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**IN THE UNITED STATES DISTRICT COURT  
FOR THE 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  
PRIVATE LTD

Defendants.

C.A. No. 2:25-cv-03326 (CCC) (LDW)

**DEFENDANTS SHANGHAI AUZONE BIOLOGICAL TECHNOLOGY CO., LTD.,  
AUZONE BIOLOGICAL TECHNOLOGY PRIVATE LTD., AND  
AUZONE BIOLOGICAL TECHNOLOGY (USA) LTD.'S ANSWER, SEPARATE  
DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF  
mitsubishi tanabe pharma corporation's complaint**

Defendants Shanghai Auzone Biological Technology Co., Ltd. (“Shanghai Auzone”), Auzone Biological Technology Private Ltd. (“Australia Auzone”), and Auzone Biological Technology (USA) Ltd. (“US Auzone”) (collectively, “Auzone”), by their undersigned attorneys, answers and responds to the Complaint of Mitsubishi Tanabe Pharma Corporation (“Plaintiff” or “MTPC”) 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”), 11,826,352 (“the ’352 patent”) and 11,957,660 (“the ’660 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.

**ANSWER:** This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Auzone admits that MTPC’s complaint purports to bring an action for patent 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 “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, but Auzone denies that MTPC is entitled to any such relief. Auzone denies the remaining allegations of this paragraph.

2. This action arises from 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 Patents-in-Suit.

**ANSWER:** Auzone admits that Shanghai Auzone filed New Drug Application (“NDA”) No. 219846 with the Food and Drug Administration (“FDA”) under 21 U.S.C. § 355(b) to obtain FDA approval to engage in the commercial manufacture, use, and sale of AUKONTALS, an

edaravone tablet product for the treatment of ALS, before the expiration of the Patents-in-Suit.

Auzone denies the remaining allegations of this paragraph.

### **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.<sup>1</sup>

**ANSWER:** Auzone admits that Amyotrophic lateral sclerosis (“ALS”) is also known as Lou Gehrig’s disease. Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and footnote 1 of this paragraph, therefore, denies those allegations.

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 healthcare industry.

**ANSWER:** Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

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.

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<sup>1</sup> Information in this paragraph sourced from [www.als.org](http://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](https://www.ninds.nih.gov/sites/default/files/migrate-documents/ALS_FactSheet-E_508C.pdf) and downloaded on April 22, 2024.

**ANSWER:** Auzone admits that RADICAVA ORS® has been approved by the FDA for treatment of ALS. Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies those allegations.

**RADICAVA ORS®**

6. MTPC is the holder of 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 edaravone API, available in the United States and marketed and sold under the trade name RADICAVA ORS®.

**ANSWER:** Auzone admits that the Orange Book maintained by the FDA lists the product details for NDA No. 215446, an NDA for RADICAVA ORS (edaravone) 105MG/5ML, including that the active ingredient is edaravone, the proprietary name is RADICAVA ORS, the dosage form is a suspension, the route of administration is oral, the approval date is May 12, 2022, and the current applicant holder's full name is K.K. BCJ-94. Auzone lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in this paragraph and, therefore, denies those allegations.

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.

**ANSWER:** Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

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®.

**ANSWER:** Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

9. On March 28, 2024, the FDA granted seven years of Orphan Drug Exclusivity 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Auzone admits the Orange Book lists that edaravone (RADICAVA ORS) oral suspension 105MG/5ML has orphan drug exclusivity for the treatment of ALS. Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the other allegations of this paragraph and, therefore, denies those allegations.

10. Pursuant to 21 C.F.R. § 316.31 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 such approval.”

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Auzone admits that 21 C.F.R. § 316.31 recites the phrase “for the same drug for the same use or indication before the expiration of 7 years from the date of such approval.” Auzone denies any remaining allegations in this paragraph.

11. The Orphan Drug Exclusivity for RADICAVA ORS® expires on May 12, 2029.

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Auzone admits the Orange Book lists RADICAVA ORS® as having orphan drug exclusivity for the treatment of ALS with an expiration date of May 12, 2029. Auzone denies any remaining allegations in this paragraph.

12. Pursuant to 21 U.S.C. § 355(b)(1)(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®.

**ANSWER:** Auzone admits that the Patents-in-Suit are listed in the Orange Book in connection with NDA No. 215446 for RADICAVA ORS®. The remaining allegations of this paragraph are conclusions of law to which no response is required. To the extent a response is

required, Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity as to whether the Patents-in-Suit are duly and legally listed in the Orange Book and, therefore, denies the same. Auzone denies any remaining allegations in this paragraph.

### **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. 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®.

**ANSWER:** Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

14. 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.

**ANSWER:** Admitted.

15. 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.

**ANSWER:** Admitted. Auzone denies that US Auzone is a proper party to this action.

16. 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.

**ANSWER:** Admitted. Auzone denies that Australia Auzone is a proper party to this action.

17. 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.

**ANSWER:** Denied.

18. 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.

**ANSWER:** Auzone admits that Shanghai Auzone is the holder of 505(b)(2) NDA No. 219846, seeking FDA approval to market AUKONTALS, an edaravone tablet product for the treatment of ALS, relying upon RADICAVA ORS® as the Reference Label Drug ("RLD") and the studies disclosed in NDA No. 215446 for RADICAVA ORS® in seeking abbreviated FDA approval for Shanghai Auzone's 505(b)(2) NDA No. 219846. Auzone denies any remaining allegations in this paragraph.

19. 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.

**ANSWER:** Admitted.

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

**ANSWER:** Denied.

21. 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.

**ANSWER:** Auzone admits that Shanghai Auzone is the holder of NDA No. 219846, which was submitted to FDA under 21 U.S.C. § 355(b) to obtain FDA approval to engage in the commercial manufacture, use, and sale of AUKONTALS, an edaravone tablet product for the treatment of ALS. Auzone denies any remaining allegations in this paragraph.

