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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MITSUBISHI TANABE PHARMA CORPORATION, Plaintiff, v. SANDOZ INC., Defendant.	Civil Action No. 25-16664

COMPLAINT FOR PATENT INFRINGEMENT

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

NATURE OF THE CASE

1. This is an action for infringement by Defendantof MTPC's 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"), 11,957,660 ("the '660 patent"), 12,194,025 ("the '025

patent"), 12,285,409 ("the '409 patent"), and 12,310,946 ("the '946 patent") (collectively, the "Patents-in-Suit"), 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.*

2. This action arises from Defendant's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 220086, seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of its pharmaceutical products before the expiration of the Patents-in-Suit, which are listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, (the FDA's "Orange Book") for RADICAVA ORS®.

AMYOTROPHIC LATERAL SCLEROSIS

3. Amyotrophic lateral sclerosis ("ALS"), also known as Lou Gehrig's disease, is a devastating and fatal 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 cure for ALS.[1]

4. 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

[1] Information in this paragraph is 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 April 22, 2024.

patient. The demands of caregiving for an ALS patient take a toll on the health and finances of the caregivers as well. Of neurodegenerative diseases, ALS is considered one of the most expensive and burdensome, imposing significant direct and indirect costs on the ALS patient, their caregivers, medical professionals, and the healthcare industry.

5. Since 1980, although over one hundred (100+) clinical trials with various compounds have been conducted and published, only four active pharmaceutical ingredients ("APIs") have been approved by the FDA for the treatment of ALS. RELYVRIO®, a drug using one of those APIs, was subsequently withdrawn from the market due to a failed clinical study. MTPC's RADICAVA ORS® is one of the few drug formulations containing one of the remaining three approved APIs for the treatment of ALS.

RADICAVA ORS®

6. MTPC holds an exclusive license to NDA No. 215446 from K.K. BCJ-94, the parent company of MTPC. On May 12, 2022, the FDA approved NDA No. 215446, thereby approving the first oral suspension formulation containing the edaravone API, available in the United States and marketed and sold under the trade name RADICAVA ORS®.

7. MTPC invested hundreds of millions of dollars in research and development demonstrating the efficacy and safety of RADICAVA ORS® for the treatment for ALS.

8. 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 the prior RADICAVA® intravenous ("IV") formulation, RADICAVA ORS® can be administered by the patient or informal caregivers in a home setting, either orally or via a feeding tube, and in only a few minutes. There is no need to transport the patient to a healthcare facility for IV injection of RADICAVA®.

9. On March 28, 2024, the FDA granted seven years of Orphan Drug Exclusivity ("ODE") for RADICAVA ORS® for the treatment of ALS based upon the FDA's conclusion that RADICAVA ORS® constitutes a major contribution to patient care for people living with ALS because it provides patients the clinically superior option of an oral suspension route of administration, reducing the burden patients faced with IV administration of the previously approved RADICAVA® formulation.

10. Pursuant to 21 C.F.R. § 316.31 relating to ODE, 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 such approval."

11. The ODE for RADICAVA ORS® expires on May 12, 2029.

12. Pursuant to 21 U.S.C. § 355(b)(l)(viii), the Patents-in-Suit are listed in the Approved Drug Products With Therapeutic Equivalence Evaluations ("Orange Book") in connection with NDA No. 215446 for RADICAVA ORS®.

THE PARTIES

13. 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. MTPC is a global research and development pharmaceutical company that has consistently dedicated itself to developing innovative therapies for some of the most rare and devastating conditions affecting humanity, including RADICAVA ORS®.

14. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

15. On information and belief, Sandoz 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 this judicial district.

16. On information and belief, Sandoz is the holder of ANDA No. 220086, seeking FDA approval to market a generic copy of RADICAVA ORS®.

17. On information and belief, Sandoz prepared Sandoz's ANDA No. 220086 in this district, submitted Sandoz's ANDA No. 220086 to FDA from this district, and seeks FDA approval of Sandoz's ANDA to market a generic copy of RADICAVA ORS®.

