UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

CIVIL DIVISION

CASE NO.: 2:23-CV-120

ADAM DISARRO, an Individual

Plaintiff,

v.

EZRICARE LLC, a New Jersey Limited Liability Company; EZRIRX LLC, a Delaware Limited Liability Company; DELSAM PHARMA LLC, a New York Limited Liability Company; ARU PHARMA INC, a New York corporation and AMAZON.COM INC., a Washington Corporation,

Defendants.

COMPLAINT

Introduction

Plaintiff, ADAM DISARRO, ("Plaintiff"), by and through his attorneys of record, Robert N. Harris, Esq. and Lisa A. Difilippo, Esq., hereby sues Defendants, EZRICARE LLC, EZRIRX LLC, DELSAM PHARMA LLC, ARU PHARMA INC, and AMAZON.COM INC. (collectively "Defendants"), state and allege as follows:

Jurisdiction and Parties

1. This Court has jurisdiction over the subject matter of this action pursuant to 28 USC § 1332(a) because the matter in controversy exceeds Seventy-Five Thousand Dollars 00/100 ($75,000.00), exclusive of costs and it is between citizens of different states (including Florida, New York, New Jersey, Washington and Delaware).

2. Plaintiff brings this lawsuit pursuant to diversity jurisdiction, 28 USC 1332 (a).

3. Plaintiff, ADAM DISARRO, is a natural person, *sui juris*, who is a resident of the State of Florida and resides in Collier County, Florida.

4. Defendant, EzriCare LLC ("EzriCare") is, at all times material hereto, a limited liability company registered in the State of New Jersey, with its principal place of business located at 1525 Prospect Street, Suite 204, Lakewood, NJ 08701. EzriCare is engaged in the business of manufacturing, labeling, packaging, importing, selling, distributing, advertising and/or marketing artificial tears products throughout the United States, including the State of Florida.

5. Defendant, EzriRx LLC ("EzriRx") is, at all times material hereto, a limited liability company registered in the State of New Jersey, with its principal place of business located at 1525 Prospect Street, Suite 204, Lakewood, NJ 08701. EzriRx is engaged in the business of manufacturing, labeling, packaging, importing, selling, distributing, advertising and /or marketing artificial tears products throughout the United States, including the State of Florida.

6. Defendant, DELSAM PHARMA LLC ("Delsam") is, at all times material hereto, a New York Limited Liability Company with its principal place of business located in Bronx, New York 10567, and process may be served upon its registered agent, Kuppusamy Arumugam at 925 Protano Lane, Mamaroneck, New York, 10543. Delsam markets, advertises, labels, distributes, and sells the artificial tear product(s) throughout the United States, including the State of Florida.

7. Defendant, Aru Pharma Inc. ("Aru") is a corporation organized, incorporated, and existing under the laws of the State of New York with its principal place of business located at 925 Protano Lane, Mamaroneck, NY 10543 and/or 696 Locust Street, Mount Vernon, NY 10552, both in Westchester County, New York. Aru is engaged in the business of importing, selling, supplying, distributing, packaging, and marketing artificial tears products throughout the United States, including the State of Florida.

8. Defendant, AMAZON.com Inc. ("Amazon"), is a worldwide seller and distributor of products. Amazon is a Washington corporation with its principle place of business located at 410 Terry Avenue North, Seattle, WA 98109. Amazon regularly does business in Florida either through its stores, distribution centers, online, or the many wholly owned subsidiaries and affiliated corporations and entities it controls. Amazon has sufficient contacts with the State of Florida by regularly selling and distributing products in Florida, including artificial tears, and by serving a market for artificial tears in Florida. Amazon, sold, distributed, advertised, and/or marketed the artificial tears which are the subject of this litigation. Amazon's contacts with Florida are sufficient that Amazon should reasonably expect to be brought into court in Florida. Amazon may be served with process through its registered agent Amazon.com, Inc. Corporation Service Company 300 Deschutes Way SW, Suite 208 MC-CSC1Tumwater, WA 98501.

9. This Court has specific personal jurisdiction over EzriCare, EzriRx, Delsam and Amazon, because they committed a tort in whole or in part in Florida. Specifically, EzriCare, EzriRx, Delsam and Amazon sold, supplied, distributed, shipped, advertised, and/or marketing

artificial tears to Florida residents and/or Florida businesses, including the artificial tears that caused harm and damages to Plaintiff.

10. This court has general personal jurisdiction over Aru because they committed a tort, in whole or in part, in Florida. Specifically, these Defendants sold, supplied, distributed, shipped, advertised and/or marketed supplied, including the artificial tears that caused damages to Plaintiff.

11. Furthermore, this Court has jurisdiction over Defendants because each was authorized to conduct and do business in the State of Florida.