### **JURISDICTION AND VENUE**

22. MTPC restates, realleges, and incorporates by reference paragraphs 1–21 as if fully set forth herein.

**ANSWER:** Auzone incorporates its responses to paragraphs 1–21 as if fully set forth herein.

23. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Auzone admits that this action cites the patent laws of the United States and the Food and Drug Laws of the United States generally. Auzone denies any remaining allegations in this paragraph.

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

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Auzone does not contest that this Court has jurisdiction over the subject matter of this action for the purposes of this action only. Auzone denies any remaining allegations in this paragraph.

25. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Shanghai Auzone does not contest personal jurisdiction in this Court for purposes of this action only. Auzone admits that Shanghai Auzone is a Chinese company. Auzone denies any remaining allegations in this paragraph.

26. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied. Auzone denies that US Auzone is a proper party to this action.

27. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Auzone admits that Australia Auzone is an Australian company. Auzone denies that Australian Auzone is a proper party to this action. Auzone denies any remaining allegations in this paragraph.

28. 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-in-Suit listed in the Orange Book for RADICAVA ORS®.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Auzone admits that Shanghai Auzone caused NDA No. 219846 to be submitted to the FDA to seek approval of NDA No. 219846 prior to the expiration of the Patents-in-Suit listed in the Orange Book for RADICAVA ORS®, which was 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. Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies those allegations.

29. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Auzone does not contest that this Court has personal jurisdiction over Shanghai Auzone for the purposes of this action only. Auzone denies that US Auzone and Australian Auzone are proper parties to this action. Auzone denies any remaining allegations in this paragraph.

30. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Auzone does not contest that venue is proper for Shanghai Auzone for the purposes of this action only. Auzone denies any remaining allegations in this paragraph.

31. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied. Auzone denies that US Auzone is a proper party to this action.

32. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Auzone does not contest that venue is proper for Australia Auzone for the purposes of this action only. Auzone denies that Australian Auzone is a proper party

to this action. Auzone denies any remaining allegations in this paragraph.

**THE PATENTS-IN-SUIT**

33. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Auzone admits that the '341 patent is titled "Edaravone Suspension for Oral Administration," was issued by the United States Patent and Trademark Office ("USPTO") on April 27, 2021, and lists Mitsubishi Tanabe Pharma Corporation as assignee. Auzone denies that the patent was duly and lawfully issued. Auzone admits that a purported copy of the '341 patent was attached to Plaintiff's Complaint as Exhibit A. Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies the same.

34. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Auzone admits that the '416 patent is titled "Edaravone Suspension for Oral Administration," was issued by the USPTO on February 8, 2022, and lists Mitsubishi Tanabe Pharma Corporation as assignee. Auzone denies that the patent was duly and lawfully issued. Auzone admits that a purported copy of the '416 patent was attached to Plaintiff's Complaint as Exhibit B. Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies the same.

35. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, Auzone admits that the '450 patent is titled "Edaravone Suspension for Oral Administration," was issued by the USPTO on October 25, 2022, and lists Mitsubishi Tanabe Pharma Corporation as assignee. Auzone denies that the patent was duly and lawfully issued. Auzone admits that a purported copy of the '450 patent was attached to Plaintiff's Complaint as Exhibit C. Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies the same.

36. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Auzone admits that the '352 patent is titled "Edaravone Suspension for Oral Administration," was issued by the USPTO on November 28, 2023, and lists Mitsubishi Tanabe Pharma Corporation as assignee. Auzone denies that the patent was duly and lawfully issued. Auzone admits that a purported copy of the '352 patent was attached to Plaintiff's Complaint as Exhibit D. Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies the same.

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

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Auzone admits that the '660 patent is titled "Edaravone Suspension for Oral Administration," was issued by the USPTO on April 16, 2024, and lists Mitsubishi Tanabe Pharma Corporation as assignee. Auzone denies that the patent was duly and lawfully issued. Auzone admits that a purported copy of the '660 patent was attached to Plaintiff's Complaint as Exhibit E. Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies the same.

**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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Auzone admits that Shanghai Auzone submitted to the FDA, and continues to maintain, its abbreviated 505(b)(2) NDA No. 219846 relying upon certain RADICAVA ORS® data for FDA approval. Auzone denies any remaining allegations in this paragraph.

39. On information and belief, Defendants seek approval of 505(b)(2) NDA No. 219846 for a proposed edaravone product containing 90 milligrams (3 x 30 milligram tablets) of edaravone.

**ANSWER:** Auzone admits that Shanghai Auzone seeks approval of 505(b)(2) NDA No. 219846 for a proposed edaravone tablet product containing 30 milligrams edaravone. Auzone denies any remaining allegations in this paragraph.

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

**ANSWER:** Auzone admits that 505(b)(2) NDA No. 219846 identifies RADICAVA ORS® as the RLD. Auzone denies any remaining allegations in this paragraph.

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.

**ANSWER:** Auzone admits that Shanghai Auzone submitted NDA No. 219846 to FDA under 21 U.S.C. § 355(b) to obtain FDA approval to engage in the commercial manufacture, use, and sale of AUKONTALS, an edaravone tablet product for the treatment of ALS. Auzone denies any remaining allegations in this paragraph.

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

**ANSWER:** Auzone admits that as of the date of filing of this Answer, Affirmative

Defenses, and Counterclaims, 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 Patents-in-Suit, and an “Access Offer Letter” offering access to certain portions of NDA No. 219846 for evaluating infringement of the Patents-in-Suit, 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 Patents-in-Suit (“Notice Letter”).

**ANSWER:** Auzone admits that Shanghai Auzone sent MTPC a “Non-Infringement Analysis Report” on March 13, 2025, alleging noninfringement of the Patents-in-Suit, and a “Confidential Access Offer Letter” offering access to certain portions of NDA No. 219846 for the purposes of evaluating possible infringement of the Patents-in-Suit that is the subject of Shanghai Auzone’s Paragraph IV Certification. Auzone admits that Shanghai Auzone intended for the “Non-Infringement Analysis Report” and “Confidential Access Offer Letter” to serve as its Notice Letter of a Paragraph IV certification of the Patents-in-Suit (“Notice Letter”). Auzone denies any remaining allegations in this paragraph.

