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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MITSUBISHI TANABE PHARMA CORPORATION, Plaintiff, v. SHANGHAI AUZONE BIOLOGICAL TECHNOLOGY CO., LTD.; AUZONE BIOLOGICAL TECHNOLOGY (USA) LTD.; and AUZONE BIOLOGICAL TECHNOLOGY PTY LTD, Defendants.	Civil Action No. 25-16665

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Mitsubishi Tanabe Pharma Corporation ("MTPC" or "Plaintiff"), by its undersigned attorneys, brings this action for patent infringement against Defendants Shanghai Auzone Biological Technology Co., Ltd. ("Shanghai Auzone"), Auzone Biological Technology (USA) Ltd., and Auzone Biological Technology Pty Ltd (collectively, "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 U.S. Patent Nos. 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. MTPC filed a previous action involving the same 505(b)(2) New Drug Application ("NDA") No. 219846 in this District for patent infringement. The first suit alleged infringement of United States Patent Nos. 10,987,341 ("the '341 patent"), 11,241,416 ("the '416 patent"), 11,478,450 ("the '450 patent"), 11,826,352 ("the '352 patent"), and 11,957,660 ("the '660 patent") (collectively, the "First Suit Patents"), in *Mitsubishi Tanabe Pharma Corporation v. Shanghai Auzone Biological Technology Co., Ltd., et al.*, Civil Action No. 25-3326 (D.N.J.) (filed Apr. 25, 2025) ("the First Suit").

3. The First Suit was filed in response to Defendants' submission of New Drug Application ("NDA") No. 219846, pursuant to Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b)(2), seeking an abbreviated approval by the U.S. Food and Drug Administration ("FDA") to engage in the commercial manufacture, use, sale, offer for sale and/or importation of its pharmaceutical products before the expiration of the First Suit Patents.

4. This action is also filed in response to Defendants' submission of NDA No. 219846, seeking an abbreviated approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products before the expiration of the Patents-in-Suit.

AMYOTROPHIC LATERAL SCLEROSIS

5. 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]

6. The care of an ALS patient is burdensome, requiring a team of medical professionals, specialized equipment, and constant attention of a caregiver. Caregivers are often relatives who have forgone their occupations in order to care for the daily activities of the ALS patient. The demands of caregiving for an ALS patient take a toll on the health and finances of the caregivers as well. Of the neurodegenerative diseases, ALS is considered one of the most expensive and burdensome, imposing significant direct and indirect costs on the ALS patient, the caregivers, medical professionals, and the healthcare industry.

7. 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.

[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.

RADICAVA ORS®

8. 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®.

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

10. 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®.

11. 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 assessment 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.

12. 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."

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

14. 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

15. 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 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®.

16. On information and belief, Defendant Shanghai Auzone is a company organized and existing under the laws of China, with a principal place of business at 19/F, No. 1366 Yangshupu Road, Yangpu District, Shanghai, 200082, P.R. China.

17. On information and belief, Defendant Auzone Biological Technology (USA) Ltd. is a company organized under the laws of Delaware, with a principal place of business at 3500 S Dupont HWY, Dover, DE 19901-6041.

18. On information and belief, Defendant Auzone Biological Technology Pty Ltd is a company organized under the laws of Australia, with a principal place of business in 17 Bungowen Ave, Thornleigh, NSW, Australia 2120.

19. On information and belief, Defendants are 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.

20. On information and belief, Shanghai Auzone is the holder of 505(b)(2) NDA No. 219846, seeking FDA approval to market AUKONTALS, an edaravone product for the treatment of ALS, relying upon MTPC's RADICAVA ORS® as the Reference Label Drug ("RLD") and the studies disclosed in MTPC's NDA No. 215446 for RADICAVA ORS® in seeking abbreviated FDA approval for Shanghai Auzone's 505(b)(2) NDA No. 219846.

21. On information and belief, Shanghai Auzone caused Shanghai Auzone's 505(b)(2) NDA No. 219846 to be submitted to FDA and seeks FDA approval of Shanghai Auzone's 505(b)(2) NDA.

22. On information and belief, Changyun Pan, Esq. is the U.S. agent for Shanghai Auzone with the FDA with respect to NDA No. 219846.

23. On information and belief, after obtaining FDA approval of Shanghai Auzone's 505(b)(2) NDA No. 219846, Defendants intend to distribute, offer to sell, and sell the proposed infringing products described in Shanghai Auzone's 505(b)(2) NDA No. 219846 throughout the United States, including this judicial district.

