IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MITSUBISHI TANABE PHARMA CORPORATION, Plaintiff, v. APOTEX INC. and APOTEX CORP., 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 Apotex Inc. and Apotex Corp. (collectively "Apotex" 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"), 11,478,450 ("the '450 patent"), and 11,826,352 ("the '352 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. 219256, seeking FDA approval to market a proposed generic version of MTPC's approved and highly successful RADICAVA ORS®, an edaravone 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, 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.

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.

[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 April 4, 2024.

6. Since 1980, however, although over one hundred (100+) clinical trials with various compounds have been conducted and published, only four drugs have been approved by the FDA for the treatment of ALS, although one of those drugs, RELYVRIO® 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 the remaining three approved drugs for the treatment of ALS.

RADICAVA ORS®

7. 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®.

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

9. On March 28, 2024, the FDA granted orphan drug exclusive approval status for RADICAVA ORS® for the treatment of ALS.

10. 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."

11. 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®.

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

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®.

THE PARTIES

14. 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®.

15. On information and belief, Defendant Apotex Inc. is a Canadian Corporation having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L1T9, Canada.

16. On information and belief, Apotex Inc., 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.

17. On information and belief Apotex Inc. is the holder of ANDA No. 219256, seeking FDA approval to market a generic copy of RADICAVA ORS®.

18. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 N. Commerce Parkway Suite 400, Weston, FL 33326.

19. Upon information and belief, Apotex Corp. is registered with the Delaware Department of State, Division of Corporations, as a corporation operating in Delaware under registration number 2293995.

20. On information and belief, Defendant Apotex Corp. is a wholly owned subsidiary of Defendant Apotex Inc.

21. On information and belief, Apotex Corp. 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.

22. On information and belief, Apotex Inc. and Apotex Corp. 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.

23. On information and belief, Apotex Inc. and Apotex Corp. are agents of one another and/or operate in concert as integrated units of the same corporate group.

24. On information and believe, Apotex Corp. is the U.S. agent for Apotex Inc. with the FDA with respect to ANDA No. 219256.

JURISDICTION AND VENUE

25. MTPC restates, realleges, and incorporates by reference paragraphs 1 - 24 as if fully set forth herein.

26. 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.

27. 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.

28. This Court has personal jurisdiction over, and venue is proper with respect to, Apotex Inc. because, Apotex Inc.: (i) controls and/or directs Apotex Corp., 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. 219256.

29. This Court further has personal jurisdiction over Apotex Inc. 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., *Vanda Pharmaceuticals Inc. v. Apotex Inc. et al*., Civil Action No. 23-cv-00153 and *Boehringer Ingelheim Pharms. Inc. et al. v. Apotex Inc. et al*., Civil Action No. 23-cv-685. and (ii) by previously initiating litigation in the District of Delaware by invoking this Court's jurisdiction. *Apotex Inc. et al v. Symplmed Pharmaceuticals LLC et al.,* Civil Action No. 17-cv-00276.

30. This Court may also exercise jurisdiction over Apotex Inc. pursuant to Fed. R. Civ. P. (4)(k)(2) because (i) MTPC's claims are based upon federal law; (2) Apotex Inc. is a foreign entity not subject to personal jurisdiction in any state court of general jurisdiction; (3) Apotex Inc. has sufficient contacts with the United States as a whole such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process; (4) Apotex Inc.'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, Apotex has designated a U.S. agent for service of process: Mr. Deepro R. Mukerjee of Katten Muchin Rosenman LLP.

31. This Court also has personal jurisdiction over, and venue is proper with respect to, Apotex Corp. because Apotex Corp.: (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 Apotex Inc. 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. 219256.

32. This Court further has personal jurisdiction over Apotex Corp. 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., *Vanda Pharmaceuticals Inc. v. Apotex Inc. et al*., Civil Action No. 23-cv-00153 and *Boehringer Ingelheim Pharms. Inc. et al. v. Apotex Inc. et al*., Civil Action No. 23-cv-685. and (ii) by previously initiating litigation in the District of Delaware by invoking this Court's jurisdiction. *Apotex Inc. et al v. Symplmed Pharmaceuticals LLC et al.,* Civil Action No. *17-cv-00276*.

33. On information and belief, as described in Defendants' notification of ANDA No. 219256 and the certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Food, Drug and Cosmetic Act ("FDCA") received March 25, 2024 (Apotex's "Notice Letter"), Defendants caused

ANDA No. 219256 to be submitted to the FDA to seek FDA approval of ANDA No. 219256 prior to the expiration of the Patents-in-Suit listed in the Orange Book for RADICAVA ORS®.

