IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca LP, AstraZeneca AB, and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiff"), by its attorneys, hereby alleges 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 Ltd., Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. (collectively "Alembic" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208576 ("ticagrelor ANDA") filed by Defendant Alembic Pharmaceuticals Ltd. with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of AstraZeneca's BRILINTA® (ticagrelor) drug product in tablet forms and in 90 mg dosage strengths, prior to expiration of AstraZeneca's U.S. Patent No. 8,425,934 ("the '934 patent") that

is 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 LP, the holder of New Drug Application ("NDA") No. 022433 for BRILINTA® (ticagrelor), is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. Defendant specifically directed its Notice Letter to AstraZeneca LP.

4. 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 patent, and Defendant specifically directed its Notice Letter to AstraZeneca AB.

5. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP markets and sells BRILINTA® in this judicial district and throughout the United States.

6. On information and belief, Alembic Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

7. On information and belief, Alembic Pharmaceuticals Ltd. 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 Pharmaceuticals Ltd. is a wholly-owned subsidiary of Alembic Ltd.

8. On information and belief, Alembic Global Holding SA is a corporation organized and existing under the laws of Switzerland, having a principal place of business at 40, Rue Fritz-Courvoisier, 2300 La Chaux-de-Fonds, Switzerland. On information and belief, Alembic Global Holding SA is a wholly-owned subsidiary of Alembic Pharmaceuticals Ltd.

9. On information and belief, Alembic Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 116 Village Blvd., Suite 200, Princeton, New Jersey 08650. On information and belief, Alembic Pharmaceuticals Inc. is a wholly-owned subsidiary of Alembic Global Holding SA.

10. On information and belief, Alembic Pharmaceuticals Inc. 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.

11. On information and belief, Alembic Pharmaceuticals Inc. 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, under file number 5197177; and (2) a statement naming "National Registered Agents, Inc." located at 160 Greentree Drive, Suite 101, Dover, Delaware 19904, as its registered agent to accept service of process in the State of Delaware.

JURISDICTION AND VENUE

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

13. 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.

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

15. On information and belief, this Court has jurisdiction over Alembic Ltd. On information and belief, Alembic Ltd., directly or through its subsidiaries Alembic Pharmaceuticals Ltd., Alembic Global Holding SA, and Alembic Pharmaceuticals Inc., manufactures, markets, imports, and sells generic drugs for distribution in the District of Delaware and throughout the United States.

16. On information and belief, this Court has jurisdiction over Alembic Pharmaceuticals Ltd. On information and belief, Alembic Pharmaceuticals Ltd., directly or through its subsidiaries Alembic Global Holding SA and Alembic Pharmaceuticals Inc., manufactures, markets, imports, and sells generic drugs for distribution in the District of Delaware and throughout the United States. On information and belief, Alembic Pharmaceuticals Ltd. purposefully has conducted and continues to conduct business, directly or through its subsidiaries Alembic Global Holding SA and Alembic Pharmaceuticals Inc., in the District of Delaware, and this judicial district is a likely destination of Alembic Pharmaceuticals Ltd.'s generic products.

17. On information and belief, this Court has jurisdiction over Alembic Global Holding SA. On information and belief, Alembic Global Holding SA, directly or through its

subsidiary Alembic Pharmaceuticals Inc., manufactures, markets, imports, and sells generic drugs for distribution in the District of Delaware and throughout the United States. Upon information and belief, Alembic's website states that "Alembic Global Holding SA is the headquarter[s] for all the overseas business in countries like USA, Europe, UAE, Australia and other developed markets." *See* http://alembicglobal.ch/index.html (accessed Oct. 29, 2015).

18. On information and belief, this Court has jurisdiction over Alembic Pharmaceuticals Inc. On information and belief, Alembic Pharmaceuticals Inc. is incorporated in Delaware and has designated an agent for service in Delaware. On information and belief, directly or indirectly, Alembic Pharmaceuticals Inc., manufactures, markets, imports, and sells generic drugs for distribution in the District of Delaware and throughout the United States. Upon information and belief, Alembic's website states that

> Alembic Pharmaceuticals Inc is the 100 % subsidiary of the Alembic Global Holding SA. It is located in New Jersey, USA. The basic objective of forming a wholly owned overseas subsidiary in USA is to establish a globally recognized organization in USA. Alembic aims as creating a strong US presence Alembic has filed 57 ANDAs, received approval for 24 and has commercialized 15 of the approved filings. [sic] We has [sic] also initiated Para IV and NDA filings and strengthened our technology capability in new finished dosage forms. Our US business revenue has been growing significantly in [the] past three years. Alembic Pharmaceuticals Inc has started the process of registration across US states and would launch its own label in early 2015.

http://alembicglobal.ch/AlembicUSA.html (accessed Oct. 29, 2015).

19. This Court also has personal jurisdiction over Alembic because, *inter alia*, Alembic Pharmaceuticals Inc. consented to jurisdiction in Delaware by affirmatively registering to do business in Delaware and by appointing a Delaware agent to accept service of process pursuant to sections 371 and 376 of title 8 of the Delaware Code.

20. On information and belief, Alembic Ltd., Alembic Pharmaceuticals Ltd., Alembic Global Holding SA, and Alembic Pharmaceuticals Inc. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products. On information and belief, Alembic Ltd. and Alembic Pharmaceuticals Ltd. are located at the same address. On information and belief, Mr. Chirayu R. Amin serves as Chairman of Alembic Ltd., Alembic Pharmaceuticals Ltd., and Alembic Global Holding SA.

