IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC, TESARO, INC., and MERCK SHARP & DOHME LLC, *Plaintiffs*, v. SUN PHARMACEUTICAL INDUSTRIES LTD., *Defendant*.	Civil Action No. _____

COMPLAINT

GlaxoSmithKline LLC ("GSK"), TESARO, Inc. ("TESARO"), and Merck Sharp & Dohme LLC ("Merck"; together with GSK and TESARO, "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, 35 U.S.C. §§ 100 *et seq.* against Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.").

2. Plaintiffs invented and developed, and GSK markets, Zejula® (niraparib) tablets for the treatments of several types of cancer. This action arises out of Sun Ltd.'s submission of Abbreviated New Drug Application ("ANDA") No. 220688 (the "Sun ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell niraparib tablet products in 100 mg, 200 mg, and 300 mg strengths (the "Sun ANDA Product") prior to the expiration of U.S. Patent Nos. 8,071,623, 11,091,459, and 11,673,877 (collectively, the "Patents-in-Suit").

PARTIES

3. GSK is a limited liability company organized and existing under the laws of Delaware, with its principal place of business at 2929 Walnut Street, Ste. 1700, Philadelphia, PA 19104.

4. TESARO is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1000 Winter Street, Waltham, Massachusetts 02451.

5. Merck is a limited liability company formed and existing under the laws of New Jersey, with its principal place of business at 126 East Lincoln Avenue, Rahway, New Jersey 07065.

6. Upon information and belief, Sun Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai – 400 063, Maharashtra, India.

7. Upon information and belief, Sun Ltd., itself and through its subsidiaries and agents, develops, manufactures, markets, distributes, and/or imports pharmaceutical products for sale and use through the United States, including in Delaware.

8. Upon information and belief, following any FDA approval of the Sun ANDA, Sun Ltd. will make, use, offer to sell, and/or sell the Sun ANDA Product that is the subject of the Sun ANDA throughout the United States, including in Delaware, and/or import such generic products into the United States, including into Delaware.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.* This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Sun Ltd. because, among other things, Sun Ltd. has committed, contributed to, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. §§ 271(a), (b) and/or (c), including in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs. For example, upon information and belief, following approval of the Sun ANDA, Sun Ltd. either directly or indirectly through affiliated companies or agents, will make, use, import, sell, and/or offer for sale the Sun ANDA Product in the United States, including in Delaware, prior to the expiration of the Patents-in-Suit.

11. The Court also has personal jurisdiction over Sun Ltd. because, among other things, this action arises from actions of Sun Ltd. directed toward Delaware, and because Sun Ltd. has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Sun Ltd. regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies or agents. Upon information and belief, Sun Ltd. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

12. The Court also has personal jurisdiction over Sun Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(1) or 4(k)(2) because: (a) Sun Ltd. is subject to the general jurisdiction of the laws of Delaware; and (b) to the extent that Sun Ltd. is not subject to personal jurisdiction in the courts of any state, Plaintiffs' claims arise under federal law and Sun Ltd. has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling

generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Sun Ltd. satisfies due process.

13. Sun Ltd. has previously availed itself of this forum for the purpose of litigating its patent infringement disputes. For example, Sun Ltd. has filed claims in this forum, including in:

- *Sun Pharm. Indus. Ltd. & Ranbaxy Signature, LLC v. Saptalis Pharms., LLC*, C.A. No. 18-648-WCB (D. Del.).

14. Sun Ltd. has also previously availed itself of this forum for the purpose of filing counterclaims in patent infringement disputes, including in:

- *Exelixis, Inc. v. Sun Pharms. Indus. Ltd. et al.*, C.A. No. 25-423-RGA (D. Del.);
- *Exelixis, Inc. v. Sun Pharms. Indus. Ltd. et al.*, C.A. No. 24-1208-RGA (D. Del.);
- *Novo Nordisk Inc. & Novo Nordisk A/S v. Sun Pharms. Indus. Ltd. et al.*, C.A. 24-1014-CFC (D. Del.);
- *Otsuka Pharm. Co., Ltd. & H. Lundbeck A/S v. Sun Pharms. Indus. Ltd. et al.*, C.A. No. 24-789-JLH (D. Del.);
- *Veloxis Pharms., Inc. v. Sun Pharm. Indus. Ltd. et al.*, C.A. No. 24-726-MN (D. Del.);
- *Novo Nordisk Inc. & Novo Nordisk A/S v. Sun Pharms. Indus. Ltd. et al.*, C.A. No. 23-1459-CFC (D. Del.);
- *Allergan Holding Ltd. et al. v. Sun Pharm. Indus. Ltd.*, C.A. No. 23-795-RGA (D. Del.);
- *Vertex Pharms. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 20-988-RGA (D. Del.);
- *Allergan USA, Inc. et al. v. Sun Pharm. Indus. Ltd.*, C.A. No. 19-1727-RGA (D. Del.); and
- *Boehringer Ingelheim Pharms. Inc. et al. v. Sun Pharms. Indus. Ltd. et al.*, C.A. No. 21-1573-CFC (D. Del.).

