IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, ASTRAZENECA UK LIMITED, and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. ALKEM LABORATORIES LIMITED and S&B PHARMA, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca AB, AstraZeneca UK Limited, and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiffs"), by their 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 Alkem Laboratories Limited ("Alkem Laboratories Ltd.") and S&B Pharma, Inc. ("S&B Pharma") (collectively, "Alkem"). This action relates to Abbreviated New Drug Applications ("ANDAs") Nos. 208567 and 210219 ("ticagrelor ANDAs") filed by Alkem 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. Reissue Patent No. RE46,276 ("the '276 patent") and U.S. Patent No. 10,300,065 ("the '065 patent"), that are listed in the *Approved Drug Products with Therapeutic*

Equivalence Evaluations ("Orange Book") for BRILINTA® (collectively "the Orange Book Patents").

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 '065 patent.

4. Plaintiff AstraZeneca UK Limited is a company operating and existing under the laws of the United Kingdom, with its principal place of business at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, United Kingdom CB2 0AA. AstraZeneca UK Limited is the owner of the '276 patent.

5. 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. Alkem specifically directed two separate letters both dated February 1, 2022 with the headings "Re: Alkem Laboratories Ltd. ANDA No. 210219 for Ticagrelor Tablets, 60 mg – Notice of Paragraph IV Certification and Offer of Confidential Access" and "Re: Alkem Laboratories Ltd. ANDA No.

208567 for Ticagrelor Tablets, 90 mg – Notice of Paragraph IV Certification and Offer of Confidential Access" ("Notice Letters") to AstraZeneca Pharmaceuticals LP.

6. On information and belief, Alkem Laboratories Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013 India. On information and belief, Alkem Laboratories Ltd., itself and through its affiliates and subsidiaries, including S&B Pharma, formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

7. On information and belief, S&B Pharma is a company organized and existing under the laws of the State of Delaware, having a registered agent in the State of Delaware at The Corporation Trust Company, located at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, and having a principal place of business at 405 South Motor Avenue, Azusa, California 91702. On information and belief, S&B Pharma is a wholly-owned subsidiary of Alkem Laboratories Ltd.

8. On information and belief, S&B Pharma is qualified to do business in the State of Delaware as a domestic corporation under file number 5100464.

9. On information and belief, Alkem Laboratories Ltd.'s website states under "Subsidiary Accounts" for S&B Pharma Inc. – USA that S&B Pharma is a Delaware corporation with an operating division consisting of Norac Pharma.

> **1.1 Principal Business Activities**
>
> S&B Pharma, Inc. ("the Company") is a component member of Alkem - India, an India based multinational pharmaceutical company. . . .The Company is a Delaware corporation with two operating divisions consisting of Norac Pharma, located in Azusa,

> California, and Alkem Laboratories ("Alkem - St. Louis"), located in Fenton, Missouri. . . . The Company's Norac Pharma division is a California based pharmaceutical company primarily engaged in the manufacture of active pharmaceutical ingredients and intermediates. Norac Pharma also is engaged in contract research, development and analytical testing of drug substances targets for Alkem - India and other companies.

https://www.alkemlabs.com/pdf/subsidiary-account/20-21/S-B-Pharma-Inc-USA.pdf (accessed March 6, 2022).

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

11. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of the ticagrelor ANDAs, Alkem will distribute and sell the generic product described in the ticagrelor ANDA throughout the United States and within 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, venue is proper in the District of Delaware for Alkem Laboratories Ltd. 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))).

16. On information and belief, venue is proper in the District of Delaware for S&B Pharma 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.").

17. Alkem Laboratories Ltd. is subject to specific personal jurisdiction in this District based on the filing of its ticagrelor ANDAs with Paragraph IV certifications regarding each of the Orange Book Patents. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762-63 (Fed. Cir. 2016).

18. As in *Acorda*, Alkem Laboratories Ltd. "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.

19. Alkem Laboratories Ltd.'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.

20. As in *Acorda*, on information and belief Alkem Laboratories Ltd., alone and/or in concert with its affiliate, S&B Pharma, "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.

