MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622
James S. Richter

Attorneys for Defendants, Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.

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. DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD., Defendants.	Honorable Christine P. O'Hearn, U.S.D.J. Civil Action No. 24 CV 6765 (CPO)(AMD) **DEFENDANTS, DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL"), by and through its undersigned attorneys, provide the following answers and affirmative defenses to the Complaint of 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"). This pleading is based upon DRL's knowledge as to its own activities, and upon information and belief as to the activities of others. Pursuant to Fed. R. Civ. P. 8(b)(3), DRL denies all allegations in Plaintiffs' Complaint, except those specifically admitted below.

THE PARTIES[1]

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.

ANSWER: DRL is without sufficient knowledge and information to form a belief as to the allegations of this paragraph, and therefore denies the same.

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.

ANSWER: DRL is without sufficient knowledge and information to form a belief as to the allegations of this paragraph, and therefore denies the same.

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.

ANSWER: DRL is without sufficient knowledge and information to form a belief as to the allegations of this paragraph, and therefore denies the same.

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

ANSWER: DRL is without sufficient knowledge and information to form a belief as to the allegations of this paragraph, and therefore denies the same.

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.

ANSWER: DRL is without sufficient knowledge and information to form a belief as to the allegations of this paragraph, and therefore denies the same.

[1] For the Court's convenience, DRL has incorporated the section titles that appear in the Complaint. DRL does not necessarily agree with the characterizations of such section titles and does not waive any right to object to those characterizations.

6. Upon information and belief, Defendant DRL Ltd. is an Indian corporation having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India.

ANSWER: DRL admits that Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") is an Indian corporation having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

7. Upon information and belief, Defendant DRL 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.

ANSWER: DRL admits that DRL 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 in the United States. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

8. Upon information and belief, Defendant DRL Inc. is a corporation organized and existing under the laws of New Jersey, having a principal place of business in New Jersey at 107 College Road East, Princeton, New Jersey 08540.

ANSWER: DRL admits that Dr. Reddy's Laboratories, Inc. ("DRL Inc.") is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

9. Upon information and belief, DRL Inc. is a wholly-owned subsidiary of DRL Ltd.

ANSWER: DRL admits that DRL Inc. is a wholly owned subsidiary of DRL Ltd. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

10. Upon information and belief, DRL Inc. is registered with New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100518911.

ANSWER: DRL admits that DRL Inc. is registered under Business ID No. 0100518911 with New Jersey's Division of Revenue and Enterprise Services. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

11. Upon information and belief, DRL Inc. is registered with New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5002312.

ANSWER: DRL admits that DRL Inc. is registered with New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5002312. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

12. Upon information and belief, DRL Inc. develops, manufactures, imports, markets, distributes, offers for sale, and/or sells, generic versions of branded pharmaceutical products throughout the United States, including in New Jersey.

ANSWER: DRL admits that it develops, manufactures, imports, markets, distributes, offers for sale, and/or sells, generic versions of branded pharmaceutical products throughout the United States. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

JURISDICTION AND VENUE

13. 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. 14. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that the Complaint purports to bring an action for infringement arising under the patent laws of the United States, Title 35, United States Code, but denies that Plaintiffs are entitled to any such relief. DRL does not contest subject matter jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

14. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest subject matter jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest venue for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

16. This Court has personal jurisdiction over DRL Ltd., and venue is proper as to DRL Ltd., because, inter alia, DRL Ltd.: (1) directs and/or controls DRL 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 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. 219300 ("DRL's ANDA Products"), including throughout New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

17. This Court has personal jurisdiction over DRL 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., Intra-Cellular Therapies, Inc. v. Dr.*

Reddy's Lab'ys, Inc. and Dr. Reddy's Lab'ys, Ltd., No. 24-cv-4314 (MAS) (JBD); *Celgene Corp. v. Dr. Reddy's Lab'ys, Ltd. and Dr. Reddy's Lab'ys, Inc.*, No. 2:21-cv- 02111 (ES) (MAH); *Dr. Reddy's Lab'ys, Inc. and Dr. Reddy's Lab'ys, Ltd. v. AstraZeneca AB, et al.*, No. 1:18-cv-16057 (RMB) (KMW).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