15. Venue is proper in this Court as to Sun Ltd. under 28 U.S.C. § 1391(c)(3) because, upon information and belief, Sun Ltd. is a foreign corporation and may thus be sued in any judicial district.

BACKGROUND

16. Zejula® (niraparib) is an orally available poly (ADP-ribose) polymerase (PARP) inhibitor that the FDA has approved for: (1) the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency-positive status defined by either: (a) a deleterious or suspected deleterious BRCA mutation and/or (b) genomic instability; and (2) maintenance treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCA*mut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

17. Zejula® is the first approved first-line maintenance targeted therapy approved for the treatment of all adult patients with advanced recurrent epithelial ovarian, fallopian or primary peritoneal cancer associated with HRD-positive status due to genomic instability regardless of *BRCA* mutation status. Zejula® represents a significant milestone in the treatment of ovarian cancer. Zejula® is an important step in personalized cancer treatment and offers a new maintenance therapy option to patients with recurrent ovarian cancer. Zejula® has contributed and contributes significantly to the improvement of cancer patient care in the United States.

18. GSK markets Zejula® in the United States, including in Delaware, pursuant to New Drug Application (NDA) No. 214876, which was approved by the FDA on April 26, 2023. GSK holds the NDA for Zejula®.

19. Zejula® is a commercial embodiment of the Patents-in-Suit and practices one or more of the claims of the Patents-in-Suit. All Patents-in-Suit have been properly listed in connection with Zejula® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

PATENTS-IN-SUIT

20. U.S. Patent No. 8,071,623 (the "'623 Patent"), titled "Amide Substituted Indazoles as Poly(ADP-Ribose)Polymerase(PARP) Inhibitors" (Ex. A), was duly and legally issued on December 6, 2011, and will expire on March 27, 2031. Merck owns the '623 Patent. TESARO is an exclusive licensee of the '623 Patent.

21. U.S. Patent No. 11,091,459 (the "'459 Patent"), titled "Niraparib Compositions" (Ex. B), was duly and legally issued on August 17, 2021, and will expire on March 27, 2038. Merck and TESARO jointly own the '459 Patent.

22. U.S. Patent No. 11,673,877 (the "'877 Patent"), titled "Niraparib Compositions" (Ex. C), was duly and legally issued on June 13, 2023, and will expire on March 27, 2038. Merck and TESARO jointly own the '877 Patent.

SUN LTD.'S INFRINGEMENT OF THE PATENTS-IN-SUIT

23. By letter dated August 7, 2025, Sun Ltd. notified GSK, TESARO, and Merck that Sun Ltd. had submitted the Sun ANDA to the FDA seeking approval to market niraparib tablets (100 mg, 200 mg, and 300 mg) (the "Notice Letter"). GSK, TESARO, and Merck received the Notice Letter on August 8, 2025.

24. By submitting the Sun ANDA, Sun Ltd. has represented to the FDA that the Sun ANDA Product has the same active ingredient as Zejula®, has the same dosage form and strength as Zejula®, and is bioequivalent to Zejula®.

25. Sun Ltd. stated in the Notice Letter that the Sun ANDA included a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) with respect to the Patents-in-Suit and alleged that the Patents-in-Suit are invalid or will not be infringed by the commercial manufacture, use, or sale of the Sun ANDA Product. Accordingly, upon information and belief, Sun Ltd. had knowledge of the Patents-in-Suit no later than when the Sun ANDA was submitted to the FDA.

26. The Notice Letter further stated that Sun Ltd. is seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Sun ANDA Product before the Patents-in-Suit expire. Accordingly, upon information and belief, Sun Ltd. intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product immediately and imminently upon approval of the Sun ANDA.

27. This action is being commenced before the expiration of 45 days from the date of Plaintiffs' receipt of the Notice Letter.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,071,623

28. Each of the preceding paragraphs 1-27 is incorporated as if fully set forth herein.

29. Sun Ltd.'s submission of the Sun ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '623 Patent constituted an act of infringement of at least one of the claims of the '623 Patent, either literally or under the doctrine of equivalents, including but not limited to claims 1-3 and 5-9, under 35 U.S.C. § 271(e)(2)(A).