12. This Court has jurisdiction over these Defendants because each engages in substantial, continuous and has substantial contacts with the State of Florida, purposefully having their activities in Florida, including the placement of their goods into the stream of commerce in Florida with the intention of having consumers here buy their products. This litigation arises out of those activities.

13. Venue is proper in the Middle District of Florida pursuant to 28 USC 1391 (a) and (b) because a substantial part of the events giving rise to the causes of action stated herein arose in this judicial district and because the Defendants were, at all times material hereto, subject to the personal jurisdiction of this court.

FACTS

14. Plaintiff is a citizen and resident of Florida, and at all times material hereto, has been a resident of Collier County. Plaintiff, at all times material hereto, is a first responder employed as a Fire Department Captain/EMT in Naples, Florida, where he has been employed for 21 years, 18 of which have been a Fire Officer for his District.

15. Plaintiff purchased a two (2) pack of EzriCare Artificial Tears on May 12, 2022 from Amazon and again purchased one (2) pack on September 12th, 2022 from Amazon, to assist him with a common condition known as dry eyes.

16. During that time, Plaintiff was unaware that the Defendants' Artificial Tear products were adulterated and contaminated with *Pseudomonas Aeruginosa*, a dangerous and inherently harmful bacteria.

17. Plaintiff utilized Artificial Tears purchased by and through Amazon and shortly thereafter, began experiencing grave complications which included, but were not limited to, irritation, swelling, extreme pain and discomfort in the eyes and skull, sensitivity to light, sensitivity to touch, blurred vision, and ultimately blindness in his left eye.

18. After the pain persisted and worsened to an unbearable state, Plaintiff was referred to Bascom Palmer Emergency Room in Miami, Florida on or about October 4, 2022. There, Plaintiff met with eye specialists who obtained cultures, provided fortified drops (including *Tobramycin* and *Vancomycin*) and ultimately identified his condition to be caused by *Pseudomonas Aeruginosa*. This bacterium is known to be antibiotic resistant making more difficult to threat[1].

19. Plaintiff underwent days of intense medical treatment. During this time, if not in transport to medical professions between Naples and Miami, Florida, he was confined to his bed where he laid in complete darkness, as any exposure to light would cause unbearable pain and discomfort.

20. On or about October 14, 2022, after weeks of intense sensitivity and extreme pain and discomfort, Plaintiff underwent experimental light therapy in conjunction with very aggressive treatment of fortified eye drops, which ultimately led to successfully defeating the *Pseudomonas Aeruginosa* in his left eye.

21. Plaintiff had three (3) of the four (4) bottles of the EzriCare Artificial Tears which were (and remain) in his possession tested at the Bascom-Palmer Eye Institute laboratory. The Artificial Tears at issue in this lawsuit that were tested, revealed that the bottles were contaminated with a heavy growth of *Pseudomonas Aeruginosa*.

22. Plaintiff has sustained long-term and permanent impairment and faces uncertain medical complications, despite ridding the *Pseudomonas Aeruginosa*.

[1] Outbreak of Extensively Drug-resistant *Pseudomonas aeruginosa* Associated with Artificial Tears; (February 7, 2023) available at https://www.cdc.gov/hai/outbreaks/CRPA-artificial-tears.html.

23. Plaintiff's medical journey continues, as he continues to suffer from left eye disfigurement, headaches, dizziness, blindness to his left eye, and emotional distress. Furthermore, Plaintiff will undoubtedly undergo future medical care and treatment, including cornea replacement surgery upon obtaining surgical clearance.

24. In January 2023, the Centers for Disease Control and Prevention and Food and Drug Administration announced a multi-state outbreak of a rare strain of *Pseudomonas Aeruginosa* eye infections linked to the use of artificial tears products made by Defendants.

25. Defendants, EzriCare, EzriRx, Delsam, and Aru manufactured, packaged, labeled, imported, sold, supplied, distributed, advertised, and/or marketed the contaminated artificial tears products referenced herein. Defendants EzriCare and EzriRx sold these products through retailers like Walmart, eBay, and named Defendant, Amazon.

26. Based on information and belief, approximately fifty-five (55) people are or have been infected with the *Pseudomonas Aeruginosa* outbreak strain throughout the United States as of February 2023.

27. According to public reports on this matter, at least one (1) person has died from this particular strain of *Pseudomonas Aeruginosa*, with five (5) reported instances of blindness, including Plaintiff named in this litigation.

28. The epidemiologic evidence indicates that the artificial tears at issue in this lawsuit is the likely source of the outbreak.

