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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.

DR. REDDY'S LABORATORIES, INC. and
DR. REDDY'S LABORATORIES, LTD.,

Defendants.

Civil Action No. 24-6765

*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 Defendants Dr. Reddy's Laboratories, Inc. ("DRL Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (collectively, "DRL" or "Defendants"), 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 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.

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.

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.

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

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.

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.

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.

## 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. 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.

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.

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.

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).

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).

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.

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.

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.

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).

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).

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.

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.

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.

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.

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.

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.

**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®."

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.

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.

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.

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.

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.

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®.

**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.

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.

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.

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.

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.

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.

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).

## ACTS GIVING RISE TO THIS ACTION

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

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

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.

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).

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.

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.

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).

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.

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).

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.

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

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

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.

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).

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.

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.

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).

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.

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).

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.

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

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

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.

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).

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.

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.

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).

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.

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).

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.

## PRAYER FOR RELIEF

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

A. A judgment decreeing that DRL has infringed the patents-in-suit by submitting ANDA No. 219300;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining DRL, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with DRL, 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 DRL'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. 219300 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 DRL 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 6, 2024
Newark, New Jersey

s/ William P. Deni, Jr.
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