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Counsel for Plaintiffs KuDOS Pharmaceuticals Limited and The University of Sheffield

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KUDOS PHARMACEUTICALS LIMITED, and THE UNIVERSITY OF SHEFFIELD, *Plaintiffs,* v. SUN PHARMACEUTICAL INDUSTRIES LIMITED and SUN PHARMACEUTICAL INDUSTRIES, INC., *Defendants.*	Civil Action No. 25-15825 **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs KuDOS Pharmaceuticals Limited and The University of Sheffield file this Complaint against Defendant Sun Pharmaceutical Industries Limited ("Sun") and Sun Pharmaceutical Industries, Inc. ("Sun USA"), and allege the following:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, which arises out of the submission by Sun of Abbreviated New Drug Application No. 220688 ("Sun's ANDA") to the United States Food and Drug Administration seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of ZEJULA (niraparib) tablets, 100 mg, 200 mg, and 300 mg, ("Sun's ANDA Product"), prior to the expiration of U.S. Patent No. 8,859,562 ("the 562 patent").

2. Sun notified Plaintiff The University of Sheffield by letter dated August 7, 2025 ("Sun's Notice Letter") that it had submitted Sun's ANDA seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product prior to the expiration of the '562 patent.

The Parties

3. Plaintiff KuDOS Pharmaceuticals Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

4. Plaintiff The University of Sheffield is a Royal Charter company organized and existing under the laws of England and Wales, whose address is Western Bank, Sheffield S10 2TN, United Kingdom.

5. Upon information and belief, Defendant Sun Pharmaceutical Industries Limited is a company organized and existing under the laws of the Republic of India and having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E),

Mumbai 400063, India.

6. Upon information and belief, Defendants Sun Pharmaceutical Industries Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2 Independent Way, Princeton, New Jersey 08540, and another place of business at 1 Commerce Drive, Cranbury, New Jersey 08512.

Jurisdiction

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

8. Based on the facts alleged in this Complaint, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Sun Pharmaceutical Industries Limited.

9. Sun is subject to personal jurisdiction in New Jersey because, among other things, Sun has purposefully availed itself of the benefits and protections of New Jersey's laws such that it would reasonably anticipate being haled into court here. On information and belief, Sun develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and transacts business within the State of New Jersey related to Plaintiffs' claims, and/or have engaged in systematic and continuous business contacts within the State of New Jersey.

10. In addition, this Court has personal jurisdiction over Sun because, on information and belief: (1) Sun filed Sun's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Sun's ANDA, Sun will directly, or indirectly through subsidiaries, intermediaries, distributers, retailers, or others, market, distribute, offer for sale, sell, and/or import Sun's ANDA Product in the United States,

including in New Jersey; and will derive substantial revenue from the use or consumption of Sun's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Sun's ANDA, Sun's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; 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.

11. This Court has personal jurisdiction over Sun because it (1) engages in patent litigation concerning Sun's products in this District, and (2) does not contest personal jurisdiction in this District. *See, e.g., TherapeuticsMD, Inc. v. Sun Pharmaceutical Industries Ltd.*, Civ. No. 24-7974-BRM-SDA, Dkt. No. 11 (D.N.J. September 30, 2024).

12. Additionally, this Court has personal jurisdiction over Sun because, on information and belief, Sun maintains its principal place of U.S. business in this District.

13. For the above reasons, it would not be unfair or unreasonable for Sun to litigate this action in this District, and the Court has personal jurisdiction over it here.

14. Upon information and belief, Sun USA is a wholly owned subsidiary and U.S. agent of Sun, and acts at the direction of, under the control of, and for the benefit of Sun.

15. Upon information and belief, upon approval of Sun's ANDA, Sun USA will act in concert with Sun directly, or indirectly through subsidiaries, intermediaries, distributers, retailers, or others, market, distribute, offer for sale, sell, and/or import Sun's ANDA Product in the United States, including in New Jersey; and will derive substantial revenue from the use or consumption of Sun's ANDA Product in New Jersey.

16. This Court has personal jurisdiction over Sun USA because it (1) engages in

patent litigation concerning Sun's products in this District, and (2) does not contest personal jurisdiction in this District. *See, e.g., TherapeuticsMD, Inc. v. Sun Pharmaceutical Industries Ltd.*, Civ. No. 24-7974-BRM-SDA, Dkt. No. 11 (D.N.J. September 30, 2024).

17. Additionally, this Court has personal jurisdiction over Sun USA because, on information and belief, Sun USA is headquartered in this District.

18. For the above reasons, it would not be unfair or unreasonable for Sun USA to litigate this action in this District, and the Court has personal jurisdiction over it here.

Venue

19. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because, on information and belief, Sun is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

20. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Sun and Sun USA have committed, or will commit, an act of infringement in this District, and have a regular and established place of business in this District. Venue is proper as to Sun and Sun USA because, on information and belief: (1) Sun filed Sun's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Sun's ANDA, Sun and Sun USA will act in concert directly, or indirectly through subsidiaries, intermediaries, distributers, retailers, or others, to market, distribute, offer for sale, sell, and/or import Sun's ANDA Product in the United States, including in New Jersey; and will derive substantial revenue from the use or consumption of Sun's ANDA Product in New Jersey. Venue is proper as to Sun because, on information and belief, Sun maintains its principal place of U.S. business in this District. Venue is proper as to Sun USA because, on information and belief, Sun USA is headquartered in this District.

