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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 BUSINESS GMBH, Plaintiffs, v. TORRENT PHARMACEUTICALS LTD., Defendant.	Civil Action No. 24-7067 *Document Electronically Filed* **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Eisai R&D Management Co., Ltd., Eisai Co., Ltd., Eisai Manufacturing Ltd., and Eisai Inc. (collectively, "Eisai") and MSD International Business GmbH (together with Eisai, "Plaintiffs"), for their Complaint against Defendant Torrent Pharmaceuticals Ltd. ("Torrent Ltd." or "Defendant"), 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, United Kingdom.

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 Business GmbH ("MSD") is a company with limited liability organized and existing under the laws of Switzerland, whose registered office is at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

6. Upon information and belief, Defendant Torrent Ltd. is a corporation operating and existing under the laws of India, with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad, Gujarat, 380009, India.

7. Upon information and belief, Defendant Torrent 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 versions of branded pharmaceutical products throughout the United States, including in New Jersey.

JURISDICTION AND VENUE

8. This is a civil action for infringement of U.S. Patent No. 7,612,208 ("the '208 patent"), 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.

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201-2202, and/or 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.

10. Venue is proper in this Court as to Torrent Ltd. under 28 U.S.C. § 1391(c)(3) because Torrent Ltd. is a foreign corporation and may be sued in any judicial district in the United States in which Torrent 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.

11. This Court has personal jurisdiction over Torrent Ltd., and venue is proper as to Torrent Ltd., because, *inter alia*, Torrent Ltd.: (1) on information and belief, directs and/or controls a wholly owned subsidiary, Torrent Pharma Inc. ("Torrent Inc."), which has a principal place of business in New Jersey located at 106 Allen Road, Suite 305, Basking Ridge, New Jersey 07920; (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 New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical products 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 generic lenvatinib mesylate eq. 4 mg base and eq. 10 mg base oral capsules for which it seeks approval under Abbreviated New Drug Application ("ANDA") No. 219352 ("Torrent's ANDA Products"), including throughout New Jersey.

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

13. Torrent Ltd. sent ERDC and ESI a letter dated May 3, 2024 ("Torrent's Paragraph IV Notice Letter") providing notice that Torrent's ANDA No. 219352 contains a certification with respect to, *inter alia*, 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"), and stating that Torrent Ltd. had filed ANDA No. 219352 seeking approval from the United States Food and Drug Administration ("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 New Jersey) prior to the expiration of the patents-in-suit. ESI received Torrent's Paragraph IV Notice Letter in New Jersey**.**

14. This Court has personal jurisdiction over Torrent Ltd. because, *inter alia*, it has availed itself of the legal protections of New Jersey by previously consenting to personal jurisdiction and asserting counterclaims in this Judicial District. *See, e.g.*, *Supernus Pharms., Inc. v. Torrent Pharms. Ltd. and Torrent Pharma Inc.*, No. 21-14268 (FLW) (LHG); *Allergan Sales, LLC et al. v. Torrent Pharms. Ltd. and Torrent Pharma Inc.*, No. 19-21709 (ES) (SCM); *Amgen Inc. v. Torrent Pharms. Ltd.*, No. 18-11156 (MAS) (DEA).

15. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Torrent Ltd. in this action, this Court may exercise jurisdiction over Torrent Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (1) Plaintiffs' claims arise under federal law; (2) Torrent Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of

general jurisdiction; and (3) Torrent Ltd. has sufficient contacts with the United States as a whole, including but not limited to submitting numerous ANDAs to the FDA and manufacturing, importing, offering to sell, or selling generic pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Torrent Ltd. satisfies due process.

THE PATENTS-IN-SUIT

16. 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®."

17. LENVIMA® has been approved by the FDA for the following indications: (1) for the treatment of adult patients with locally recurrent or metastatic, progressive, radioactive iodine refractory differentiated thyroid cancer ("DTC"); (2) in combination with pembrolizumab for the first-line treatment of adult patients with advanced renal cell carcinoma ("RCC"); (3) in combination with everolimus for the treatment of adult patients with advanced RCC following one prior anti-angiogenic therapy; (4) for the first-line treatment of patients with unresectable hepatocellular carcinoma ("HCC"); and (5) in combination with pembrolizumab for the treatment of patients with advanced endometrial carcinoma ("EC") that is mismatch repair proficient ("pMMR"), as determined by an FDA-approved test, or not microsatellite instability high ("MSI-H"), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

18. 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.

19. The ’208 patent was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on November 3, 2009, and is titled “Crystalline Form of the Salt of 4-(3-Chloro-4-(Cyclopropylaminocarbonyl)aminophenoxy)-7-methoxy-6-quinolinecarboxamide or the Solvate of the Salt and a Process for Preparing the Same.” A copy of the ’208 patent is attached as Exhibit A.

20. The ’393 patent was duly and legally issued by the 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 B.

21. 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 C.

22. 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®.

TORRENT LTD.’S ANDA AND NOTICE LETTER

23. Upon information and belief, Torrent Ltd. submitted ANDA No. 219352 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 Torrent’s ANDA Products prior to the expiration of the patents-in-suit. Upon information and belief, Torrent Ltd.’s ANDA No. 219352 contains a Paragraph IV Certification with respect to the patents-in-suit.

