

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

LALITHA E. JACOB,

Plaintiff,

v.

Case No: 8:19-cv-229-MSS-SPF

MENTOR WORLDWIDE, LLC,

Defendant.

ORDER

THIS CAUSE comes before the Court for consideration of Defendant’s Motion for Summary Judgment, (Dkt. 73), Plaintiff’s papers in opposition thereto, (Dkts. 84-89), Defendant’s reply in support, (Dkt. 91), and all other pending motions. (Dkts. 74, 75, 76, 77 & 90) Upon consideration of all relevant filings, case law, and being otherwise fully advised, Defendant’s Motion for Summary Judgment is **DENIED**.

I. BACKGROUND

A. FACTUAL BACKGROUND¹

In June 2005, Plaintiff Lalitha E. Jacob, M.D., (“Dr. Jacob”), underwent a combined abdominoplasty with submuscular inframammary fold 350-cc implants.

¹ On September 7, 2023, Defendant Mentor Worldwide, LLC (“Mentor”) emailed a proposed Joint Stipulation of Agreed Material facts to Ms. Jacob. (Dkt. 91 n.1) Mentor offered an email from Ms. Jacob dated October 2, 2023, which states “I DO NOT agree with your stipulation of material facts dated 9/21/2023.” Plaintiff concedes in her response to Defendant’s unilateral submission of agreed facts, (Dkt. 94-1), that she only challenges certain facts as disputed. Accordingly, this Court accepts only the recited proposed facts as undisputed because they have been supported by “particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials.” Fed. R. Civ. P. 56(c)(1)(A).

(Dkt. 28-1) On November 17, 2006, the U.S. Food and Drug Administration (“FDA”) approved the premarket approval application (PMA) for the Mentor MemoryGel™ Silicone Gel-Filled Breast (“MemoryGel”) Implants. (Dkt. 73-1) On January 30, 2007, Plaintiff Lalitha E. Jacob, M.D., (“Dr. Jacob”), was implanted with 600-cc MemoryGel breast implants. (Dkt. 28 at 4; Dkt. 28-1 at 1; Dkt. 91-1 ¶ 1) Dr. Jacob’s MemoryGel implants were manufactured as part of Lot 5710404. On January 2, 2019, Dr. Jacob had the implants removed during a bilateral capsulectomy. (Dkt. 28-1 at 1; Dkt. 91-1 at ¶ 1) Dr. Jacob’s MemoryGel implants were destroyed in January 2022.

B. PROCEDURAL BACKGROUND

Dr. Jacob, proceeding *pro se*, commenced this action against Mentor on January 29, 2019. (Dkt. 1) During the briefing on Mentor’s first motion to dismiss, Plaintiff filed an addendum containing a report dated April 16, 2019, from Pierre Blais, Ph.D. (Dkt. 16) On August 7, 2019, Dr. Jacob amended her complaint. On August 21, 2019, Mentor moved to dismiss Dr. Jacob’s amended complaint. (Dkt. 30) On December 10, 2019, the Court granted Mentor’s motion. (Dkt. 41) Dr. Jacob timely appealed the Court’s dismissal of her complaint. (Dkt. 42)

On August 18, 2022, the Eleventh Circuit issued its Mandate to this Court reversing the Order on Mentor’s second motion to dismiss. (Dkt. 45) On August 8, 2023, Mentor moved for summary judgment. (Dkt. 73) The briefing on Mentor’s motion is complete and this matter is now ripe for consideration.

II. LEGAL STANDARD

Summary judgment is appropriate where the movant can show that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law. Fennell v. Gilstrap, 559 F.3d 1212, 1216 (11th Cir. 2009) (citing Welding Servs., Inc. v. Forman, 509 F.3d 1351, 1356 (11th Cir. 2007)). Which facts are material depends on the substantive law applicable to the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The moving party bears the burden of showing that no genuine issue of material fact exists. Clark v. Coats & Clark, Inc., 929 F.2d 604, 608 (11th Cir. 1991).