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

**ANSWER:** Admitted.

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

**ANSWER:** Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

47. MTPC commenced this action within 45 days of receiving Defendants' Notice Letter on March 16, 2025, 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(c)(3)(C).

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Auzone admits that MTPC filed its Complaint on April 25, 2025. Auzone lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies those allegations.

### **CLAIMS FOR RELIEF**

#### **COUNT 1: INFRINGEMENT OF THE '341 PATENT**

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

**ANSWER:** Auzone incorporates its responses to paragraphs 1–47 as if fully set forth herein.

49. 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 '341 patent.

**ANSWER:** Auzone admits Shanghai Auzone submitted 505(b)(2) NDA No. 219846 to the FDA seeking approval of NDA No. 219846 for its proposed edaravone tablet product in the United States prior to the expiration of the '341 patent. Auzone denies any remaining allegations in this paragraph.

50. On information and belief, Defendants' proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '341 patent, including at least Independent Claim 1 of the '341 patent. For example, on information and belief, differences, if any, between the features of Defendants' proposed edaravone product and the claims of the '341 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 '341 patent.

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

51. 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 505(b)(2) NDA No. 219846 with Defendants' Notice Letter, seeking approval of Defendants' proposed edaravone

product prior to the expiration of the '341 patent listed in the FDA Orange Book.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

52. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

53. 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 '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).

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

54. Defendants had actual and constructive notice of the '341 patent prior to filing 505(b)(2) NDA No. 219846, seeking approval of Defendants' proposed edaravone product.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

55. 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 '341 patent or the later expiration of any patent term extension or exclusivity for the '341 patent to which MTPC is or becomes entitled.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

56. 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 '341 patent under 35 U.S.C. §§ 271(a), (b) and (c).

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

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

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

## **COUNT 2: INFRINGEMENT OF THE '416 PATENT**

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

**ANSWER:** Auzone incorporates its responses to paragraphs 1–57 as if fully set forth herein.

59. 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 '416 patent.

**ANSWER:** Auzone admits Shanghai Auzone submitted 505(b)(2) NDA No. 219846 to the FDA seeking approval of NDA No. 219846 for its proposed edaravone tablet product in the United States prior to the expiration of the '416 patent. Auzone denies any remaining allegations in this paragraph.

60. On information and belief, Defendants' proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '416 patent, including at least Independent Claim 1 of the '416 patent. For example, on information and belief, differences, if any, between the features of Defendants' proposed edaravone product and the claims of the '416 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 '416 patent.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

61. 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 505(b)(2) NDA No. 219846 with Defendants' Notice Letter, seeking approval of Defendants' proposed edaravone product prior to the expiration of the '416 patent listed in the FDA Orange Book.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

62. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

63. 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 '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).

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

64. Defendants had actual and constructive notice of the '416 patent prior to filing 505(b)(2) NDA No. 219846, seeking approval of Defendants' proposed edaravone product.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

65. 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 '416 patent or the later expiration of any patent term extension or exclusivity for the '416 patent to which MTPC is or becomes entitled.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

66. 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 '416 patent under 35 U.S.C. §§ 271(a), (b) and (c).

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

67. MTPC will be irreparably harmed if Defendants are not enjoined from Defendants'

activities infringing the '416 patent. MTPC does not have an adequate remedy at law and an award of damages would not make MTPC whole.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

**COUNT 3: INFRINGEMENT OF THE '450 PATENT**

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

**ANSWER:** Auzone incorporates its responses to paragraphs 1–67 as if fully set forth herein.

69. 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 '450 patent.

**ANSWER:** Auzone admits Shanghai Auzone submitted 505(b)(2) NDA No. 219846 to the FDA seeking approval of NDA No. 219846 for its proposed edaravone tablet product in the United States prior to the expiration of the '450 patent. Auzone denies any remaining allegations in this paragraph.

70. On information and belief, Defendants' proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '450 patent, including at least Independent Claim 1 of the '450 patent. For example, on information and belief, differences, if any, between the features of Defendants' proposed edaravone product and the claims of the '450 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 '450 patent.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

71. 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 505(b)(2) NDA No. 219846 with Defendants' Notice Letter, seeking approval of Defendants' proposed edaravone product prior to the expiration of the '450 patent listed in the FDA Orange Book.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

72. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

73. 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 '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).

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

74. Defendants had actual and constructive notice of the '450 patent prior to filing 505(b)(2) NDA No. 219846, seeking approval of Defendants' proposed edaravone product.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

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

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

76. 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 '450 patent under 35 U.S.C. §§ 271(a), (b) and (c).

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

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

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

**COUNT 4: INFRINGEMENT OF THE '352 PATENT**

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

**ANSWER:** Auzone incorporates its responses to paragraphs 1–77 as if fully set forth herein.

79. 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 '352 patent.

**ANSWER:** Auzone admits Shanghai Auzone submitted 505(b)(2) NDA No. 219846 to the FDA seeking approval of NDA No. 219846 for its proposed edaravone tablet product in the United States prior to the expiration of the '352 patent. Auzone denies any remaining allegations in this paragraph.

80. On information and belief, Defendants' proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '352 patent, including at least Independent Claim 1 of the '352 patent. For example, on information and belief, differences, if any, between the features of Defendants' proposed edaravone product and the claims of the '352 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 '352 patent.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

81. 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 505(b)(2) NDA No 219846 with Defendants' Notice Letter, seeking approval of Defendants' proposed edaravone product prior to the expiration of the '352 patent listed in the FDA Orange Book.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

82. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

83. 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 '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).

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

84. Defendants had actual and constructive notice of the '352 patent prior to filing 505(b)(2) NDA No. 219846, seeking approval of Defendants' proposed edaravone product.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

85. 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 '352 patent or the later expiration of any patent term extension or exclusivity for the '352 patent to which MTPC is or becomes entitled.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

86. 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 '352 patent under 35 U.S.C. §§ 271(a), (b) and (c).