18. On information and belief, upon obtaining FDA approval of Sandoz's ANDA No. 220086, Defendant intends to distribute, offer to sell, and sell the proposed infringing products described in Sandoz's ANDA No. 220086 throughout the United States, including this judicial district.

JURISDICTION AND VENUE

19. MTPC restates, realleges, and incorporates by reference paragraphs 1–18 as if fully set forth herein.

20. 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.

21. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

22. This Court may exercise jurisdiction over Sandoz because, on information and belief, Sandoz is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Sandoz

directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. On information and belief, Sandoz purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Sandoz's generic products.

23. On information and belief, as described in Sandoz's notification of ANDA No. 220086 and the certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), dated August 29, 2025 and received by MTPC on September 2, 2025 ("Notice Letter"), Sandoz caused ANDA No. 220086 to be submitted to the FDA to seek FDA approval of ANDA No. 220086 prior to the expiration of the Patents-in-Suit listed in the Orange Book for RADICAVA ORS®.

24. This Court also has personal jurisdiction over Sandoz because Sandoz has 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 this judicial district, which have led to foreseeable harm and injury to MTPC in this judicial district.

25. Venue is proper, pursuant to 28 U.S.C. §§ 1391 and/or 1400, in this Court for Sandoz for reasons stated above and, *inter alia*, on information and belief, because Sandoz has a regular and established place of business in New Jersey and has committed acts of infringement in New Jersey.

THE PATENTS-IN-SUIT

26. MTPC owns the '341 patent, which was duly and legally issued on April 27, 2021, and is entitled "Edaravone Suspension for Oral Administration." A copy of the '341 patent is attached as Exhibit A.

27. MTPC owns the ’416 patent, which was duly and legally issued on February 8, 2022, and is entitled “Edaravone Suspension for Oral Administration.” A copy of the ’416 patent is attached as Exhibit B.

28. MTPC owns the ’450 patent, which was duly and legally issued on October 25, 2022, and is entitled “Edaravone Suspension for Oral Administration.” A copy of the ’450 patent is attached as Exhibit C.

29. MTPC owns the ’352 patent, which was duly and legally issued on November 28, 2023, and is entitled “Edaravone Suspension for Oral Administration.” A copy of the ’352 patent is attached as Exhibit D.

30. MTPC owns the ’660 patent, which was duly and legally issued on April 16, 2024, and is entitled “Edaravone Suspension for Oral Administration.” A copy of the ’660 patent is attached as Exhibit E.

31. MTPC owns the ’025 patent, which was duly and legally issued on January 14, 2025, and is entitled “Pharmaceutical composition for oral administration of edaravone and method of administering same.” A copy of the ’025 patent is attached as Exhibit F.

32. 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 G.

33. MTPC owns the ’946 patent, which was duly and legally issued on May 27, 2025, and is entitled “Pharmaceutical composition for oral administration of edaravone and method of administering same.” A copy of the ’946 patent is attached as Exhibit H.

DEFENDANT'S ANDA

34. On information and belief, Defendant Sandoz submitted to the FDA, and continues to maintain, its abbreviated ANDA No. 220086 relying upon the MTPC's RADICAVA ORS® data for FDA approval.

35. On information and belief, Sandoz seeks approval of ANDA No. 220086 for a proposed edaravone suspension, administered at a dose concentration of 105 mg/5 ml.

36. On information and belief, ANDA No. 220086 identifies MTPC's RADICAVA ORS® as the Reference Listed Drug.

37. On information and belief, Sandoz seeks FDA approval of ANDA No. 220086 to engage in the commercial manufacture, use, sale, offer for sale and/or importation of its proposed edaravone suspension as a proposed generic copy of RADICAVA ORS®.