21. On information and belief, Alkem Laboratories Ltd., alone and/or in concert with its affiliate, S&B Pharma, will engage in marketing of the products of its proposed ticagrelor ANDAs in Delaware, upon approval of its ticagrelor ANDAs.

22. Alkem Laboratories Ltd.'s ANDA filing, including its Paragraph IV certifications regarding the Orange Book 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 Alkem.

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

24. On information and belief, Alkem Laboratories Ltd. and S&B Pharma hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

25. On information and belief, Alkem Laboratories Ltd. and S&B Pharma 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.

26. On information and belief, Alkem Laboratories Ltd. and S&B Pharma acted in concert to develop the proposed generic products that are the subject of the ticagrelor ANDAs to seek regulatory approval from FDA to market and sell the proposed ANDA products in the District of Delaware and throughout the United States.

27. In the Notice Letters, Alkem Laboratories Ltd. notified AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and AstraZeneca UK Limited that it had submitted its ticagrelor ANDAs to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letters state that Alkem advised the AstraZeneca entities of the name and address of an agent in the United States authorized to accept service of process for Alkem. The Notice Letters were sent by Alkem Laboratories Ltd. to AstraZeneca Pharmaceuticals LP in the United States.

28. On information and belief, the preparations and submissions of the ticagrelor ANDAs by Alkem Laboratories Ltd. were done at the direction, under the control, in concert with, and/or for the direct benefit of S&B Pharma.

29. Further, on information and belief, Alkem Laboratories Ltd. and S&B Pharma will manufacture, market, and/or sell within the United States the generic products described in the ticagrelor ANDAs if FDA approval is granted. If the ticagrelor ANDAs are approved, on information and belief the generic products 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.

30. Furthermore, Alkem Laboratories Ltd. and S&B Pharma have both previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and have availed themselves of Delaware courts through the assertion of counterclaims. *See, e.g.*, *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 22-32-LPS; *Anacor Pharms., Inc. et al. v. Alkem Labs. Ltd.*, C.A. No. 21-1348-CFC; *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No.

21-1330-LPS; *Allergan USA, Inc. et al. v. Alkem Labs. Ltd.*, C.A. No. 21-1061-RGA; *Astellas Pharma Inc. et al. v. Alkem Labs. Ltd.*, C.A. No. 21-992-JFB-CJB; *Merck Sharp & Dohme Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 21-824-RGA; *Bial-Portela & CA SA et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 21-186-CFC; *Otsuka Pharma. Co., Lt. et al. v. Alkem Labs. Ltd.*, C.A. No. 20-1286-LPS; *Azurity Pharms., Inc. f/k/a CutisPharma, Inc. v. Alkem Labs. Ltd.*, C.A. No. 20-1094-MSG; *Takeda Pharms. U.S.A., Inc. v. Alkem Labs. Ltd. et al.*, C.A. No. 20-325-RGA; *Vifor Pharma, Inc. et al. v. Alkem Labs. Ltd. et al..*, C.A. No. 20-106-MN; *Insys Therapeutics, Inc. et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 17-1419-LPS; *Biogen Int'l GmbH et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 17-850-LPS; and *Medicis Pharma. Corp. v. Alkem Labs Ltd.*, C.A. No. 12-1663-LPS.

31. This Court also has personal jurisdiction over Alkem Laboratories Ltd. and S&B Pharma because, *inter alia*, Alkem Laboratories Ltd. and S&B Pharma have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Alkem Laboratories Ltd. and S&B Pharma regularly and continuously transact 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, Alkem Laboratories Ltd. and S&B Pharma derive substantial revenue from the sale of those products in Delaware and has availed themselves of the privilege of conducting business within the State of Delaware.

32. For example, on information and belief, "S&B Pharma, Inc." was registered with the State of Delaware on January 25, 2012 as a domestic corporation under file number 5100464.

Upon information and belief, S&B Pharma maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, The Corporation Trust Company, located at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

33. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Alkem Laboratories Ltd. and S&B Pharma.