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

87. MTPC will be irreparably harmed if Defendants are not enjoined from Defendants' activities infringing the '352 patent. MTPC does not have an adequate remedy at law and an award of damages would not make MTPC whole.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

**COUNT 5: INFRINGEMENT OF THE '660 PATENT**

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

**ANSWER:** Auzone incorporates its responses to paragraphs 1–87 as if fully set forth herein.

89. 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 '660 patent.

**ANSWER:** Auzone admits Shanghai Auzone submitted 505(b)(2) NDA No. 219846 to the FDA seeking approval of NDA No. 219846 for its proposed edaravone tablet product in the United States prior to the expiration of the '660 patent. Auzone denies any remaining allegations in this paragraph.

90. On information and belief, Defendants' proposed edaravone product infringes, literally and/or under the doctrine of equivalents, one or more claims of the '660 patent, including at least Independent Claim 1 of the '660 patent. For example, on information and belief, differences, if any, between the features of Defendants' proposed edaravone product and the claims of the '660 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 '660 patent.

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

91. 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 '660 patent by submitting 505(b)(2) NDA No. 219846 with Defendants' Notice Letter, seeking approval of Defendants' proposed edaravone product prior to the expiration of the '660 patent listed in the FDA Orange Book.

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

92. 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.

**ANSWER:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

93. 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 '660 patent will infringe, literally and/or under the doctrine of equivalents, one or more claims of the '660 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

94. Defendants had actual and constructive notice of the '660 patent prior to filing 505(b)(2) NDA No. 219846, seeking approval of Defendants' proposed edaravone product.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

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 505(b)(2) NDA No. 219846 be a date that is not earlier than the expiration date of the '660 patent or the later expiration of any patent term extension or exclusivity for the '660 patent to which MTPC is or becomes entitled.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

96. 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 '660 patent under 35 U.S.C. §§ 271(a), (b) and (c).

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

97. MTPC will be irreparably harmed if Defendants are not enjoined from Defendants' activities infringing the '660 patent. MTPC does not have an adequate remedy at law and an award of damages would not make MTPC whole.

**ANSWER:** This paragraph contains conclusions of law for which no response is required.

To the extent a response is required, denied.

**PRAYER FOR RELIEF**

Auzone denies that MTPC is entitled to any remedy or relief.

**GENERAL DENIAL**

Auzone denies all remaining allegations not specifically admitted herein. Auzone further denies that MTPC is entitled to any judgment or relief requested in the Complaint, or to any relief whatsoever.

**SEPARATE DEFENSES**

Without any admissions as to the burden of proof, burden of persuasion, or the truth of any allegations in Plaintiff's complaint, Auzone states the following defenses:

**First Separate Defense**

The filing of Shanghai Auzone's NDA No. 219846 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of any of the Patents-in-Suit. By way of example, Shanghai Auzone's proposed products that are the subject of NDA No. 219846 are edaravone tablets, not the claimed edaravone oral suspension.

**Second Separate Defense**

The manufacture, use, sale, offer for sale, or importation of edaravone tablets (30 mg) that are the subject of NDA No. 219846 has not, does not, and would not infringe, directly or indirectly, any valid and enforceable claim of any of the Patents-in-Suit, either literally or under the doctrine of equivalents.

**Third Separate Defense**

The claims of the Patents-in-Suit are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

**Fourth Separate Defense**

MTPC's complaint fails to state a claim upon which relief may be granted. By way of example, Auzone does not infringe, as a matter of law, any claim of the Patents-in-Suit because Shanghai Auzone does seek authorization from the FDA to market the oral suspension form of edaravone.

**Fifth Separate Defense**

Auzone's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

**Sixth Separate Defense**

Auzone has not willfully infringed any claim of the Patents-in-Suit.

**Seventh Separate Defense**

MTPC is estopped from asserting infringement, including infringement under the doctrine of equivalents, by the doctrine of prosecution history estoppel, the disclosure-dedication rule, judicial estoppel, and/or other equitable doctrines.

**Eight Separate Defense**

MTPC's assertion of Patents-in-Suit covering edaravone oral suspension against Auzone for seeking to market edaravone tablets, such that MTPC seeks to enjoin Auzone's market entry entirely, constitutes patent misuse, and therefore MTPC cannot enforce its patents in this context.

**Ninth Separate Defense**

Any additional defenses or counterclaims that discovery may reveal.

WHEREFORE, Auzone requests that MTPC's Complaint be dismissed with prejudice and that Auzone be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

**SHANGHAI AUZONE BIOLOGICAL TECHNOLOGY CO., LTD., AUZONE  
BIOLOGICAL TECHNOLOGY PRIVATE LTD., AND AUZONE BIOLOGICAL  
TECHNOLOGY (USA) LTD.'S COUNTERCLAIMS**

Defendants Shanghai Auzone Biological Technology Co., Ltd. (“Shanghai Auzone”), Auzone Biological Technology Private Ltd. (“Australia Auzone”), and Auzone Biological Technology (USA) Ltd. (“US Auzone”) (collectively, “Auzone”), by way of Counterclaim against Plaintiff Mitsubishi Tanabe Pharma Corporation (“Plaintiff” or “MTPC”), states as follows:

**PARTIES**

1. On information and belief, 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.

2. 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.

3. 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.

4. Australia Auzone is a company organized under the laws of Australia, with a principal place of business in 17 Bungowen Ave, Thornleigh, NSW, Australia 2120.

**NATURE OF THE ACTION**

6. Auzone seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that 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 “Patents-in-Suit”) are invalid and/or not infringed.

### **JURISDICTION AND VENUE**

7. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over MTPC on the basis of, *inter alia*, its contacts with New Jersey relating to the subject matter of this action, including having filed its suit here.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by MTPC's choice of forum.

10. There is an actual and justiciable controversy between the parties as to the noninfringement and invalidity of the Patents-in-Suit.

