly infringe the '314 patent. On information and belief, AstraZeneca encourage acts of direct infringement with knowledge of the '314 patent and knowledge that they are encouraging infringement thereof.

53. On information and belief, AstraZeneca are actively inducing infringement of the '314 patent. AstraZeneca's activities are done with knowledge of the '314 patent and specific intent to infringe that patent.

54. On information and belief, prior to the '314 patent issuing, AstraZeneca were aware of the corresponding European Patent 1 848 414 B1 (or respectively, the underlying PCT application publication WO 2006/084058), issued April 6, 2011, including the same or similar claims as the '314 patent and having the same owner (Plaintiff Wyeth LLC) and exclusive licensee (Plaintiff Puma). Two patents that are listed in the FDA Orange Book for Tagrisso®, US 8946235 and US 9732058, recite the inventors' WO 2006/084058 as important

prior art. On information and belief, as of March 31, 2020, the date of issuance of the '314 patent, AstraZeneca knew that a U.S. patent containing claims such as those in the '314 patent would issue.

55. On information and belief, AstraZeneca know that the Tagrisso® Products and Tagrisso® Product Label are especially made or adapted for use in infringing the '314 patent, that the Tagrisso® Products are not staple articles or commodities of commerce, and that the Tagrisso® Products and accompanying Tagrisso® Product Label are not suitable for substantial noninfringing use. On information and belief, AstraZeneca contribute to infringement of the '314 patent.

56. The foregoing actions by AstraZeneca constitute and/or will constitute direct infringement of the '314 patent, active inducement of infringement by others of the '314 patent, and contribution to the infringement by others of the '314 patent under 35 U.S.C. § 271(a)–(c).

57. Plaintiffs have been and will continue to be damaged by AstraZeneca's infringement of the '314 patent. Plaintiffs are entitled to recover from AstraZeneca the damages sustained by Plaintiffs as a result of AstraZeneca's wrongful acts, including at a minimum a reasonable royalty.

58. AstraZeneca's infringement is deliberate and willful, entitling Plaintiffs to seek enhanced damages under 35 U.S.C. § 284 and to seek attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285. AstraZeneca's infringement of the '314 patent is with full and complete knowledge of the '314 patent and its applicability to the use of Tagrisso® Products without a good faith belief that the '314 patent is invalid or not infringed.

59. Plaintiffs have been and will continue to be substantially and irreparably damaged by infringement of the ’314 patent. Unless AstraZeneca are enjoined from actively inducing infringement of the ’314 patent, and contributing to the infringement of the ’314 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law, and considering the balance of hardships between Plaintiffs and AstraZeneca, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT II: INFRINGEMENT OF THE ’162 PATENT

60. Plaintiffs re-allege and incorporate by reference each of the allegations set forth in Paragraphs 1–59.

61. The use of Tagrisso® Products to treat patients according to the Tagrisso® Product Label is covered by one or more claims of the ’162 patent, including at least claim 1 of the ’162 patent, because claim 1 of the ’162 patent encompasses treating patients with gefitinib and/or erlotinib resistant NSCLC having a T790M mutation in EGFR using an irreversible EGFR TKI administered daily in a dosage amount of 2–500 mg.

62. AstraZeneca’s commercial manufacture, use, importation, marketing, sale, and/or offer for sale of the Tagrisso® Products, including tablets of 40 mg and 80 mg dosage strength, in or into the United States directly infringes, contributes to the infringement of, and/or actively induces the infringement by others of one or more claims of the ’162 patent under 35 U.S.C. § 271(a)–(c).

63. The use of AstraZeneca’s Tagrisso® Products by pharmacies, hospitals, clinics, healthcare professionals, and other end users to treat NSCLC patients under the indications specified in the Tagrisso® Product Label directly infringes one or more claims of the ’162 patent under 35 U.S.C. § 271(a).

64. On information and belief, prior to the '162 patent issuing, AstraZeneca were aware of the corresponding European Patent 1 848 414 B1, issued April 6, 2011 (or respectively, the underlying PCT application publication WO 2006/084058), circumscribing the same or similar claims as the '162 patent and having the same owner (Plaintiff Wyeth LLC) and exclusive licensee (Plaintiff Puma). Two patents that are listed in the FDA Orange Book for Tagrisso®, US 8946235 and US 9732058, recite the inventors' WO 2006/084058 as important prior art. On information and belief, as of March 24, 2020, the date of issuance of the '162 patent, AstraZeneca knew that a U.S. patent containing claims such as those in the '162 patent would issue.

65. On information and belief, AstraZeneca, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute Tagrisso® Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, AstraZeneca knowingly and intentionally accompany the Tagrisso® Products with a product label or product insert that includes instructions for using or administering the Tagrisso® Products to treat NSCLC patients that infringes the '162 patent. Accordingly, AstraZeneca induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the Tagrisso® Products to directly infringe the '162 patent. On information and belief, AstraZeneca encourage acts of direct infringement with knowledge of the '162 patent and knowledge that they are encouraging infringement.

66. On information and belief, AstraZeneca are actively inducing infringement of the '162 patent. AstraZeneca's activities are done with knowledge of the '162 patent and specific intent to infringe that patent.

67. On information and belief, AstraZeneca know that the Tagrisso® Products and Tagrisso® Product Label are especially made or adapted for use in infringing the '162 patent, that the Tagrisso® Products are not staple articles or commodities of commerce, and that the Tagrisso® Products and accompanying Tagrisso® Product Label are not suitable for substantial noninfringing use. On information and belief, AstraZeneca contribute to infringement of the '162 patent.

68. The foregoing actions by AstraZeneca constitute and/or will constitute direct infringement of the '162 patent, active inducement of infringement by others of the '162 patent, and contribution to the infringement by others of the '162 patent under 35 U.S.C. § 271(a) –(c).

69. Plaintiffs have been and will continue to be damaged by AstraZeneca's infringement of the '162 patent. Plaintiffs are entitled to recover from AstraZeneca the damages sustained by Plaintiffs as a result of AstraZeneca's wrongful acts, including at a minimum a reasonable royalty.

70. AstraZeneca's infringement is deliberate and willful, permitting Plaintiffs to seek enhanced damages under 35 U.S.C. § 284 and to seek attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285. AstraZeneca's infringement of the '162 patent is with full and complete knowledge of the '162 patent and its applicability to the use of Tagrisso® Products without a good faith belief that the '162 patent is invalid or not infringed.

71. Plaintiffs are and will continue to be substantially and irreparably damaged by infringement of the '162 patent. Unless AstraZeneca are enjoined from actively inducing infringement of the '162 patent, and contributing to the infringement of the '162 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law, and considering

the balance of hardships between Plaintiffs and AstraZeneca, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

JURY DEMAND

72. Plaintiffs request a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against AstraZeneca as follows:

a) For judgment that AstraZeneca have contributed to and induced, and continue to contribute to and induce, infringement of the '314 patent;

b) For judgment that AstraZeneca's infringement of the '314 patent has been and continues to be willful;

c) For judgment that AstraZeneca have contributed to and induced, and continue to contribute to and induce, infringement of the '162 patent;

d) For judgment that AstraZeneca's infringement of the '162 patent has been and continues to be willful;

e) For an order permanently enjoining AstraZeneca's infringing activities;

f) For an accounting of all damages sustained by Plaintiffs as a result of AstraZeneca's infringing activities;

g) For actual damages, together with prejudgment interest;

h) For increased or enhanced damages pursuant to 35 U.S.C. § 284;

i) For an award of attorneys' fees and costs pursuant to 35 U.S.C. § 285 or as otherwise permitted by law; and

j) For such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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