21. On information and belief, Alembic Ltd., Alembic Pharmaceuticals Ltd., Alembic Global Holding SA, and Alembic Pharmaceuticals Inc. work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products in the District of Delaware and throughout the United States.

22. On information and belief, Alembic Ltd., Alembic Pharmaceuticals Ltd., Alembic Global Holding SA, and Alembic Pharmaceuticals Inc. acted in concert to develop 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 in the District of Delaware and throughout the United States.

23. On information and belief, the preparation and submission of the ticagrelor ANDA by Alembic Pharmaceuticals Ltd. was done at the direction, under the control, in concert with, and/or for the direct benefit of Alembic Ltd., Alembic Global Holding SA, and Alembic Pharmaceuticals Inc.

24. Alembic is subject to personal jurisdiction in this district because, *inter alia*, Alembic has committed, aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiff, including Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca LP,

which are both Delaware limited partnerships. For example, Alembic Pharmaceuticals Ltd. sent the Notice Letter to AstraZeneca LP, which is incorporated in and has its principal place of business in Delaware, which has led and/or will lead to foreseeable harm and injury to the Plaintiffs in Delaware.

25. Further, on information and belief, Defendant will manufacture, market, and/or sell within the United States the generic product described in the ticagrelor ANDA if FDA approval is granted. If the ticagrelor ANDA is approved, on information and belief the generic product would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

26. This Court also has jurisdiction over Alembic because Alembic has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertion of counterclaims. *See, e.g., Pfizer Inc. et al. v. Alembic Limited et al.,* C.A. No. 11-cv-01213; *Pfizer Inc. et al. v. Breckenridge Pharmaceutical Inc. et al.,* C.A. No. 12-cv-00810; *Pfizer Inc. et al. v. Zydus Pharmaceuticals USA Inc. et al.,* C.A. No. 12-cv-00808; *Teijin Ltd., et al. v. Alembic Pharmaceuticals Limited et al.,* C.A. No. 13-cv-01939; and *Sanofi et al. v. Alembic Pharmaceuticals Limited et al.,* C.A. No. 14-cv-00424.

27. This Court also has personal jurisdiction over Alembic because, *inter alia*, Alembic has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the state of Delaware. On information and belief, Alembic regularly and continuously transacts business within the state of Delaware, including by selling pharmaceutical products in Delaware, directly and/or through affiliates, and/or by

continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware. On information and belief, Alembic Ltd., Alembic Pharmaceuticals Ltd., Alembic Global Holding SA, and Alembic Pharmaceuticals Inc. have done so with each other's authorization, participation, assistance, and/or acting in concert with each other. On information and belief, Alembic derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

28. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Alembic.

PATENT-IN-SUIT

29. On April 23, 2013, the U.S. Patent and Trademark Office duly and legally issued the '934 patent, entitled "Pharmaceutical compositions." A true and correct copy of the '934 patent is attached hereto as **Exhibit A**. The claims of the '934 patent are valid and enforceable. AstraZeneca AB is the owner of the '934 patent by assignment and has the right to enforce it.

30. AstraZeneca LP is the holder of NDA No. 022433 by which FDA granted approval for the marketing and sale of ticagrelor tablets in 90 mg and 60 mg dosage strengths, to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome (ACS) or a history of myocardial infarction (MI). AstraZeneca markets ticagrelor tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "BRILINTA®." FDA's official publication of approved drugs, the Orange Book, includes BRILINTA® in 90 mg and 60 mg dosage strengths together with the Orange Book Patents.

INFRINGEMENT BY DEFENDANT

31. Each of the preceding paragraphs 1 to 30 is re-alleged and re-incorporated as if fully set forth herein.

32. In a letter dated September 18, 2015 ("the Notice Letter"), Alembic notified AstraZeneca LP that Alembic Pharmaceutical Ltd. had submitted its ticagrelor ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

33. The Notice Letter states that Alembic is seeking approval from the FDA to engage in the commercial manufacture, use, and sale of generic ticagrelor tablets before the expiration of the '934 patent. On information and belief, Alembic intends to engage in the commercial manufacture, use, and sale of its generic ticagrelor tablets after receiving FDA approval to do so.

34. In the Notice Letter, Alembic notified AstraZeneca that its ANDA contained a "Paragraph IV certification" asserting that the '934 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Alembic's generic ticagrelor tablets.

35. This Complaint is being filed before the expiration of the forty-five days from the date AstraZeneca received the Notice Letter.

COUNT I (INFRINGEMENT OF THE '934 PATENT)

36. Each of the preceding paragraphs 1 to 35 is re-alleged and re-incorporated as if fully set forth herein.

37. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '934 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

38. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '934 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca respectfully prays that this Court grant the following relief:

A. A judgment that the claims of the '934 patent are not invalid, not unenforceable, and are infringed by Defendant's submission of its ticagrelor ANDA, and that Defendant's making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's generic ticagrelor tablets will infringe the '934 patent.

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Defendant's ticagrelor ANDA shall be a date which is not earlier than the expiration date of the '934 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

C. An order permanently enjoining Defendant, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's generic ticagrelor tablets until after the latest expiration date of the '934 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

D. Damages or other monetary relief to AstraZeneca if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Defendant's generic ticagrelor tablets prior to the latest expiration date of the '934 patent,

including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

E. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: October 30, 2015

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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