PATENTS-IN-SUIT

34. On May 28, 2019, the U.S. Patent and Trademark Office duly and legally issued the '065 patent, entitled "Method of treating or prevention of atherothrombotic events in patients with history of myocardial infarction." A true and correct copy of the '065 patent is attached hereto as **Exhibit A**. The claims of the '065 patent are valid and enforceable. AstraZeneca AB is the owner of the '065 patent by assignment and has the right to enforce it.

35. On February 25, 2003, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 6,525,060 ("the '060 patent"), entitled "Triazolo(4,5-d)pyrimidine compounds." A true and correct copy of the '060 patent is attached hereto as **Exhibit B**. On January 17, 2017, the '060 patent was surrendered when the U.S. Patent and Trademark Office duly and legally issued the '276 patent, a reissue of the '060 patent. A true and correct copy of the '276 patent is attached hereto as **Exhibit C**. The claims of the '276 patent are valid and enforceable. AstraZeneca UK Limited is the owner of the '276 patent by assignment and has the right to enforce it.

36. AstraZeneca Pharmaceuticals 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), to reduce the risk of stent thrombosis in patients who have been stented for treatment of ACS, and to reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events. AstraZeneca markets ticagrelor tablets in the United States, through 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 Orange Book-listed patents protecting BRILINTA® and its use, including the '065 and '276 patents.

INFRINGEMENT BY ALKEM

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

38. In the Notice Letters, Alkem notified AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and AstraZeneca UK Limited that it had submitted its ticagrelor ANDAs to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

39. The Notice Letters state that Alkem is seeking approval from FDA to engage in the commercial manufacture, use, and sale of generic ticagrelor tablets before the expiration of, *inter alia*, the '065 and '276 patents. On information and belief, Alkem intends to engage in the commercial manufacture, use, and sale of its generic ticagrelor tablets after receiving FDA approval to do so.

40. In the Notice Letters, Alkem notified AstraZeneca that its ANDAs contained a "paragraph IV certification" asserting that the '065 and '276 patents are invalid, unenforceable,

and/or will not be infringed by the commercial manufacture, use, and sale of Alkem's generic ticagrelor tablets.

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

COUNT I (INFRINGEMENT OF THE '065 PATENT)

42. Each of the preceding paragraphs 1 to 41 is re-alleged and re-incorporated as if fully set forth herein.

43. Alkem's submission of its ticagrelor ANDAs 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 '065 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

44. On information and belief, upon FDA approval of Alkem's ticagrelor ANDAs, Alkem will further infringe at least one claim of the '065 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

45. If Alkem's marketing and sale of generic ticagrelor tablets prior to expiration of the '065 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II (INFRINGEMENT OF THE '276 PATENT)

46. Each of the preceding paragraphs 1 to 45 is re-alleged and re-incorporated as if fully set forth herein.

47. Alkem's submission of its ticagrelor ANDAs 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 '276 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

48. On information and belief, upon FDA approval of Alkem's ticagrelor ANDAs, Alkem will further infringe at least one claim of the '276 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

49. If Alkem's marketing and sale of generic ticagrelor tablets prior to expiration of the '276 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:

1. A judgment that the claims of the '065 and '276 patents are not invalid, not unenforceable, and are infringed by Alkem's submission of its ticagrelor ANDAs, and that Alkem's making, using, offering to sell, or selling in the United States, or importing into the United States Alkem's generic ticagrelor tablets will infringe the '065 and '276 patents.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Alkem's ticagrelor ANDAs shall be a date which is not earlier than the latest expiration date of the '065 and '276 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

3. An order permanently enjoining Alkem, 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 Alkem's generic ticagrelor tablets until after the latest expiration date of the '065 and '276 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

4. Damages or other monetary relief to AstraZeneca if Alkem engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Alkem's generic ticagrelor tablets prior to the latest expiration date of the '065 and '276 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

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

DATED: March 18, 2022

MCCARTER & ENGLISH, LLP

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