IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MITSUBISHI TANABE PHARMA CORPORATION, Plaintiff, v. CIPLA USA INC., CIPLA LIMITED, ET AL., Defendants.	)	C.A. No. 23-759-JLH-CJB (CONSOLIDATED)

LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), by and through the undersigned attorneys, respond to Mitsubishi Tanabe Pharma Corporation's ("Mitsubishi" or "Plaintiff") Complaint[1] for Patent Infringement as follows:

Pursuant to Fed. R. Civ. P. 8(b)(3), Lupin denies all allegations in Plaintiff's Complaint, except those expressly admitted below.

NATURE OF THE CASE[2]

1. This is an action for infringement by Defendants, under the Patent Laws of the United States, 35 U.S.C. §§ 1 et seq., of MTPC's United States Patent No. 12,285,409 ("the '409 patent") under the United States Patent Laws, 35 U.S.C. §§ 100 et seq., the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

RESPONSE: Lupin admits that Plaintiff's Complaint against Lupin alleges infringement of United States Patent No. 12,285,409 ("the '409 patent") and purports to bring a claim for patent

[1] The Complaint was filed in C.A. No. 25-828-JLH, which action has been consolidated into the above-captioned action by order of the Court. (*See* D.I. 129 in C.A. No. 25-759-JLH-CJB).
[2] For ease of reference and organization, Lupin has adopted the section headers used in the Complaint. For clarity, Lupin does not agree with the section headers ascribed by Plaintiff in the Complaint.

infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100 et seq., the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, but denies that Plaintiff is entitled to any such relief. Lupin denies any remaining allegations in this paragraph.

2. MTPC filed a previous action involving the same ANDA No. 219415 in this Court for patent infringement. The first suit alleged infringement of United States Patent Nos. 10,987,341 ("the '341 patent"), 11,241,416 ("the '416 patent"), 11,478,450 ("the '450 patent"), 11,826,352 ("the '352 patent"), and 11,957,660 ("the '660 patent") (collectively, "First Suit Patents") in *Mitsubishi Tanabe Pharma Corporation v. Lupin Limited et al.*, No. 1:24-cv-01423 (JLH) (D. Del. filed December 30, 2024) ("the First Suit").

RESPONSE: Lupin admits that Plaintiff filed an action involving the same ANDA No. 219415 alleging infringement of United States Patent Nos. 10,987,341 ("the '341 patent"), 11,241,416 ("the '416 patent"), 11,478,450 ("the '450 patent"), 11,826,352 ("the '352 patent"), and 11,957,660 ("the '660 patent") (collectively, "First Suit Patents") in *Mitsubishi Tanabe Pharma Corporation v. Lupin Limited et al.*, No. 1:24-cv-01423 (JLH) (D. Del. filed December 30, 2024) ("the First Suit"). Lupin denies any remaining allegations in this paragraph.

3. The First Suit was filed in response to a letter from Lupin dated November 19, 2024 ("Lupin's First Notice Letter"), purporting to include a "Notification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95): ANDA No. 219415 and RADIVACA ORS® (edaravone)" and a "Factual and Legal Basis for Lupin's Certification That the Claims of [the First Suit Patents] are Invalid, Unenforceable, and/or Will Not Be Infringed." The First Suit included counts of infringement of the First Suit Patents. Lupin's First Notice Letter defined Lupin as Lupin Ltd.

RESPONSE: Lupin admits that it sent Plaintiff a letter for ANDA No. 219415. Lupin denies any remaining allegations in this paragraph.

4. This complaint is filed in response to a new, second letter from Lupin dated May 20, 2025 ("Lupin's Second Notice Letter"), purporting to include a "Notification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95): ANDA No. 219415 and RADIVACA ORS® (edaravone)" and a "Detailed Statement of the Factual and Legal Bases for Lupin's ANDA Certification That the Claims of [the '409 patent] Will Not Be Infringed, Are Invalid, and/or Are Unenforceable." Lupin's Notice Letter stated that Lupin had filed ANDA No. 219415, seeking approval to manufacture, use, import, offer to sell and/or

sell Lupin's generic products before the expiration of the '409 patent. Lupin's Second Notice Letter defined Lupin as Lupin Ltd.