18. DRL Ltd. has further availed itself of the jurisdiction of New Jersey by initiating litigation in this Judicial District. *See, e.g.*, *Dr. Reddy's Lab'ys, Inc. and Dr. Reddy's Lab'ys, Ltd. v. AstraZeneca AB et al.*, No. 1:18-cv-16057 (RMB) (KMW); *Dr. Reddy's Lab'ys, Inc. and Dr. Reddy's Lab'ys, Ltd. v. Purdue Pharm. Prods. Ltd. et al.*, No. 2:14-cv-03230 (JLL) (JAD).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

19. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over DRL Ltd. in this action, this Court may exercise jurisdiction over DRL Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Plaintiffs' claims arise under federal law; (2) DRL Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) DRL Ltd. has sufficient contacts with the United States as a whole, including but not limited to submitting numerous ANDAs to the United States Food and Drug Administration ("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 DRL Ltd. satisfies due process.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

20. Venue is proper in this Court as to DRL Inc. under 28 U.S.C. § 1400(b) because DRL Inc. resides and is incorporated in New Jersey and 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest venue for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

21. This Court has personal jurisdiction over DRL Inc., and venue is proper as to DRL Inc., because, *inter alia*, DRL Inc.: (1) is incorporated in New Jersey; (2) has a principal place of business and business addresses in New Jersey; (3) has employees in the places of business that it maintains in New Jersey; (4) 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. 5002312) and New Jersey Business Entity identification numbers (Registration No. 0100518911); (5) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in New Jersey; (6) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical products in New Jersey; (7) directly or indirectly maintains pervasive, continuous, and systematic contacts with New Jersey, including through a network of wholesalers and distributors, for the purposes of marketing, distribution, and/or sale of generic pharmaceutical products in New Jersey; (8) enjoys substantial income from sales of its generic pharmaceutical products in New Jersey; and (9) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute DRL's ANDA Products in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

22. This Court has personal jurisdiction over DRL Inc. 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.*, *Intra-Cellular Therapies, Inc. v. Dr. Reddy's Lab'ys, Inc. and Dr. Reddy's Lab'ys, Ltd.*, No. 24-cv-4314 (MAS) (JBD); *Celgene Corp. v. Dr. Reddy's Lab'ys, Ltd. and Dr. Reddy's Lab'ys, Inc.*, No. 2:21-cv- 02111 (ES) (MAH); *Dr. Reddy's Lab'ys, Inc. and Dr. Reddy's Lab'ys, Ltd. v. AstraZeneca AB, et al.*, No. 1:18-cv-16057 (RMB) (KMW).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest personal jurisdiction for the purposes of this

action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

23. DRL Inc. has further availed itself of the jurisdiction of this Judicial District by previously initiating litigation in this Judicial District. *See, e.g.*, *Dr. Reddy's Lab'ys, Inc. and Dr. Reddy's Lab'ys, Ltd. v. AstraZeneca AB et al.*, No. 1:18-cv-16057 (RMB) (KMW); *Dr. Reddy's Lab'ys, Inc. and Dr. Reddy's Lab'ys, Ltd., Inc. v. Purdue Pharm. Prods. Ltd. et al.*, No. 2:14-cv-03230 (JLL) (JAD).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

24. This Court also has personal jurisdiction over DRL because, *inter alia*, DRL Ltd. and DRL Inc. have each 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

25. Upon information and belief, DRL Ltd. and DRL 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 DRL's ANDA Products.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that DRL Inc. acted as DRL Ltd.'s agent in submitting DRL's ANDA No. 219300. Further, DRL does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

26. Upon information and belief, DRL Ltd. and DRL 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 DRL's ANDA Products.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that DRL Inc. acted as DRL Ltd.'s agent in submitting DRL's ANDA No. 219300. Further, DRL does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

27. Upon information and belief, DRL Ltd., alone and/or together with its affiliate and agent DRL Inc., filed or caused to be filed ANDA No. 219300 with the FDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that DRL Inc. acted as DRL Ltd.'s agent in submitting DRL's ANDA No. 219300. Further, DRL does not contest personal jurisdiction for the purposes of this action only. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

28. Upon information and belief, the actions of DRL Inc. of, *inter alia*, causing DRL's ANDA No. 219300 to be filed and maintaining its distribution channels, including in New Jersey, establish that, if granted approval, DRL Inc. will commercially manufacture, use, offer to sell, sell, and/or import DRL's ANDA Products throughout the United States, including in New Jersey.

