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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA UK LIMITED, and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. UNICHEM LABORATORIES LIMITED and UNICHEM PHARMACEUTICALS (USA), INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca AB, AstraZeneca UK Limited, and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiffs"), 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 Unichem Laboratories Limited ("Unichem India") and Unichem Pharmaceuticals (USA), Inc. ("Unichem USA") (collectively, "Unichem" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 217984 ("ticagrelor ANDA") filed by Defendant with the U.S. Food and Drug Administration ("FDA") for approval to market 60 mg and 90 mg 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. Defendant specifically directed a letter dated November 7, 2022 with the heading "Re: Notification of Paragraph IV Certification Regarding U.S. Patent Nos. 8,425,934; 10,300,065; and RE46,276 Pursuant to Section 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug, and Cosmetic Act" ("Notice Letter") to AstraZeneca AB.

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. Unichem specifically directed the Notice Letter to AstraZeneca UK Limited.

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. Unichem specifically directed the Notice Letter to AstraZeneca Pharmaceuticals LP.

6. On information and belief, Unichem India is a corporation organized and existing under the laws of India, having a principal place of business and "registered office" at Unichem Bhavan, Prabhat Estate, off S.V. Road, Jogeshwari (West), Mumbai - 400102, Maharashtra, India. On information and belief, Unichem India, itself and through its affiliates and subsidiaries, including Unichem USA, formulates, manufactures, packages, and markets generic drug products for distribution in the State of New Jersey and throughout the United States.

7. On information and belief, Unichem USA is a company organized and existing under the laws of the State of New Jersey, having a registered agent in the State of New Jersey at C T Corporation System, located at 820 Bear Tavern Road, West Trenton, New Jersey 08628, and having a principal place of business at 1 Tower Center Boulevard, Suite 2200, East Brunswick, New Jersey 08816. On information and belief, Unichem USA is a wholly-owned subsidiary and U.S. agent of Unichem India.

8. On information and belief, Unichem USA is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in New Jersey and throughout the United States.

9. On information and belief, Unichem USA is qualified to do business in the State of New Jersey and appointed a registered agent for service of process, by filing with the Secretary of State on March 9, 2004 as a domestic profit corporation, under business ID number 0100921871, and by naming "C T Corporation System" located at 1 Tower Center Boulevard, Suite 2200, East Brunswick, New Jersey 08816, as its registered agent to accept service of process in the State of New Jersey.

10. On information and belief, Defendant developed the proposed generic products that are the subject of the ticagrelor ANDA to seek regulatory approval from FDA to market and sell the proposed ANDA products throughout the United States, including within New Jersey. Defendant admits it has "69 ANDAs" and "45+ approvals in US[,]" and "[t]he key objective of generic research programs at [Unichem] is to file top quality ANDAs and dossiers in regulated markets like the US[.]" *See* https://www.unichemlabs.com/research-centre-goa.php (accessed Dec. 21, 2022).

11. 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 products described in the ticagrelor ANDA throughout the United States and within New Jersey.

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 this District for Unichem 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))).

16. On information and belief, venue is proper in this District for Unichem USA because it is incorporated in New Jersey, and thus the District of New Jersey 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. Unichem 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 '276 and '065 patents. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762-63 (Fed. Cir. 2016).

18. As in *Acorda*, Unichem 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.

19. Unichem 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.

20. As in *Acorda*, on information and belief Unichem India, alone and/or in concert with its agent, Unichem 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.

21. On information and belief, Unichem India, alone and/or in concert with its agent, Unichem USA, will engage in marketing of its proposed ticagrelor ANDA products in New Jersey, upon approval of its ticagrelor ANDA.

22. Unichem India's ANDA filing, including its Paragraph IV certification regarding the '276 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.

23. "[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.

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

25. On information and belief, Unichem India and Unichem USA 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 New Jersey and throughout the United States.

26. On information and belief, Unichem India and Unichem USA acted in concert to develop the proposed generic products that are the subject of the ticagrelor ANDA to seek regulatory approval from FDA to market and sell the proposed ANDA products in the District of New Jersey and throughout the United States.

27. On information and belief, Unichem India and Unichem USA 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 New Jersey and throughout the United States.

28. In the Notice Letter, Defendant notified AstraZeneca that it 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)). The Notice Letter states that "Timothy H. Kratz is authorized to accept service of process for [Unichem] at Kratz & Barry LLP, 1050 Crown Pointe Parkway, Suite 500, Atlanta, GA 30338." The Notice Letter was sent by Unichem to AstraZeneca in the United States.

