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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EISAI R&D MANAGEMENT CO., LTD.; EISAI CO., LTD.; EISAI MANUFACTURING LTD.; EISAI INC.; and MSD INTERNATIONAL GMBH,

Plaintiffs,

v.

SHILPA MEDICARE LIMITED; SUN PHARMACEUTICAL INDUSTRIES LTD.; and SUN PHARMACEUTICAL INDUSTRIES, INC.,

Defendants.

Civil Action No. 19-19998 (GC) (DEA)
(CONSOLIDATED)

Document Electronically Filed

AMENDED COMPLAINT FOR PATENT INFRINGEMENT AGAINST SUN

Plaintiffs Eisai R&D Management Co., Ltd., Eisai Co., Ltd., Eisai Manufacturing Ltd., and Eisai Inc. (collectively, "Eisai"), and MSD International GmbH (together with Eisai, "Plaintiffs"), for their Amended Complaint against Defendants Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, "Sun"), hereby allege as follows:

THE PARTIES

1. Plaintiff Eisai R&D Management Co., Ltd. ("ERDC") is a Japanese corporation having a principal place of business at 6-10 Koishikawa 4-Chome, Bunkyo-ku, Tokyo 112-8088, Japan.

2. Plaintiff Eisai Co., Ltd. ("ECL") is a Japanese corporation having a principal place of business at 6-10 Koishikawa 4-Chome, Bunkyo-ku, Tokyo 112-8088, Japan.

3. Plaintiff Eisai Manufacturing Ltd. ("EML") is an English and Welsh corporation having a principal place of business at European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, U.K.

4. Plaintiff Eisai Inc. ("ESI") is a Delaware corporation having a principal place of business at 200 Metro Boulevard, Nutley, New Jersey 07110.

5. Plaintiff MSD International GmbH ("MSD") is a Swiss limited liability company having a principal place of business at Weystrasse 20, 6006 Lucerne, Switzerland.

6. Upon information and belief, Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") is an Indian corporation having a principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai-400063, Maharashtra, India.

7. Upon information and belief, Defendant Sun Ltd., either directly or through one or more of its wholly-owned subsidiaries and/or agents, develops, manufactures, markets, distributes, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

8. Upon information and belief, Defendant Sun Pharmaceutical Industries, Inc. ("Sun Inc.") is a Delaware corporation having a principal place of business in the State of New Jersey at 1 Commerce Drive, Cranbury, New Jersey 08512.

9. Upon information and belief, Sun Inc. has several places of business in the State of New Jersey, including but not limited to the following business addresses: (1) 270 Prospect Plains Road, Cranbury, New Jersey 08512 and (2) 2 Independence Way, Princeton, New Jersey 08540.

10. Upon information and belief, Sun Inc. is a wholly-owned subsidiary of Sun Ltd.

11. Upon information and belief, Sun Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID Nos. 0100954087 and/or 0100970132.

12. Upon information and belief, Sun Inc. is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5003437.

13. Upon information and belief, Defendant Sun Inc. develops, manufactures, markets, distributes, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

JURISDICTION AND VENUE

14. This is a civil action for infringement of U.S. Patent No. 10,407,393 ("the '393 patent") and U.S. Patent No. 11,186,547 ("the '547 patent") (collectively, "the patents-in-suit"). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201-2202, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-2202 because this case is an actual controversy within the Court's jurisdiction.

16. Sun has not previously contested personal jurisdiction or venue in this action. *See* ECF No. 9 (filed in Civil Action No. 19-21857 prior to consolidation) at ¶¶ 9, 11, 13, 16-25.

17. Venue is proper in this Court as to Sun Ltd. under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Sun Ltd. is a foreign corporation and may be sued in any judicial district in the United States in which Sun Ltd. is subject to the court's personal jurisdiction. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

18. This Court has personal jurisdiction over Sun Ltd., and venue is proper as to Sun Ltd., because, *inter alia*, Sun Ltd.: (1) directs and/or controls Sun Inc., which has a principal place of business and business addresses in New Jersey; (2) has purposely availed itself of the privilege of doing business in New Jersey, directly or indirectly through its subsidiary, agent, and/or alter ego; (3) maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (4) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; and (5) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Sun's ANDA Products (as defined in paragraph 38, *infra*).