ANSWER: DRL admits that it filed DRL's ANDA No. 219300 seeking FDA approval of DRL's ANDA Products before the expiration of the patents-in-suit. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

29. DRL sent ERDC and ESI a letter dated April 22, 2024 ("DRL's Paragraph IV Notice Letter") providing notice that DRL's ANDA No. 219300 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 DRL had filed ANDA No. 219300 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 New Jersey) prior to the expiration of the patents-in-suit. ESI received DRL's Paragraph IV Notice Letter in New Jersey.

ANSWER: DRL admits that it sent Plaintiffs a letter dated April 22, 2024 ("DRL's Paragraph IV Notice Letter") notifying Plaintiffs that DRL submitted ANDA No. 219300 with the FDA seeking approval to manufacture, use, market, or sell DRL's ANDA Products before the expiration of the patents-in-suit. DRL further admits that DRL's Paragraph IV Notice Letter includes a Paragraph IV Certification with respect to the patents-in-suit because said patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of DRL's ANDA Products. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

THE PATENTS-IN-SUIT

30. 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®."

ANSWER: DRL admits that the FDA's website indicates that ESI holds NDA No. 206947, which has an approval date of February 13, 2015. DRL is without sufficient knowledge and information to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

31. 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.

ANSWER: DRL admits that the product labeling available on the FDA's website indicates that LENVIMA® is indicated (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. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

32. 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.

ANSWER: DRL admits that the patents-in-suit, on their face, identify ERDC as the assignee. DRL is without sufficient knowledge and information to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

33. 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.

ANSWER: DRL admits that a purported copy of the '208 patent is attached to the Complaint as Exhibit A. DRL admits that, on its face, the '208 patent 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" and bears an issuance date of November 3, 2009. DRL denies that the '208 patent was duly or legally issued. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

34. 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.

ANSWER: DRL admits that a purported copy of the '393 patent is attached to the Complaint as Exhibit B. DRL admits that, on its face, the '393 patent is titled "High-purity quinoline derivative and method for manufacturing same" and bears an issuance date of September 10, 2019. DRL denies that the '393 patent was duly or legally issued. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

35. 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.

ANSWER: DRL admits that a purported copy of the '547 patent is attached to the Complaint as Exhibit C. DRL admits that, on its face, the '547 patent is titled "High-purity quinoline derivative and method for manufacturing same" and bears an issuance date of November 30, 2021. DRL denies that the '547 patent was duly or legally issued. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

36. 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®.

ANSWER: DRL admits that the FDA's website indicates that the patents-in-suit are listed in the Orange Book in connection with LENVIMA®. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

DRL'S ANDA AND NOTICE LETTER

37. Upon information and belief, DRL submitted ANDA No. 219300 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 DRL's ANDA Products prior to the expiration of the patents-in-suit. Upon information and belief, DRL's ANDA No. 219300 contains a Paragraph IV Certification with respect to the patents-in-suit.

ANSWER: DRL admits that it submitted ANDA No. 219300 with the FDA seeking approval to manufacture, use, market, or sell DRL's ANDA Products before the expiration of the patents-in-suit. DRL further admits that, in connection with the filing of ANDA No. 219300, DRL provided a Paragraph IV Certification with respect to the patents-in-suit because said patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of DRL's ANDA Products. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

38. Upon information and belief, DRL sent DRL'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, DRL represented that ANDA No. 219300 included Paragraph IV Certifications with respect to, *inter alia*, the patents-in-suit, and that DRL sought approval of ANDA No. 219300 prior to the expiration of the patents-in-suit.

ANSWER: DRL admits that it sent Eisai DRL's Paragraph IV Notice Letter notifying Eisai that DRL submitted ANDA No. 219300 with the FDA seeking approval to manufacture, use, market, or sell DRL's ANDA Products before the expiration of the patents-in-suit. DRL further admits that DRL's Paragraph IV Notice Letter includes a Paragraph IV Certification with respect to the patents-in-suit because said patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of DRL's ANDA Products. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

39. DRL's Paragraph IV Notice Letter included an Offer of Confidential Access ("OCA") to certain DRL confidential information regarding DRL's ANDA Products. Shortly after receiving DRL's Paragraph IV Notice Letter, Plaintiffs requested that DRL revise its OCA to provide Plaintiffs with access to a complete copy of DRL's ANDA No. 219300, a complete copy of any Drug Master File ("DMF") referenced in ANDA No. 219300, unexpired samples of DRL's ANDA Products, unexpired samples of the active pharmaceutical ingredient contained within DRL's ANDA Products, and unexpired samples of each excipient used in DRL's ANDA Products.

