IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, AND ALEMBIC PHARMACEUTICALS, INC.,	)	
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 Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. of an amendment to Abbreviated New Drug Application ("ANDA") No. 214195 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 generic versions 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 Alembic Pharmaceuticals Limited ("APL") is a corporation organized and existing under the laws of India, with a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

5. On information and belief, Defendant Alembic Global Holding SA ("Alembic Global") is a corporation organized and existing under the laws of Switzerland, with a principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland.

6. On information and belief, Defendant Alembic Pharmaceuticals, Inc. ("Alembic Pharma") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 750 Route 202, Bridgewater, NJ 08807.

7. On information and belief, Alembic Global is a wholly owned subsidiary of APL, and is controlled and dominated by APL.

8. On information and belief, Alembic Pharma is a wholly owned subsidiary of Alembic Global, and is controlled and dominated by Alembic Global and APL. On information and belief, Alembic Pharma is the U.S. agent for APL.

9. On information and belief, APL 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, APL, acting in concert with Alembic Global and Alembic Pharma, 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, APL, acting in concert with Alembic Global and Alembic Pharma, 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.

10. On information and belief, APL, Alembic Global, and Alembic Pharma acted in concert to prepare, submit, and amend ANDA No. 214195 for their 40 mg and 80 mg osimertinib mesylate tablets ("Alembic's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of APL. These three entities are hereafter collectively referred to as "Alembic." APL has admitted in pending patent litigation concerning infringement of the '020 patent that it submitted ANDA No. 214195 for 40 mg and 80 mg osimertinib mesylate tablets. *See AstraZeneca AB et al. v. Alembic Pharmaceuticals Limited et al.*, C.A. No. 20-202-RGA (D. Del. April 14, 2020) ("Pending Infringement Action"), D.I. 22 at ¶¶ 10, 26.

JURISDICTION

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

12. This Court has personal jurisdiction over each of APL, Alembic Global, and Alembic Pharma.

13. APL is subject to personal jurisdiction in Delaware because, among other things, APL, itself and through its wholly owned subsidiaries Alembic Global and Alembic 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, APL, itself and through its subsidiaries Alembic Global and Alembic 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, APL is subject to personal jurisdiction in Delaware because, upon information and belief, APL, itself and through its subsidiary Alembic Global, controls and dominates Alembic Pharma and therefore the activities of Alembic Pharma in this jurisdiction are attributed to APL.

14. Alembic Global is subject to personal jurisdiction in Delaware because, among other things, Alembic Global, itself and together with APL, and through its wholly owned subsidiary Alembic 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, Alembic Global, itself and together with APL, and through its subsidiary Alembic 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, Alembic Global is subject to personal jurisdiction in Delaware because, upon information and belief, Alembic Global, itself and together

with APL, controls and dominates Alembic Pharma and therefore the activities of Alembic Pharma in this jurisdiction are attributed to Alembic Global.

15. Alembic 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. Alembic Pharma is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, upon information and belief, Alembic 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 related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

16. On information and belief, Alembic knows and intends that following any approval of Alembic's ANDA No. 214195, as amended, Alembic will manufacture and import into the United States Alembic's ANDA Products and directly or indirectly market, sell, and distribute Alembic's ANDA Products throughout the United States, including in Delaware. On information and belief, following any FDA approval of ANDA No. 214195, as amended, Alembic knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

17. On information and belief, APL, Alembic Global, and Alembic 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 Alembic's ANDA Products at issue. On information and belief, Alembic Pharma, itself and together with Alembic Global, participated in, assisted, and cooperated with APL in the acts complained of herein.

18. Alembic 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.

19. On information and belief, Alembic, with knowledge of the Hatch-Waxman Act process, directed Alembic's Second Notice Letter (defined below) to, *inter alia*, AstraZeneca Pharmaceuticals LP, to an address in Delaware, and alleged in Alembic's Second Notice Letter that the '020 patent will not be infringed by the commercial manufacture, use or sale of Alembic's ANDA Products. On information and belief, Alembic 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.

20. Because AstraZeneca Pharmaceuticals LP is a limited partnership organized in Delaware, it suffers injury and consequences from Alembic's submission of Alembic's amended ANDA No 214195, challenging the '020 patent in Delaware.