Evidence is reviewed in the light most favorable to the non-moving party. Fennell, 559 F.3d at 1216 (citing Welding Servs., Inc., 509 F.3d at 1356). A moving party discharges its burden on a motion for summary judgment by showing or highlighting to the Court that no evidence supports the non-moving party's case. Denney v. City of Albany, 247 F.3d 1172, 1181 (11th Cir. 2001) (citation omitted).

When a moving party has discharged its burden, the non-moving party must then designate specific facts (by its own affidavits, depositions, answers to interrogatories, or admissions on file) that demonstrate there is a genuine issue for trial. Porter v. Ray, 461 F.3d 1315, 1320 (11th Cir. 2006) (citation omitted). The party opposing a motion for summary judgment must rely on more than conclusory statements or allegations unsupported by facts. Evers v. Gen. Motors Corp., 770 F.2d 984, 986 (11th Cir. 1985) (“conclusory allegations without specific supporting facts have no probative value.”). “If a party fails to properly support an assertion of fact or

fails to properly address another party’s assertion of fact . . . the court may grant summary judgment if the motion and supporting materials . . . show that the movant is entitled to it.” FED. R. CIV. P. 56(e).

III. DISCUSSION

Mentor argues it is entitled to summary judgment because Dr. Jacob has offered no evidence to establish a parallel state law claim that is not preempted by the Medical Device Amendments of 1976 (“MDA”). (Dkt. 73) Mentor specifically raises four arguments in support of summary judgment. First, Mentor argues Dr. Jacob’s MemoryGel Implants were manufactured properly and were not defective. (*Id.* at 14) Second, Mentor argues Dr. Jacob has not pointed to any applicable PMA specification that Mentor violated when manufacturing her MemoryGel Implants. (*Id.*) Third, Mentor argues its expert engineer, Hoshang Kotivand, confirmed that the process used in manufacturing Plaintiff’s MemoryGel Implants (Lot No. 5710404) was the same as the process detailed in the manufacturing specifications reviewed and approved by the FDA in its pre-market approval order. (*Id.*) Fourth, Mentor argues Dr. Jacob’s implants underwent exhaustive pre-shipment quality assurance testing, inspections, and validations prior to distribution. (*Id.*) Dr. Jacob references her expert’s report and other medical reports in opposition to summary judgment. (Dkt. 85) The Court finds factual issues preclude summary judgment for the reasons that follow.

The MDA can expressly or impliedly pre-empt certain state law claims relating to medical devices. See *Godelia v. Doe 1*, 881 F.3d 1309, 1317 (11th Cir. 2018) “[T]he MDA expressly pre-empts only state requirements different from, or in addition to,

any requirement applicable ... to the device under federal law, § 360k(a)(1)” Wolicki-Gables v. Arrow Int’l, Inc., 634 F.3d 1296, 1300 (11th Cir. 2011) (citation omitted). The MDA impliedly pre-empts claims seeking to privately enforce a duty that is owed to the FDA. See Jacob v. Mentor Worldwide, LLC, 40 F.4th 1329, 1336 (11th Cir. 2022) (citation omitted). There is “a ‘narrow gap’ through which a plaintiff’s claim must pass to survive: ‘a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption) but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption).’” Once a plaintiff’s claim passes the preemption inquiry, the plaintiff must allege and then prove “(1) the device suffered from a defect; (2) the defect resulted from a violation of a particular PMA requirement; and (3) the defect caused his injury.” See Marmol v. St. Jude Med. Ctr., 132 F. Supp. 3d 1359, 1365 (M.D. Fla. 2015) (citation omitted); Jacob, 40 F.4th at 1338 (distinguishing the requisite showing at the pleading and proof stages). Because the Eleventh Circuit has already decided the preemption question, this Court proceeds to examine whether Dr. Jacob has offered some evidence from which a reasonable jury could conclude she has proved her case.