ANSWER: DRL admits that DRL's Paragraph IV Notice Letter contained an "Offer of Confidential Access to [the] relevant portions of [the] ANDA pursuant to 21 U.S.C. § 355 (j)(5)(C)(i)(III)," providing Eisai "confidential access to the relevant portion of the ANDA subject

to restrictions as to persons entitled access to, and on the use and disposition, of the ANDA". DRL further admits that Eisai requested that DRL revise its OCA to provide Eisai with access to a complete copy of DRL's ANDA No. 219300, a complete copy of any Drug Master File ("DMF") referenced in ANDA No. 219300, unexpired samples of DRL's ANDA Products, unexpired samples of the active pharmaceutical ingredient contained within DRL's ANDA Products, and unexpired samples of each excipient used in DRL's ANDA Products. DRL further admits that DRL engaged in good faith negotiations with Eisai regarding Eisai's request, but DRL and Eisai could not reach agreement before Plaintiffs filed this Complaint. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

40. DRL responded to Plaintiffs' request by stating that the availability of samples would be investigated, and provided proposed revisions to DRL's OCA that, *inter alia*, indicated that DRL would not provide Plaintiffs with all of the materials and information that Plaintiffs requested, including a complete copy of DRL's ANDA No. 219300 or a complete copy of any DMF referenced therein.

ANSWER: DRL admits that it did not agree to provide Eisai with all of the materials and information that Eisai requested. DRL admits that it agreed to provide: (1) a copy of the relevant portions of its proprietary ANDA No. 219300 (including Sections 3.2.s.3 (drug substance characterization), 3.2.s.4 (drug substance control), 3.2.p.1 (drug product description), 3.2.p.3 (drug product manufacturing), 3.2.p.5 (drug product control)); (2) 30 unexpired samples of DRL's proposed 4 mg Lenvatinib Mesylate Capsule to the extent available, (3) 30 unexpired samples of DRL's proposed 10 mg Lenvatinib Mesylate Capsule to the extent available; (4) 1.5 g of an unexpired sample of the active pharmaceutical ingredient used in DRL's proposed ANDA product to the extent available, and (5) 1 g of an unexpired sample of each excipient and/or inactive ingredient used in DRL's proposed ANDA product to the extent available, to attorneys from one outside law firm representing Eisai. DRL admits that, after further inquiry from Eisai's counsel, DRL confirmed that the listed sections of the ANDA would "include relevant information

regarding the polymorphic form of lenvatinib mesylate and impurity specifications for DRL's API and drug product." Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

41. Plaintiffs subsequently attempted to negotiate with DRL in an effort to agree on reasonable terms for DRL's OCA, but the parties were not able to reach an agreement as of the date of this Complaint. To date, DRL has not provided Plaintiffs with a copy of any portions of its ANDA No. 219300, any of the DMFs that may be cited therein, or any of the samples that Plaintiffs requested.

ANSWER: DRL admits that DRL worked diligently to locate and ship the requested samples from abroad to comply with Eisai's requests, but the samples were ultimately delayed. DRL admits that DRL notified Eisai of this update and stated that "DRL remains willing to produce the relevant portions of the ANDA, if acceptable to Eisai." DRL admits that counsel for Eisai did not respond. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

42. Plaintiffs are not aware of any other means, other than discovery in this lawsuit, to obtain information regarding DRL's ANDA Products. In the absence of receiving such information within the 45-day statutory period, 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 DRL's ANDA Products fall within the scope of one or more claims of the patents-in-suit.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL is without sufficient knowledge and information to form a belief as to the allegations of this paragraph, and therefore denies the same.

43. Plaintiffs are commencing this action within 45 days of the date of receipt of DRL'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).

ANSWER: DRL admits that Plaintiffs filed the present action on June 6, 2024, which was within 45 days of receipt of DRL's Paragraph IV Notice Letter. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

ACTS GIVING RISE TO THIS ACTION

COUNT I: ALLEGED INFRINGEMENT OF THE '208 PATENT BY DRL

44. Plaintiffs re-allege paragraphs 1–43 as if fully set forth herein.

ANSWER: DRL re-alleges paragraphs 1–43 as if fully set forth.