RESPONSE: Lupin admits that it sent Plaintiff a letter dated May 20, 2025 for ANDA No. 219415. Lupin denies any remaining allegations in this paragraph.

AMYOTROPIC LATERAL SCLEROSIS

5. ALS, also known as Lou Gehrig's disease, is a devastating and fatal disease. It is a neurodegenerative disease that causes motor neurons – nerve cells in the brain and spinal cord – to progressively decay and die. When this happens, the brain's ability to control muscle movement is progressively lost as the patient loses the ability to speak, eat, move and eventually breathe. The causes of ALS are not known. Once diagnosed with ALS, patients, on average, live for 3 to 5 additional years, although their quality of life deteriorates substantially throughout their few remaining years. There is no known cure for ALS.

RESPONSE: Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

6. The care of an ALS patient is burdensome, requiring a team of medical professionals, specialized equipment, and constant attention of a caregiver. Caregivers are often relatives who have forgone their occupations in order to care for the daily activities of the ALS patient. The demands of caregiving for an ALS patient take a toll on the health and finances of the caregivers as well. Of the neurodegenerative diseases, ALS is considered one of the most expensive and burdensome, imposing significant direct and indirect costs on the ALS patient, the caregivers, medical professionals, and the health care industry.

RESPONSE: Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

7. There is no cure and there are few treatments for ALS. There is a significant need for treatments that slow the progression of, if not cure, ALS, thereby reducing demands on patients, caregivers, medical professionals, and the healthcare industry.

RESPONSE: Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

8. Since 1980, however, although over one hundred (100+) clinical trials with various compounds have been conducted and published, only four active pharmaceutical ingredients (API) have been approved by the FDA for the treatment of ALS. RELYVRIO®, a drug formulation using one of those APIs, was subsequently withdrawn from the market due to a failed clinical study. MTPC's RADICAVA ORS®, which is the subject of this lawsuit, is one of a

handful of drug formulations containing one of the remaining three approved APIs for the treatment of ALS.

RESPONSE: Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

RADICAVA ORS®

9. MTPC is the holder of New Drug Application ("NDA") No. 215446. Through its approval of NDA No. 215446 on May 12, 2022, the FDA granted approval of the first oral suspension formulation containing the active pharmaceutical ingredient, edaravone, available in the United States and marketed and sold under the trade name RADICAVA ORS®.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin denies the allegations in this paragraph.

10. RADICAVA ORS® is indicated for the treatment of ALS.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that the publicly available prescribing information for RADICAVA ORS® states that it is indicated for the treatment of amyotrophic lateral sclerosis (ALS). Lupin denies any remaining allegations in this paragraph.

11. On March 28, 2024, the FDA granted orphan drug exclusivity for RADICAVA ORS® for the treatment of ALS.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits the Orange Book reports that RADICAVA ORS® has orphan drug exclusivity for the treatment of ALS. Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the other allegations of this paragraph and, therefore, denies those allegations.

12. The FDA granted seven years of Orphan Drug Exclusivity for RADICAVA ORS® based upon the FDA's assessment that RADICAVA ORS® constitutes a major contribution to patient care for people living with ALS because it provides a clinically superior option for patients due to its oral suspension route of administration that can help reduce the burden patients face with intravenous (IV) administration of previously approved RADICAVA® injection formulation.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits the Orange Book reports that RADICAVA ORS® has orphan drug exclusivity for the treatment of ALS. Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the other allegations of this paragraph and, therefore, denies those allegations.

13. Although there is no cure for ALS, RADICAVA ORS® helps slow the progression (i.e., loss of physical function) of the disease in ALS patients by approximately thirty-three percent (33%) as compared to a placebo over the same six-month period. Unlike a prior intravenous formulation of RADICAVA®, RADICAVA ORS® can be administered by the patient or informal caregivers in a home setting either orally or via a feeding tube in only a few minutes. There is no need to transport the patient to a health care facility for intravenous injection of RADICAVA®.