### **BACKGROUND**

#### **A. FDA Approval of New Brand Name Drugs**

11. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), Pub. L. No. 75-717, 52 Stat. 1040, codified at 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

12. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

13. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

14. Upon approval of the NDA, the FDA publishes patent information for the approved

drug in “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” *See* 21 C.F.R. § 314.53(e).

**B. FDA Approval of New Drugs**

15. Applications covered by Section 505(b)(2) of the FDCA (“505(b)(2) applications”) (codified as amended at 21 U.S.C. § 355(b)(2)) are NDAs that contain full reports of safety and effectiveness evaluations, where at least some of the information in the application comes from studies that are not conducted on behalf of the NDA applicant. *See* 21 U.S.C. § 355(b)(2); *see also* <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/abbreviated-approval-pathways-drug-product-505b2-or-anda-september-19-2019-issue>.

505(b)(2) applications are submitted under Section 505(b)(2) of the FDCA. 21 U.S.C. § 355(b)(2).

16. Among other things, a 505(b)(2) application must contain a “certification” to each patent that an existing NDA holder has submitted to the FDA for listing in the FDA’s Orange Book in connection with the reference listed drug.

17. One such certification is called a “Paragraph IV” certification, which asserts that the Orange Book listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(b)(2)(A)(iv); *see also* 21 C.F.R. § 314.50(i)(1)(i)(A)(4).

18. An applicant submitting a 505(b)(2) application containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(b)(3).

19. Upon receiving notice of the Paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(c)(3)(C); 35 U.S.C. § 271(e)(2)(A).

**C. Shanghai Auzone's NDA and MTPC's Patents**

20. Shanghai Auzone submitted New Drug Application ("NDA") No. 219846 ("Shanghai Auzone's NDA") under 21 U.S.C. § 355(b) to obtain FDA approval to engage in the commercial manufacture, use, and sale of AUKONTALS, an edaravone tablet product for the treatment of ALS ("Shanghai Auzone's Proposed NDA Product").

21. On information and belief, MTPC was the original applicant holder of approved NDA No. 215446 for RADICAVA ORS®, an oral suspension formulation containing edaravone as the active ingredient.

22. On information and belief, K.K. BCJ-94 is the current applicant holder of approved NDA No. 215446 for RADICAVA ORS®, an oral suspension formulation containing edaravone as the active ingredient.

23. On information and belief, the holder of the RADICAVA ORS® NDA caused 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 "Patents-in-Suit") to be listed in the Orange Book, as patents that purportedly claim the drug listed in, and/or purportedly claim a method of using the drug for which MTPC submitted NDA No. 215446.

24. The '341 patent, titled "Edaravone Suspension for Oral Administration," issued on April 27, 2021.

25. Upon information and belief, MTPC is the assignee of the '341 patent.

26. The '416 patent, titled "Edaravone Suspension for Oral Administration," issued on February 8, 2022.

27. Upon information and belief, MTPC is the assignee of the '416 patent.

28. The '450 patent, titled "Edaravone Suspension for Oral Administration," issued on

October 25, 2022.

29. Upon information and belief, MTPC is the assignee of the '450 patent.

30. The '352 patent, titled "Edaravone Suspension for Oral Administration," issued on November 28, 2023.

31. Upon information and belief, MTPC is the assignee of the '352 patent.

32. The '660 patent, titled "Edaravone Suspension for Oral Administration," issued on April 16, 2024.

33. Upon information and belief, MTPC is the assignee of the '660 patent.

34. Shanghai Auzone does not seek permission from the FDA through its NDA to market an edaravone oral suspension.

35. As described in its NDA, Shanghai Auzone's Proposed NDA Product is not an edaravone oral suspension.

**D. Shanghai Auzone's Paragraph IV Certifications and Notice Letter**

36. Shanghai Auzone's NDA contains "Paragraph IV" certifications under 21 U.S.C. § 355(b)(2)(A)(iv) directed to the Patents-in-Suit.

37. On March 13, 2025, Shanghai Auzone sent MTPC a "Non-Infringement Analysis Report" alleging at least noninfringement of the Patents-in-Suit, and a "Confidential Access Offer Letter" offering access to certain portions of NDA No. 219846.

38. Shanghai Auzone intended for the "Non-Infringement Analysis Report" and "Confidential Access Offer Letter" to serve as its Notice Letter of a Paragraph IV certification of the Patents-in-Suit ("Shanghai Auzone's Notice Letter") pursuant to 21 U.S.C. § 355(b)(3). Shanghai Auzone's Notice Letter asserted that the claims of the Patents-in-Suit will not be infringed by Shanghai Auzone's NDA or the products or activities described therein.

39. Upon information and belief, based upon the allegations in paragraphs 28 and 47

of MTPC's Complaint, MTPC received Shanghai Auzone's Notice Letter on March 16, 2025.

40. Shanghai Auzone's Non-Infringement Analysis Report set forth Shanghai Auzone's detailed factual and legal basis supporting its Paragraph IV Certifications.

41. Shanghai Auzone's Non-Infringement Analysis Report stated, at p. 1, "Edaravone Tablets (AUKONTALS, Manufactured by SHANGHAI AUZONE BIOLOGICAL TECHNOLOGY CO., LTD.), hereinafter also referred to as 'Applicant's product' 30 mg, are an oral solid dosage form manufactured without formulation overage." (emphasis omitted).

42. Shanghai Auzone's Non-Infringement Analysis Report stated, at p. 2, "U.S. Patent No. 10,987,341 protects an Edaravone suspension for oral administration. This patent includes four (4) independent claims: Claims 1, 17, 18, and 20." (emphasis omitted).

43. Shanghai Auzone's Non-Infringement Analysis Report stated, at p. 4, "Claim 1 of the Subject Patent is directed to an edaravone suspension, whereas the Applicant's product is formulated as a tablet. Given the distinct dosage forms, the technical features set forth in Claim 1 materially differ from those of the Applicant's product. Accordingly, the Applicant's product does not fall within the scope of Claim 1 of the Subject Patent."