JURISDICTION AND VENUE

24. MTPC restates, realleges, and incorporates by reference paragraphs 1–23 as if fully set forth herein.

25. 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.

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

27. This Court may exercise personal jurisdiction over Shanghai Auzone because, on information and belief, Shanghai Auzone is a Chinese company and is in the business of

manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Shanghai Auzone directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. On information and belief, Shanghai Auzone purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

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

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

30. On information and belief, as described in Shanghai Auzone's notification of NDA No. 219846 and the certification under 21 U.S.C. § 355(b)(2)(A)(iv) of the FDCA received March 16, 2025 ("Access Offer Letter"), Shanghai Auzone caused NDA No. 219846 to be submitted to the FDA to seek FDA approval of NDA No. 219846 prior to the expiration of the patents listed in the Orange Book for RADICAVA ORS®.

31. This Court also has personal jurisdiction over Defendants because Defendants have 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.

32. Venue is proper, pursuant to 28 U.S.C. §§ 1391 and/or 1400, in this Court for Shanghai Auzone for reasons stated above and, *inter alia*, because Shanghai Auzone is a foreign corporation and may be sued in any judicial district in the United States.

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

34. Venue is proper, pursuant to 28 U.S.C. §§ 1391 and/or 1400, in this Court for Auzone Biological Technology Pty Ltd for reasons stated above and, *inter alia*, because Auzone Biological Technology Pty Ltd is a foreign corporation and may be sued in any judicial district in the United States.

THE PATENTS-IN-SUIT

35. 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.

36. 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 B.

37. 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 C.

DEFENDANTS’ ABBREVIATED 505(b)(2) NDA

38. On information and belief, Defendant Shanghai Auzone submitted to the FDA, and continues to maintain, its abbreviated 505(b)(2) NDA No. 219846 relying upon the MTPC’s RADICAVA ORS® data for FDA approval.

39. On information and belief, Defendants seek approval of 505(b)(2) NDA No. 219846 for a proposed edaravone product containing 90 milligrams of edaravone.

40. On information and belief, 505(b)(2) NDA No. 219846 identifies MTPC’s RADICAVA ORS® as the RLD.

41. On information and belief, Shanghai Auzone seeks FDA approval of NDA No. 219846 to engage in the commercial manufacture, use, sale, offer for sale and/or importation its proposed edaravone product.

42. On information and belief, the FDA has not approved NDA No. 219846.

43. On information and belief, Defendants sent MTPC a "Non-Infringement Analysis Report" on March 13, 2025, providing Defendants' bases for alleging noninfringement of the First Suit Patents and the '025 patent, and an "Access Offer Letter" offering access to certain portions of NDA No. 219846 for evaluating infringement of the First Suit Patents and the '025 patent, the subject of Defendants' Paragraph IV Certification. On information and belief, Defendants intended for the "Non-Infringement Analysis Report" and "Access Offer Letter" to serve as its Notice Letter of a Paragraph IV certification of the First Suit Patents and the '025 patent.

44. MTPC received access to certain redacted portions of NDA No. 219846 on April 22, 2025, 3 days before the filing of the complaint in the First Suit.

45. To date, MTPC has not received samples of Defendants' infringing edaravone product or the edaravone API used by Defendants.

46. Based on the limited information relating to Defendants' proposed edaravone product available to MTPC, Defendants do not provide support for Defendants' representation that Defendants' proposed edaravone product that is the subject of NDA No. 219846 will not infringe at least some of the claims of each of the Patents-in-Suit.

CLAIMS FOR RELIEF

COUNT 1: INFRINGEMENT OF THE '025 PATENT

47. MTPC restates, realleges, and incorporates by reference paragraphs 1–46 as if fully set forth herein.

48. On information and belief, Defendants submitted and/or caused the submission of 505(b)(2) NDA No. 219846 to the FDA, seeking approval of Defendants' proposed edaravone product, prior to the expiration of the '025 patent.

49. On information and belief, Defendants' 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 Defendants' proposed edaravone product and the claims of the '025 patent are insubstantial, and Defendants' 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.

50. 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 '025 patent by submitting 505(b)(2) NDA No. 219846 seeking approval of Defendants' proposed edaravone product prior to the expiration of the '025 patent listed in the FDA Orange Book.