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

22. APL, Alembic Global, and Alembic Pharma regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court, *see, e.g.*, *CyDex Pharmaceuticals, Inc. v. Alembic Global Holding SA et al.*, No. 1:19-cv-00956-LPS, D.I. 15 (D. Del. July 29, 2019); *Genentech, Inc. et al. v. Alembic Pharmaceuticals, Ltd., et al.*, No. 1:19-cv-00177-RGA, D.I. 10 (D. Del. March 15, 2019); *H. Lundbeck A/S et al. v. Alembic Pharmaceuticals Limited, et al.*, No. 1:18-cv-00113-LPS, D.I. 17 (D. Del. April 13, 2018); and *Adverio Pharma GmbH et al. v. MSN Laboratories Private Limited et al.*, No. 1:18-cv-00073-LPS, D.I. 18 (D. Del. April 3, 2018). In particular, APL is currently engaged in the Pending Infringement Action in this district. Accordingly, this Court has personal jurisdiction over Alembic.

23. On information and belief, if Alembic's ANDA No. 214195 as amended is approved, Alembic will directly or indirectly manufacture, market, sell, and/or distribute Alembic's ANDA Products within the United States, including in Delaware, consistently with Alembic's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Alembic regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Alembic's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Alembic's ANDA Products will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. On information and belief, each of these activities would have a substantial effect within Delaware and would constitute infringement

of the ’020 patent in the event that Alembic’s ANDA No. 214195 as amended is approved before the ’020 patent expires.

24. On information and belief, Alembic derives substantial revenue from pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Alembic and/or for which APL, Alembic Global, or Alembic Pharma is the named applicant on approved ANDAs. On information and belief, various products for which APL, Alembic Global, or Alembic Pharma is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

VENUE

25. Venue is proper in this district for APL pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, APL is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

26. Venue is proper in this district for Alembic Global pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Alembic Global is a corporation organized and existing under the laws of Switzerland and is subject to personal jurisdiction in this judicial district.

27. Venue is proper in this district for Alembic Pharma pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Alembic Pharma is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

28. Plaintiffs incorporate each of the preceding paragraphs 1–27 as if fully set forth herein.

29. The ’020 patent, entitled “Pharmaceutical Compositions Comprising AZD9291,” (Exhibit A hereto), was duly and legally issued on January 22, 2019, to AstraZeneca AB.

30. As set forth in greater detail in the ’020 patent, the claims of the ’020 patent, incorporated by reference herein, cover pharmaceutical compositions comprising osimertinib mesylate and methods of using them.

31. AstraZeneca AB is the assignee of the ’020 patent.

32. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208065 for Tagrisso® (osimertinib mesylate), which has been approved by the FDA. Tagrisso® is a kinase inhibitor indicated for (i) “as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test”; (ii) “the first-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test”; and (iii) “the treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy.” Tagrisso® is for oral use and is available as tablets in 40 mg and 80 mg dosage strengths.

33. Pursuant to 21 U.S.C. § 355, the ’020 patent has been listed in connection with Tagrisso® in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the “Orange Book.”

34. AstraZeneca will be substantially and irreparably damaged by infringement of the ’020 patent.

COUNT I – ALEMBIC’S INFRINGEMENT OF THE ’020 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

35. Plaintiffs incorporate each of the preceding paragraphs 1–34 as if fully set forth herein.

36. By letter dated December 30, 2019, Alembic notified Plaintiffs that it had submitted to the FDA ANDA No. 214195, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of Alembic’s ANDA Products prior to the expiration of the ’020 patent (“Alembic’s First Notice Letter”). On information and belief, the purpose of the submission of ANDA No. 214195 was to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Alembic’s ANDA Products prior to the expiration of the ’020 patent.

37. In Alembic’s First Notice Letter, Alembic also notified Plaintiffs that, as part of ANDA No. 214195, Alembic had filed certifications 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), with respect to the ’020 patent. On information and belief, Alembic submitted ANDA No. 214195 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’020 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Alembic’s ANDA Products.

38. Subsequent to receiving Alembic’s First Notice Letter, AstraZeneca sued Alembic for infringement of the ’020 patent on February 11, 2020 in this district in the Pending Infringement Action.