Global Pharma Healthcare Issues Voluntary Nationwide Recall of Artificial Tears Lubricant Eye Drops Due to Possible Contamination

Company Contacts:

Aru Pharma/EzriCare, LLC: Phone Number 1-516-715-5181

Delsam Pharma: Mr. Kuppusamy Arumugam
Phone Number 1-866-826-1306

29. Laboratory testing conducted by the CDC and the FDA identified the presence of *Pseudomonas Aeruginosa* in opened bottles from multiple lots. The contagion recovered from opened bottles matched the outbreak strain.

30. The FDA and CDC alerted consumers they should stop using EzriCare Artificial Tears pending additional guidance from them.

31. Moreover, the FDA recommended a recall due to Defendants' Current Good Manufacturing Practice ("CGMP") violations, including lack of appropriate microbial testing, formulation issues, and lack of proper controls concerning packaging.

COUNT I
Strict Product Liability

32. Plaintiff incorporates and realleges paragraphs 1 through 31 as though fully set forth herein.

33. Defendants are in the business of manufacturing, packaging, labeling, importing, selling, supplying, distributing, advertising and/or marketing the artificial tears product at issue in this lawsuit.

34. Defendants manufactured, packaged, labeled, imported, sold, supplied, distributed, advertised and/or marketed the artificial tears product at issue in this lawsuit that caused Plaintiff's catastrophic and continuing infection and injuries that will have a negative impact on him for the rest of his life.

35. Plaintiff was a reasonably foreseeable and intended user of Defendants defective product.

36. The artificial tears manufactured, packaged, labeled, imported, sold, supplied, distributed, advertised and/or marketed by Defendants were defective and unreasonably dangerous for their reasonably foreseeable uses because they were contaminated with the harmful and deadly bacteria, known as *Pseudomonas Aeruginosa*.

37. Because the Defendants' artificial tears were contaminated with *Pseudomonas Aeruginosa*, the eye drops that Defendants manufactured, packaged, labeled, imported, sold, supplied, distributed, advertised and/or marketed, and that Plaintiff purchased and used, as described

previously, were in a condition that Plaintiff had not contemplated, and were in a condition that rendered the product unreasonably dangerous for their ordinary and expected use.

38. At all times material hereto, Plaintiff used the products in a manner expected and intended to be used.

39. Plaintiff suffered the significant injuries as a direct and proximate result of his use of the contaminated, defective products manufactured, distributed and sold by Defendants.

40. Defendants are strictly liable to the Plaintiff for the harm proximately caused by the manufacture and sale of an unsafe and defective product.

COUNT II
Negligence

41. Plaintiff incorporates and realleges paragraphs 1 through 31 as though fully set forth herein.

42. Defendants, as manufacturer(s) and/or seller(s) of the artificial tears products at issue in this action, owed a duty to the consuming public, including Plaintiff.

43. Defendants owed a duty to exercise reasonable care to design, manufacture. Inspect, test, distribute and sell products free of unreasonable risk of harm to users and patients when said product is used in its intended manner.

44. Defendants manufactured, prepared, distributed and sold products that were adulterated with *Pseudomonas Aeruginosa* and that were not reasonably safe as designed, manufactured or sold.

45. Defendants manufactured, distributed, packaged, labeled, supplied, marketed, advertised, and/or sold products that were contaminated and/or adulterated with *Pseudomonas Aeruginosa,* and that were not reasonably safe as designed, manufactured or sold.

46. Defendants were negligent in how they manufactured, distributed packaged, labeled, supplied, marketed, advertised, and/or sold products that were adulterated with Pseudomonas aeruginosa, contaminated with *Pseudomonas Aeruginosa*, and not reasonably safe because they were contaminated with *Pseudomonas Aeruginosa* and because adequate warnings or instructions were not provided, including but not limited to the warning that its products may contain *Pseudomonas Aeruginosa*, and thus should not be given to, or used by humans.

47. Defendants had a duty to properly supervise, train, and monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of its products, to ensure compliance with Defendants' operating standards and to ensure compliance with all applicable health regulations. Defendants failed to properly supervise, train, and monitor these employees, or the employees of its agents or subcontractors engaged in the import, manufacture, preparation and delivery of the products, and thus breached that duty.

48. Defendants owed a duty to Plaintiff to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling, and sale of its products, including all applicable local, state, and federal health and safety regulations.

49. Defendants, by their manufacture, distribution, storage, labeling, and sale of adulterated and unsafe products, failed to conform to this duty.

50. Defendants owed Plaintiff the duty to exercise reasonable care in the preparation and sale of its products, as it was reasonably foreseeable that the defendant's manufacture, distribution and sale of products contaminated with *Pseudomonas Aeruginosa* would cause

injury and harm to all persons potentially exposed to Pseudomonas aeruginosa as a result. Defendants breached that duty, thereby causing injury to Plaintiff.

51. Defendant was negligent in manufacturing, preparing, distributing and selling products adulterated and/or contaminated with *Pseudomonas Aeruginosa*, a dangerous pathogen.

