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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MITSUBISHI TANABE PHARMA CORPORATION, Plaintiff, v. CIPLA USA, INC. and CIPLA LIMITED, Defendants.	Civil Action No. 25-16677

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Mitsubishi Tanabe Pharma Corporation ("MTPC" or "Plaintiff"), by its undersigned attorneys, brings this action for patent infringement against Defendants Cipla USA, Inc. and Cipla Limited (collectively, "Cipla" or "Defendants"), 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 Defendants of MTPC's United States Patent Nos. 12,194,025 ("the '025 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 Cipla's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 218428, 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]

[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 September 28, 2025.

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 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, 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.

15. On information and belief, Cipla USA, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 10 Independence Blvd., Suite 300, Warren, New Jersey 07059.

16. On information and belief, Cipla USA, Inc. is, directly and/or indirectly, a wholly owned subsidiary of Cipla Limited.

17. On information and belief, each of Cipla Limited and Cipla USA, Inc. is in the business of, *inter alia*, directly, or indirectly, developing, manufacturing, marketing, distributing, selling, offering for sale, and/or importing generic versions of branded pharmaceutical products throughout the world, including the United States and the State of New Jersey, either individually or in cooperation.

18. On information and belief, Cipla Limited is the holder of ANDA No. 218428, seeking FDA approval to market a generic version of RADICAVA ORS®.

19. On information and belief, Cipla Limited and Cipla USA, Inc. 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 New Jersey.

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

21. On information and belief, the acts of Cipla Limited set forth in this Complaint were done with the cooperation, participation, and assistance of Cipla USA, Inc.

22. On information and belief, Cipla Limited and Cipla USA, Inc. caused Cipla's ANDA No. 218428 to be submitted to FDA and seek FDA approval of Cipla's ANDA.

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

24. On information and belief, after obtaining FDA approval of Cipla's ANDA No. 218428, Cipla Limited and Cipla USA, Inc. will act cooperatively to distribute, offer to sell, and sell the proposed generic products described in Cipla's ANDA No. 218428 throughout the United States, including the State of New Jersey, consistent with their earlier actions with respect to other generic versions of branded pharmaceutical products.

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).

28. This Court may exercise jurisdiction over Cipla because, on information and belief, Cipla is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Cipla directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. On information and belief, Cipla purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Cipla's generic products.

29. On information and belief, as described in Cipla's notification of ANDA No. 218428 and the certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), dated June 9, 2025 and received by MTPC on June 10, 2025 ("Notice Letter"), Cipla 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®.

30. This Court also has personal jurisdiction over Cipla because Cipla 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. This Court also has personal jurisdiction over Cipla because Cipla USA, Inc. and/or Cipla Limited have previously consented to personal jurisdiction in this Court. *See, e.g., Theravance Biopharma R&D IP, LLC, et al, v. Eugia Pharma Specialities Ltd., et al*, No. 25-3790, ECF No. 9 (D.N.J. May 30, 2025); *Am. Regent, Inc. f/k/a Luitpold Pharm., Inc. v. Cipla USA, Inc., et al*, No. 24-8435, ECF No. 9 (D.N.J. Sep. 18, 2024); *Teva Branded Pharm. Prods. R&D, Inc., et al. v. Cipla USA, Inc., et al.*, No. 24-9691, ECF No. 9 (D.N.J. Dec. 9, 2024); *In re Selenious Acid Litig.: Am. Regent, Inc. f/k/a Luitpold Pharm., Inc. v. Accord Healthcare, Inc., et al.*, No. 24-7791, ECF No. 69 (D.N.J. Jan. 8, 2025); *Salix Pharm., Inc.,et al. v. Cipla USA, Inc., et al.*, No. 24-10213, ECF No. 18 (D.N.J. Jan. 16, 2025); *AstraZeneca Pharms. LP, et al. v. Cipla Ltd., et al.*, No. 24-8167, ECF No. 14 (D.N.J. Oct. 7, 2024); *Jazz Pharms. Rsch. UK Ltd. f/k/a GW Rsch. Ltd. v. Apotex Inc., et al.*, No. 24-7550, ECF No. 45 (D.N.J. Sep. 24, 2024); *Am. Regent, Inc. f/k/a Luitpold Pharms., Inc. v. Cipla USA, Inc., et al.*, No. 24-8435, ECF No. 9 (D.N.J. Sep. 18, 2024); *AstraZeneca Pharm. LP, et al. v. Sandoz Inc., et al*, No. 23-796, ECF No. 116 (D.N.J. Sep. 3, 2024); *Theravance Biopharma R&D IP, LLC, et al. v. Eugia Pharma Specialities Ltd., et al.*, No. 23-926, ECF No. 50 (D.N.J. May 17, 2023).