38. On information and belief, the FDA has not approved ANDA No. 220086.

39. On information and belief, Sandoz sent MTPC a letter, purporting to include "Confidential Detailed Factual and Legal Bases for Sandoz's Paragraph IV Certification that U.S. Patent Nos. 10,987,341; 11,241,416; 11,478,450; 11,826,352; 12,285,409; 11,957,660; 12,194,025; and 12,310,946 Are Invalid, Unenforceable, and/or Will Not Be Infringed" dated August 29, 2025 (Sandoz's "Notice Letter"), stating that Sandoz Inc. had submitted ANDA No. 220086, seeking FDA approval to commercially manufacture, use, market, and/or sell a generic copy of RADICAVA ORS®, in the United States, including New Jersey, prior to the expiration of the Patents-in-Suit. Although Sandoz's Notice Letter purports that Sandoz's proposed edaravone product will not infringe the Patents-in-Suit, Sandoz's Notice Letter provides no legitimate factual or legal basis for noninfringement.

40. Sandoz's Notice Letter contained an offer of confidential access ("Offer") to certain confidential information regarding Sandoz's proposed generic version of RADICAVA ORS® and ANDA No. 220086.

41. To date, MTPC has not received samples of Sandoz's infringing edaravone product or the edaravone API used by Sandoz.

42. This action is being brought within 45 days of MTPC's receipt on September 2, 2025, of Sandoz's Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, MTPC is entitled to a thirty (30) month stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and 21 U.S.C. § 355(j)(5)(F)(ii).

CLAIMS FOR RELIEF

COUNT 1: INFRINGEMENT OF THE '341 PATENT

43. MTPC restates, realleges, and incorporates by reference paragraphs 1–42 as if fully set forth herein.

44. On information and belief, Sandoz submitted and/or caused the submission of ANDA No. 220086 to the FDA, seeking approval of Sandoz's proposed edaravone product in the United States prior to the expiration of the '341 patent.

45. On information and belief, Sandoz's proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '341 patent, including at least Independent Claim 1 of the '341 patent. For example, on information and belief, differences, if any, between the features of Sandoz's proposed edaravone product and the claims of the '341 patent are insubstantial, and Sandoz's proposed edaravone product performs substantially the same function in substantially the same way to obtain the same result as the products claimed in the '341 patent.

46. Sandoz has infringed, pursuant to 35 U.S.C. § 271(e)(2), literally and/or under the doctrine of equivalents, one or more claims of the ’341 patent by submitting ANDA No. 220086 with Sandoz’s Notice Letter, seeking approval of Sandoz’s proposed edaravone product prior to the expiration of the ’341 patent listed in the FDA Orange Book.

47. On information and belief, Sandoz 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 Sandoz’s proposed edaravone product upon receipt of final FDA approval of ANDA No. 220086.

48. On information and belief, the importation, manufacture, offer to sell, sale, or use of Sandoz’s proposed edaravone product in the United States prior to the expiration of the ’341 patent will infringe, literally and/or under the doctrine of equivalents, one or more claims of the ’341 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

49. Sandoz had actual and constructive notice of the ’341 patent prior to filing ANDA No. 220086, seeking approval of Sandoz’s proposed edaravone product.

50. 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. 220086 be a date that is not earlier than the expiration date of the ’341 patent or the later expiration of any patent term extension or exclusivity for the ’341 patent to which MTPC is or becomes entitled.

51. MTPC is entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, or sells Sandoz’s proposed edaravone product within the United States, or imports Sandoz’s proposed edaravone product into the United States, or induces or contributes to such activities, Sandoz will infringe one or more claims of the ’341 patent under 35 U.S.C. §§ 271(a), (b) and (c).

52. MTPC will be irreparably harmed if Sandoz is not enjoined from Sandoz's activities infringing the '341 patent. MTPC does not have an adequate remedy and an award of damages would not make MTPC whole.

COUNT 2: INFRINGEMENT OF THE '416 PATENT

53. MTPC restates, realleges, and incorporates by reference paragraphs 1–52 as if fully set forth herein.

54. On information and belief, Sandoz submitted and/or caused the submission of ANDA No. 220086 to the FDA, seeking approval of Sandoz's proposed edaravone product in the United States prior to the expiration of the '416 patent.