19. This Court has personal jurisdiction over Sun Ltd. because, *inter alia*, Sun Ltd. has availed itself of the legal protections of the State of New Jersey by previously consenting to personal jurisdiction and asserting counterclaims in this Judicial District. *See, e.g.*, *Eisai R&D Management Co., Ltd., et al. v. Sun Pharm. Indus. Ltd., et al.*, No. 19-21857 (FLW) (DEA) (consolidated with *Eisai R&D Management Co., Ltd., et al. v. Shilpa Medicare Limited, et al.*, No. 19-19998 (GC) (DEA)); *Corcept Therapeutics, Inc. v. Sun Pharma Global FZE, et al.*, No. 19-15678 (SDW) (CLW); *Sucampo AG, et al. v. Sun Pharm. Indus., Ltd., et al.*, No. 18-15482 (FLW) (TJB); *Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, No. 18-11630 (SDW) (LDW);

Boehringer Ingelheim Pharms., Inc., et al. v. Sun Pharm. Indus. Ltd., et al., No. 17-08819 (MAS) (LHG); *Actelion Pharms. Ltd. v. Sun Pharm. Indus., Inc., et al.*, No. 17-05015 (PGS) (DEA).

20. Sun Ltd. has further availed itself of the jurisdiction of courts in this Judicial District by initiating litigation in this Judicial District. *See, e.g.*, *Sun Pharm. Indus. Ltd. v. Pfizer Inc., et al.*, No. 19-09330 (KM) (SCM); *Sun Pharm. Indus. Ltd. v. Pfizer Inc., et al.*, No. 19-09335 (KM) (SCM); *Sun Pharm. Indus. Ltd. v. VistaPharm, Inc.*, No. 19-07536 (SRC) (CLW); *Sun Pharm. Indus. Ltd. v. Novartis Pharms. Corp., et al.*, No. 19-00276 (SRC) (CLW); *Sun Pharm. Indus. Ltd., et al. v. Altana Pharma AG, et al.*, No. 05-02391 (KSH) (PS).

21. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Sun Ltd. in this action, this Court may exercise jurisdiction over Sun Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Plaintiffs' claims arise under federal law; (2) Sun Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Sun Ltd. has sufficient contacts with the United States as a whole, including but not limited to submitting various Abbreviated New Drug Applications ("ANDAs") to the United States Food and Drug Administration ("FDA") and manufacturing, importing, offering to sell, or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun Ltd. satisfies due process.

22. Venue is proper in this Court as to Sun Inc. under 28 U.S.C. § 1400(b) because Sun Inc. has committed acts of infringement and has a regular and established place of business in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

23. This Court has personal jurisdiction over Sun Inc., and venue is proper as to Sun Inc., because, *inter alia*, Sun Inc.: (1) has a principal place of business and business addresses in New Jersey; (2) has employees in the places of business it maintains in New Jersey; (3) has purposely availed itself of the privilege of doing business in New Jersey, including securing a New Jersey wholesale drug distributor's license (Registration No. 5003437) and New Jersey Business Entity identification numbers (Registration Nos. 0100954087 and 0100970132); (4) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in the State of New Jersey; (5) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical drugs in the State of New Jersey; (6) directly or indirectly maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including through a network of wholesalers and distributors, for the purposes of marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (7) enjoys substantial income from sales of its generic pharmaceutical drugs in the State of New Jersey; and (8) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Sun's ANDA Products (as defined in paragraph 38, *infra*).

24. This Court has personal jurisdiction over Sun Inc. because, *inter alia*, Sun Inc. has availed itself of the legal protections of the State of New Jersey by previously consenting to personal jurisdiction and asserting counterclaims in this Judicial District. *See, e.g.*, *Eisai R&D Management Co., Ltd., et al. v. Sun Pharm. Indus. Ltd., et al.*, No. 19-21857 (FLW) (DEA) (consolidated with *Eisai R&D Management Co., Ltd., et al. v. Shilpa Medicare Limited, et al.*, No. 19-19998 (GC) (DEA)); *Corcept Therapeutics, Inc. v. Sun Pharma Global FZE, et al.*, No. 19-15678 (SDW) (CLW); *Sucampo AG, et al. v. Sun Pharm. Indus., Ltd., et al.*, No. 18-15482

(FLW) (TJB); *Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, No. 18-11630 (SDW) (LDW); *Boehringer Ingelheim Pharms., Inc., et al. v. Sun Pharm. Indus. Ltd., et al.*, No. 17-08819 (MAS) (LHG); *Actelion Pharms. Ltd. v. Sun Pharm. Indus., Inc., et al.*, No. 17-05015 (PGS) (DEA).