RESPONSE: Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

14. Pursuant to 21 C.F.R. 316.21 relating to orphan drug exclusivity, the FDA may not approve another application "for the same drug for the same use or indication before the expiration of 7 years from the date of approval."

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that 21 C.F.R. 316.21 recites the phrase "for the same drug for the same use or indication before the expiration of 7 years from the date of approval." Lupin denies any remaining allegations in this paragraph.

15. The orphan drug exclusivity for RADICAVA ORS® expires on May 12, 2029.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that the Orange Book reports that RADICAVA ORS® has orphan drug exclusivity for the treatment of ALS with an expiration date of May 12, 2029. Lupin denies any remaining allegations in this paragraph.

16. Pursuant to 21 U.S.C. § 355(b)(l)(viii), the '409 patent is listed in the FDA Orange Book in association with NDA No. 215446 for RADICAVA ORS®.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that the '409 patent is listed in the Orange Book in association with NDA No. 215446 for RADICAVA ORS®. Lupin denies any remaining allegations in this paragraph.

17. MTPC invested over a hundred million dollars in research and development of the edaravone oral suspension formulation, and demonstrating its efficacy and safety, as a treatment for ALS.

RESPONSE: Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

THE PARTIES

18. MTPC is a corporation organized and existing under the laws of Japan and having its corporate headquarters at 3-2-10, Dosho-machi, Chuo-ku, Osaka, 541-8505, Japan. With its predecessor having been established in 1678, MTPC is one of the oldest pharmaceutical companies in the world. It is a global research and development pharmaceutical company that has consistently dedicated itself to developing innovative therapies, including RADICAVA ORS®, for some of the most rare and devastating conditions affecting humanity.

RESPONSE: Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

19. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of Delaware, having a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, with a place of business at 5801 Pelican Bay Blvd., Suite 500, Naples, Florida 34108.

RESPONSE: Lupin admits that Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, with a place of business at 5801 Pelican Bay Blvd., Suite 500, Naples, Florida 34108. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

20. On information and belief, Lupin Pharmaceuticals is, directly and/or indirectly, a wholly owned subsidiary of Lupin Limited.

RESPONSE: Lupin admits that Lupin Pharmaceuticals, Inc. is a subsidiary of Lupin Limited. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

21. On information and belief, each of Lupin Limited and Lupin Pharmaceuticals is in the business of, inter alia, directly or indirectly, developing, manufacturing, marketing, distributing, selling, offering for sale, and/or importing generic versions of branded pharmaceutical products throughout the world, including the United States and the State of Delaware, either individually or in cooperation.

RESPONSE: Lupin admits that Lupin Pharmaceuticals, Inc. is a subsidiary of Lupin Limited. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

22. On information and belief Lupin Limited is the holder of ANDA No. 219415, seeking FDA approval to market a generic version of RADICAVA ORS®.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Lupin admits that Lupin Limited is the holder of ANDA No. 219415 for its proposed generic edaravone oral suspension 105 mg/5 mL.

23. On information and belief, Lupin Limited and Lupin Pharmaceuticals collaborate with respect to the development, regulatory approval, marketing, distribution and/or sale of generic versions of branded pharmaceutical products in the United States, including in the State of Delaware.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Pharmaceuticals, Inc. is a subsidiary of Lupin Limited. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

24. On information and belief, Lupin Limited and Lupin Pharmaceuticals are agents of one another and/or operate in concert as integrated units of the same corporate group.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Pharmaceuticals, Inc. is a subsidiary of Lupin Limited. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

25. On information and belief, the acts of Lupin Limited set forth in this Complaint were done with the cooperation, participation, and assistance of Lupin Pharmaceuticals.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Lupin admits that Lupin Pharmaceuticals, Inc. is a subsidiary of Lupin Limited. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

26. On information and belief, Lupin Limited and Lupin Pharmaceuticals caused Lupin's ANDA No. 219415 to be submitted to FDA and seek FDA approval of Lupin's ANDA.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Lupin admits that Lupin Limited submitted ANDA No. 219415 to the FDA. Lupin denies any remaining allegations in this paragraph.

