

UNITED STATES DISTRICT COURT
for the
Western District of North Carolina

CAROLINE ELIZABETH WATT MASTROSANTE
and JOSEPH ALBERT MASTROSANTE

Plaintiff

v.

Civil Action No.

FUJIFILM IRVINE SCIENTIFIC, INC.

Defendant

SUMMONS IN A CIVIL ACTION

TO: *(Defendant's name and address)*

FujiFilm Irvine Scientific, Inc.
c/o CSC - Lawyers Incorporating Service, Registered Agent
2710 Gateway Oaks Drive, Suite 150N
Sacramento, California 95833-3505

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) – or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12(a)(2) or (3) – you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

CHARLES J. BRIDGMON (NC Bar # 37887)
JAMES DENOBRIGA LONG, PLLC
831 East Morehead Street, Suite 940
Charlotte, North Carolina 28202
Phone: (704) 755-9465 Email: charlie@jdlawcarolinas.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4(1))

This summon for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

- I personally served the summons on the defendant at *(place)* _____ on *(date)* _____; or
- I left the summons at the individual's residence or usual place of abode with *(name)* _____, a person of suitable age and discretion who resides there, on *(date)* _____, and mailed a copy to the individual's last known address; or
- I served the summons on *(name of individual)* _____, who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____; or
- I returned the summons unexecuted because _____; or
- Other *(specify)*: _____

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION**

CAROLINE ELIZABETH WATT
MASTROSANTE; and JOSEPH ALBERT
MASTROSANTE,

Plaintiffs,

vs.

FUJIFILM IRVINE SCIENTIFIC, INC.

Defendant.

Civil Action No.: 3:24-cv-00758

COMPLAINT
(Jury Trial Demanded)

NOW COMES Plaintiffs Caroline Elizabeth Watt Mastrosante and Joseph Albert Mastrosante, by and through their undersigned counsel, and bring this Complaint against Defendant FujiFilm Irvine Scientific, Inc. (“FujiFilm” or “Defendant”) and allege as follows:

NATURE OF THE ACTION

1. Defendant FujiFilm has been in the business of providing “oil” to preserve and protect embryos during the “in vitro fertilization” (hereinafter the “IVF process”), including, but not limited to, such embryos as those produced by the Plaintiffs in this action.

2. Instead, Defendant manufactured, marketed, distributed, and/or sold an embryo oil that was not safe for its intended purpose.

3. In this case, Plaintiffs are informed, believe, and therefore allege that Defendant’s embryo oil destroyed the embryos of the Plaintiffs.

4. Plaintiffs are demanding damages for the loss of their viable embryos and to hold Defendant responsible for its actions.

PARTIES

5. Plaintiffs Caroline Elizabeth Watt (“Caroline”) Mastrosante and Joseph Albert (“Joe”) Mastrosante are citizens and residents of Charlotte, Mecklenburg County, North Carolina, and at all times referenced herein, were legally married and living together as husband and wife.

6. Defendant FujiFilm Irvine Scientific, Inc. (“FujiFilm” or “Defendant”), is a corporation organized under the laws of the State of California with its principal place of business and corporate headquarters in Santa Ana, California.

7. Defendant developed, manufactured, marketed, promoted, distributed, and sold in the foreseeable chain of commerce a sterile oil product specifically intended for the culturing and storage of human embryos for IVF.

8. Defendant knowingly marketed, distributed, and sold the Fujifilm branded embryo oil in the State of North Carolina.

9. Upon information and belief, Defendant also knowingly sent fertility doctors, clinics, and/or hospitals in North Carolina information about the use and benefits of its embryo oil at issue in the current matter.

JURISDICTION AND VENUE

10. Subject matter jurisdiction in this matter is proper because the amount in controversy, exclusive of interest and costs, exceeds Seventy-Five Thousand Dollars (\$75,000) and the parties are citizens of different states, as required by 28 U.S.C. § 1332(a).

11. To the extent relevant, this Court has supplemental jurisdiction over Plaintiff’s state law claims pursuant to 28 U.S.C. § 1367.

12. Venue of this matter is proper in this District pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claim set forth herein occurred in this judicial district. Specifically, Defendant’s embryo oil was marketed, distributed, and sold to Reproductive Endocrinology Associates of Charlotte (“REACH”) in Charlotte, North Carolina, where Defendant’s embryo oil ultimately destroyed Plaintiffs’ embryos.

FACTUAL BACKGROUND

13. Among the products Defendant developed, marketed, manufactured, distributed, and sold is a sterile mineral oil for use with embryos.

14. Defendant FujiFilm describes this subject product as follows:

Oil for Embryo Culture is a sterile light mineral oil intended for use as an overlay when culturing in reduced volumes of media to prevent evaporation, and to protect the media from changes in osmolality and pH.

15. The product is designated by Defendant as “Model # 9305.”

16. Defendant represented that its oil products were properly tested and carefully manufactured to prevent toxicity to embryos.

17. Defendant, however, knew or should have known that its testing and manufacturing process was not adequate to prevent toxicity to human embryos.

18. On January 16, 2023, Defendant issued an “Urgent Field Safety Notice (product removal)” notifying the doctors, clinics, laboratories, and hospitals who had purchased its product that it should not be used and was effectively being recalled.

19. This safety notice identified four lots that were toxic. The recalled toxic products were identified as follows: “Oil for Embryo Culture, Catalog #9305, Lots 0000011351, 0000011367, 0000015999, 0000016001.”

