IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES LIMITED, and SUN PHARMACEUTICAL INDUSTRIES, INC., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff AstraZeneca AB ("AstraZeneca"), 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 Sun Pharmaceutical Industries Limited ("Sun Ltd.") and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively, "Sun"). This action relates to Abbreviated New Drug Application ("ANDA") No. 211491 filed by Sun with the U.S. Food and Drug Administration ("FDA") for approval to market 2.5 mg/1000 mg, 5 mg/500 mg, 5 mg/1000 mg, 10 mg/500 mg, and 10 mg/1000 mg dapagliflozin/metformin hydrochloride extended-release tablets, generic versions of AstraZeneca's XIGDUO XR® drug product (the "ANDA Products"), prior to expiration of U.S. Patent No. 6,515,117 ("the '117 patent").

PARTIES

2. Plaintiff AstraZeneca is a company operating and existing under the laws of Sweden, with a principal place of business at SE-151 85 Södertälje, Sweden. AstraZeneca is the

owner of the '117 patent and the holder of New Drug Application ("NDA") No. 205649 for XIGDUO XR®.

3. Plaintiff's subsidiary, 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.

4. 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 type 2 diabetes. Through its subsidiary, AstraZeneca Pharmaceuticals LP, AstraZeneca markets and sells XIGDUO XR® in this judicial district and throughout the United States.

5. Upon information and belief, Sun Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063.

6. On information and belief, Sun Ltd., itself and through its affiliates and subsidiaries, including Sun Inc., 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, Sun Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2 Independence Way, Princeton, New Jersey 08540. On information and belief, Sun Inc. is a wholly-owned subsidiary and U.S. agent of Sun Ltd.

8. On information and belief, Sun 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.

9. On information and belief, Sun 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 March 11, 2020 pursuant to sections 371 and 376 of title 8 of the Delaware Code: (1) a certificate of incorporation as a domestic corporation, under file number 7893212; and (2) a statement naming "Corporation Service Company" located at 251 Little Falls Drive, Wilmington, Delaware, 19808, as its registered agent to accept service of process in the State of Delaware.

10. On information and belief, Sun developed the proposed generic products that are the subject of ANDA No. 211491 to seek regulatory approval from FDA to market and sell the proposed ANDA products 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 ANDA No. 211491, Sun will distribute and sell the generic products described in ANDA No. 211491 throughout the United States and within Delaware.

JURISDICTION AND VENUE

12. AstraZeneca realleges, and incorporates in full herein, each preceding paragraph.

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. Sun Ltd. is subject to specific personal jurisdiction in this District based on the filing of ANDA No. 211491 with a Paragraph IV certification regarding the '117 patent. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762-63 (Fed. Cir. 2016).

15. As in *Acorda*, Sun 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.

16. Sun 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.

17. As in *Acorda*, on information and belief Sun Ltd., alone and/or in concert with its agent, Sun Inc., "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, Sun Ltd., alone and/or in concert with its agent, Sun Inc., will engage in marketing of its proposed ANDA products in Delaware, upon approval of its ANDA.

19. Sun Ltd.'s ANDA filing, including its Paragraph IV certifications regarding the '117 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.

20. "[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.

21. On information and belief, Sun Ltd. and Sun Inc. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

22. On information and belief, Sun Ltd. and Sun 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.

23. On information and belief, Sun Ltd. and Sun Inc. acted in concert to develop the proposed generic products that are the subject of ANDA No. 211491 to seek regulatory approval

from FDA to market and sell the proposed ANDA products in the District of Delaware and throughout the United States.

24. In an October 20, 2023 letter ("Notice Letter"), Defendant notified AstraZeneca that it had submitted ANDA No. 211491 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 "Sun provides this letter." The Notice Letter was sent by Sun Ltd. to AstraZeneca in the United States, including employees in this District.

25. This Complaint is being filed within 45 days of AstraZeneca's receipt of the Notice Letter.

26. On information and belief, the preparation and submission of ANDA No. 211491 by Sun Ltd. was done at the direction, under the control, in concert with, and/or for the direct benefit of Sun Inc.

27. Further, on information and belief, Sun Ltd. and Sun Inc. will manufacture, market, and/or sell within the United States the generic products described in ANDA No. 211491 if FDA approval is granted. If ANDA No. 211491 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.

28. Furthermore, Sun Ltd. and Sun Inc. 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.*, *Novo Nordisk Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 22-896-CFC; *Novo Nordisk Inc. v. Sun Pharm. Indus. Inc.*, C.A. No. 22-897-CFC; *Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 22-182-RGA; *Boehringer*

Ingelheim Pharms. Inc. v. Sun Pharm. Indus. Ltd., C.A. No. 21-1573-CFC; *Boehringer Ingelheim Pharms. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 21-1487-CFC; *Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 21-1065-RGA.

29. Sun Ltd. and Sun Inc. have also availed themselves of Delaware courts by filing cases in this District as plaintiffs. *See, e.g., Sun Pharm. Indus. Ltd. v. Saptalis Pharms., LLC*, C.A. No. 18-648-WCB; *Sun Pharm. Indus., Inc. v. Perrigo Co.*, C.A. No. 18-703-CFC; *Sun Pharm. Glob. FZE v. Teva Pharm. Indus. Ltd.*, C.A. No. 18-1552-RGA.