45. DRL Ltd. and DRL Inc. are jointly and severally liable for any infringement of the '208 patent because, upon information and belief, DRL Ltd. and DRL Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 219300 and its accompanying Paragraph IV Certification directed to the '208 patent to the FDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that it submitted ANDA No. 219300 with the FDA seeking approval to manufacture, use, market, or sell DRL's ANDA Products. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

46. By seeking approval of ANDA No. 219300 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of DRL's ANDA Products prior to the expiration of the '208 patent, DRL has infringed one or more claims of the '208 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

48. Upon information and belief, DRL 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 DRL's ANDA Products upon receipt of final FDA approval of ANDA No. 219300.

ANSWER: DRL admits that it submitted ANDA No. 219300 with the FDA seeking approval to manufacture, use, market, or sell DRL's ANDA Products. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

50. 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 DRL's ANDA No. 219300 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

COUNT II: ALLEGED INFRINGEMENT OF THE '393 PATENT BY DRL

53. Plaintiffs re-allege paragraphs 1–52 as if fully set forth herein.

ANSWER: DRL re-alleges paragraphs 1–52 as if fully set forth.

54. DRL Ltd. and DRL Inc. are jointly and severally liable for any infringement of the '393 patent because, upon information and belief, DRL Ltd. and DRL Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 219300 and its accompanying Paragraph IV Certification directed to the '393 patent to the FDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that it submitted ANDA No. 219300 with the FDA seeking approval to manufacture, use, market, or sell DRL's ANDA Products. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

55. By seeking approval of ANDA No. 219300 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of DRL's ANDA Products prior to the expiration of the '393 patent, DRL has infringed one or more claims of the '393 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

57. Upon information and belief, DRL 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 DRL's ANDA Products upon receipt of final FDA approval of ANDA No. 219300.

ANSWER: DRL admits that it submitted ANDA No. 219300 with the FDA seeking approval to manufacture, use, market, or sell DRL's ANDA Products. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

59. 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 DRL's ANDA No. 219300 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

COUNT III: ALLEGED INFRINGEMENT OF THE '547 PATENT BY DRL

62. Plaintiffs re-allege paragraphs 1–61 as if fully set forth herein.

ANSWER: DRL re-alleges paragraphs 1–61 as if fully set forth.

63. DRL Ltd. and DRL Inc. are jointly and severally liable for any infringement of the '547 patent because, upon information and belief, DRL Ltd. and DRL Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 219300 and its accompanying Paragraph IV Certification directed to the '547 patent to the FDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that it submitted ANDA No. 219300 with the FDA

seeking approval to manufacture, use, market, or sell DRL's ANDA Products. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

64. By seeking approval of ANDA No. 219300 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of DRL's ANDA Products prior to the expiration of the '547 patent, DRL has infringed one or more claims of the '547 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

66. Upon information and belief, DRL 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 DRL's ANDA Products upon receipt of final FDA approval of ANDA No. 219300.

ANSWER: DRL admits that it submitted ANDA No. 219300 with the FDA seeking approval to manufacture, use, market, or sell DRL's ANDA Products. Except as expressly admitted, DRL denies any remaining allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

68. 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 DRL's ANDA No. 219300 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

PRARYER FOR RELIEF

The remainder of Plaintiffs' Complaint recites a prayer for relief for which no response is required. To the extent any response is required, DRL denies that Plaintiffs are entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Further answering Plaintiffs' Complaint, DRL asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. DRL reserves the right to amend this Answer with additional defenses as further information is obtained. DRL asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise denied.

First Defense

The filing of DRL's ANDA No. 219300 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the patents-in-suit.

Second Defense

The manufacture, use, sale, offer for sale, or importation of DRL's ANDA Products has not, does not, and would not infringe, directly or indirectly, any valid and enforceable claim of the patents-in-suit, either literally or under the doctrine of equivalents.

Third Defense

The claims of the patents-in-suit are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

Fourth Defense

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Fifth Defense

DRL's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Defense

DRL has not willfully infringed any claim of the Patents-in-Suit.

Seventh Defense

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, unclean hands and/or other equitable doctrines.

Eighth Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendants, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") by way of Counterclaim against 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, "Counterclaim-Defendants") state as follows:

PARTIES

1. Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") is a limited liability company organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India 500 034.

2. Dr. Reddy's Laboratories, Inc. ("DRL Inc.") is a limited liability company organized and existing under the laws of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey, 08540.

3. On information and belief, 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.

4. On information and belief, 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.

5. On information and belief, 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.

6. On information and belief, Eisai Inc. ("ESI") is a Delaware corporation having a principal place of business at 200 Metro Boulevard, Nutley, New Jersey 07110.