44. Shanghai Auzone's Non-Infringement Analysis Report also stated, at pp. 4-5, "[i]ndependent claims 17 and 18 are also directed to an edaravone suspension," and "Claim 20 [of the '341 patent] protects an edaravone suspension for an ALS therapeutic agent, with dosing defined in a liquid form (1–20 mL containing 50–210 mg of edaravone)."

45. Shanghai Auzone's Non-Infringement Analysis Report explained, at p. 5, "[i]n contrast, the product is an oral tablet, which does not embody the liquid suspension nor its associated dosing parameters. As such, the tablet falls outside the literal scope—and is not equivalent—to the claimed edaravone suspension."

46. Shanghai Auzone's Non-Infringement Analysis Report stated, at p. 5, "U.S. Patent

No. 11,241,416 protects an Edaravone suspension for oral administration. This patent includes two (2) independent claims: Claims 1 and 14.” (emphasis omitted).

47. Shanghai Auzone’s Non-Infringement Analysis Report stated, at p. 7, “Claim 1 of the Subject Patent is directed to an edaravone suspension, whereas the Applicant’s product is formulated as a tablet. Given the distinct dosage forms, the technical features set forth in Claim 1 materially differ from those of the Applicant’s product. Accordingly, the Applicant’s product does not fall within the scope of Claim 1 of the Subject Patent.”

48. Shanghai Auzone’s Non-Infringement Analysis Report also explained, at p. 7, “[l]ikewise, Independent Claims 14 is also directed to an edaravone suspension. As the Applicant’s product is a tablet formulation, it similarly does not fall within the scope of Claim 14.”

49. Shanghai Auzone’s Non-Infringement Analysis Report stated, at pp. 7-8, “U.S. Patent No. 11,478,450 protects treating amyotrophic lateral sclerosis by orally administering an edaravone suspension—comprising water, edaravone particles dispersed and maintained in a solid state by a dispersant—in specified dosages to achieve targeted plasma concentration level. This patent includes one (1) independent claim.” (emphasis omitted).

50. Shanghai Auzone’s Non-Infringement Analysis Report further stated, at p. 8, “[t]he method claim relates to a method for treating ALS, but explicitly requires the oral formulation to be an edaravone suspension, comprising water, wherein edaravone particles are dispersed in the water, and a dispersant is present to maintain the particles in a solid state within that suspension.”

51. Shanghai Auzone’s Non-Infringement Analysis Report explained, at p. 8, “[i]n contrast, the Applicant’s method is also a method for treating ALS, but involves a solid oral tablet, which does not include water, or the required suspension vehicle or dispersant. The formulation differences are fundamental.”

52. Shanghai Auzone’s Non-Infringement Analysis Report stated, at p. 9, “U.S. Patent

No. 11,826,352 protects an Edaravone suspension for oral administration. This patent includes two (2) independent claims: Claims 1 and 24.” (emphasis omitted).

53. Shanghai Auzone’s Non-Infringement Analysis Report explained, at p. 10, “Claim 1 of the Subject Patent is directed to an edaravone suspension, whereas the Applicant’s product is formulated as a tablet. Given the distinct dosage forms, the technical features set forth in Claim 1 materially differ from those of the Applicant’s product. Accordingly, the Applicant’s product does not fall within the scope of Claim 1 of the Subject Patent.”

54. Shanghai Auzone’s Non-Infringement Analysis Report also explained, at p. 11, “Claim 24 protects an edaravone suspension for an ALS therapeutic agent, with dosing defined in a liquid form (1–20 mL containing 50–210 mg of edaravone). In contrast, the Applicant’s product is an oral tablet, which does not embody the liquid suspension nor its associated dosing parameters. As such, the tablet falls outside the literal scope—and is not equivalent—to the claimed edaravone suspension.”

55. Shanghai Auzone’s Non-Infringement Analysis Report stated, at p. 11, “U.S. Patent No. 11,957,660 protects an Edaravone suspension for oral administration. This patent includes two (2) independent claims: Claims 1 and 2[0].” (emphasis omitted).

56. Shanghai Auzone’s Non-Infringement Analysis Report explained, at p. 13, “Claim 1 of the Subject Patent is directed to an edaravone suspension, whereas the Applicant’s product is formulated as a tablet. Given the distinct dosage forms, the technical features set forth in Claim 1 materially differ from those of the Applicant’s product. Accordingly, the Applicant’s product does not fall within the scope of Claim 1 of the Subject Patent.”

57. Shanghai Auzone’s Non-Infringement Analysis Report also explained, at p. 13, “Claim 20 protects an ALS therapeutic agent comprising a drug product that includes edaravone and a thickening agent, with dosing defined in a liquid form (1–20 mL containing 50–210 mg of

edaravone). That is, the claim is directed to a liquid formulation that incorporates a thickening agent to achieve a specific suspension, with dosing parameters defined in milliliters. In contrast, Applicant's product as a tablet does not embody these critical features: it is not administered as a liquid dose, it lacks the requisite thickening agent, and its formulation does not conform to the dosing specifications outlined in the claim. Consequently, the Applicant's product falls outside the literal scope of the claim, and the significant differences in formulation preclude a finding of equivalence."

58. MTPC received access to certain redacted portions of NDA No. 219846 on April 22, 2025.

59. On April 25, 2025, MTPC filed the present lawsuit alleging infringement of the Patents-in-Suit.

60. Before MTPC filed its lawsuit, Shanghai Auzone had stated to MTPC that Shanghai Auzone's Proposed NDA Product was formulated as a tablet. For instance, before MTPC filed its lawsuit, Shanghai Auzone had represented to MTPC at least by Shanghai Auzone's Non-Infringement Analysis Report that Shanghai Auzone's Proposed NDA Product was a "tablet" rather than a "suspension" form of edaravone.

