IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. SCIEGEN PHARMACEUTICALS, INC., Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca AB 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 defendant ScieGen Pharmaceuticals, Inc. ("ScieGen" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 218962 ("ticagrelor ANDA") filed by ScieGen with the U.S. Food and Drug Administration ("FDA") for approval to market 90 mg and 60 mg generic versions of AstraZeneca's BRILINTA® (ticagrelor) drug product prior to expiration of AstraZeneca's U.S. Patent No. 10,300,065 ("the '065 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 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. Defendant specifically directed a letter dated November 8, 2023 with the heading "Re: Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95" ("Notice Letter") to AstraZeneca AB.

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 the Notice Letter to AstraZeneca Pharmaceuticals LP.

5. On information and belief, ScieGen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 89 Arkay Drive, Hauppauge, New York 11788.

6. On information and belief, ScieGen 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.

7. On information and belief, ScieGen 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 Delaware.

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

JURISDICTION AND VENUE

9. Each of the preceding paragraphs 1 to 8 is re-alleged and re-incorporated as if fully set forth herein.

10. 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.

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

12. ScieGen, through its counsel, by e-mail dated December 9, 2023, consented to personal jurisdiction and venue in this Court for purposes of this matter only.

13. ScieGen 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).

14. As in *Acorda*, ScieGen "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.

15. ScieGen'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.

16. As in *Acorda*, on information and belief ScieGen, alone and/or in concert with its affiliates, "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.

17. On information and belief, ScieGen, alone and/or in concert with its affiliates, will engage in marketing of its proposed ticagrelor ANDA products in Delaware, upon approval of its ticagrelor ANDA.

18. ScieGen's ANDA filing, including its Paragraph IV certification regarding the '065 patent 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.

19. "[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.

20. On information and belief, ScieGen 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 in the District of Delaware and throughout the United States.

21. On information and belief, ScieGen works either alone or in concert with its affiliates 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, the preparation and submission of the ticagrelor ANDA was done by, at the direction, under the control, and/or for the direct benefit of ScieGen.

23. Further, on information and belief, ScieGen 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 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.

24. Furthermore, ScieGen has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and/or has availed itself of Delaware courts through the assertion of counterclaims. *See, e.g.*, *Genentech, Inc. et al. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 19-131-RGA; *Genentech, Inc. et al. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 19-132-RGA; *UCB Inc. v. ScieGen Pharmaceuticals, Inc. et al.*, C.A. No. 13-1217-LPS.

25. This Court also has personal jurisdiction over ScieGen because, *inter alia*, ScieGen 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, ScieGen 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, ScieGen 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.

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

PATENT-IN-SUIT

27. 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.

28. 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 patent.

INFRINGEMENT BY DEFENDANT

29. Each of the preceding paragraphs 1 to 28 is re-alleged and re-incorporated as if fully set forth herein.

30. In the Notice Letter, ScieGen notified AstraZeneca AB and AstraZeneca Pharmaceuticals LP 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)).

31. The Notice Letter states that ScieGen 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 patent. On information and belief, ScieGen intends to engage in the commercial manufacture, use, and sale of its generic ticagrelor tablets after receiving FDA approval to do so.

32. In the Notice Letter, ScieGen notified AstraZeneca that its ANDA contained a “Paragraph IV Certification” asserting that the ’065 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of ScieGen’s ANDA products.

33. 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)

34. Each of the preceding paragraphs 1 to 33 is re-alleged and re-incorporated as if fully set forth herein.

35. 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 '065 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

36. 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 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.

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

38. If Defendant'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.

PRAYER FOR RELIEF

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

1. A judgment that the claims of the '065 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 '065 patent.

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 patent, 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 generic ticagrelor tablets until after the latest expiration date of the '065 patent, 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 generic ticagrelor tablets prior to the latest expiration date of the '065 patent, 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 21, 2023

MCCARTER & ENGLISH, LLP

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