IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MITSUBISHI TANABE PHARMA CORPORATION, Plaintiff, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	)	C.A. No. 1:25-cv-00828-UNA

COMPLAINT FOR PATENT INFRINGEMENT

Mitsubishi Tanabe Pharma Corporation ("MTPC" or "Plaintiff"), by its undersigned attorneys, brings this action for patent infringement against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively "Lupin" or "Defendants"), and hereby alleges, on knowledge as to its own actions, and upon information and belief as to all other matters, as follows:

NATURE OF THE ACTION

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 U.S. 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.

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").

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.

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.

AMYOTROPHIC LATERAL SCLEROSIS

5. Amyotrophic Lateral Sclerosis ("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.[1]

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.

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.

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.

[1] Information in this paragraph sourced from www.als.org and the National Institute of Health's "Amyotrophic Lateral Sclerosis fact sheet" (January 2017), available from https://www.ninds.nih.gov/sites/default/files/migrate-documents/ALS_FactSheet-E_508C.pdf and downloaded on May 30, 2025.

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®.

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

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

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.

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®.

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."

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

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®.

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.

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.

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.

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

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.

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®.

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.

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.

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.

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.

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.

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

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.

JURISDICTION AND VENUE

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

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.

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.

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.

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.

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 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.

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®.

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 Plaintiff in Delaware.

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.

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.

THE PATENT-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.

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).

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.

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

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®").

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

46. On information and belief, Lupin sent MTPC Lupin's First Notice Letter and Lupin's 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.

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 generic version of RADICAVA ORS® and ANDA No. 219415. Defendants imposed unreasonable conditions to obtain access.

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.

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

COUNT I

(INFRINGEMENT OF THE '409 PATENT)

50. Plaintiff realleges, and incorporates fully herein, 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.

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.

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.

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.

55. Upon information and belief, 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.

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).

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®.

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®.

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.

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).

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

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A judgment that Lupin Pharmaceuticals and Lupin Limited have each infringed each of the '409 patent pursuant to 35 U.S.C. § 271(e)(2) by submitting ANDA No. 219415 to the FDA seeking approval of Defendants' proposed generic version of RADICAVA ORS® prior to the expiration of the '409 patent;

B. A declaration that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendants' proposed generic version of RADICAVA ORS® described in ANDA No. 219415 will infringe, induce, and/or contribute to

the infringement of each of the ’409 patent;

C. An order issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 219415 be a date not earlier than the expiration date of the last to expire of the ’409 patent, including any patent term extensions and/or patent term adjustments and any additional periods of exclusivity to which MTPC is or becomes entitled;

D. A preliminary and permanent injunction restraining and enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of any drug product, or the use thereof, claimed in the ’409 patent, before the expiration date of the last to expire of the ’409 patent, including any patent term extensions and/or patent term adjustments and any periods of exclusivity, including orphan drug exclusivity, to which MTPC is or becomes entitled;

E. A declaration that this is an exceptional case and an award to MTPC of its reasonable expenses, including attorneys’ fees pursuant to 35 U.S.C. § 285;

F. An award to MTPC of costs incurred in this action; and

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

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