7. On information and belief, 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.

NATURE OF THE ACTION

8. DRL seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, et seq., and the Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., that 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") are invalid and/or not infringed.

JURISDICTION AND VENUE

9. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Counterclaim-Defendants because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing their Complaint here.

11. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Counterclaim-Defendants' choice of forum.

12. There is an actual and justiciable controversy between the parties as to the noninfringement and invalidity of the patents-in-suit.

BACKGROUND

A. FDA Approval of New Brand Name Drugs

13. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

14. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

15. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b)(1), -(c)(2).

16. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

17. FDA's duties with respect to the Orange Book are purely ministerial. If the NDA holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval of New Generic Drugs

18. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

19. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

20. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

21. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

22. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

23. Upon receiving notice of the paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

24. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the paragraph IV certifications because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court action. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

25. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the proposed product in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. DRL's ANDA and Counterclaim-Defendants' Complaint

26. DRL submitted Abbreviated New Drug Application ("ANDA") No. 219300 ("DRL's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of lenvatinib capsules 4 mg and 10 mg ("DRL's ANDA Products").

27. On information and belief, ESI holds approved New Drug Application ("NDA") No. 206947 for Lenvima® (lenvatinib) capsules 4 mg and 10 mg.

28. On information and belief, Counterclaim-Defendants caused the patents-in-suit to be listed in the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly called the "Orange Book," as patents that purportedly claim the drug listed in, and/or purportedly claim a method of using the drug for which ESI submitted NDA No. 206947.

29. The '208 patent, 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," issued on November 3, 2009.

30. The '393 patent, titled "High-purity quinoline derivative and method for manufacturing same," issued on September 10, 2019.

31. The '574 patent, titled "High-purity quinoline derivative and method for manufacturing same," issued on November 30, 2021.

32. On information and belief, ERDC is the assignee of the patents-in-suit.

33. DRL's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 355 5(j)(2)(A)(vii)(IV) that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of DRL's ANDA Products.

34. On April 22, 2024, DRL sent Counterclaim-Defendants written notice of DRL's Paragraph IV Certifications ("DRL's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). DRL's

Notice Letter asserted that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by DRL's ANDA or the products or activities described therein.

35. DRL's Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in DRL's ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

36. On June 6, 2024, Counterclaim-Defendants filed the present lawsuit alleging infringement of the patents-in-suit. There has been and now is an actual and justiciable controversy between DRL and Counterclaim-Defendants as to whether DRL's ANDA Products infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of the patents-in-suit.

COUNT I: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '208 PATENT

37. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

38. Counterclaim-Defendants allege ownership of the '208 patent and have brought claims against DRL alleging infringement of the '208 patent.

39. The manufacture, use, or sale of DRL's ANDA Products would not infringe any valid or enforceable claim of the '208 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

40. There is an actual, substantial, continuing and justiciable controversy between Counterclaim-Defendants and DRL regarding whether the filing of DRL's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '208 patent.

41. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations that the '208 patent is not infringed by DRL's ANDA or the products or activities described therein.

42. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '208 patent and is not liable for such infringement.

43. DRL is entitled to a declaration that all that the manufacture, use or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '208 patent.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE '208 PATENT

44. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

45. Counterclaim-Defendants allege ownership of the '208 patent and have brought claims against DRL alleging infringement of the '208 patent.

46. One or more claims of the '208 patent are invalid under one or provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

47. There is an actual, substantial, continuing and justiciable controversy between Counterclaim-Defendants and DRL regarding whether the claims of the '208 patent are invalid.

48. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '208 patent are invalid.

49. DRL is entitled to a declaration that all claims of the '208 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT III: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '393 PATENT

50. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

51. Counterclaim-Defendants allege ownership of the '393 patent and have brought claims against DRL alleging infringement of the '393 patent.

52. The manufacture, use, or sale of DRL's ANDA Products would not infringe any valid or enforceable claim of the '393 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

53. There is an actual, substantial, continuing and justiciable controversy between Counterclaim-Defendants and DRL regarding whether the filing of DRL's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '393 patent.

54. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations that the '393 patent is not infringed by DRL's ANDA or the products or activities described therein.

55. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '393 patent and is not liable for such infringement.