29. On information and belief, the preparation and submission of the ticagrelor ANDA by Unichem India was done at the direction, under the control, in concert with, and/or for the direct benefit of Unichem USA.

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

31. Furthermore, Unichem India and Unichem USA have both previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and have availed themselves of New Jersey courts through the assertion of counterclaims or defenses. *See, e.g.*, *Celgene Corp. v. Unichem Labs., Ltd.*, C.A. No. 3:18-cv-11268-MAS-DEA; *Eli Lilly & Co. et al. v. Unichem Labs., Ltd. et al.*, C.A. No. 2:17-cv-13312-KSH-CLW.

32. This Court also has personal jurisdiction over Unichem India and Unichem USA because, *inter alia*, Unichem India and Unichem USA have purposefully availed themselves of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Unichem India and Unichem USA regularly and continuously transact business within the state of New Jersey, including by selling pharmaceutical products in New Jersey, 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 New Jersey. On information and belief, Unichem India and Unichem USA derive substantial revenue from the sale of those products in New Jersey and have availed themselves of the privilege of conducting business within the State of New Jersey.

33. For example, on information and belief, on March 9, 2004, Unichem USA was incorporated in the State of New Jersey as a "domestic" corporation under business ID number 0100921871.

34. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Unichem India and Unichem USA.

PATENTS-IN-SUIT

35. 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 is the owner of the '065 patent and has the right to enforce it.

36. 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 is the owner of the '276 patent and has the right to enforce it.

37. 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 '276 and '065 patents.

INFRINGEMENT BY DEFENDANT

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

39. In the Notice Letter, Unichem India notified AstraZeneca AB, AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Limited that it 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)).

40. The Notice Letter states that Unichem is seeking approval from FDA to engage in the commercial manufacture, use, and sale of 60 mg and 90 mg generic ticagrelor tablets before the expiration of, *inter alia*, the '276 and '065 patents. On information and belief, Unichem intends

to engage in the commercial manufacture, use, and sale of its 60 mg and 90 mg generic ticagrelor tablets after receiving FDA approval to do so.

41. In the Notice Letter, Unichem notified AstraZeneca that its ANDA contained a "paragraph IV certification" asserting that the '276 and '065 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Unichem's 60 mg and 90 mg generic ticagrelor tablets.

42. 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 '065 PATENT)

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

44. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 60 mg and 90 mg 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).

45. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least claim 1 of the '065 patent by making, using, offering to sell, and selling its 60 mg and/or 90 mg 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.

46. Defendant, in its Notice Letter, provides no relevant factual basis for contending that its ticagrelor ANDA product will not infringe the claims of the '065 patent under 35 U.S.C. §§ 271(a), 271(b), or 271(c).

47. If Defendant's marketing and sale of 60 mg and 90 mg 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)

48. Each of the preceding paragraphs 1 to 47 is re-alleged and re-incorporated as if fully set forth herein.

49. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 60 mg and 90 mg 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).

50. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least claim 1 of the '276 patent by making, using, offering to sell, and selling its 60 mg and/or 90 mg 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.

51. Defendant, in its Notice Letter, provides no relevant factual basis for contending that its ticagrelor ANDA product will not infringe the claims of the '276 patent under 35 U.S.C. §§ 271(a), 271(b), or 271(c).

52. If Defendant's marketing and sale of 60 mg and 90 mg 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 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 60 mg and 90 mg 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 Defendant’s ticagrelor ANDA 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 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 60 mg and 90 mg 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 Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Defendant’s 60 mg and 90 mg 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: December 22, 2022

McCARTER & ENGLISH, LLP

/s/ *John E. Flaherty*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned attorney of record for Plaintiffs, hereby certifies that to the best of my knowledge and based upon information available to me, the matter in controversy is not the subject of any other action pending of any court or of any pending arbitration or administrative proceeding.

This action alleges infringement of the same patents at issue in:

- *AstraZeneca LP et al v. HEC Pharm Co. Ltd. et al*, No. 2:19-cv-14737-CCC-MF, (’276 patent)
- *AstraZeneca LP et al v. Dr. Reddy’s Laboratories, Ltd. et al*, No. 2:19-cv-15739-CCC-MF (’276 patent)
- *AstraZeneca AB, et al. v. Taro Pharmaceuticals U.S.A., Inc.*, No. 1:22-cv-00892-KMW-EAP (’065 patent)

DATED: December 22, 2022

McCARTER & ENGLISH, LLP

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