30. Sun Ltd.'s commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product and/or its active ingredient prior to expiration of the '623 Patent, and

Sun Ltd.'s inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the '623 Patent, including but not limited to claims 1-3 and 5-9, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

31. Upon FDA approval of the Sun ANDA, Sun Ltd. will infringe at least one claim of the '623 Patent under 35 U.S.C. § 271(a), including but not limited to claims 1-3 and 5-9, either literally or under the doctrine of equivalents, by making, using, offering to sell, or selling the Sun ANDA Product in the United States or by importing the Sun ANDA Product into the United States.

32. Upon FDA approval of the Sun ANDA, Sun Ltd. will actively induce infringement of at least one claim of the '623 Patent under 35 U.S.C. § 271(b), including but not limited to claims 1-3 and 5-9, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to distributors, healthcare providers, and patients, to use, offer for sale, or sell the Sun ANDA Product in the United States, or to import the Sun ANDA Product into the United States. Upon information and belief, Sun Ltd. has knowledge of the '623 Patent and knowledge that its acts are encouraging infringement.

33. Upon FDA approval of the Sun ANDA, Sun Ltd. will contributorily infringe at least one claim of the '623 Patent under 35 U.S.C. § 271(c), including but not limited to claims 1-3 and 5-9, either literally or under the doctrine of equivalents, by offering to sell or selling the Sun ANDA Product in the United States or by importing the Sun ANDA Product into the United States. The Sun ANDA Product and/or its active ingredient constitute a material part of the inventions of the claims of the '623 Patent. Upon information and belief, Sun Ltd. knows that the Sun ANDA Product and/or its active ingredient are especially made or adapted for use in

infringing the ’623 Patent and that the Sun ANDA Product and/or its active ingredient are not a staple article or commodity of commerce suitable for substantial non-infringing use.

34. If Sun Ltd.’s marketing and sale of the Sun ANDA Product prior to expiration of the ’623 Patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,091,459

35. Each of the preceding paragraphs 1-27 is incorporated as if fully set forth herein.

36. Sun Ltd.’s submission of the Sun ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the ’459 Patent constituted an act of infringement of at least one of the claims of the ’459 Patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 20-24, and 26, under 35 U.S.C. § 271(e)(2)(A).

37. Sun Ltd.’s commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product and/or its active ingredient prior to expiration of the ’459 Patent, and Sun Ltd.’s inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the ’459 Patent, including but not limited to claims 1, 20-24, and 26, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

38. Upon FDA approval of the Sun ANDA, Sun Ltd. will infringe at least one claim of the ’459 Patent under 35 U.S.C. § 271(a), including but not limited to claims 1, 20-24, and 26, either literally or under the doctrine of equivalents, by making, using, offering to sell, or selling the Sun ANDA Product in the United States or by importing the Sun ANDA Product into the United States.

39. Upon FDA approval of the Sun ANDA, Sun Ltd. will actively induce infringement of at least one claim of the '459 Patent under 35 U.S.C. § 271(b), including but not limited to claims 1, 20-24, and 26, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to distributors, healthcare providers, and patients, to use, offer for sale, or sell the Sun ANDA Product in the United States, or to import the Sun ANDA Product into the United States. Upon information and belief, Sun Ltd. has knowledge of the '459 Patent and knowledge that its acts are encouraging infringement.

40. Upon FDA approval of the Sun ANDA, Sun Ltd. will contributorily infringe at least one claim of the '459 Patent under 35 U.S.C. § 271(c), including but not limited to claims 1, 20-24, and 26, either literally or under the doctrine of equivalents, by offering to sell or selling the Sun ANDA Product in the United States or by importing the Sun ANDA Product into the United States. The Sun ANDA Product and/or its active ingredient constitute a material part of the inventions of the claims of the '459 Patent. Upon information and belief, Sun Ltd. knows that the Sun ANDA Product and/or its active ingredient are especially made or adapted for use in infringing the '459 Patent and that the Sun ANDA Product and/or its active ingredient are not a staple article or commodity of commerce suitable for substantial non-infringing use.

41. If Sun Ltd.'s marketing and sale of the Sun ANDA Product prior to expiration of the '459 Patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,673,877

42. Each of the preceding paragraphs 1-27 is incorporated as if fully set forth herein.

43. Sun Ltd.'s submission of the Sun ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product

before the expiration of the '877 Patent constituted an act of infringement of at least one of the claims of the '877 Patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 11, under 35 U.S.C. § 271(e)(2)(A).