56. DRL is entitled to a declaration that all that the manufacture, use or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '393 patent.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE '393 PATENT

57. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

58. Counterclaim-Defendants allege ownership of the '393 patent and have brought claims against DRL alleging infringement of the '393 patent.

59. One or more claims of the '393 patent are invalid under one or provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

60. There is an actual, substantial, continuing and justiciable controversy between Counterclaim-Defendants and DRL regarding whether the claims of the '393 patent are invalid.

61. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '393 patent are invalid.

62. DRL is entitled to a declaration that all claims of the '393 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT V: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '547 PATENT

63. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

64. Counterclaim-Defendants allege ownership of the '547 patent and have brought claims against DRL alleging infringement of the '547 patent.

65. The manufacture, use, or sale of DRL's ANDA Products would not infringe any valid or enforceable claim of the '547 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

66. There is an actual, substantial, continuing and justiciable controversy between Counterclaim-Defendants and DRL regarding whether the filing of DRL's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '547 patent.

67. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations that the '547 patent is not infringed by DRL's ANDA or the products or activities described therein.

68. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '547 patent and is not liable for such infringement.

69. DRL is entitled to a declaration that all that the manufacture, use or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '547 patent.

COUNT VI: DECLARATORY JUDGMENT OF INVALIDITY OF THE '547 PATENT

70. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

71. Counterclaim-Defendants allege ownership of the '547 patent and have brought claims against DRL alleging infringement of the '547 patent.

72. One or more claims of the '547 patent are invalid under one or provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

73. There is an actual, substantial, continuing and justiciable controversy between Counterclaim-Defendants and DRL regarding whether the claims of the '547 patent are invalid.

74. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '547 patent are invalid.

75. DRL is entitled to a declaration that all claims of the '547 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

PRAYER FOR RELIEF

WHEREFORE, DRL requests that the Court enter judgment in its favor and against Counterclaim-Defendants as follows:

76. Declaring that the filing of DRL's ANDA has not infringed, and does not infringe, any valid and enforceable claim of the '208 patent;

77. Declaring that the filing of DRL's ANDA has not infringed, and does not infringe, any valid and enforceable claim of the '393 patent;

78. Declaring that the filing of DRL's ANDA has not infringed, and does not infringe, any valid and enforceable claim of the '547 patent;

79. Declaring that the claims of the '208 patent are invalid and/or unenforceable;

80. Declaring that the claims of the '393 patent are invalid and/or unenforceable;

81. Declaring that the claims of the '547 patent are invalid and/or unenforceable;

82. Awarding DRL its costs and expenses in this action;

83. Declaring this an exceptional case in favor of DRL and awarding DRL its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

84. Awarding such other and further relief as this Court deems just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendants, Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.

By: s/ James S. Richter
James S. Richter
jrichter@midlige-richter.com

Dated: August 13, 2024

OF COUNSEL *(Pro Hac Vice Forthcoming)*

Jovial Wong
WINSTON & STRAWN LLP
1901 L Street NW
Washington, DC 20036
(202) 282-5000
jwong@winston.com

George Lombardi
Alison King
Annie R. Steiner
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, Illinois 60601
(312) 558-5600
glombard@winston.com
amking@winston.com
asteiner@winston.com

Noorossadat Torabi
WINSTON & STRAWN LLP
101 California Street, Fl 35
San Francisco, CA 94111
(415) 591-1000
ntorabi@winston.com

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendants/Counterclaim-Plaintiffs Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc., by their undersigned counsel, hereby certify that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding, but it appears, at the time of this certification, that the Asserted Patents in this matter are also the subject of the following actions:

- *Eisai R&D Management Co., Ltd. et al v. Torrent Pharmaceuticals Ltd.*, Civil Action No. 24-7067 (CPO)(AMD)
- *Eisai R&D Management Co., Ltd. et al v. Sun Pharmaceuticals Industries Limited f/k/a Ranbaxy Laboratories Ltd. et al*, Civil Action No. 19-21857 (FLW)(DEA)
- *Eisai R&D Management Co., Ltd. et al v. Shilpa Medicare Limited*, Civil Action No. 19-19998 (CPO)(AMD)

s/ James S. Richter
James S. Richter

Dated: August 13, 2024

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants/Counterclaim-Plaintiffs Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc., by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: August 13, 2024

CERTIFICATION OF SERVICE

The undersigned attorney certifies that a copy of the foregoing Answer, Affirmative Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on August 13, 2024.

s/ James S. Richter
James S. Richter

Dated: August 13, 2024