IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MITSUBISHI TANABE PHARMA CORPORATION, Plaintiff, v. CIPLA USA INC. and CIPLA LIMITED, Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Mitsubishi Tanabe Pharma Corporation ("MTPC"), by its undersigned attorneys, brings this action for patent infringement against Defendant Cipla USA, Inc. ("Cipla USA") and Cipla Limited (collectively "Cipla" 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 CASE

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 Nos. 10,987,341 ("the '341 patent"), 11,241,416 ("the '416 patent") and 11,478,450 ("the '450 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*., and as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

2. This action arises from Defendants' submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 218428, seeking FDA approval to market a proposed generic version of MTPC's newly approved and highly

successful RADICAVA ORS®, a pharmaceutical oral suspension for the treatment of amyotrophic lateral sclerosis ("ALS"), prior to the expiration of the Patents-in-Suit, which are listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, (commonly referenced as the FDA's "Orange Book") for RADICAVA ORS®.

AMYOTROPIC LATERAL SCLEROSIS

3. 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]

4. The care of an ALS patient is burdensome, often 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.

[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 June 16, 2023.

5. 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.

6. 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. One of those approved APIs is the API in MTPC's RADICAVA ORS®, which is the subject of this lawsuit.

RADICAVA ORS®

7. MTPC is the holder of New Drug Application ("NDA") No. 215446. Through its approval of NDA No. 215446, 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®.

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

9. Pursuant to 21 U.S.C. § 355(b)(l)(viii), the Patents-in-Suit are listed in the FDA Orange Book in association with NDA No. 215446 for RADICAVA ORS®.

10. 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.

11. 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®.

THE PARTIES

12. 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 for some of the most rare and devastating conditions affecting humanity, including RADICAVA ORS®.

13. On information and belief, Defendant Cipla Limited is a corporation organized and existing under the laws of India, with a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

14. On information and belief, Cipla Limited, either directly or indirectly, develops, manufactures, markets, distributes, sells, offers for sale, and/or imports generic versions of branded pharmaceutical products throughout the world, including the United States and the State of Delaware.

15. On information and belief Cipla Limited is the holder of Drug Master File No. 36244 for edaravone and ANDA No. 218428, seeking FDA approval to market a proposed generic version of RADICAVA ORS®.

16. On information and belief, the FDA inspected Cipla Limited facilities that are used to manufacture sterile and non-sterile liquids and suspensions for the United States between February 6, 2023 and February 17, 2023. See https://www.fda.gov/media/165827/download at 2 and 9.

17. On information and belief, during the inspections that occurred between February 5, 2023 and February 17, 2023, the FDA identified several serious deficiencies with respect to Cipla Limited's facilities that are used to manufacture sterile and non-sterile liquids and suspensions for the United States. See https://www.fda.gov/media/165827/download at *passim*.

18. On information and belief, the FDA reported, based on documentation provided by Cipla Limited, thousands of complaints from US customers between 2020 and 2022 regarding the performance of Cipla's medication, including concerns that the medication was not working. See https://www.fda.gov/media/165827/download at 10-14. The FDA reported "over 91% (2747/3008) of the complaints are related to the performance of the product." See id. at 11.

19. The FDA inspection report stated: "Even with the increasing number of complaints received in subsequent years (2021 and 2022), the QA Site Head stated on 2/16/2023 that the firm has adequate controls in place, there is no risk to product quality & patient safety, and the firm's risk assessment performed on 1/2021 is still valid. The firm's Quality Unit failed to implement effective corrective actions to reduce the number of complaints related to the performance of the product." See https://www.fda.gov/media/165827/download at 11-12.

20. On information and belief, Defendant Cipla USA is a corporation organized and existing under the laws of Delaware, with a principal place of business at 10 Independence Blvd., Suite 300, Warren, NJ 07059.

21. Upon information and belief, Cipla USA is registered with the Delaware Department of State, Division of Corporations, as a corporation operating in Delaware under Business ID No. 5207954.

22. On information and belief, Defendant Cipla USA is a wholly owned subsidiary of Defendant Cipla Limited.

23. On information and belief, Cipla USA develops, manufactures, markets, distributes, sells, offers for sale, and/or imports generic versions of branded pharmaceutical products for sale throughout the United States including in the State of Delaware.

24. On information and belief, Cipla USA is the U.S. agent for Cipla Limited.

25. On information and belief, Cipla Limited and Cipla USA 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.

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

27. On information and believe, Cipla USA is the U.S. agent for Cipla Limited with the FDA with respect to ANDA No. 218428.

JURISDICTION AND VENUE

28. MTPC restates, realleges, and incorporates by reference paragraphs 1 - 27 as if fully set forth herein.

29. 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.

30. 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.

31. This Court has personal jurisdiction over, and venue is proper with respect to, Cipla Limited because, Cipla Limited: (i) controls and/or directs Cipla USA, 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. 218428.