27. According to the FDA FOIA Request log, available at https://www.fda.gov/media/162035/download?attachment, on September 1, 2022, Lupin Pharmaceuticals submitted Freedom of Information Act Request No. 2022-6329 to the FDA for the Summary Basis of Approval for Radicava ORS (edaravone) oral suspension, 105 mg/5mL.

RESPONSE: Lupin admits that the FDA FOIA Request log available at https://www.fda.gov/media/162035/download?attachment shows that Freedom of Information Act Request No. 2022-6329 was submitted by Lupin Pharmaceuticals, Inc. requesting the Summary Basis of Approval for Radicava ORS (edaravone) oral suspension, 105 mg/5mL. Lupin denies any remaining allegations in this paragraph.

28. On information and believe, Lupin Pharmaceuticals is the U.S. agent for Lupin Limited with the FDA with respect to ANDA No. 219415.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Lupin admits that Lupin Pharmaceuticals Inc. is a subsidiary of Lupin Limited. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

29. On information and belief, after obtaining FDA approval of Lupin's ANDA No. 219415, Lupin Limited and Lupin Pharmaceuticals will act cooperatively to distribute, offer to sell, and sell the proposed generic products described in Lupin's ANDA No. 219415 throughout the United States, including the State of Delaware, consistent with their earlier actions with respect to other generic versions of branded pharmaceutical products.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Limited filed ANDA No. 219415 to the FDA pursuant to 21 U.S.C. § 355(j) seeking approval as described therein for Lupin's Proposed ANDA Product. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

JURISDICTION AND VENUE

30. MTPC restates, realleges, and incorporates by reference paragraphs 1 - 29 as if fully set forth herein.

RESPONSE: Lupin repeats and incorporates by reference its Answers to paragraphs 1-29.

31. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that this action cites the patent laws of the United States generally. Lupin denies any remaining allegations in this paragraph.

32. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 – 2202, and 35 U.S.C. §271. This Court may declare the rights and legal relations of the parties under 28 U.S.C. §§ 2201 – 2022 because this case involves an actual controversy within this Court's jurisdiction.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that this Court has jurisdiction over the subject matter of this action for the purposes of this action only. Lupin denies any remaining allegations in this paragraph.

33. This Court has personal jurisdiction over, and venue is proper with respect to, Lupin Limited because, Lupin Limited: (i) controls and/or directs Lupin Pharmaceuticals, a corporation organized and existing under the laws of the State of Delaware; (ii) has, directly or indirectly through others acting on its behalf, purposefully availed itself of doing business in Delaware; (iii) maintains continuous and systematic contacts with the State of Delaware, i.e., the marketing, distribution, importation, offer for sale and/or sale of generic versions of branded pharmaceutical products; (iv) directly and/or indirectly, derives substantial revenue from the sale of generic versions of branded pharmaceutical products in Delaware; (v) on information and belief intends to market, sell and/or distribute, directly or indirectly, a generic version of RADICAVA ORS® throughout the United States, including Delaware, if it obtains FDA approval of ANDA No. 219415.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that this Court has personal jurisdiction over Lupin Limited for the purposes of this action only. Lupin admits that Lupin Pharmaceuticals Inc., is a subsidiary of Lupin Limited. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

34. This Court also has personal jurisdiction over, and venue is proper with respect to, Lupin Pharmaceuticals because Lupin Pharmaceuticals: (i) is a Delaware corporation; (ii) has purposefully availed itself of the privilege of doing business in Delaware by registering with the Delaware Department of State, Division of Corporations; (iii) develops, manufactures, sells, offers to sell and/or imports generic versions of branded pharmaceutical products into the United States, including the State of Delaware; (iv) on information and belief, derives substantial revenues from the sale of generic versions of branded pharmaceutical products in Delaware; (iv) on information and belief, acts as the U.S. agent for Lupin Limited regarding regulatory submissions to the FDA; and (v) on information and belief intends to market, sell and/or distribute, directly or indirectly, a generic version of RADICAVA ORS® throughout the United States, including Delaware, if it obtains FDA approval of ANDA No. 219415.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin admits that Lupin Pharmaceuticals, Inc. is a corporation

organized and existing under the laws of the State of Delaware. Lupin denies any remaining allegations of this paragraph.