31. 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.

32. Venue is proper, pursuant to 28 U.S.C. §§ 1391 and/or 1400, for reasons stated above and, *inter alia*, because Cipla USA, Inc. is incorporated in New Jersey, has a regular and established place of business in New Jersey and has committed acts of infringement in New Jersey. Venue is also proper in this Court because Cipla USA, Inc. and/or Cipla Limited have previously consented to venue in this Court. *See, e.g., Theravance Biopharma R&D IP, LLC, et al v. Eugia Pharma Specialities Ltd., et al*, No. 25-3790, ECF No. 9 (D.N.J. May 30, 2025); *Am. Regent, Inc. f/k/a Luitpold Pharm., Inc. v. Cipla USA, Inc., et al.*, No. 24-8435, ECF No. 9 (D.N.J. Sep. 18, 2024); *Teva Branded Pharm. Prods. R&D, Inc., et al. v. Cipla USA, Inc., et al.*, No. 24-9691, ECF No. 9 (D.N.J. Dec. 9, 2024); *In re Selenious Acid Litig.: Am. Regent, Inc. f/k/a Luitpold Pharm., Inc. v. Accord Healthcare, Inc., et al.*, No. 24-7791, ECF No. 69 (D.N.J. Jan. 8, 2025); *Salix Pharm., Inc., et al. v. Cipla USA, Inc., et al.*, No. 24-10213, ECF No.18 (D.N.J. Jan. 16, 2025); *AstraZeneca Pharm. LP, et al. v. Cipla Ltd., et al.*, No. 24-8167, ECF No. 14 (D.N.J. Oct. 7, 2024); *Jazz Pharm. Rsch. UK Ltd. f/k/a GW Rsch. Ltd. v. Apotex Inc., et al.*, No. 24-7550, ECF No. 45 (D.N.J. Sep. 24, 2024); *Am. Regent, Inc. f/k/a Luitpold Pharm., Inc. v. Cipla USA, Inc., et al.*, No. 24-8435, ECF No. 9 (D.N.J. Sep. 18, 2024); *AstraZeneca Pharms. LP, et al. v. Sandoz Inc., et al.*, No. 23-796, ECF No. 116 (D.N.J. Sep. 3, 2024); *Theravance Biopharma R&D IP, LLC, et al. v. Eugia Pharma Specialities Ltd., et al.*, No. 23-926, ECF No. 50 (D.N.J. May 17, 2023).

33. Moreover, on information and belief, this venue is proper for reasons stated above and, *inter alia*, because Cipla USA, Inc. and/or Cipla Limited have previously litigated patent infringement disputes in this judicial district and have affirmatively availed themselves of the

jurisdiction of this Court by filing counterclaims in this judicial district. *See, e.g.*, *Theravance Biopharma R&D IP, LLC, et al. v. Eugia Pharma Specialities Ltd., et al*, No. 25-3790, ECF No. 9 (D.N.J. May 30, 2025); *Am. Regent, Inc. f/k/a Luitpold Pharm., Inc. v. Cipla USA, Inc., et al*, No. 24-8435, ECF No. 9 (D.N.J. Sep. 18, 2024); *Teva Branded Pharm. Prods. R&D, Inc., et al. v. Cipla USA, Inc. et al*., No. 24-9691, ECF No. 9 (D.N.J. Dec. 9, 2024); *In re Selenious Acid Litig.: Am. Regent, Inc. f/k/a Luitpold Pharm., Inc. v. Accord Healthcare, Inc., et al.*, No. 24-7791, ECF No. 69 (D.N.J. Jan. 8, 2025); *Salix Pharm., Inc., et al. v. Cipla USA, Inc., et al.*, No. 24-10213, ECF No.18 (D.N.J. Jan. 16, 2025); *AstraZeneca Pharm. LP, et al. v. Cipla Ltd., et al.*, No. 24-8167, ECF No. 14 (D.N.J. Oct. 7, 2024); *Jazz Pharm. Rsch. UK Ltd. f/k/a GW Rsch. Ltd. v. Apotex Inc., et al.*, No. 24-7550, ECF No. 45 (D.N.J. Sep. 24, 2024); *Am. Regent, Inc. f/k/a Luitpold Pharm., Inc. v. Cipla USA, Inc., et al.*, No. 24-8435, ECF No. 9 (D.N.J. Sep. 18, 2024); *AstraZeneca Pharms. LP, et al. v. Sandoz Inc., et al.*, No. 23-796, ECF No. 116 (D.N.J. Sep. 3, 2024); *Theravance Biopharma R&D IP, LLC, et al. v. Eugia Pharma Specialities Ltd., et al.*, No. 23-926, ECF No. 50 (D.N.J. May 17, 2023).