55. On information and belief, Sandoz's proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '416 patent, including at least Independent Claim 1 of the '416 patent. For example, on information and belief, differences, if any, between the features of Sandoz's proposed edaravone product and the claims of the '416 patent are insubstantial, and Sandoz's proposed edaravone product performs substantially the same function in substantially the same way to obtain the same result as the products claimed in the '416 patent.

56. Sandoz has infringed, pursuant to 35 U.S.C. § 271(e)(2), literally and/or under the doctrine of equivalents, one or more claims of the '416 patent by submitting ANDA No. 220086 with Sandoz's Notice Letter, seeking approval of Sandoz's proposed edaravone product prior to the expiration of the '416 patent listed in the FDA Orange Book.

57. On information and belief, Sandoz 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 Sandoz's proposed edaravone product upon receipt of final FDA approval of ANDA No. 220086.

58. On information and belief, the importation, manufacture, offer to sell, sale, or use of Sandoz's proposed edaravone product in the United States prior to the expiration of the '416 patent will infringe, literally and/or under the doctrine of equivalents, one or more claims of the '416 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

59. Sandoz had actual and constructive notice of the '416 patent prior to filing ANDA No. 220086, seeking approval of Sandoz's proposed edaravone product.

60. 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. 220086 be a date that is not earlier than the expiration date of the '416 patent or the later expiration of any patent term extension or exclusivity for the '416 patent to which MTPC is or becomes entitled.

61. MTPC is entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, or sells Sandoz's proposed edaravone product within the United States, or imports Sandoz's proposed edaravone product into the United States, or induces or contributes to such activities, Sandoz will infringe one or more claims of the '416 patent under 35 U.S.C. §§ 271(a), (b) and (c).

62. MTPC will be irreparably harmed if Sandoz is not enjoined from Sandoz's activities infringing the '416 patent. MTPC does not have an adequate remedy and an award of damages would not make MTPC whole.

COUNT 3: INFRINGEMENT OF THE '450 PATENT

63. MTPC restates, realleges, and incorporates by reference paragraphs 1–62 as if fully set forth herein.

64. On information and belief, Sandoz submitted and/or caused the submission of ANDA No. 220086 to the FDA, seeking approval of Sandoz's proposed edaravone product in the United States prior to the expiration of the '450 patent.

65. On information and belief, Sandoz's proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '450 patent, including at least Independent Claim 1 of the '450 patent. For example, on information and belief, differences, if any, between the features of Sandoz's proposed edaravone product and the claims of the '450 patent are insubstantial, and Sandoz's proposed edaravone product performs substantially the same function in substantially the same way to obtain the same result as the products claimed in the '450 patent.

66. Sandoz has infringed, pursuant to 35 U.S.C. § 271(e)(2), literally and/or under the doctrine of equivalents, one or more claims of the '450 patent by submitting ANDA No. 220086 with Sandoz's Notice Letter, seeking approval of Sandoz's proposed edaravone product prior to the expiration of the '450 patent listed in the FDA Orange Book.

67. On information and belief, Sandoz 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 Sandoz's proposed edaravone product upon receipt of final FDA approval of ANDA No. 220086.

68. On information and belief, the importation, manufacture, offer to sell, sale, or use of Sandoz's proposed edaravone product in the United States prior to the expiration of the '450 patent will infringe, literally and/or under the doctrine of equivalents, one or more claims of the '450 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

69. Sandoz had actual and constructive notice of the ’450 patent prior to filing ANDA No. 220086, seeking approval of Sandoz’s proposed edaravone product.

70. 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. 220086 be a date that is not earlier than the expiration date of the ’450 patent or the later expiration of any patent term extension or exclusivity for the ’450 patent to which MTPC is or becomes entitled.

71. MTPC is entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, or sells Sandoz’s proposed edaravone product within the United States, or imports Sandoz’s proposed edaravone product into the United States, or induces or contributes to such activities, Sandoz will infringe one or more claims of the ’450 patent under 35 U.S.C. §§ 271(a), (b) and (c).

72. MTPC will be irreparably harmed if Sandoz is not enjoined from Sandoz’s activities infringing the ’450 patent. MTPC does not have an adequate remedy and an award of damages would not make MTPC whole.