35. This Court further has personal jurisdiction over Lupin Limited and Lupin Pharmaceuticals because they have availed themselves of the legal protections of the State of Delaware by: (i) having previously consented to personal jurisdiction and/or having previously asserted counterclaims in the District of Delaware. *See e.g., Harmony Biosciences, LLC et al v. Lupin Limited et al.*, Civil Action No. 23-cv-01286 and *Astellas Pharma Inc. et al v. Lupin Limited et al.*, Civil Action No. 23-cv-00819.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that this Court has personal jurisdiction over Lupin Limited for the purposes of this action only. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

36. On information and belief, as described in ("Lupin's Second Notice Letter") Defendants caused ANDA No. 219415 to be submitted to the FDA to seek FDA approval of ANDA No. 219415 prior to the expiration of the '409 patent listed in the Orange Book for RADICAVA ORS®.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Limited filed ANDA No. 219415 pursuant to 21 U.S.C. § 355(j) seeking approval as described therein for its generic edaravone oral suspension 105 mg/5 mL. Lupin further admits it sent Mitsubishi a Notice Letter for ANDA No. 219415. Lupin denies any remaining allegations in this paragraph.

37. This Court also has personal jurisdiction over Lupin because Lupin Limited and Lupin Pharmaceuticals have each committed, aided, abetted and participated and/or will commit, will aid, will abet and/or will participate in the commission of acts of patent infringement, including acts in Delaware, which have led to foreseeable harm and injury to Plaintiffs in Delaware.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that this Court has personal jurisdiction over Lupin Limited for the purposes of this action only. Lupin denies that Lupin

Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

38. Venue is proper, pursuant to 28 U.S.C. §§ 1391 and/or 1400, in this Court for Lupin Limited, for reasons stated above and, inter alia, because Lupin Limited is a foreign corporation and may be sued in any judicial district in the United States in which Defendant Lupin Limited is subject to personal jurisdiction.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that venue is proper for the purposes of this action only. Lupin denies any remaining allegations in this paragraph.

39. Venue is proper, pursuant to 28 U.S.C. §§ 1391 and/or 1400, in this Court for Lupin Pharmaceuticals, for reasons stated above and, inter alia, because Lupin Pharmaceuticals is a corporation organized and existing under the laws of Delaware.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

THE PATENTS-IN-SUIT

40. MTPC owns the '409 patent, which was duly and legally issued on April 29, 2025 and is entitled "Edaravone Suspension for Oral Administration." A copy of the '409 patent is attached as Exhibit A.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that the United States Patent and Trademark Office ("USPTO") issued the '409 patent, titled "Edaravone Suspension for Oral Administration," on April 29, 2025 but specifically denies that the patent was duly and lawfully issued. Lupin admits that a purported copy of the '409 patent was attached to Plaintiff's Complaint as Exhibit A. Lupin denies any remaining allegations in this paragraph.

DEFENDANTS' ANDA

41. On information and belief, Defendants Lupin Limited and Lupin Pharmaceuticals submitted to the FDA, and continue to maintain, ANDA No. 219415, pursuant to 21 U.S.C. § 355(j).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Limited submitted ANDA No. 219415 to the FDA pursuant to 21 U.S.C. § 355(j). Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

42. On information and belief, Lupin seeks approval of ANDA No. 219415 for an edaravone oral suspension containing 105 milligrams of edaravone (the active pharmaceutical ingredient) per 5 mL.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Limited submitted ANDA No. 219415 seeking FDA approval as described therein for its proposed generic edaravone oral suspension 105 mg/5 mL. Lupin denies any remaining allegations in this paragraph.