THE PATENTS-IN-SUIT

34. 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 A.

35. 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 B.

DEFENDANTS' ANDA

36. On information and belief, Cipla submitted to the FDA, and continues to maintain, its abbreviated ANDA No. 218428 relying upon the MTPC's RADICAVA ORS® data for FDA approval.

37. On information and belief, Cipla seeks approval of ANDA No. 218428 for a proposed edaravone suspension, administered at a dose concentration of 105 mg/5 ml.

38. On information and belief, ANDA No. 218428 identifies MTPC's RADICAVA ORS® as the reference listed drug ("RLD").

39. On information and belief, Cipla seeks FDA approval of ANDA No. 218428 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®.

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

41. On information and belief, Cipla sent MTPC a letter ("Cipla's Notice Letter"), purporting to include a "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act regarding [the '025 patent and the '409 patent] Pursuant to Section 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95: ANDA No. 218428 and RADICAVA ORS®" and a "Detailed Factual and Legal Basis for CIPLA's Paragraph IV Certification Regarding [the '025 patent and the '409 patent]." Cipla's Notice Letter defined Cipla as Cipla Limited and Cipla USA, Inc. Cipla's Notice Letter stated that Cipla had filed ANDA No. 218428, seeking approval to manufacture, use, import, offer to sell and/or sell Cipla's generic products before the expiration of the '025 patent. Although Cipla's Notice Letter purports that Cipla's proposed edaravone product will not infringe the '025 patent, Cipla's Notice Letter provides no factual basis for noninfringement.

CLAIMS FOR RELIEF

COUNT 1: INFRINGEMENT OF THE ’025 PATENT

42. MTPC restates, realleges, and incorporates by reference paragraphs 1–41 as if fully set forth herein.

43. On information and belief, Cipla submitted and/or caused the submission of ANDA No. 218428 to the FDA, seeking approval of Cipla’s proposed edaravone product in the United States prior to the expiration of the ’025 patent.

44. On information and belief, Cipla’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 Cipla’s proposed edaravone product and the claims of the ’025 patent are insubstantial, and Cipla’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.

45. Cipla 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. 218428 with Cipla’s Notice Letter, seeking approval of Cipla’s proposed edaravone product prior to the expiration of the ’025 patent listed in the FDA Orange Book.

46. On 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 Cipla’s proposed edaravone product upon receipt of final FDA approval of ANDA No. 218428.

47. On information and belief, the importation, manufacture, offer to sell, sale, or use of Cipla'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).

48. Cipla had actual and constructive notice of the '025 patent prior to filing ANDA No. 218428, seeking approval of Cipla's proposed edaravone product.

49. 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 '025 patent or the later expiration of any patent term extension or exclusivity for the '025 patent to which MTPC is or becomes entitled.

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

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

COUNT 2: INFRINGEMENT OF THE '946 PATENT

52. MTPC restates, realleges, and incorporates by reference paragraphs 1–51 as if fully set forth herein.

53. On information and belief, Cipla submitted and/or caused the submission of ANDA No. 218428 to the FDA, seeking approval of Cipla's proposed edaravone product in the United States prior to the expiration of the '946 patent.

54. On information and belief, Cipla'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 Cipla's proposed edaravone product and the claims of the '946 patent are insubstantial, and Cipla'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.

55. Cipla 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. 218428, seeking approval of Cipla's proposed edaravone product prior to the expiration of the '946 patent listed in the FDA Orange Book.

56. On 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 Cipla's proposed edaravone product upon receipt of final FDA approval of ANDA No. 218428.

57. On information and belief, the importation, manufacture, offer to sell, sale, or use of Cipla'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).

58. Cipla had actual and constructive notice of the ’946 patent prior to filing ANDA No. 218428, seeking approval of Cipla’s proposed edaravone product.

59. MTPC is entitled to entry of an order, pursuant to 35 U.S.C. § 271(e)(4), that the effective date of the FDA approval of ANDA No. 218428 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.

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

61. MTPC will be irreparably harmed if Cipla is not enjoined from Cipla’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 Defendants 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 Defendants’ 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 Defendants’ proposed edaravone product 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, Defendants' directors, officers, agents, attorneys, affiliates, divisions, successors, and employees, and those acting in privity or concert with Defendants, 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 16, 2025
Newark, New Jersey

s/ William P. Deni, Jr.

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