34. This Court also has personal jurisdiction over Apotex because Apotex Inc. and Apotex Corp. 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.

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

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

THE PATENTS-IN-SUIT

37. 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.

38. 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.

39. 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.

40. 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.

DEFENDANTS' ANDA

41. On information and belief, Defendants Apotex Inc. and Apotex Corp. submitted to the FDA, and continue to maintain, ANDA No. 219256, pursuant to 21 U.S.C. § 355(j).

42. On information and belief, Apotex seeks approval of ANDA No. 219256 for an edaravone oral suspension.

43. On information and belief, Apotex's ANDA No. 219256 identifies MTPC's RADICAVA ORS® as the reference listed drug.

44. On information and belief, Apotex seeks FDA approval of ANDA No. 219256 to commercially manufacture, market, offer to sell, and sell its proposed edaravone oral suspension as a proposed generic copy of RADICAVA ORS® ("proposed generic copy of RADICAVA ORS®").

45. On information and belief, the FDA has not approved ANDA No. 219256.

46. On information and belief, Defendants sent MTPC their Notice Letter dated March 22, 2024, stating that Defendants had submitted ANDA No. 219256, seeking FDA approval to commercially manufacture, use, market, and/or sell a generic copy of RADICAVA ORS®, in the United States, including Delaware, prior to the expiration of the Patents-in-Suit.

47. Defendants' Notice Letter contained an offer of confidential access ("Offer") to certain confidential information regarding Defendants' proposed copy version of RADICAVA ORS® and ANDA No. 219256. Defendants imposed unreasonable conditions on access.

48. To date, MTPC has not had access to any portion of ANDA No. 219256 nor any information related to Defendants' proposed generic copy of RADICAVA ORS®, other than the information required by law in their Notice Letter.

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

50. The very limited information relating to Defendants' proposed generic copy of RADICAVA ORS® available to MTPC does not provide support for Defendants' representation that their proposed generic version of RADICAVA ORS® in ANDA No. 219256 will not fall within the scope of at least some of the claims of the Patents-in-Suit.

51. Defendants' Notice Letter does not allege a basis for non-infringement of the Patents-in-Suit, other than invalidity.

52. This action is being brought within 45 days of MTPC's receipt on March 25, 2024 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

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

54. On information and belief, Defendants submitted and/or caused the submission of ANDA No. 219256 to the FDA, seeking approval of Defendants' proposed generic copy of RADICAVA ORS®, prior to the expiration of the '341 patent.

55. 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.

56. 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. 219256 with Defendants' Notice Letter, seeking approval of Defendants' proposed generic copy of RADICAVA ORS® prior to the expiration of the '341 patent listed in the FDA Orange Book.

57. Upon information and belief, Apotex 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 copy of RADICAVA ORS® upon receipt of final FDA approval of ANDA No. 219256.

58. 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 copy of RADICAVA ORS® meets all elements of one or more claims of the '341 patent.

59. On information and belief, the importation, manufacture, offer to sell, sale, or use of Defendants' proposed generic copy 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).

60. Defendants had actual and constructive notice of the '341 patent prior to filing ANDA No. 219256, seeking approval of Defendants' proposed generic copy of RADICAVA ORS®.

61. 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 copy of RADICAVA ORS®.

62. 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. 219256 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.

63. Plaintiffs are entitled to a declaration that, if Apotex commercially manufactures, uses, offers for sale, or sells Defendants' proposed generic copy of RADICAVA ORS® within the United States, or imports Defendants' proposed generic copy of RADICAVA ORS® into the United States, or induces or contributes to such activities, Apotex will infringe one or more claims of the '341 patent under 35 U.S.C. §§ 271(a), (b) and (c).

64. 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

65. MTPC restates, realleges, and incorporates by reference paragraphs 1-64 as if fully set forth herein.

66. On information and belief, Defendants' proposed generic copy of RADICAVA ORS® infringes, literally and/or under the doctrine of equivalents, one or more claims of the '416 patent.

67. 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.

219256 with Defendants' Notice Letter, seeking approval of Defendants' proposed generic copy of RADICAVA ORS® prior to the expiration of the '416 patent listed in the FDA Orange Book.

68. Upon information and belief, Apotex 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 copy of RADICAVA ORS® upon receipt of final FDA approval of ANDA No. 219256.

69. 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 copy of RADICAVA ORS® meets all elements of one or more claims of the '416 patent.

70. On information and belief, the importation, manufacture, offer to sell, sale, or use of Defendants' proposed generic copy 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).