COUNT 4: INFRINGEMENT OF THE ’352 PATENT

73. MTPC restates, realleges, and incorporates by reference paragraphs 1–72 as if fully set forth herein.

74. On information and belief, Sandoz submitted and/or caused the submission of ANDA No. 220086 to the FDA, seeking approval of Sandoz’s proposed edaravone product in the United States prior to the expiration of the ’352 patent.

75. On information and belief, Sandoz’s proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the ’352 patent, including at least Independent Claim 1 of the ’352 patent. For example, on information and belief, differences,

if any, between the features of Sandoz's proposed edaravone product and the claims of the '352 patent are insubstantial, and Sandoz's proposed edaravone product performs substantially the same function in substantially the same way to obtain the same result as the products claimed in the '352 patent.

76. Sandoz has infringed, pursuant to 35 U.S.C. § 271(e)(2), literally and/or under the doctrine of equivalents, one or more claims of the '352 patent by submitting ANDA No. 220086 with Sandoz's Notice Letter, seeking approval of Sandoz's proposed edaravone product prior to the expiration of the '352 patent listed in the FDA Orange Book.

77. On information and belief, Sandoz 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 Sandoz's proposed edaravone product upon receipt of final FDA approval of ANDA No. 220086.

78. On information and belief, the importation, manufacture, offer to sell, sale, or use of Sandoz's proposed edaravone product in the United States prior to the expiration of the '352 patent will infringe, literally and/or under the doctrine of equivalents, one or more claims of the '352 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

79. Sandoz had actual and constructive notice of the '352 patent prior to filing ANDA No. 220086, seeking approval of Sandoz's proposed edaravone product.

80. 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. 220086 be a date that is not earlier than the expiration date of the '352 patent or the later expiration of any patent term extension or exclusivity for the '352 patent to which MTPC is or becomes entitled.

81. MTPC is entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, or sells Sandoz's proposed edaravone product within the United States, or imports Sandoz's proposed edaravone product into the United States, or induces or contributes to such activities, Sandoz will infringe one or more claims of the '352 patent under 35 U.S.C. §§ 271(a), (b) and (c).

82. MTPC will be irreparably harmed if Sandoz is not enjoined from Sandoz's activities infringing the '352 patent. MTPC does not have an adequate remedy and an award of damages would not make MTPC whole.

COUNT 5: INFRINGEMENT OF THE '660 PATENT

83. MTPC restates, realleges, and incorporates by reference paragraphs 1–82 as if fully set forth herein

84. On information and belief, Sandoz submitted and/or caused the submission of ANDA No. 220086 to the FDA, seeking approval of Sandoz's proposed edaravone product in the United States prior to the expiration of the '660 patent.

85. On information and belief, Sandoz's proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '660 patent, including at least Independent Claim 1 of the '660 patent. For example, on information and belief, differences, if any, between the features of Sandoz's proposed edaravone product and the claims of the '660 patent are insubstantial, and Sandoz's proposed edaravone product performs substantially the same function in substantially the same way to obtain the same result as the products claimed in the '660 patent.

86. Sandoz has infringed, pursuant to 35 U.S.C. § 271(e)(2), literally and/or under the doctrine of equivalents, one or more claims of the '660 patent by submitting ANDA No. 220086

with Sandoz's Notice Letter, seeking approval of Sandoz's proposed edaravone product prior to the expiration of the '660 patent listed in the FDA Orange Book.

87. On information and belief, Sandoz 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 Sandoz's proposed edaravone product upon receipt of final FDA approval of ANDA No. 220086.

88. On information and belief, the importation, manufacture, offer to sell, sale, or use of Sandoz's proposed edaravone product in the United States prior to the expiration of the '660 patent will infringe, literally and/or under the doctrine of equivalents, one or more claims of the '660 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

89. Sandoz had actual and constructive notice of the '660 patent prior to filing ANDA No. 220086, seeking approval of Sandoz's proposed edaravone product.

90. 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. 220086 be a date that is not earlier than the expiration date of the '660 patent or the later expiration of any patent term extension or exclusivity for the '660 patent to which MTPC is or becomes entitled.