Here, Dr. Jacob has offered evidence from her rheumatologist Dr. Arthur Brawer (Dkt. 77-1), her explanting physician Dr. Marguerite Barnett (Dkt. 28-1), and her expert Dr. Pierre Blais. (Dkt. 28-1 at 13) Dr. Brawer conducted a physical examination of Dr. Jacob, and his letter dated December 17, 2018 contained his findings based on his examination. (Dkt. 77-1) Dr. Barnett has offered her opinion based on her personal observation of Dr. Jacob, her removal of Dr. Jacob’s implants,

and her experience as a plastic surgeon who has worked with implants and over 3000 patients. (Dkts. 28-1 & 75-1) Finally, Dr. Blais opined on the failure of Dr. Jacob's implants.

Mentor counters Dr. Jacob's evidence with a sworn declaration from their expert engineer, Hoshang Kotivand. Based on his review of the device history record and his experience and knowledge as a staff engineer for Mentor, Dr. Kotivand declared that "all materials and components used in the manufacture of the implants conformed with design and manufacturing specifications as approved by the FDA in the November 2006 PMA Approval." (Dkt. 73-2 at ¶ 10) Dr. Kotivand further declared that "all in-process procedures, inspections and testing were accomplished using calibrated and/or validated procedures and equipment approved by the FDA, and the implant(s) at issue in the case contained no defects at the time they left Mentor's control." (*Id.* at ¶ 11) Given the conflict between Mentor and Dr. Jacob's experts, the Court finds a genuine issue of material fact exists as to whether Dr. Jacob's implants were defective.

Additionally, Mentor challenges the opinions of Dr. Jacobs' experts on the grounds that they do not meet the strictures of Daubert, i.e., relevancy, scientific reliability, and methodology. (Dkts. 74, 75 & 77) The Court finds that Mentor's challenges go to the weight of the experts' opinions and not the admissibility of their opinions. Therefore, Mentor's motions are **DENIED WITHOUT PREJUDICE**. Mentor may, however, reassert its Daubert challenges after voir dire at trial.

As a final point, Mentor has moved to strike Dr. Blais' opinions as a sanction

for his alleged spoliation of evidence – destroying Dr. Jacob’s implants. The Court is unpersuaded by Mentor’s arguments for two reasons. First, Mentor was put on notice on April 30, 2019, that Dr. Jacob’s expert had examined the implants and Mentor never requested the implants from that point until the case was initially dismissed. Mentor’s substantial delay in requesting the implants for inspection distinguishes Mentor’s position from all other cases that Mentor has cited. Additionally, this Court finds Mentor will suffer minimal prejudice because Mentor will have an opportunity to voir dire and cross-examine Dr. Jacob’s experts at trial. Therefore, Mentor’s spoliation motion is **DENIED**.

IV. CONCLUSION

Upon consideration of the foregoing, it is hereby **ORDERED** that:


1. Defendant’s Motion for Summary Judgment, (Dkt. 73), is **DENIED**.
2. Defendant’s Motion to Exclude the Manufacturing Defect Opinions of Pierre Blais, Ph.D., (Dkt. 74), is **DENIED WITHOUT PREJUDICE**. Mentor may reassert the motion, if warranted, after voir dire or on cross-examination of Dr. Jacob’s expert at trial.
3. Defendant’s Motion to Strike Marguerite Barnett, M.D.’s letter, (Dkt. 75), is **DENIED WITHOUT PREJUDICE**. Mentor may reassert the motion, if warranted, after voir dire or on cross-examination of Dr. Jacob’s expert at trial.
4. Defendant’s Motion to Strike Pierre Blais, Ph.D.’s Report and Testimony for Spoliation, (Dkt. 76) is **DENIED**.

5. Defendant's Motion to Strike Arthur Brawer, [M.D.'s] Letter, (Dkt. 77), is **DENIED WITHOUT PREJUDICE**. Mentor may reassert the motion, if warranted, after voir dire or on cross-examination of Dr. Jacob's expert at trial.

6. Defendant's Motion for Leave to File a Reply, (Dkt. 90), is **DENIED as MOOT**.

7. The Parties are **DIRECTED** to confer and advise the Court of their availability for trial within fourteen days of this Order.

DONE and ORDERED in Tampa, Florida, this 14th day of March 2024.



MARY S. SCRIVEN
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel of Record
Any pro se party