32. This Court further has personal jurisdiction over Cipla Limited because it has availed itself 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., Acerta Pharma BV et al. v. Cipla Ltd. et al*., Civil Action No. 22-162-RGA and *Boehringer Ingelheim Pharms. Inc. et al. v. Cipla Ltd. et al*., Civil Action No. 19-1494-CFC. and (ii) by previously initiating litigation in the District of Delaware by invoking this Court's jurisdiction. *See, e.g., Cipla Ltd. v. Boehringer Ingelheim Pharms. Inc. et al*., Civil Action No. 22-300-MN.

33. This Court may also exercise jurisdiction over Cipla Limited pursuant to Fed. R. Civ. P. (4)(k)(2) because (i) MTPC's claims are based upon federal law; (2) Cipla Limited is a foreign entity not subject to personal jurisdiction in any state court of general jurisdiction; (3) Cipla Limited has sufficient contacts with the United States as a whole such that this Court's exercise of jurisdiction over Cipla Limited satisfies due process; (4) Cipla Limited's contacts with the United States include the submission, directly or indirectly through others acting on its behalf, of multiple

ANDAs to the FDA and the manufacture, sale, offering to sell, sale and/or importation of generic versions of branded pharmaceutical products; and (5) on information and belief, pursuant to 21 C.F.R. § 314.95, Cipla has designated a U.S. agent for service of process: Dennies Varughese of Sterne, Kessler, Goldstein & Fox, P.L.L.C.

34. This Court also has personal jurisdiction over, and venue is proper with respect to, Cipla USA because Cipla USA: (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; 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. 218428.

35. This Court further has personal jurisdiction over Cipla USA because it has availed itself of the legal protections of the State of Delaware by: (i) having previously consented to personal jurisdiction and/or maintaining counterclaims in the District of Delaware. *See, e.g., Acerta Pharma BV et al. v. Cipla Ltd. et al*., Civil Action No. 22162-RGA and *Boehringer Ingelheim Pharms. Inc. et al. v. Cipla Ltd. et al*., Civil Action No. 19-1494-CFC and (ii) by previously initiating litigation in the District of Delaware by invoking this Court's jurisdiction. *See, e.g., Cipla Ltd. et al. v. AstraZeneca AB et al.,* Civil Action No. 19-733-MN.

36. On information and belief, as described in Defendants' notification of ANDA No. 218428 and the certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Food, Drug and Cosmetic Act

("FDCA") received May 31, 2023 (Cipla's "Notice Letter"), Defendants caused ANDA No. 218428 to be submitted to the FDA to seek FDA approval of ANDA No. 218428 prior to the expiration of the Patents-in-Suit listed in the Orange Book for RADICAVA ORS®.

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

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

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

THE PATENTS-IN-SUIT

40. 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.

41. 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.

42. 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.

DEFENDANTS' ANDA

43. On information and belief, Defendants Cipla Limited and Cipla USA submitted to the FDA, and continue to maintain, ANDA No. 218428, pursuant to 21 U.S.C. § 355(j).

44. On information and belief, Cipla seeks approval of ANDA No. 218428 for an edaravone oral suspension containing 105 milligrams of edaravone (the active ingredient) per 5 mL.

45. On information and belief, Cipla's ANDA No. 218428 identifies MTPC's RADICAVA ORS® as the reference listed drug.

46. On information and belief, Cipla seeks FDA approval of ANDA No. 218428 to commercially manufacture, market, offer to sell, and sell its proposed edaravone oral suspension containing 105 milligrams of edaravone (the active ingredient) per 5 mL as a proposed generic version of RADICAVA ORS® ("proposed generic version of RADICAVA ORS®").

47. On information and belief, the FDA has not approved ANDA No. 218428.

48. On information and belief, Defendants sent MTPC their Notice Letter dated May 30, 2023, stating that Defendants had submitted ANDA No. 218428, seeking FDA approval to commercially manufacture, use, market, and/or sell a generic version of RADICAVA ORS®, in the United States, including Delaware, prior to the expiration of the Patents-in-Suit.

49. Defendants' Notice Letter contained an offer of confidential access ("Offer") to certain confidential information regarding Defendants' proposed generic version of RADICAVA ORS® and ANDA No. 218428. MTPC provided Defendants with proposed revisions to Defendants' Offer in an attempt to reach agreement on the terms for confidential access, but Defendants

imposed unreasonable conditions on access and the parties were unable to reach agreement with respect to reasonable conditions for access in sufficient time to review and analyze Defendants' ANDA and formulation prior to filing this complaint. The inability to timely negotiate access to the requested samples and ANDA No. 218428 impaired MTPC's ability to evaluate the veracity of statements made in the Defendants' Notice Letter with respect to the '341 patent.

50. To date, MTPC has not had access to any portion of ANDA No. 218428 nor any information related to Defendants' proposed generic version of RADICAVA ORS®, other than the information required by law in their Notice Letter.

51. To date, MTPC has not received any samples of Defendants' proposed generic version of RADICAVA ORS® or the active principal ingredient, edaravone, used by Defendants.

52. The very 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. 218428 will not fall within the scope of at least some of the claims of the '341 Patent.

