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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. TARO PHARMACEUTICALS U.S.A., INC., Defendant.	Civil Action No.22-CV-1405

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 Taro Pharmaceuticals U.S.A., Inc. ("Taro"). This action relates to Abbreviated New Drug Application ("ANDA") No. 211498 ("ticagrelor

ANDA") filed by Taro 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 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. Taro specifically directed two identical letters dated January 4, 2022 and January 7, 2022 with the heading "Re: Notification Certification Pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act and Section 314.95 of the Food and Drug Administration Regulations Concerning ANDA No. 211498 and Brilinta® (Ticagrelor Tablets 60 mg and 90 mg)" ("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. Taro specifically directed the Notice Letter to AstraZeneca Pharmaceuticals LP.

5. On information and belief, Taro is a corporation organized and existing under the laws of the State of New York, having a place of business at 3 Skyline Drive, Hawthorne, New York 10532.

6. On information and belief, Taro is qualified to do business in the State of New York under business ID number 185681.

7. On information and belief, Taro, itself and through its affiliates, is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the Southern District of New York and throughout the United States.

8. On information and belief, Taro 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 the Southern District of New York.

9. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of the ticagrelor ANDA, Taro will distribute and sell the generic product described in the ticagrelor ANDA throughout the United States and within the Southern District of New York.

JURISDICTION AND VENUE

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

11. 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.

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

13. On information and belief, venue is proper in the Southern District of New York for Taro because it is incorporated in the State of New York and has its principal place of business within the Southern District of New York, and thus the Southern District of New York 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. 1515, 1521 (2017) ("[a]s applied to domestic corporations, 'reside[nce]' in § 1400(b) refers only to the State of incorporation").

14. Taro 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).

15. As in *Acorda*, Taro "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.

16. Taro'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.

17. As in *Acorda*, on information and belief Taro, 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.

18. On information and belief, Taro, alone and/or in concert with its affiliates, will engage in marketing of its proposed ticagrelor ANDA product in New York, upon approval of its ticagrelor ANDA.

19. Taro'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 Taro.

20. "[T]he minimum-contacts standard is satisfied by the particular actions [Taro] 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.

21. On information and belief, Taro 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 in the Southern District of New York and throughout the United States.

22. On information and belief, Taro 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 Southern District of New York and throughout the United States.

23. In the Notice Letter, Taro 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)). The Notice Letter states that it advised the AstraZeneca entities of "the name and address of an agent in the United States authorized to accept service of process for Taro in connection with the Taro ANDA." The Notice Letter was sent by Taro to AstraZeneca Pharmaceuticals LP in the United States.

24. 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 Taro.

25. Further, on information and belief, Taro 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 New York, prescribed by physicians practicing in New York, and dispensed by pharmacies located within New York, and/or used by patients in New York, all of which would have a substantial effect on New York.

26. Furthermore, Taro has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of federal courts in this District through the assertion of counterclaims. *See, e.g.*, *Promius Pharma LLC v. Taro Pharms., Inc.*, C.A. No. 1:18-cv-04576; *Arbor Pharms., LLC v. Taro Pharms. U.S.A., Inc. et al.*, C.A. No. 1:17-cv-09846-SHS; *Delcor Asset Corp. et al. v. Taro Pharma. Indus., Ltd. et al.*, C.A. No. 17-05405-RJS; *Merz Pharms., LLC et al. v. Taro Pharms. U.S.A., Inc. et al.*, C.A. No. 1:15-cv-10168-WHP; *Merz Pharms., LLC et al. v. Taro Pharms. U.S.A., Inc. et al.*, C.A. No. 1:15-cv-03720-WHP;

27. This Court also has personal jurisdiction over Taro because, *inter alia*, Taro has purposefully availed itself of the rights and benefits of New York law by engaging in systematic and continuous contacts with the State of New York. On information and belief, Taro regularly and continuously transacts business within the State of New York, including by selling pharmaceutical products in New York, 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 York. On information and belief, Taro derives substantial revenue from the sale of those products in New York and has availed itself of the privilege of conducting business within the State of New York.

28. For example, on information and belief, on March 23, 1965, Taro was incorporated in the State of New York as a "domestic" corporation under New York Department of State ID number 185681.

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

PATENT-IN-SUIT

30. 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.

31. 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 TARO

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

33. In the Notice Letter, Taro 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)).

34. The Notice Letter states that Taro 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, Taro intends to engage in the commercial manufacture, use, and sale of its generic ticagrelor tablets after receiving FDA approval to do so.

35. In the Notice Letter, Taro 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, and sale of Taro's generic ticagrelor tablets.

36. 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)

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

38. Taro'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).

39. On information and belief, upon FDA approval of Taro's ticagrelor ANDA, Taro 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.

40. If Taro'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 Taro's submission of its ticagrelor ANDA, and that Taro's making, using, offering to sell, or selling in the United States, or importing into the United States Taro'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 Taro'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 Taro, 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 Taro'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 Taro engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Taro'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: February 18, 2022

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