52. Defendants' negligent acts and omissions included but were not limited to the following: Defendants' current good manufacturing practice (CGMP) violations, including lack of appropriate microbial testing, formulation issues (the company manufactures and distributes ophthalmic drugs in multi-use bottles, without an adequate preservative), and lack of proper controls concerning tamper-evident packaging.

53. Defendants owed Plaintiff a duty to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling and sale of its products, including the applicable provisions of the federal U.S. Food, Drug and Cosmetic Act.

54. The products that Defendants manufactured, distributed and sold, and that the consumers purchased and consumed, was "adulterated" within the meaning of the Federal Food, Drug and Cosmetic Act.

55. Defendants violated federal, state, and local safety regulations by its manufacture, distribution, and sale of adulterated products.

56. Plaintiff's injuries proximately and directly resulted from the negligence of Defendants.

57. Defendants breached its duties owed to Plaintiff.

COUNT III
Negligence Per Se

58. Plaintiff incorporates and realleges paragraphs 1 through 31 as though fully set forth herein.

59. Defendants had a duty to comply with all applicable state and federal regulations intended to ensure the purity and safety of their products, including, but not limited to, the requirements of the Federal Food, Drug and Cosmetics Act.

60. Defendants failed to comply with the provisions of the health and safety acts identified above and, as a result, were negligent per se in their manufacture, distribution, and/or sale of products adulterated with Pseudomonas aeruginosa, a dangerous and deadly pathogen.

61. Defendants violated federal, state, and local safety regulations by its manufacture, distribution, and sale of adulterated products.

62. The federal, state, and local product safety regulations applicable here, and as set forth above, establish a positive and definite standard of care in the manufacture, distribution and sale of products, and the violation of these regulations constitutes negligence per se.

63. Plaintiff was in the class of persons intended to be protected by these statutes and regulations and was injured as the direct and proximate result of Defendants' violation of applicable federal, state, and local safety regulations.

64. Plaintiff's injuries proximately and directly resulted from the negligence of Defendants, and from Defendants' violations of statutes, laws, regulations, and safety codes pertaining to the manufacture, production, supply, distribution, storage, and sale of products.

65. As a direct and proximate result of conduct by Defendants that was negligent per se, Plaintiff was harmed and sustained damages.

COUNT IV
Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA")
(Florida Statutes §§501.201-.213)

66. Plaintiff incorporates and realleges paragraphs 1 through 31 as though fully set forth herein.

67. Defendants knew that the Artificial Tears were adulterated and contaminated with *Pseudomonas Aeruginosa*, a dangerous and inherently harmful bacteria. They failed to adhere to appropriate testing and proper control concerning packaging, but decided to distribute and sale to the consumers.

68. Defendants knowingly packaged, labeled, imported, sold, supplied, distributed, advertised, and/or marketed the contaminated artificial tears products referenced herein throughout the United States and, specifically, in the State of Florida.

69. Defendants engaged in unfair methods of competition, unconscionable acts or practices, and unfair and deceptive acts or practices in the conduct of any trade or commerce which is unlawful under the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §501.204(1).

70. Defendants' actions, misrepresentations and circumventions were acts within the scope of the Florida Statutes §§501.201, et seq.

71. Defendants deceptive and unfair practices offend established public policy and are immoral, unethical, oppressive, unscrupulous.

72. Defendants' conduct is/was deceptive, immoral, unethical, oppressive, unscrupulous, offends established public policy and has resulted in substantial, and potentially irreparable, harm and damage to Plaintiff.

73. As a direct and proximate result of Defendants' violation of Florida Statute 501.204, et seq.

PRAYER FOR RELIEF AND DAMAGES TO ALL COUNTS

74. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, travel and travel-related expenses, emotional distress, lost wages, and lost earning capacity.

75. WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

a. That the Court award Plaintiff judgment against Defendants for past and future economic and non-economic damages; including income, wages, and benefits.

b. That the Court award all such other sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental and consequential damages incurred, or to be incurred, by Plaintiff as the direct and proximate result of the acts and omissions of Defendants;

c. That the Court award Plaintiff costs, disbursements and reasonable attorneys' fees incurred (to the extent recoverable);

d. Pre- and post-judgment interest at the highest rate allowed by law;

e. Punitive and/or exemplary damages;

f. That the Court award Plaintiff the opportunity to amend or modify the provisions of this Complaint as necessary or appropriate after additional or further discovery is completed in this matter, and after all appropriate parties have been served; and

g. That the Court award such other and further relief as it deems necessary and proper in the circumstances.

DEMAND FOR JURY TRIAL

Plaintiff, ADAM DISARRO hereby demands a jury trial as to all issues triable by a jury.

Respectfully submitted on this 23rd day of February 2023.

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