61. There has been and now is an actual and justiciable controversy between Auzone and MTPC as to whether Shanghai Auzone's Proposed NDA Product infringes, induces infringement, or contributes to the infringement of any valid and enforceable claim of the Patents-in-Suit.

**COUNT I: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '341 PATENT**

62. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

63. There is an actual, substantial, continuing, and justiciable controversy between MTPC and Auzone regarding whether the claims of the '341 patent are invalid.

64. Auzone is entitled to a declaration that all claims of the '341 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

**COUNT II: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '416 PATENT**

65. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

66. There is an actual, substantial, continuing, and justiciable controversy between MTPC and Auzone regarding whether the claims of the '416 patent are invalid.

67. Auzone is entitled to a declaration that all claims of the '416 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

**COUNT III: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '450 PATENT**

68. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

69. There is an actual, substantial, continuing, and justiciable controversy between MTPC and Auzone regarding whether the claims of the '450 patent are invalid.

70. Auzone is entitled to a declaration that all claims of the '450 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

**COUNT IV: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '352 PATENT**

71. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

72. There is an actual, substantial, continuing, and justiciable controversy between MTPC and Auzone regarding whether the claims of the '352 patent are invalid.

73. Auzone is entitled to a declaration that all claims of the '352 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

**COUNT V: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '660 PATENT**

74. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

75. There is an actual, substantial, continuing, and justiciable controversy between MTPC and Auzone regarding whether the claims of the '660 patent are invalid.

76. Auzone is entitled to a declaration that all claims of the '660 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

**COUNT VI: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '341 PATENT**

77. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

78. MTPC asserts that MTPC is the owner of all legal rights, title, and interests in the '341 patent, including the right to enforce the '341 patent. MTPC has asserted its alleged rights against Auzone by filing an infringement action.

79. Shanghai Auzone's Proposed NDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '341 patent.

80. Unless MTPC is enjoined, Auzone believes that MTPC will continue to assert that Shanghai Auzone's Proposed NDA Product is infringing the claims of the '341 patent and will continue to interfere with Shanghai Auzone's Proposed NDA Product.

81. Auzone will be irreparably harmed if MTPC is not enjoined from continuing to assert the '341 patent against Shanghai Auzone's Proposed NDA Product.

82. A definite and concrete, real and substantial, justiciable controversy exists between Auzone and MTPC concerning non-infringement of the '341 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

83. Auzone is entitled to a declaratory judgment that Shanghai Auzone's Proposed NDA Product has not infringed, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '341 patent.

**COUNT VII: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '416 PATENT**

84. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

85. MTPC asserts that MTPC is the owner of all legal rights, title, and interests in the '416 patent, including the right to enforce the '416 patent. MTPC has asserted its alleged rights against Auzone by filing an infringement action.

86. Shanghai Auzone's Proposed NDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '416 patent.

87. Unless MTPC is enjoined, Auzone believes that MTPC will continue to assert that Shanghai Auzone's Proposed NDA Product is infringing the claims of the '416 patent and will continue to interfere with Shanghai Auzone's Proposed NDA Product.

88. Auzone will be irreparably harmed if MTPC is not enjoined from continuing to assert the '416 patent against Shanghai Auzone's Proposed NDA Product.

89. A definite and concrete, real and substantial, justiciable controversy exists between Auzone and MTPC concerning non-infringement of the '416 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

90. Auzone is entitled to a declaratory judgment that Shanghai Auzone's Proposed NDA Product has not infringed, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '416 patent.

**COUNT VIII: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '450 PATENT**

91. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

92. MTPC asserts that MTPC is the owner of all legal rights, title, and interests in the '450 patent, including the right to enforce the '450 patent. MTPC has asserted its alleged rights against Auzone by filing an infringement action.

93. Shanghai Auzone's Proposed NDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '450 patent.

94. Unless MTPC is enjoined, Auzone believes that MTPC will continue to assert that Shanghai Auzone's Proposed NDA Product is infringing the claims of the '450 patent and will continue to interfere with Shanghai Auzone's Proposed NDA Product.

95. Auzone will be irreparably harmed if MTPC is not enjoined from continuing to assert the '450 patent against Shanghai Auzone's Proposed NDA Product.

96. A definite and concrete, real and substantial, justiciable controversy exists between Auzone and MTPC concerning non-infringement of the '450 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

97. Auzone is entitled to a declaratory judgment that Shanghai Auzone's Proposed NDA Product has not infringed, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '450 patent.

**COUNT IX: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '352 PATENT**

98. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

99. MTPC asserts that MTPC is the owner of all legal rights, title, and interests in the '352 patent, including the right to enforce the '352 patent. MTPC has asserted its alleged rights against Auzone by filing an infringement action.

100. Shanghai Auzone's Proposed NDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '352 patent.

101. Unless MTPC is enjoined, Auzone believes that MTPC will continue to assert that Shanghai Auzone's Proposed NDA Product is infringing the claims of the '352 patent and will continue to interfere with Shanghai Auzone's Proposed NDA Product.

102. Auzone will be irreparably harmed if MTPC is not enjoined from continuing to assert the '352 patent against Shanghai Auzone's Proposed NDA Product.

103. A definite and concrete, real and substantial, justiciable controversy exists between

Auzone and MTPC concerning non-infringement of the '352 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

104. Auzone is entitled to a declaratory judgment that Shanghai Auzone's Proposed NDA Product has not infringed, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '352 patent.

**COUNT X: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '660 PATENT**

105. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

106. MTPC asserts that MTPC is the owner of all legal rights, title, and interests in the '660 patent, including the right to enforce the '660 patent. MTPC has asserted its alleged rights against Auzone by filing an infringement action.

107. Shanghai Auzone's Proposed NDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '660 patent.

108. Unless MTPC is enjoined, Auzone believes that MTPC will continue to assert that Shanghai Auzone's Proposed NDA Product is infringing the claims of the '660 patent and will continue to interfere with Shanghai Auzone's Proposed NDA Product.