24. Upon information and belief, Torrent Ltd. sent Torrent’s Paragraph IV Notice Letter with respect to, *inter alia*, the patents-in-suit to ERDC and ESI, which ESI received in New Jersey. In its Paragraph IV Notice Letter, Torrent Ltd. represented that ANDA No. 219352

included Paragraph IV Certifications with respect to, *inter alia*, the patents-in-suit, and that Torrent Ltd. sought approval of ANDA No. 219352 prior to the expiration of the patents-in-suit.

25. Torrent's Paragraph IV Notice Letter included an Offer of Confidential Access ("OCA") to certain portions of Torrent Ltd.'s ANDA No. 219352. Shortly after receiving Torrent's Paragraph IV Notice Letter, Plaintiffs requested that Torrent Ltd. revise its OCA to provide Plaintiffs with access to a complete copy of Torrent Ltd.'s ANDA No. 219352 and a complete copy of any Drug Master File ("DMF") referenced in ANDA No. 219352.

26. Over two weeks later, Torrent Ltd. responded to Plaintiffs' request by stating that additional limitations should be imposed on those accessing materials under any OCA.

27. Plaintiffs promptly responded to Torrent Ltd. and attempted to further negotiate potential terms for an OCA. Over a week later, and days before the expiration of the 45-day period for filing suit provided by 21 U.S.C. § 355(j)(5)(B)(iii), thus leaving insufficient time for further negotiations, Torrent Ltd. sent a response that continued to be insufficient and did not meaningfully address Plaintiffs' questions about the unreasonable terms Torrent wanted to impose under an OCA. The parties have not reached an agreement on an OCA.

28. To date, Torrent Ltd. has not provided Plaintiffs with a copy of any portions of its ANDA No. 219352 or any DMF that may be referenced therein.

29. Plaintiffs are not aware of any other means, other than discovery in this lawsuit, to obtain information regarding Torrent's ANDA Products. In the absence of receiving such information through an OCA, Plaintiffs will utilize the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to support their allegations of infringement and to present the Court with evidence that Torrent's ANDA Products fall within the scope of one or more claims of the patents-in-suit.

30. Plaintiffs are commencing this action within 45 days of the date of receipt of Torrent's Paragraph IV Notice Letter in accordance with the time frame for filing such a suit established by the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iii).

ACTS GIVING RISE TO THIS ACTION

COUNT I: INFRINGEMENT OF THE '208 PATENT

31. Plaintiffs re-allege paragraphs 1-30 as if fully set forth herein.

32. By seeking approval of ANDA No. 219352 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Torrent's ANDA Products prior to the expiration of the '208 patent, Torrent Ltd. has infringed one or more claims of the '208 patent under 35 U.S.C. § 271(e)(2)(A).

33. Upon information and belief, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Torrent's ANDA Products meets or embodies all elements of one or more claims of the '208 patent.

34. Upon information and belief, Torrent Ltd. 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 Torrent's ANDA Products upon receipt of final FDA approval of ANDA No. 219352.

35. If Torrent Ltd. manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Torrent's ANDA Products prior to the expiration of the '208 patent, Torrent Ltd. will infringe one or more claims of the '208 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

36. 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 Torrent Ltd.'s ANDA No. 219352

be a date that is not earlier than the expiration date of the '208 patent, or any later expiration of any patent term extension or exclusivity for the '208 patent to which Plaintiffs are or become entitled.

37. Plaintiffs are entitled to a declaration that, if Torrent Ltd. commercially manufactures, uses, offers for sale, or sells Torrent's ANDA Products within the United States, imports Torrent's ANDA Products into the United States, or induces or contributes to such conduct, Torrent Ltd. will infringe one or more claims of the '208 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

38. Plaintiffs will be irreparably harmed by Torrent Ltd.'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 '393 PATENT

39. Plaintiffs re-allege paragraphs 1-38 as if fully set forth herein.

40. By seeking approval of ANDA No. 219352 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Torrent's ANDA Products prior to the expiration of the '393 patent, Torrent Ltd. has infringed one or more claims of the '393 patent under 35 U.S.C. § 271(e)(2)(A).

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

42. Upon information and belief, Torrent Ltd. 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 Torrent's ANDA Products upon receipt of final FDA approval of ANDA No. 219352.

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

44. 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 Torrent Ltd.'s ANDA No. 219352 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.

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

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

COUNT III: INFRINGEMENT OF THE '547 PATENT

47. Plaintiffs re-allege paragraphs 1-46 as if fully set forth herein.

48. By seeking approval of ANDA No. 219352 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Torrent's ANDA Products prior to the expiration of the '547 patent, Torrent Ltd. has infringed one or more claims of the '547 patent under 35 U.S.C. § 271(e)(2)(A).

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

50. Upon information and belief, Torrent Ltd. 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 Torrent's ANDA Products upon receipt of final FDA approval of ANDA No. 219352.

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

52. 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 Torrent Ltd.'s ANDA No. 219352 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.

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

54. Plaintiffs will be irreparably harmed by Torrent Ltd.'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 Torrent Ltd. has infringed the patents-in-suit by submitting ANDA No. 219352;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Torrent Ltd., its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Torrent Ltd., 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 Torrent'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. 219352 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-in-suit to which Plaintiffs are or become entitled;

D. An award of monetary relief to the extent Torrent Ltd. 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 17, 2024
Newark, New Jersey

s/ William P. Deni, Jr.

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