43. On information and belief, Lupin's ANDA No. 219415 identifies MTPC's RADICAVA ORS® as the reference listed drug.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that ANDA No. 219415 lists RADICAVA ORS® as the reference listed drug. Lupin denies any remaining allegations in this paragraph.

44. On information and belief, Lupin seeks FDA approval of ANDA No. 219415 to commercially manufacture, market, offer to sell, and sell its proposed edaravone oral suspension as a proposed generic version of RADICAVA ORS® ("proposed generic version of RADICAVA ORS®").

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Limited submitted ANDA

No. 219415 seeking FDA approval as described therein for its proposed generic edaravone oral suspension 105 mg/5 mL. Lupin denies any remaining allegations in this paragraph.

45. On information and belief, the FDA has not approved ANDA No. 219415.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that as of the date of filing of this Answer, Affirmative Defenses, and Counterclaims, that the FDA has not approved ANDA No. 219415. Lupin denies any remaining allegations in this paragraph.

46. On information and belief, Lupin sent MTPC Lupin's First Notice Letter and Second Notice Letter, each stating that Lupin Limited had submitted ANDA No. 219415, seeking FDA approval to commercially manufacture, use, and/or sell a generic version of RADICAVA ORS®, in the United States, including Delaware, prior to the expiration of the '409 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that it sent a letter to Plaintiff ("First Notice Letter") on or about November 19, 2024, that provided written notice of ANDA No. 219415. Lupin also admits that the First Notice Letter informed Plaintiff that Lupin seeks approval of Lupin's Proposed ANDA Product before the Patents-in-Suit expire. Lupin admits that it sent a letter to Plaintiff ("Second Notice Letter") dated May 20, 2025, that provided written notice of ANDA No. 219415. Lupin also admits that the Second Notice Letter informed Plaintiff that Lupin seeks approval of Lupin's Proposed ANDA Product before the '409 patent expires. Lupin denies any remaining allegations in this paragraph.

47. Lupin's First Notice Letter and Lupin's Second Notice Letter each contained an offer of confidential access ("Offer") to certain confidential information regarding Defendants' proposed copy version of RADICAVA ORS® and ANDA No. 219415. Defendants imposed unreasonable conditions to obtain access.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that the First and Second Notice Letters each contained an offer of confidential access to certain confidential information regarding

ANDA No. 219415, but specifically denies that such offers imposed unreasonable conditions. Lupin denies any remaining allegations in this paragraph.

48. The limited information relating to Defendants' proposed generic version of RADICAVA ORS® available to MTPC does not provide support for Defendants' representation that their proposed generic version of RADICAVA ORS® in ANDA No. 219415 will not fall within the scope of at least one claim of the '409 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

49. This action is being brought within 45 days of MTPC's receipt on on May 21, 2025, of Lupin's Second Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that the Complaint was filed on July 3, 2025. Lupin denies any remaining allegations in this paragraph.

CLAIMS FOR RELIEF

COUNT 1: INFRINGEMENT OF THE '409 PATENT

50. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

RESPONSE: Lupin repeats and incorporates by reference its Answers to each preceding paragraph.

51. On information and belief, Defendants submitted and/or caused the submission of ANDA No. 219415 to the FDA, seeking approval of Defendants' proposed generic version of RADICAVA ORS®, prior to the expiration of the '409 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Limited submitted ANDA No. 219415 to the FDA pursuant to 21 U.S.C. § 355(j) seeking FDA approval as described therein for its proposed generic edaravone oral suspension 105 mg/5 mL. Lupin denies any remaining allegations in this paragraph.