53. This action is being brought within 45 days of MTPC's receipt on May 31, 2023 of Defendants' 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

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

55. On information and belief, Defendants submitted and/or caused the submission of ANDA No. 218428 to the FDA, seeking approval of Defendants' proposed generic version of RADICAVA ORS®, prior to the expiration of the '341 patent.

56. 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 '341 patent.

57. 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 '341 patent by submitting ANDA No. 218428 with Defendants' Notice Letter, seeking approval of Defendants' proposed generic version of RADICAVA ORS® prior to the expiration of the '341 patent listed in the FDA Orange Book.

58. Upon information and belief, Cipla 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. 218428.

59. Upon information and belief, including Defendants' failure to produce the requested 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 '341 patent.

60. 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 '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).

61. Defendants had actual and constructive notice of the '341 patent prior to filing ANDA No. 218428, seeking approval of Defendants' proposed generic version of RADICAVA ORS®.

62. Defendants filed their ANDA without adequate justification for asserting that the '341 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®.

63. 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. 218428 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.

64. Plaintiffs are entitled to a declaration that, if Cipla commercially manufactures, uses, offers for sale, or sells Cipla's ANDA Product within the United States, imports Cipla's ANDA Product into the United States, or induces or contributes to such activities, Cipla will infringe one or more claims of the '341 patent under 35 U.S.C. §§ 271(a), (b) and (c).

65. MTPC will be irreparably harmed if Defendants are not enjoined from their 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

66. MTPC restates, realleges, and incorporates by reference paragraphs 1-65 as if fully set forth herein.

67. 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 '416 patent.

68. 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 '416 patent by submitting ANDA No. 218428 with Defendants' Notice Letter, seeking approval of Defendants' proposed generic version of RADICAVA ORS® prior to the expiration of the '416 patent listed in the FDA Orange Book.

69. Defendants' Notice Letter does not dispute the infringement of any claim of the '416 patent .

70. Upon information and belief, Cipla 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. 218428.

71. 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 '416 patent.

72. 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 '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).

73. Defendants had actual and constructive notice of the '416 patent prior to filing ANDA No. 218428, seeking approval of Defendants' proposed generic version of RADICAVA ORS®.

74. Defendants filed ANDA No. 218428 and Defendants' Notice Letter without adequate justification for asserting that the '416 patent is invalid.

75. 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. 218428 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.

76. Plaintiffs are entitled to a declaration that, if Cipla commercially manufactures, uses, offers for sale, or sells Cipla's ANDA Product within the United States, imports Cipla's ANDA Product

into the United States, or induces or contributes to such activities, Cipla will infringe one or more claims of the '416 patent under 35 U.S.C. §§ 271(a), (b) and (c).

77. MTPC will be irreparably harmed if Defendants are not enjoined from their activities infringing the '416 patent. MTPC does not have an adequate remedy at law and an award of damages would not make MTPC whole.

COUNT 3: INFRINGEMENT OF THE '450 PATENT

78. MTPC restates, realleges, and incorporates by reference paragraphs 1-77 as if fully set forth herein.

79. 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 '450 patent.

80. 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 '450 patent by submitting ANDA No. 218428 with Defendants' Notice Letter, seeking approval of Defendants' proposed generic version of RADICAVA ORS® prior to the expiration of the '450 patent listed in the FDA Orange Book.

81. Defendants' Notice Letter does not dispute the infringement of any claim of the '450 patent.

82. Upon information and belief, Cipla 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. 218428.

83. 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 '450 patent.

84. 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 '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).

85. Defendants had actual and constructive notice of the '450 patent prior to filing ANDA No. 218428, seeking approval of Defendants' proposed generic version of RADICAVA ORS®.

86. Defendants filed ANDA No. 218428 and Defendants' Notice Letter without adequate justification for asserting that the '450 patent is invalid.

87. 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. 218428 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.

88. Plaintiffs are entitled to a declaration that, if Cipla commercially manufactures, uses, offers for sale, or sells Cipla's ANDA Product within the United States, imports Cipla's ANDA Product into the United States, or induces or contributes to such activities, Cipla will infringe one or more claims of the '450 patent under 35 U.S.C. §§ 271(a), (b) and (c).

89. MTPC will be irreparably harmed if Defendants are not enjoined from their activities infringing the '450 patent. MTPC does not have an adequate remedy at law and an award of damages would not make MTPC whole.

PRAYER FOR RELIEF

WHEREFORE, MTPC respectfully requests the following relief:

A. A judgment that Cipla USA and Cipla Limited have infringed each of the Patents-in-Suit pursuant to 35 U.S.C. § 271(e)(2) by submitting ANDA No. 218428 to the FDA seeking approval of their proposed ANDA 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 Defendants' proposed generic version of RADICAVA ORS® described in ANDA No. 218428 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. 218428 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 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 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 additional periods of exclusivity to which MTPC is or becomes entitled;

E. An award of monetary relief to MTPC if Defendants commercially manufacture, use, offer for sale, or sell within the United States, and/or import into the United States, Defendants' proposed generic version of RADICAVA ORS® described in ANDA No. 218428, or any other

product that infringes or induces or contributes to the infringement of the Patents-in-Suit, before the latest expiration date 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;

F. 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;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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