71. Defendants had actual and constructive notice of the '416 patent prior to filing ANDA No. 219256, seeking approval of Defendants' proposed generic copy of RADICAVA ORS®.

72. Defendants filed ANDA No. 219256 and Defendants' Notice Letter without adequate justification for asserting that the '416 patent is invalid.

73. 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. 219256 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.

74. Plaintiffs are entitled to a declaration that, if Apotex commercially manufactures, uses, offers for sale, or sells Defendants' proposed generic copy of RADICAVA ORS® within the United States, or imports Defendants' proposed generic copy of RADICAVA ORS® into the United States, or induces or contributes to such activities, Apotex will infringe one or more claims of the '416 patent under 35 U.S.C. §§ 271(a), (b) and (c).

75. 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

76. MTPC restates, realleges, and incorporates by reference paragraphs 1-75 as if fully set forth herein.

77. On information and belief, Defendants' proposed generic copy of RADICAVA ORS® infringes, literally and/or under the doctrine of equivalents, one or more claims of the '450 patent.

78. 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. 219256 with Defendants' Notice Letter, seeking approval of Defendants' proposed generic copy of RADICAVA ORS® prior to the expiration of the '450 patent listed in the FDA Orange Book.

79. Upon information and belief, Apotex 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 copy of RADICAVA ORS® upon receipt of final FDA approval of ANDA No. 219256.

80. 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 copy of RADICAVA ORS® meets all elements of one or more claims of the '450 patent.

81. On information and belief, the importation, manufacture, offer to sell, sale, or use of Defendants' proposed generic copy 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).

82. Defendants had actual and constructive notice of the '450 patent prior to filing ANDA No. 219256, seeking approval of Defendants' proposed generic copy of RADICAVA ORS®.

83. Defendants filed ANDA No. 219256 and Defendants' Notice Letter without adequate justification for asserting that the '450 patent is invalid.

84. 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. 219256 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.

85. Plaintiffs are entitled to a declaration that, if Apotex commercially manufactures, uses, offers for sale, or sells Defendants' proposed generic copy of RADICAVA ORS® within the United States, or imports Defendants' proposed generic copy of RADICAVA ORS® into the United States, or induces or contributes to such activities, Apotex will infringe one or more claims of the '450 patent under 35 U.S.C. §§ 271(a), (b) and (c).

86. 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.

COUNT 4: INFRINGEMENT OF THE '352 PATENT

87. MTPC restates, realleges, and incorporates by reference paragraphs 1-86 as if fully set forth herein.

88. On information and belief, Defendants' proposed generic copy of RADICAVA ORS® infringes, literally and/or under the doctrine of equivalents, one or more claims of the '352 patent.

89. 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 '352 patent by submitting ANDA No. 219256 with Defendants' Notice Letter, seeking approval of Defendants' proposed generic copy of RADICAVA ORS® prior to the expiration of the '352 patent listed in the FDA Orange Book.

90. Upon information and belief, Apotex 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 copy of RADICAVA ORS® upon receipt of final FDA approval of ANDA No. 219256.

91. 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 copy of RADICAVA ORS® meets all elements of one or more claims of the '352 patent.

92. On information and belief, the importation, manufacture, offer to sell, sale, or use of Defendants' proposed generic copy of RADICAVA ORS® 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).

93. Defendants had actual and constructive notice of the '352 patent prior to filing ANDA No. 219256, seeking approval of Defendants' proposed generic copy of RADICAVA ORS®.

94. Defendants filed ANDA No. 219256 and Defendants' Notice Letter without adequate justification for asserting that the '352 patent is invalid.

95. 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. 219256 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.

96. Plaintiffs are entitled to a declaration that, if Apotex commercially manufactures, uses, offers for sale, or sells Defendants' proposed generic copy of RADICAVA ORS® within the United States, or imports Defendants' proposed generic copy of RADICAVA ORS® into the United States, or induces or contributes to such activities, Apotex will infringe one or more claims of the '352 patent under 35 U.S.C. §§ 271(a), (b) and (c).

97. MTPC will be irreparably harmed if Defendants are not enjoined from their activities infringing the '352 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 Apotex Corp. and Apotex Inc. have infringed each of the Patents-in-Suit pursuant to 35 U.S.C. § 271(e)(2) by submitting ANDA No. 219256 to the FDA seeking approval of Defendants' proposed generic copy of RADICAVA ORS® 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. 219256 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. 219256 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 periods of exclusivity, including orphan drug 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 copy of RADICAVA ORS® described in ANDA No. 219256, 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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