52. On information and belief, Defendants' proposed generic version of RADICAVA ORS® infringes, literally and/or under the doctrine of equivalents, one or more claims of the '409 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

53. Defendants have infringed, pursuant to 35 U.S.C. § 271(e)(2), literally and/or under the doctrine of equivalents, one or more claims of the '409 patent by submitting ANDA No. 219415 with Lupin's Second Notice Letter, seeking approval of Defendants' proposed generic version of RADICAVA ORS® prior to the expiration of the '409 patent listed in the FDA Orange Book.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin denies that it infringes any valid and enforceable claim of the '409 patent. Lupin denies any remaining allegations in this paragraph.

54. Upon information and belief, Lupin 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 Defendants' proposed generic version of RADICAVA ORS® upon receipt of final FDA approval of ANDA No. 219415.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Limited submitted ANDA No. 219415 to the FDA seeking approval as described therein for Lupin's Proposed ANDA Product. Lupin denies any remaining allegations in this paragraph.

55. Upon information and belief, including Defendants' failure to produce samples and information, Defendants' commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Defendants' proposed generic version of RADICAVA ORS® meets all elements of one or more claims of the '409 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

56. On information and belief, the importation, manufacture, offer to sell, sale, or use of Defendants' proposed generic version of RADICAVA ORS® in the United States prior to the expiration of the '409 patent will infringe, literally and/or under the doctrine of equivalents, one or more claims of the '409 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

57. Defendants had actual and constructive notice of the '409 patent prior to filing ANDA No. 219415, seeking approval of Defendants' proposed generic version of RADICAVA ORS®.

RESPONSE: This paragraph contains legal conclusions for which no response is needed. To the extent a response is required, denied.

58. Defendants filed their ANDA without adequate justification for asserting that the '409 patent is invalid and/or not infringed by the commercial manufacture, use, offer for sale, and/or sale of Defendants' proposed generic version of RADICAVA ORS®.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

59. MTPC is entitled to entry of an order, pursuant to 35 U.S.C. § 271(e)(4), that the effective date of the FDA approval of ANDA No. 219415 be a date that is not earlier than the expiration date of the '409 Patent or the later expiration of any patent term extension or exclusivity for the '409 Patent to which MTPC is or becomes entitled.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

60. MTPC is entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells Defendants' proposed generic version of RADICAVA ORS® within the United States, or imports Defendants' proposed generic version of RADICAVA ORS® into the United States, or induces or contributes to such activities, Lupin will infringe one or more claims of the '409 patent under 35 U.S.C. §§ 271(a), (b) and (c).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

61. MTPC will be irreparably harmed if Defendants are not enjoined from their activities infringing the '409 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

REQUEST FOR RELIEF

Lupin denies that Plaintiff is entitled to any of the relief requested in their Prayer for Relief or to any relief whatsoever, including those specifically requested against Lupin.

GENERAL DENIAL

Lupin denies all remaining allegations not specifically admitted herein. Lupin further denies that Plaintiff is entitled to any judgment or relief requested in the Complaint, or to any relief whatsoever.

LUPIN'S AFFIRMATIVE DEFENSES

Further answering the Complaint, Lupin 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. Lupin reserves the right to amend this Answer with additional defenses as further information is obtained in discovery. Lupin asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(Invalidity)

The '409 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 or under other judicially created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE
(No Direct Infringement)

Lupin does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '409 patent. If the product that is the subject of ANDA No. 219415 were marketed, Lupin would not infringe any valid and enforceable claim of the '409 patent.

THIRD AFFIRMATIVE DEFENSE
(No Indirect Infringement)

Lupin has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '409 patent. If the product that is the subject of ANDA No. 219415 were marketed, Lupin would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '409 patent.

FOURTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Lupin.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Lupin for an exceptional case under 35 U.S.C. § 285.

SIXTH AFFIRMATIVE DEFENSE

Lupin has not willfully infringed any claim of the '409 patent.

SEVENTH AFFIRMATIVE DEFENSE

Lupin Pharmaceuticals, Inc. is not a proper party to this action.

EIGHTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Lupin respectfully requests that Plaintiff take nothing by way of its Complaint, that judgment be entered in favor of Lupin, and that Lupin be awarded its attorneys' fees and costs and all other just and proper relief.