25. Sun Inc. has further availed itself of the jurisdiction of this Judicial District by initiating litigation in this Judicial District. *See, e.g., Sun Pharma Global FZE, et al. v. Lupin Ltd., et al.*, No. 18-02213 (FLW) (TJB).

26. This Court also has personal jurisdiction over Sun because, *inter alia*, Sun Ltd. and Sun Inc. have each committed, aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

27. Upon information and belief, Sun Ltd. and Sun Inc. are agents of each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to Sun's proposed products that are the subject of ANDA No. 213092, for which Sun has sought approval from the FDA.

28. Upon information and belief, Sun Ltd. and Sun Inc. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to Sun's proposed products that are the subject of ANDA No. 213092, for which Sun has sought approval from the FDA.

29. Upon information and belief, Sun Ltd., alone and/or together with its affiliate and agent Sun Inc., filed or caused to be filed ANDA No. 213092 with the FDA.

30. Upon information and belief, the actions of Sun Inc. of, *inter alia*, causing Sun's ANDA No. 213092 to be filed and maintaining its distribution channels, including in the State of New Jersey, establish that if granted approval, Sun Inc. will commercially manufacture, use, offer to sell, sell, and/or import Sun's ANDA Products throughout the United States, including in New Jersey.

31. Sun Ltd. sent Paragraph IV notice letters (as discussed in paragraphs 39 and 40, *infra*) to ERDC and ESI, which stated that Sun had filed ANDA No. 213092 seeking approval from the FDA to commercially manufacture, use, market, or sell generic lenvatinib mesylate eq. 4 mg base and eq. 10 mg base oral capsules, in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the patents-in-suit. ESI received Sun's Paragraph IV notice letters in the State of New Jersey.

THE PATENTS-IN-SUIT

32. ESI holds approved New Drug Application ("NDA") No. 206947, which the FDA approved on February 13, 2015. ESI markets and sells the oral capsules that are the subject of NDA No. 206947 in the United States under the brand name "LENVIMA®." The LENVIMA® labeling states that "LENVIMA capsules for oral administration contain 4 mg or 10 mg of lenvatinib, equivalent to 4.90 mg or 12.25 mg of lenvatinib mesylate, respectively."

33. LENVIMA® has been approved by the FDA for five indications. First, on February 13, 2015, the FDA approved LENVIMA® for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer. Second, on May 13, 2016, the FDA approved LENVIMA® in combination with everolimus, for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy. Third, on August 15, 2018, the FDA approved LENVIMA® for the first-line treatment of patients with unresectable hepatocellular carcinoma. As part of this FDA approval, Eisai

received Orphan Drug Exclusivity, which expires August 15, 2025. Fourth, on September 17, 2019, the FDA granted accelerated approval for LENVIMA® in combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation, and on July 21, 2021, the FDA approved LENVIMA® in combination with pembrolizumab for this indication. Fifth, on August 10, 2021, the FDA approved LENVIMA® in combination with pembrolizumab, for the first-line treatment of adult patients with advanced renal cell carcinoma.

34. ERDC is the assignee of the patents-in-suit. ECL is an exclusive licensee of the patents-in-suit. EML and MSD are co-exclusive sub-licensees of the patents-in-suit. ESI is a wholly-owned, indirect subsidiary of ECL and markets and sells LENVIMA® in the United States.

35. The ’393 patent was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on September 10, 2019, and is titled “High-Purity Quinoline Derivative and Method for Manufacturing Same.” A copy of the ’393 patent is attached as Exhibit A.

36. The ’547 patent was duly and legally issued by the USPTO on November 30, 2021, and is titled “High-Purity Quinoline Derivative and Method for Manufacturing Same.” A copy of the ’547 patent is attached as Exhibit B.

37. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA’s publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the “Orange Book”) as covering Plaintiffs’ LENVIMA®.

SUN'S ANDA AND PARAGRAPH IV NOTICE LETTERS

38. Upon information and belief, Sun submitted ANDA No. 213092 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation in the United States, of generic lenvatinib mesylate eq. 4 mg base and eq. 10 mg base oral capsules ("Sun's ANDA Products"), prior to the expiration of the patents-in-suit. Upon information and belief, Sun's ANDA No. 213092 contains a certification with respect to each of the patents-in-suit under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification").

39. Upon information and belief, on or about November 11, 2019, Sun Ltd. sent a letter providing notice of Sun's Paragraph IV Certification with respect to the '393 patent to ERDC and ESI, which ESI received in the State of New Jersey. In this Paragraph IV notice letter, Sun Ltd. represented that ANDA No. 213092 includes a Paragraph IV Certification with respect to the '393 patent, and that Sun sought approval of ANDA No. 213092 prior to the expiration of the '393 patent.