91. MTPC is entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, or sells Sandoz's proposed edaravone product within the United States, or imports Sandoz's proposed edaravone product into the United States, or induces or contributes to such activities, Sandoz will infringe one or more claims of the '660 patent under 35 U.S.C. §§ 271(a), (b) and (c).

92. MTPC will be irreparably harmed if Sandoz is not enjoined from Sandoz's activities infringing the '660 patent. MTPC does not have an adequate remedy and an award of damages would not make MTPC whole.

COUNT 6: INFRINGEMENT OF THE '025 PATENT

93. MTPC restates, realleges, and incorporates by reference paragraphs 1–92 as if fully set forth herein.

94. On information and belief, Sandoz submitted and/or caused the submission of ANDA No. 220086 to the FDA, seeking approval of Sandoz's proposed edaravone product in the United States prior to the expiration of the '025 patent.

95. On information and belief, Sandoz's proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '025 patent, including at least Independent Claim 1 of the '025 patent. For example, on information and belief, differences, if any, between the features of Sandoz's proposed edaravone product and the claims of the '025 patent are insubstantial, and Sandoz's proposed edaravone product performs substantially the same function in substantially the same way to obtain the same result as the products claimed in the '025 patent.

96. Sandoz has infringed, pursuant to 35 U.S.C. § 271(e)(2), literally and/or under the doctrine of equivalents, one or more claims of the '025 patent by submitting ANDA No. 220086 with Sandoz's Notice Letter, seeking approval of Sandoz's proposed edaravone product prior to the expiration of the '025 patent listed in the FDA Orange Book.

97. On information and belief, Sandoz 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 Sandoz's proposed edaravone product upon receipt of final FDA approval of ANDA No. 220086.

98. On information and belief, the importation, manufacture, offer to sell, sale, or use of Sandoz's proposed edaravone product in the United States prior to the expiration of the '025 patent will infringe, literally and/or under the doctrine of equivalents, one or more claims of the '025 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

99. Sandoz had actual and constructive notice of the '025 patent prior to filing ANDA No. 220086, seeking approval of Sandoz's proposed edaravone product.

100. 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. 220086 be a date that is not earlier than the expiration date of the '025 patent or the later expiration of any patent term extension or exclusivity for the '025 patent to which MTPC is or becomes entitled.

101. MTPC is entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, or sells Sandoz's proposed edaravone product within the United States, or imports Sandoz's proposed edaravone product into the United States, or induces or contributes to such activities, Sandoz will infringe one or more claims of the '025 patent under 35 U.S.C. §§ 271(a), (b) and (c).

102. MTPC will be irreparably harmed if Sandoz is not enjoined from Sandoz's activities infringing the '025 patent. MTPC does not have an adequate remedy and an award of damages would not make MTPC whole.

COUNT 7: INFRINGEMENT OF THE '409 PATENT

103. MTPC restates, realleges, and incorporates by reference paragraphs 1–102 as if fully set forth herein.

104. On information and belief, Sandoz submitted and/or caused the submission of ANDA No. 220086 to the FDA, seeking approval of Sandoz's proposed edaravone product in the United States prior to the expiration of the '409 patent.

105. On information and belief, Sandoz's proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '409 patent, including at least Independent Claim 1 of the '409 patent. For example, on information and belief, differences, if any, between the features of Sandoz's proposed edaravone product and the claims of the '409 patent are insubstantial, and Sandoz's proposed edaravone product performs substantially the same function in substantially the same way to obtain the same result as the products claimed in the '409 patent.

106. Sandoz has 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. 220086 with Sandoz's Notice Letter, seeking approval of Sandoz's proposed edaravone product prior to the expiration of the '409 patent listed in the FDA Orange Book.

107. On information and belief, Sandoz 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 Sandoz's proposed edaravone product upon receipt of final FDA approval of ANDA No. 220086.

108. On information and belief, the importation, manufacture, offer to sell, sale, or use of Sandoz's proposed edaravone product 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).