LUPIN LIMITED'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT

For its counterclaims against Mitsubishi Tanabe Pharma Corporation ("Counterclaim Defendant" or "Mitsubishi"), Defendant Lupin Limited ("Counterclaim Plaintiff" or "Lupin") states as follows.

PARTIES

1. On information and belief, Mitsubishi is a corporation organized and existing under the laws of Japan and having its corporate headquarters at 3-2-10, Dosho-machi, Chuo-ku, Osaka, 541-8505, Japan.

2. Lupin Limited is a corporation organized and existing under the laws of India having a registered office at Kalpataru Inspire, 3rd Floor, Off Western Express Highway, Santacruz (East), Mumbai 400 055, India.

JURISDICTION AND VENUE

3. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

4. This Court has personal jurisdiction over Counterclaim Defendant on the basis of, inter alia, its contacts with Delaware relating to the subject matter of this action, including having filed suit.

BACKGROUND

5. Upon information and belief, Mitsubishi has represented that it holds approved New Drug Application ("NDA") No. 215446 for RADICAVA ORS®, which contains the active ingredient edaravone.

6. An NDA must include, among other things, the number of any patent that 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 authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

7. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

8. U.S. Patent No. 12,285,409 ("the '409 patent"), titled "Edaravone Suspension for Oral Administration," issued on April 29, 2025.

9. Upon information and belief, Mitsubishi is the assignee of the '409 patent.

10. Upon information and belief, Mitsubishi caused the '409 patent to be listed in the Orange Book as a patent that claims a pharmaceutical composition comprising and/or a method of using such a drug for which Mitsubishi submitted NDA No. 215446.

11. Lupin Limited submitted Abbreviated New Drug Application ("ANDA") No. 219415 to obtain FDA approval as described therein for its edaravone oral suspension 105 mg/5 mL ("Lupin's Proposed ANDA Product"), prior to the expiration of '409 patent.

12. ANDA No. 219415 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '409 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lupin's ANDA Product.

13. On July 3, 2025, Counterclaim Defendant filed the instant lawsuit alleging infringement of the '409 patent.

COUNT I
(Declaratory Judgment of Non-Infringement of the '409 Patent)

14. Lupin realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

15. Mitsubishi alleges ownership of the '409 patent, and Mitsubishi has brought claims against Lupin alleging infringement of the '409 patent.

16. The manufacture, use, offer to sell, sale, and/or importation of Lupin's ANDA Product would not infringe any valid or enforceable claim of the '409 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

17. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA No. 219415 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '409 patent.

18. Lupin has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '409 patent and is not liable for such infringement.

19. Lupin is entitled to a declaration that the manufacture, use, offer to sell, sale, and/or importation of its ANDA Product would not infringe any valid or enforceable claim of the '409 patent.

COUNT II
(Declaratory Judgment of Invalidity or Unenforceability of the '409 Patent)

20. Lupin realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

21. Mitsubishi alleges ownership of the '409 patent, and Mitsubishi has brought claims against Lupin alleging infringement of the '409 patent.

22. One or more claims of the '409 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b).

23. The ’409 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

24. The alleged invention of the ’409 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’409 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’409 patent and would have had a reasonable expectation of success in doing so.

25. The subject matter claimed in the ’409 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

26. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin ANDA No. 219415 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’409 patent.

27. Lupin is entitled to a declaration that all claims of the ’409 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Lupin requests judgment in its favor and against Counterclaim Defendant as follows:

a. Declaring that all claims of the '409 patent are invalid;

b. Declaring that the filing of Lupin's ANDA No. 219415 has not infringed and does not infringe any valid and enforceable claim of the '409 patent.

c. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Products does not, and would not, if marketed, infringe any valid and enforceable claim of the '409 patent.

d. Declaring this an exceptional case in favor of Lupin and awarding its attorneys' fees pursuant to 35 U.S.C. § 285.

e. Awarding costs and expenses; and

f. Awarding any and all such other relief as the Court determines to be just and proper.

HEYMAN ENERIO
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