51. On information and belief, Defendants intend 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 edaravone product upon receipt of final FDA approval of 505(b)(2) NDA No. 219846.

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

53. Defendants had actual and constructive notice of the '025 patent prior to filing 505(b)(2) NDA No. 218946, seeking approval of Defendants' proposed edaravone product.

54. 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 505(b)(2) NDA No. 219846 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.

55. MTPC is entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell Defendants’ proposed edaravone product within the United States, or import Defendants’ proposed edaravone product into the United States, or induce or contribute to such activities, Defendants will infringe one or more claims of the ’025 patent under 35 U.S.C. §§ 271(a), (b) and (c).

56. MTPC will be irreparably harmed if Defendants are not enjoined from Defendants’ activities infringing the ’025 patent. MTPC does not have an adequate remedy at law and an award of damages would not make MTPC whole.

COUNT 2: INFRINGEMENT OF THE ’409 PATENT

57. MTPC restates, realleges, and incorporates by reference paragraphs 1–56 as if fully set forth herein.

58. On information and belief, Defendants submitted and/or caused the submission of 505(b)(2) NDA No. 219846 to the FDA, seeking approval of Defendants’ proposed edaravone product in the United States prior to the expiration of the ’409 patent.

59. On information and belief, Defendants’ 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 Defendants’ proposed edaravone product and the claims of the ’409 patent are insubstantial, and Defendants’ 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.

60. Defendants have infringed, pursuant to 35 U.S.C. § 271(e)(2), literally and/or under the doctrine of equivalents, one or more claims of the ’409 patent by submitting 505(b)(2) NDA No. 219846 seeking approval of Defendants’ proposed edaravone product prior to the expiration of the ’409 patent listed in the FDA Orange Book.

61. On information and belief, Defendants intend 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 edaravone product upon receipt of final FDA approval of 505(b)(2) NDA No. 219846.

62. On information and belief, the importation, manufacture, offer to sell, sale, or use of Defendants’ 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).

63. Defendants had actual and constructive notice of the ’409 patent prior to filing 505(b)(2) NDA No. 219846, seeking approval of Defendants’ proposed edaravone product.

64. 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 505(b)(2) NDA No. 219846 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.

65. MTPC is entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell Defendants’ proposed edaravone product within the United States, or import Defendants’ proposed edaravone product into the United States, or induce or contribute to such activities, Defendants will infringe one or more claims of the ’409 patent under 35 U.S.C. §§ 271(a), (b) and (c).

66. MTPC will be irreparably harmed if Defendants are not enjoined from Defendants' activities infringing the '409 patent. MTPC does not have an adequate remedy and an award of damages would not make MTPC whole.

COUNT 3: INFRINGEMENT OF THE '946 PATENT

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

68. On information and belief, Defendants submitted and/or caused the submission of 505(b)(2) NDA No. 219846 to the FDA, seeking approval of Defendants' proposed edaravone product, prior to the expiration of the '946 patent.

69. On information and belief, Defendants' 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 Defendants' proposed edaravone product and the claims of the '946 patent are insubstantial, and Defendants' 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.

70. 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 '946 patent by submitting 505(b)(2) NDA No. 219846, seeking approval of Defendants' proposed edaravone product prior to the expiration of the '946 patent listed in the FDA Orange Book.

71. On information and belief, Defendants intend 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 edaravone product upon receipt of final FDA approval of 505(b)(2) NDA No. 219846.

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

73. Defendants had actual and constructive notice of the '946 patent prior to filing 505(b)(2) NDA No. 219846, seeking approval of Defendants' proposed edaravone product.

74. 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 505(b)(2) NDA No. 219846 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.

75. MTPC is entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell Defendants' proposed edaravone product within the United States, or import Defendants' proposed edaravone product into the United States, or induce or contribute to such activities, Defendants will infringe one or more claims of the '946 patent under 35 U.S.C. §§ 271(a), (b) and (c).

76. MTPC will be irreparably harmed if Defendants are not enjoined from Defendants' activities infringing the '946 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 Defendants have infringed each of the Patents-in-Suit (*i.e.*, the '025, '409, and '946 patents) pursuant to 35 U.S.C. § 271(e)(2) by submitting 505(b)(2) NDA No. 219846 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 505(b)(2) NDA No. 219846 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 505(b)(2) NDA No. 219846 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 15, 2025
Newark, New Jersey

s/ William P. Deni, Jr.

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