109. Sandoz had actual and constructive notice of the ’409 patent prior to filing ANDA No. 220086, seeking approval of Sandoz’s proposed edaravone product.

110. 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. 220086 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.

111. MTPC is entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, or sells Sandoz’s proposed edaravone product within the United States, or imports Sandoz’s proposed edaravone product into the United States, or induces or contributes to such activities, Sandoz will infringe one or more claims of the ’409 patent under 35 U.S.C. §§ 271(a), (b) and (c).

112. MTPC will be irreparably harmed if Sandoz is not enjoined from Sandoz’s activities infringing the ’409 patent. MTPC does not have an adequate remedy and an award of damages would not make MTPC whole.

COUNT 8: INFRINGEMENT OF THE ’946 PATENT

113. MTPC restates, realleges, and incorporates by reference paragraphs 1–112 as if fully set forth herein.

114. On information and belief, Sandoz submitted and/or caused the submission of ANDA No. 220086 to the FDA, seeking approval of Sandoz’s proposed edaravone product in the United States prior to the expiration of the ’946 patent.

115. On information and belief, Sandoz’s proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the ’946 patent, including at least Independent Claim 1 of the ’946 patent. For example, on information and belief, differences,

if any, between the features of Sandoz's proposed edaravone product and the claims of the '946 patent are insubstantial, and Sandoz's proposed edaravone product performs substantially the same function in substantially the same way to obtain the same result as the products claimed in the '946 patent.

116. Sandoz has infringed, pursuant to 35 U.S.C. § 271(e)(2), literally and/or under the doctrine of equivalents, one or more claims of the '946 patent by submitting ANDA No. 220086 with Sandoz's Notice Letter, seeking approval of Sandoz's proposed edaravone product prior to the expiration of the '946 patent listed in the FDA Orange Book.

117. On information and belief, Sandoz 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 Sandoz's proposed edaravone product upon receipt of final FDA approval of ANDA No. 220086.

118. On information and belief, the importation, manufacture, offer to sell, sale, or use of Sandoz's proposed edaravone product in the United States prior to the expiration of the '946 patent will infringe, literally and/or under the doctrine of equivalents, one or more claims of the '946 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

119. Sandoz had actual and constructive notice of the '946 patent prior to filing ANDA No. 220086, seeking approval of Sandoz's proposed edaravone product.

120. 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. 220086 be a date that is not earlier than the expiration date of the '946 patent or the later expiration of any patent term extension or exclusivity for the '946 patent to which MTPC is or becomes entitled.

121. MTPC is entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, or sells Sandoz's proposed edaravone product within the United States, or imports Sandoz's proposed edaravone product into the United States, or induces or contributes to such activities, Sandoz will infringe one or more claims of the '946 patent under 35 U.S.C. §§ 271(a), (b) and (c).

122. MTPC will be irreparably harmed if Sandoz is not enjoined from Sandoz's activities infringing the '946 patent. MTPC does not have an adequate remedy and an award of damages would not make MTPC whole.

PRAYER FOR RELIEF

WHEREFORE, MTPC respectfully requests the following relief:

A. A judgment that Defendant has infringed each of the Patents-in-Suit pursuant to 35 U.S.C. § 271(e)(2) by submitting ANDA No. 220086 to the FDA seeking approval of Defendant's proposed edaravone product prior to the expiration of the Patents-in-Suit;

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 Defendant's proposed edaravone product described in ANDA No. 220086 will infringe, induce, and/or contribute to the infringement of each of the Patents-in-Suit;

C. An order issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 220086 be a date not earlier than the expiration date of the last to expire of the Patents-in-Suit, 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 Defendant, Defendant's directors, officers, agents, attorneys, affiliates, divisions, successors, and employees,

and those acting in privity or concert with Defendant, 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 Patents-in-Suit, before the expiration date of the last to expire of the Patents-in-Suit, including any patent term extensions and/or patent term adjustments and any periods of exclusivity, including ODE, 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.

Dated: October 15, 2025
Newark, New Jersey

s/ William P. Deni, Jr.

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