44. Sun Ltd.'s commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product and/or its active ingredient prior to expiration of the '877 Patent, and Sun Ltd.'s inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the '877 Patent, including but not limited to claim 1, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c). Sun Ltd.'s commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product for the same treatment claimed in the '877 Patent prior to the expiration of the '877 Patent, and Sun Ltd.'s inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the '877 Patent, including but not limited to claim 11, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

45. Upon FDA approval of the Sun ANDA, Sun Ltd. will infringe at least one claim of the '877 Patent under 35 U.S.C. § 271(a), including but not limited to claim 1, either literally or under the doctrine of equivalents, by making, using, offering to sell, or selling the Sun ANDA Product in the United States or by importing the Sun ANDA Product into the United States. Upon FDA approval of the Sun ANDA, Sun Ltd. will infringe at least one claim of the '877 Patent under 35 U.S.C. § 271(a), including but not limited to claim 11, either literally or under the doctrine of equivalents, by making, using, offering to sell, or selling the Sun ANDA Product in the United States, or by importing the Sun ANDA Product into the United States, for the same treatment claimed in the '877 Patent.

46. Upon FDA approval of the Sun ANDA, Sun Ltd. will actively induce infringement of at least one claim of the '877 Patent under 35 U.S.C. § 271(b), including but not limited to claim 1, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to distributors, healthcare providers, and patients, to use, offer for sale, or sell the Sun ANDA Product in the United States, or to import the Sun ANDA Product into the United States. Upon FDA approval of the Sun ANDA, Sun Ltd. will actively induce infringement of at least one claim of the '877 Patent under 35 U.S.C. § 271(b), including but not limited to claim 11, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to distributors, healthcare providers, and patients, to use, offer for sale, or sell the Sun ANDA Product in the United States, or to import the Sun ANDA Product into the United States, for the same treatment claimed in the '877 Patent. Upon information and belief, Sun Ltd. has knowledge of the '877 Patent and knowledge that its acts are encouraging infringement.

47. Upon FDA approval of the Sun ANDA, Sun Ltd. will contributorily infringe at least one claim of the '877 Patent under 35 U.S.C. § 271(c), including but not limited to claim 1 and 11, either literally or under the doctrine of equivalents, by offering to sell or selling the Sun ANDA Product in the United States or by importing the Sun ANDA Product into the United States. The Sun ANDA Product and/or its active ingredient constitute a material part of the inventions of the claims of the '877 Patent, including the method of treatment claimed in the '877 Patent. Upon information and belief, Sun Ltd. knows that the Sun ANDA Product and/or its active ingredient are especially made or adapted for use in infringing the '877 Patent and that the Sun ANDA Product and/or its active ingredient are not a staple article or commodity of commerce suitable for substantial non-infringing use.

48. If Sun Ltd.'s marketing and sale of the Sun ANDA Product prior to expiration of the '877 Patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court grant the following relief:

(a) A judgment that one or more claims of the Patents-in-Suit are infringed by Sun Ltd.'s submission of the Sun ANDA, and that the making, using, offering to sell, or selling the United States, or importing into the United States, of the Sun ANDA Product will directly infringe, actively induce infringement, and/or contribute to the infringement of the Patents-in-Suit, either literally or under the doctrine of equivalents;

(b) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Sun ANDA shall be a date which is not earlier than the expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, or such later date as the Court may determine;

(c) An order permanently enjoining Sun Ltd., its affiliates, subsidiaries, and each of their 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, the Sun ANDA Product in any form that infringes, induces infringement, or contributes to the infringement of the Patents-in-Suit, until after the expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, or such later date as the Court may determine;

(d) Damages or other monetary relief, including costs, fees, and pre- and post-judgment interest, to Plaintiffs if Sun Ltd. engages in commercial manufacture, use, offers to

sell, sale, and/or importation in or into the United States the Sun ANDA Product prior to the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(f) Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: September 19, 2025

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King St., 8th Floor
Wilmington, DE 19801
Tel: (302) 984-6330
dsilver@mccarter.com
ajoyce@mccarter.com

Counsel for Plaintiffs GlaxoSmithKline LLC, TESARO, Inc., and Merck Sharp & Dohme LLC

Of Counsel:

Christopher R. Noyes
Scott G. Greene
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Tel: (212) 230-8800

Timothy A. Cook
Anna Wong
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel: (617) 526-6000

Christopher M. Cherry
WILMER CUTLER PICKERING
HALE AND DORR LLP
1225 Seventeenth St.
Suite 2600
Denver, CO 80202
Tel: (720) 274-3135

Akkad Y. Moussa
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
Tel: 202-663-6000