21. Venue is proper as to Sun and Sun USA in this District because those entities (1) engage in patent litigation concerning Sun's products in this District, and (2) do not contest venue in this District. *See, e.g.*, *TherapeuticsMD, Inc. v. Sun Pharmaceutical Industries Ltd.*, Civ. No. 24-7974-BRM-SDA, Dkt. No. 11 (D.N.J. September 30, 2024).

Factual Background

22. ZEJULA is approved by FDA for the treatment of certain cancers. The active pharmaceutical ingredient in ZEJULA is niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor.

23. In Sun's Notice Letter, Sun states that the subject of Sun's ANDA is niraparib tablets, 100 mg, 200 mg, and 300 mg. In Sun's Notice Letter, Sun states that Sun's ANDA was submitted under 21 U.S.C. § 355(j). On information and belief, Sun's ANDA Product is a generic version of ZEJULA.

24. The purpose of Sun's submission of Sun's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

25. In Sun's Notice Letter, Sun stated that it had submitted Paragraph IV Certifications to FDA alleging that, *inter alia*, U.S. Patent No. 8,859,562 is invalid, unenforceable, and/or not infringed, and that Sun is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Sun's ANDA Product prior to the expiration of the '562 patent.

26. On information and belief, Sun has not challenged U.S. Patent No. 8,071,579 or U.S. Patent No. 8,143,241, which are listed in connection with ZEJULA in the FDA's Orange Book and expire on August 12, 2027. On information and belief, Sun has not challenged U.S. Patent No. 8,436,185, which is listed in connection with ZEJULA in the FDA's Orange Book

and expires on April 24, 2029. On information and belief, following the expiration of those patents, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately upon FDA approval of Sun's ANDA.

Count I – Infringement of the '562 Patent Under 35 U.S.C. § 271(e)(2)

27. On October 14, 2014, the USPTO duly and lawfully issued the '562 patent, entitled "Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer." A copy of the '562 patent is attached hereto as Exhibit A.

28. Plaintiff The University of Sheffield is the assignee of the '562 patent. Plaintiff KuDOS Pharmaceuticals Limited is the exclusive licensee of the '562 patent and has the right to enforce the '562 patent against infringers.

29. The '562 patent claims, *inter alia*, a method of treatment of cancer cells defective in homologous recombination (HR).

30. Methods of using ZEJULA are covered by claim 1 of the '562 patent and the '562 patent has been listed in connection with ZEJULA in the FDA's Orange Book.

31. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product prior to the expiration of the '562 patent was an act of infringement of the '562 patent under 35 U.S.C. § 271(e)(2)(A).

32. On information and belief, the use of Sun's ANDA Product in accordance with and as directed by Sun's proposed prescribing information and labeling for Sun's ANDA Product would infringe claim 1 of the '562 patent.

33. On information and belief, Sun and Sun USA were aware of the '562 patent at least as of the time of submitting Sun's Paragraph IV certification to FDA with respect to the '562 patent.

34. On information and belief, Sun and Sun USA plan and intend to, and will, actively induce infringement of the ’562 patent.

35. On information and belief, Sun and Sun USA plan and intend to, and will, contribute to infringement of the ’562 patent and know that Sun’s ANDA Product and its proposed labeling are not suitable for substantial non-infringing use.

36. The foregoing actions by Sun and Sun USA constitute and/or will constitute infringement of the ’562 patent, active inducement of infringement of the ’562 patent, and contribution to the infringement by others of the ’562 patent.

37. On information and belief, Sun and Sun USA have acted with knowledge of the ’562 patent and without a reasonable basis for believing that those entities would not be liable for infringement of the ’562 patent, and for inducing and contributing to the infringement by others of the ’562 patent.

38. Unless Sun and Sun USA are enjoined from infringing the ’562 patent, actively inducing the infringement of the ’562 patent, and contributing to the infringement by others of the ’562 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count II – Declaratory Judgment of Infringement of the ’562 Patent

39. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Sun and Sun USA on the other regarding infringement and/or invalidity of the ’562 patent.

40. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sun’s ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the ’562 patent, will infringe, induce the

infringement of, and contribute to the infringement by others of the ’562 patent, and that the claims of the ’562 patent are valid and enforceable.

Prayer for Relief

WHEREFORE, Plaintiffs respectfully request the following relief:

1. A judgment that the ’562 patent has been infringed under 35 U.S.C. § 271(e)(2) by Sun’s submission to the FDA of Sun’s ANDA;
2. A judgment that the ’562 patent is valid and enforceable;
3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval of Sun’s ANDA and for Sun and Sun USA to make, use, offer for sale, sell, market, distribute, or import Sun’s ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the ’562 patent, shall not be earlier than the latest of the expiration dates of the ’562 patent, inclusive of any extension(s) and additional period(s) of exclusivity.
4. A preliminary and permanent injunction pursuant to 35 U.S.C. § 371(e)(4)(B) enjoining Sun, Sun USA, their officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Sun’s ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the ’562 patent, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the ’562 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

5. An order pursuant to this Court's equitable power that the effective date of any final approval of Sun's ANDA shall be a date that is not earlier than the latest of the expiration date of the '562 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

6. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Sun's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '562 patent, prior to the expiration date of the '562 patent, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '562 patent;

7. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

8. An award of Plaintiffs' costs and expenses in this action; and

9. Such further and other relief as this Court may deem just and proper.

Dated: September 19, 2025

Respectfully submitted,

s/Charles H. Chevalier

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