IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. ALEMBIC PHARMACEUTICALS LTD., and ALEMBIC PHARMACEUTICALS, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiffs"), by its attorneys, 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, against defendants Alembic Pharmaceuticals Ltd. ("Alembic India") and Alembic Pharmaceuticals, Inc. ("Alembic USA") (collectively, "Alembic" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208576 ("ticagrelor ANDA") filed by Defendant with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of AstraZeneca's BRILINTA® (ticagrelor) drug product prior to expiration of AstraZeneca's U.S. Patent Nos. 8,425,934 ("the '934 patent") and 10,300,065 ("the '065 patent") (collectively "the Orange Book patents"), that

are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for BRILINTA®.

PARTIES

2. AstraZeneca is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail against serious diseases, including treatments for cardiovascular diseases.

3. Plaintiff AstraZeneca AB is a company operating and existing under the laws of Sweden, with its principal place of business at SE-151 85 Södertälje, Sweden. AstraZeneca AB is the owner of the '934 and '065 patents.

4. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at One MedImmune Way, Gaithersburg, Maryland 20878. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application ("NDA") No. 022433 for BRILINTA® (ticagrelor). AstraZeneca Pharmaceuticals LP markets and sells BRILINTA® in this judicial district and throughout the United States. Defendant specifically directed a letter dated May 7, 2021 with the heading "Re: Notification of Certification Under 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug & Cosmetic Act, and Under 21 C.F.R. § 314.95 Alembic Pharmaceuticals Ltd. – Ticagrelor Tablet 60 mg ANDA No. 208576" ("Notice Letter") to AstraZeneca Pharmaceuticals LP.

5. On information and belief, Alembic India is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India. On information and belief, Alembic India, itself and through its affiliates and subsidiaries, including Alembic USA, formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

6. On information and belief, Alembic USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Highway 202, Bridgewater, New Jersey 08807. On information and belief, Alembic USA is a wholly-owned subsidiary and U.S. agent of Alembic India.

7. On information and belief, Alembic USA is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

8. On information and belief, Alembic USA is qualified to do business in Delaware and appointed a registered agent for service of process, by filing with the Secretary of State on August 10, 2012 pursuant to sections 371 and 376 of title 8 of the Delaware Code: (1) a certificate of incorporation as a domestic corporation, under file number 5197177; and (2) a statement naming "National Registered Agents, Inc." located at 1209 Orange Street, Wilmington, Delaware, 19801, as its registered agent to accept service of process in the State of Delaware.

9. On information and belief, Defendant developed the proposed generic product that is the subject of the ticagrelor ANDA to seek regulatory approval from FDA to market and sell the proposed ANDA product throughout the United States, including within Delaware.

10. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of the ticagrelor ANDA, Defendant will distribute and sell the generic product described in the ticagrelor ANDA throughout the United States and within Delaware.

JURISDICTION AND VENUE

11. Each of the preceding paragraphs 1 to 10 is re-alleged and re-incorporated as if fully set forth herein.

12. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

14. On information and belief, venue is proper in the District of Delaware for Alembic India because it is an Indian corporation "not resident in the United States" that accordingly "may be sued in any judicial district" for venue purposes. 28 U.S.C. § 1391(c)(3); *see also In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018) (reaffirming the "long-established rule that suits against aliens are wholly outside the operation of all the federal venue laws, general and special" (quoting *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 714 (1972))).

15. On information and belief, venue is proper in the District of Delaware for Alembic USA because it is incorporated in Delaware, and thus the District of Delaware is the judicial district "where the defendant resides." 28 U.S.C. § 1400(b); *see also TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 581 U.S. ____, 137 S. Ct. 1514, 1521 (2017) ("[a]s applied to domestic corporations, 'reside[nce]' in § 1400(b) refers only to the State of incorporation").

16. Alembic India is subject to specific personal jurisdiction in this District based on the filing of its ticagrelor ANDA with a Paragraph IV certification regarding the '065 patent. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762-63 (Fed. Cir. 2016).

17. As in *Acorda*, Alembic India "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at," on information and belief, this District and elsewhere. *Acorda Therapeutics*, 817 F.3d at 759.

18. Alembic India's "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Acorda Therapeutics*, 817 F.3d at 760.

19. As in *Acorda*, on information and belief Alembic India, alone and/or in concert with its agent, Alembic USA, "intends to direct sales of its drugs" into this District, among other places, "once it has the requested FDA approval to market them." *Acorda Therapeutics*, 817 F.3d at 758.

20. On information and belief, Alembic India, alone and/or in concert with its agent, Alembic USA, will engage in marketing of its proposed ticagrelor ANDA product in Delaware, upon approval of its ticagrelor ANDA.

21. Alembic India's ANDA filing, including its Paragraph IV certifications regarding the '934 and '065 patents at issue here, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities in this District by Defendant.

22. "[T]he minimum-contacts standard is satisfied by the particular actions [Defendant] has already taken—its ANDA filing[]—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct" in this District. *Acorda Therapeutics*, 817 F.3d at 760.

23. On information and belief, Alembic India and Alembic USA hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

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