40. Upon information and belief, on or about January 11, 2022, Sun Ltd. sent a letter providing notice of Sun's Paragraph IV Certification with respect to the '547 patent to ERDC and ESI, which ESI received in the State of New Jersey. In this Paragraph IV notice letter, Sun Ltd. represented that ANDA No. 213092 includes a Paragraph IV Certification with respect to the '547 patent, and that Sun sought approval of ANDA No. 213092 prior to the expiration of the '547 patent.

ACTS GIVING RISE TO THIS ACTION

COUNT I: INFRINGEMENT OF THE '393 PATENT BY SUN

41. Plaintiffs re-allege paragraphs 1-40 as if fully set forth herein.

42. Sun Ltd. and Sun Inc. are jointly and severally liable for any infringement of the '393 patent because, upon information and belief, Sun Ltd. and Sun Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 213092 and the Paragraph IV Certification for the '393 patent to the FDA.

43. By seeking approval of ANDA No. 213092 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Products prior to the expiration of the '393 patent, Sun has infringed one or more claims of the '393 patent under 35 U.S.C. § 271(e)(2)(A).

44. Upon information and belief, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Products meets or embodies all elements of one or more claims of the '393 patent.

45. Upon information and belief, Sun intends to and will engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Products upon receipt of final FDA approval of ANDA No. 213092.

46. If Sun manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Sun's ANDA Products prior to the expiration of the '393 patent, Sun will infringe one or more claims of the '393 patent under 35 U.S.C. §§ 271(a), (b), or (c).

47. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Sun's ANDA No. 213092 be a date that is not earlier than the expiration date of the '393 patent, or any later expiration of any patent term extension or exclusivity for the '393 patent to which Plaintiffs are or become entitled.

48. Plaintiffs are entitled to a declaration that, if Sun commercially manufactures, uses, offers for sale, or sells Sun's ANDA Products within the United States, imports Sun's ANDA Products into the United States, or induces or contributes to such conduct, Sun will infringe one or more claims of the '393 patent under 35 U.S.C. §§ 271(a), (b), or (c).

49. Plaintiffs will be irreparably harmed by Sun's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT II: INFRINGEMENT OF THE '547 PATENT BY SUN

50. Plaintiffs re-allege paragraphs 1-40 as if fully set forth herein.

51. Sun Ltd. and Sun Inc. are jointly and severally liable for any infringement of the '547 patent because, upon information and belief, Sun Ltd. and Sun Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 213092 and the Paragraph IV Certification for the '547 patent to the FDA.

52. By seeking approval of ANDA No. 213092 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Products prior to the expiration of the '547 patent, Sun has infringed one or more claims of the '547 patent under 35 U.S.C. § 271(e)(2)(A).

53. Upon information and belief, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Products meets or embodies all elements of one or more claims of the '547 patent.

54. Upon information and belief, Sun intends to and will engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Products upon receipt of final FDA approval of ANDA

No. 213092.

55. If Sun manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Sun's ANDA Products prior to the expiration of the '547 patent, Sun will infringe one or more claims of the '547 patent under 35 U.S.C. §§ 271(a), (b), or (c).

56. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Sun's ANDA No. 213092 be a date that is not earlier than the expiration date of the '547 patent, or any later expiration of any patent term extension or exclusivity for the '547 patent to which Plaintiffs are or become entitled.

57. Plaintiffs are entitled to a declaration that, if Sun commercially manufactures, uses, offers for sale, or sells Sun's ANDA Products within the United States, imports Sun's ANDA Products into the United States, or induces or contributes to such conduct, Sun will infringe one or more claims of the '547 patent under 35 U.S.C. §§ 271(a), (b), or (c).

58. Plaintiffs will be irreparably harmed by Sun's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court grant the following relief:

A. A judgment decreeing that Sun has infringed the patents-in-suit by submitting ANDA No. 213092;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Sun, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Sun, from infringing the patents-in-suit by the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Sun's ANDA Products;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 213092 be a date that is not earlier than the expiration date of the latest to expire of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the aforementioned patents to which Plaintiffs are or become entitled;

D. An award of monetary relief to the extent Sun commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States any product that infringes or induces or contributes to the infringement of the patents-in-suit within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

E. Such other and further relief as the Court may deem just and proper.

Dated: June 30, 2022

s/ William P. Deni, Jr.
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