39. By letter dated June 8, 2021, Alembic notified Plaintiffs that it had amended ANDA No. 214195 "to address its certification to the '020 patent with respect to Use Code U-3016" ("Alembic's Second Notice Letter"). On information and belief, Alembic's ANDA No. 214195 as amended contains an amended certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '020 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Products. Alembic's Second Notice Letter indicates that Alembic seeks approval from the FDA to engage in the commercial manufacture, use and/or sale of Alembic's ANDA Products prior to the expiration of the '020 patent. On information and belief, the purpose of amending ANDA No. 214195 was to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Alembic's ANDA Products prior to the expiration of the '020 patent.

40. According to information in Alembic's Second Notice Letter, Alembic's ANDA Products are a generic version of Tagrisso® tablets.

41. According to the FDA website, APL is the holder of Drug Master File No. 33409 for osimertinib mesylate.

42. On information and belief, Alembic's ANDA Products are not publicly available, nor is ANDA No. 214195 as amended accessible to the public.

43. Plaintiffs are filing this Complaint within forty-five days of receipt of Alembic's Second Notice Letter.

44. According to Alembic's Second Notice Letter, Alembic's ANDA Products contain osimertinib mesylate. On information and belief, Alembic's ANDA Products contain osimertinib mesylate in an amount that literally satisfies the requirements of claim 1 of the '020 patent.

45. According to information in Alembic's Second Notice Letter, Alembic's ANDA Products are in the form of oral tablets for pharmaceutical use. Accordingly, Alembic's ANDA Products are pharmaceutical tablets.

46. On information and belief, Alembic's ANDA Products contain inactive ingredients that satisfy, literally and/or by equivalents, the limitations of claim 1 concerning materials other than osimertinib mesylate that are contained in the claimed pharmaceutical composition. Alembic's Second Notice Letter did not contest that Alembic's ANDA Products literally satisfy various limitations of claim 1 of the '020 patent.

47. On information and belief, and in light of Alembic's Second Notice Letter, the proposed amended product labeling for Alembic's ANDA Products provides, *inter alia*, that Alembic's ANDA Products are indicated as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. The proposed amended product labeling for Alembic's ANDA Products thus directs, encourages, and induces a method of treating cancer in a patient in need thereof, which method comprises the oral administration of an effective number of tablets that are Alembic's ANDA Products to the patient, wherein the cancer is non-small cell lung cancer.

48. Alembic has now, and has had since at least before submitting ANDA No. 214195, knowledge of the '020 patent.

49. Alembic's submission of the amendment to ANDA No. 214195 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Products before the expiration of the '020 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

50. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Products, together with their proposed amended product labeling, immediately and imminently upon approval of ANDA No. 214195 as amended and expiration of any other Orange Book-listed patent or relevant exclusivity for Tagrisso®.

51. On information and belief, the manufacture, use (including the use of Alembic's ANDA Products in accordance with, and as directed by Alembic's proposed amended product labeling for Alembic's ANDA Products), sale, offer for sale, and/or importation of Alembic's ANDA Products would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '020 patent, including at least claims 1, 8, 9, and 11-13.

52. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the '020 patent when ANDA No. 214195 as amended is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

53. On information and belief, the foregoing actions by Alembic constitute and/or will constitute infringement of the '020 patent and active inducement of infringement of the '020 patent.

54. Unless Alembic is enjoined from infringing the '020 patent and actively inducing infringement of the '020 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT BY ALEMBIC OF THE '020 PATENT

55. Plaintiffs incorporate each of the preceding paragraphs 1–54 as if fully set forth herein.

56. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Alembic on the other regarding Alembic's liability for infringement and active inducement of infringement of the '020 patent.

57. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Alembic's ANDA Products will infringe and induce the infringement of the '020 patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Alembic has infringed the '020 patent;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Alembic's ANDA Products be not earlier than the expiration of the '020 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Alembic, and all persons acting in concert with Alembic, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Alembic's ANDA Products prior to the expiration of the '020 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Alembic's ANDA Products prior to the expiration of the '020 patent will infringe and induce the infringement of the '020 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,

Dated: July 1, 2021

MCCARTER & ENGLISH LLP

/s/ Daniel M. Silver

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