20. Defendant has admitted it had received complaints regarding oil from the identified lots, including the destruction of human embryos from contact with its oil.

21. Through no fault of the Plaintiffs, Defendant's toxic oil destroyed Plaintiffs' embryos.

22. As a result of Defendant's toxic product, Plaintiffs suffered the loss of their embryos, suffered, and continue to suffer, significant emotional distress, and had to undergo otherwise unnecessary and stressful medical procedures.

FOR A FIRST CAUSE OF ACTION

(Breach of Warranty)

23. Plaintiffs incorporate the above allegations by reference.

24. Defendant developed, designed, manufactured, distributed, marketed, promoted, and sold the subject embryo oil.

25. Defendant intended that this oil be used in the manner that it was fact used it.

26. Plaintiffs, their doctors, clinic, hospital, and all other relevant personnel used Defendant's subject embryo oil as intended.

27. Defendant expressly and impliedly warranted that its oil was safe and non-toxic for use with embryos; was of merchantable quality; met or exceeded the quality of other comparable oils; and was adequately tested and fit for its intended use.

28. Defendant breached these express and implied warranties with respect to its embryo oil by, among other things, inadequately testing the oil and selling oil that was actually toxic to embryos.

29. Defendant breached these express and implied warranties when it developed, designed, manufactured, distributed, and sold embryo oil that was unfit and unreasonably

dangerous for the ordinary purposes for which this oil is used. Specifically, the oil was intended to be used to preserve and protect embryos, and Defendant's oil was, in fact, toxic to those embryos.

30. At the time the oil left Defendant's possession, the oil had been defectively manufactured such that it differed substantially from Defendant's intended product specifications. Rather than safe to use with human embryos, Defendant's oil was toxic to such embryos.

31. As a direct result of Defendant's breach of its express warranties and implied warranties, including but not limited to the implied warranty of merchantability and the implied warranty for a particular purpose, Plaintiffs suffered the harms and losses set forth above and request damages as set forth above and below.

FOR A SECOND CAUSE OF ACTION
(Negligent Manufacture, Design, and Warning)

32. Plaintiffs incorporate the above allegations by reference.

33. Defendant owed a duty to the fertility doctors, clinics, hospitals, and their patients to use reasonable care in the production of its embryo oil. The Defendant's duty included a responsibility to adequately assess and test all raw materials for any signs of toxicity that might be used in the production of the final product.

34. Defendant knew its product would be used in highly specialized medical procedures involving sensitive cellular material, specifically including embryos. Defendant knew that if their product was toxic to a developing embryo that it could cause the death of a human being.

35. Defendant breached its duty by failing to design, manufacture, monitor, inspect and/or test its oil products and their component raw materials to ensure that they were non-toxic and free of contamination.

36. Defendant provided no warning to Plaintiffs or their doctors including the Plaintiffs' physicians regarding the toxicity or risks of toxicity of the embryo oil.

37. Defendant was negligent, reckless, and grossly negligent in their failure to warn Plaintiffs and their doctor regarding the toxicity of the embryo oil; and Defendant knew or should have known at the time it was used with Plaintiffs' embryos that its acts and/or omissions would cause harm to Plaintiffs' embryos as set forth above.

38. Upon information and belief, there was a delay in Defendant's failure to warn their infertility clinic customers of the toxicity in the Defendant's oil product, and this delay caused an increased number of embryos to be injured.

39. Defendant owed Plaintiffs and all others similarly situated to exercise the highest level of care in manufacturing, producing, inspecting, monitoring, and testing of their mineral oil products used for its intended purpose in IVF, ART, and/or embryology across the United States.

40. Defendant owed Plaintiffs and all others similarly situated the highest degree of utmost care when maintaining, caring for, and otherwise protecting Plaintiffs' embryos.

41. Defendant owed a duty of care to Plaintiffs to act reasonably in the creation of embryo storage materials, avoid destroying embryos, or jeopardizing the viability of the embryos.

42. Defendant's actions breached the duty of care owed and were negligent as set forth above and below.

FOR A THIRD CAUSE OF ACTION
(Wrongful Death)

43. Plaintiffs' unborn implanted embryo was negatively affected by Defendant's product, causing the embryo to not develop properly and ultimately causing the death of the embryo. The right to life for each born and preborn human being vests at fertilization.

44. As a direct result of the actionable conduct of Defendant, Plaintiffs' unborn implanted embryo met his or her untimely death.

45. Plaintiffs have experienced great mental anguish, suffering, grief, sorrow, bereavement, and loss of society, advice, companionship, protection, and pecuniary benefit from the loss of their unborn implanted embryos.

46. Plaintiffs are informed and believe they are entitled to judgment against Defendant for an award of actual and/or punitive damages in an amount to be determined by the trier of fact and for any additional relief the court deems just and proper.

DEMAND FOR JURY TRIAL

47. Plaintiffs pray for a jury trial on all issues of fact so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendant as follows:

A. For an award of compensatory damages, including damages against Defendant for their medical and other expenses, pain and suffering, mental anguish, disability, and other damages according to proof at trial in excess of Seventy-Five Thousand Dollars (\$75,000.00);

B. For punitive damages to be awarded if Plaintiffs prove by clear and convincing evidence that the Defendant acted recklessly or willfully in causing harm;

C. For their reasonable attorneys' fees and costs;

D. That the Court award Plaintiffs 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

E. For such further and other relief this Court deems just and equitable.

Respectfully submitted this 20th day of August, 2024.

By: s/ Charles J. Bridgmon
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