109. Auzone will be irreparably harmed if MTPC is not enjoined from continuing to assert the '660 patent against Shanghai Auzone's Proposed NDA Product.

110. A definite and concrete, real and substantial, justiciable controversy exists between Auzone and MTPC concerning non-infringement of the '660 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

111. Auzone is entitled to a declaratory judgment that Shanghai Auzone's Proposed

NDA Product has not infringed, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '660 patent.

**COUNT XI: DECLARATORY JUDGMENT OF  
NO INJUNCTIVE REMEDY FOR THE '341 PATENT**

112. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

113. MTPC will not in fact experience any harm from any sales of Shanghai Auzone's Proposed NDA Product that have a nexus to the '341 patent claims.

114. MTPC cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages, even if infringement of a valid and enforceable patent were presumed.

115. MTPC's assertion of the '341 patent covering an edaravone suspension for oral administration against Auzone for seeking to market an edaravone tablet, such that MTPC seeks to enjoin such marketing entirely, constitutes patent misuse, and therefore MTPC cannot enforce its patent in this context.

116. MTPC is not entitled to any injunctive remedy of any kind.

**COUNT XII: DECLARATORY JUDGMENT OF  
NO INJUNCTIVE REMEDY FOR THE '416 PATENT**

117. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

118. MTPC will not in fact experience any harm from any sales of Shanghai Auzone's Proposed NDA Product that have a nexus to the '416 patent claims.

119. MTPC cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages, even if infringement of a valid and enforceable patent were presumed.

120. MTPC's assertion of the '416 patent covering an edaravone suspension for oral administration against Auzone for seeking to market an edaravone tablet, such that MTPC seeks to enjoin such marketing entirely, constitutes patent misuse, and therefore MTPC cannot enforce its patent in this context.

121. MTPC is not entitled to any injunctive remedy of any kind.

**COUNT XIII: DECLARATORY JUDGMENT OF  
NO INJUNCTIVE REMEDY FOR THE '450 PATENT**

122. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

123. MTPC will not in fact experience any harm from any sales of Shanghai Auzone's Proposed NDA Product that have a nexus to the '450 patent claims.

124. MTPC cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages, even if infringement of a valid and enforceable patent were presumed.

125. MTPC's assertion of the '450 patent covering treating amyotrophic lateral sclerosis by orally administering an edaravone suspension against Auzone for seeking to market an edaravone tablet, such that MTPC seeks to enjoin such marketing entirely, constitutes patent misuse, and therefore MTPC cannot enforce its patent in this context.

126. MTPC is not entitled to any injunctive remedy of any kind.

**COUNT XIV: DECLARATORY JUDGMENT OF  
NO INJUNCTIVE REMEDY FOR THE '352 PATENT**

127. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

128. MTPC will not in fact experience any harm from any sales of Shanghai Auzone's Proposed NDA Product that have a nexus to the '352 patent claims.

129. MTPC cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages, even if infringement of a valid and enforceable patent were presumed.

130. MTPC's assertion of the '352 patent covering an edaravone suspension for oral administration against Auzone for seeking to market an edaravone tablet, such that MTPC seeks to enjoin such marketing entirely, constitutes patent misuse, and therefore MTPC cannot enforce its patent in this context.

131. MTPC is not entitled to any injunctive remedy of any kind.

**COUNT XV: DECLARATORY JUDGMENT OF  
NO INJUNCTIVE REMEDY FOR THE '660 PATENT**

132. Auzone incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

133. MTPC will not in fact experience any harm from any sales of Shanghai Auzone's Proposed NDA Product that have a nexus to the '660 patent claims.

134. MTPC cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages, even if infringement of a valid and enforceable patent were presumed.

135. MTPC's assertion of the '660 patent covering an edaravone suspension for oral administration against Auzone for seeking to market an edaravone tablet, such that MTPC seeks to enjoin such marketing entirely, constitutes patent misuse, and therefore MTPC cannot enforce its patent in this context.

136. MTPC is not entitled to any injunctive remedy of any kind.

**PRAYER FOR RELIEF**

WHEREFORE, Auzone requests that the Court enter judgment in its favor and against MTPC as follows:

- a. Dismissing the Complaint with prejudice and denying each and every prayer for relief contained therein;
- b. Declaring that the claims of the '341, '416, '450, '352, and '660 patents are invalid and/or unenforceable;
- c. Declaring that Shanghai Auzone's Proposed NDA Product does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '341, '416, '450, '352, and '660 patents;
- d. Declaring that MTPC is not entitled to any injunctive remedy for the '341, '416, '450, '352, and '660 patents;
- e. Enjoining MTPC, and its officers, employees, agents, representatives, attorneys and others acting on its behalf, from representing to anyone, either directly or indirectly, that Shanghai Auzone's Proposed NDA Product has infringed, is infringing or will infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '341, '416, '450, '352, and '660 patents;
- f. Awarding Auzone its costs and expenses in this action;
- g. Declaring this an exceptional case in favor of Auzone and awarding Auzone its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and
- h. Awarding such other and further relief as this Court deems just and proper.

Dated: October 15, 2025

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and Auzone Biological Technology  
Private Ltd.*

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: October 15, 2025

*s/ Gregory D. Miller*  
Gregory D. Miller

**LOCAL CIVIL RULE 201.1 CERTIFICATION**

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, injunctive and declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: October 15, 2025

*s/ Gregory D. Miller*  
Gregory D. Miller

**CERTIFICATE OF SERVICE**

I hereby certify that, on October 15, 2025 the foregoing document described as **DEFENDANTS SHANGHAI AUZONE BIOLOGICAL TECHNOLOGY CO., LTD., AUZONE BIOLOGICAL TECHNOLOGY PRIVATE LTD., AND AUZONE BIOLOGICAL TECHNOLOGY (USA) LTD.’S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF MITSUBISHI TANABE PHARMA CORPORATION’S COMPLAINT** was served on all counsel of record via electronic mail.

*s/ Gregory D. Miller*  
Gregory D. Miller