30. This Court also has personal jurisdiction over Sun Ltd. and Sun Inc. because, *inter alia*, Sun Ltd. and Sun Inc. 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, Sun Ltd. and Sun Inc. 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, Sun Ltd. and Sun Inc. derive substantial revenue from the sale of those products in Delaware and have availed themselves of the privilege of conducting business within the State of Delaware.

31. For example, on information and belief, on March 11, 2020, Sun Inc. was incorporated in the State of Delaware as a "domestic" corporation under file number 7893212.

32. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Sun Ltd. and Sun Inc.

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

34. On information and belief, venue is proper in the District of Delaware for Sun 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))).

35. On information and belief, venue is proper in the District of Delaware for Sun Inc. 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").

COUNT I (INFRINGEMENT OF THE '117 PATENT)

36. AstraZeneca realleges, and incorporates in full herein, each preceding paragraph.

37. The PTO issued the '117 patent on February 4, 2003, entitled "C-Aryl Glucoside SGLT2 Inhibitors and Method." The '117 patent identifies Bruce Ellsworth, William N. Washburn, and Wei Meng as inventors of the claimed subject matter. A true and correct copy of the '117 patent is attached hereto as **Exhibit A**.

38. AstraZeneca is the owner of the '117 patent by virtue of assignment and has the right to enforce it.

39. The '117 patent expires on October 4, 2025, inclusive of patent term extension under 35 U.S.C. § 156 and excluding any pediatric exclusivity.

40. The '117 patent is directed to and claims, *inter alia*, compounds and methods for treating diabetes and related diseases.

41. The '117 patent is listed in the Orange Book for NDA No. 205649 for dapagliflozin/metformin hydrochloride extended-release tablets.

42. The FDA approved NDA No. 205649 on October 30, 2014, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate.

43. AstraZeneca markets dapagliflozin/metformin hydrochloride extended-release tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trademark XIGDUO XR®.

44. AstraZeneca received the Notice Letter, purporting to include a Notice of Certification for ANDA No. 211491 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '117 patent.

45. Sun thus has actual knowledge of the '117 patent.

46. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sun has infringed at least one claim including at least claim 1 of the '117 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 211491 seeking approval to manufacture, use, import, offer to sell or sell Sun's ANDA Products before the expiration date of the '117 patent. Upon information and belief, the products described in ANDA No. 211491 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '117 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Sun's ANDA Products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 and/or claim 14 of the '117 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

48. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 and/or claim 14 of the ’117 patent by the use of Sun’s ANDA Products upon approval.

49. Upon information and belief, upon approval, Sun will take active steps to encourage the use of Sun’s ANDA Products by physicians and/or patients with the knowledge and intent that Sun’s ANDA Products will be used by physicians and/or patients, in a manner that infringes at least one claim including at least claim 14 of the ’117 patent for the pecuniary benefit of Sun. Pursuant to 21 C.F.R. § 314.94, Sun is required to copy the FDA-approved FARXIGA® labeling. Upon information and belief, Sun will thus induce infringement of at least one claim including at least claim 14 of the ’117 patent.

50. On information and belief, if the FDA approves ANDA No. 211491, Sun will sell or offer to sell Sun’s ANDA Products specifically labeled for use in practicing at least one claim including at least claim 14 of the ’117 patent, wherein Sun’s ANDA Products are a material part of the claimed invention, wherein Sun knows that physicians will prescribe and patients will use Sun’s ANDA Products in accordance with the instructions and/or label provided by Sun in practicing at least one claim including at least claim 14 of the ’117 patent, and wherein dapagliflozin tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, Sun will thus contribute to the infringement of at least one claim including at least claim 14 of the ’117 patent.

51. Upon information and belief, Sun’s actions relating to Sun’s ANDA No. 211491 complained of herein were done by and for the benefit of Sun.

52. If Sun's marketing and sale of Sun's ANDA Products prior to expiration of the '117 patent and all other relevant activities are not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca respectfully requests that the Court enter judgment in its favor and against Defendants Sun Ltd. and Sun Inc. on the patent infringement claims set forth above and respectfully requests that this Court:

1. enter a judgment under 35 U.S.C. § 271(e)(2)(A) that Sun has infringed one or more claims of the '117 patent through Sun's submission of ANDA No. 211491 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Sun's ANDA Products in the United States before the expiration of the '117 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

2. enter a judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Sun's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Sun's ANDA Products prior to the expiration of the '117 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271(a), (b), and/or (c);

3. order that the effective date of any approval by the FDA of Sun's ANDA Products be a date that is not earlier than the expiration date of the '117 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

4. enjoin Sun, and all persons acting in concert with Sun, from the manufacture, use, import, offer for sale and sale of Sun's ANDA Products until the expiration of the '117 patent,

including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

5. enjoin Sun, and all persons acting in concert with Sun, from seeking, obtaining or maintaining approval of Sun's ANDA No. 211491 until the expiration of the '117 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled, or such later date as the Court may determine;

6. award damages or other monetary relief to AstraZeneca if Sun engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Sun's ANDA Products prior to the latest expiration date of the '117 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled;

7. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award AstraZeneca costs, expenses and disbursements in this action, including reasonable attorney fees; and

8. award such further and other relief as this Court deems proper and just.

DATED: December 4, 2023

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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