UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

CLIFTON DREYFUS	CIVIL ACTION
VERSUS	NO: 06-585
ADVANCED MEDICAL OPTICS, INC.	SECTION: "J" (1)

ORDER AND REASONS

Before the Court is defendant's Motion for Summary Judgment. (Doc. 18.) The motion is opposed. For the following reasons, the Court finds that the motion should be GRANTED in part and DENIED in part.

BACKGROUND

Plaintiff, Clifton Dreyfus, had surgery to remove a cataract in his eye. As part of the surgery a manufactured lens was to be implanted in his eye. Defendant, Advanced Medical Optics ("AMO") manufactured and distributed the lens initially used during Dreyfus's surgery. When the doctor implanted the lens, he noticed that a piece of the device, the "haptic", was broken off. The broken device had to be removed, and as it was being removed the broken part tore into Dreyfus's eye. This was painful and

required further surgery to correct. Dreyfus sued AMO in state court for damages alleging various theories of recovery under the Louisiana Products Liability Act ("LPLA") and otherwise. AMO removed to this Court based upon diversity.[1]

LEGAL STANDARD

Summary judgment is appropriate if "there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If that burden has been met, the non-moving party must then come forward and establish the specific material facts in dispute to survive summary judgment. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986).

DISCUSSION

AMO argues that plaintiff has insufficient evidence to support the elements of any of his LPLA theories of recovery or to prove causation of his alleged injuries. The theories of

[1] Dreyfus's Petition states that the federal jurisdictional amount is not met, but AMO argued in removing that it was apparent from the face of the complaint that allegations of permanent eye/vision damage, disability, medical bills past present and future, and suffering likely exceed $75,000. The Court agrees that the potential damages as stated in the petition are likely enough to satisfy jurisdiction.

recovery allowed under the LPLA are design defect, manufacturing defect, failure to warn, and breach of express warranty. As Dreyfus points out, however, the Medical Devices Amendment to the Food Drug and Cosmetics Act likely preempts all of these theories except manufacturing defect and perhaps express warranty. *See Gomez v. St. Jude Medical*, 442 F.3d 919 (5th Cir. 2006). In *Gomez* the Fifth Circuit found in a similar suit that the "district judge properly limited Gomez's negligence claims to a claim that the [device] used in her surgery was defectively manufactured because it did not comply with the FDA-approved specifications." *Id*. at 933. There is no allegation in this case of express warranty, so, as in *Gomez*, that leaves only the claim of manufacturing defect viable.

To prove a products liability claim plaintiff must show that (1) defendant is the manufacturer of the product; (2) the product proximately caused the plaintiff's damage; (3) the damaging characteristic of the product rendered it "unreasonably dangerous", and (4) the plaintiff's damage arose from a reasonably anticipated use of the product. La. R.S. § 9:2800.54. To show that a product is "unreasonably dangerous" because of a manufacturing defect the plaintiff must show that (1) at the time the product left its manufacturer's control (2) it deviated in a material way from the manufacturer's specifications or

performance standards. *Id* § 9:2800.55. In this case, as in *Gomez*, it is the FDA specifications and not necessarily the manufacturer's that matter.

AMO argues that Dreyfus "has failed to timely serve an expert report" or "to produce any documents supporting his claim" that the product deviated from its specifications. AMO cites legal authority for the proposition that a product defect cannot be presumed from the occurrence of an accident. AMO also argues that there is no expert report establishing medical causation of injury.

Defendant's suggestion that there is no evidence to support the existence of a defect or that an expert report would be required borders on frivolous. The operating doctor testifies that the device was broken when he released it into Dreyfus's eye. Unless AMO intends to argue that the device was supposed to be that way, it is apparent that the device was defective by that point.

To support the "at the time it left the manufacturer" element, Dreyfus points to the operating physician's deposition testimony that, because of the nature of the packaging and the nature of the defect, the damage could not have been sustained in shipment. Dreyfus argues that there has been no suggestion that the doctor damaged the device. In addition, there is testimony

supporting the conclusion that the doctor did not break the device. (Slagle Depo. pp 151-52.) Dreyfus argues that the only other possibility is that the device left the manufacturer's with a defect. The evidence is circumstantial and inferential, but it clearly could support a jury finding that the device left the manufacturer with the defect. Consequently, a genuine issue remains for determination at trial.

The argument that there is no medical causation evidence is incredible. The operating doctor testifies that he directly observed through the microscope as the broken piece of the device tore Dreyfus's eye. (Slagle Depo. pp 74-75.) The doctor's operating report indicates that it was painful, caused distress, and required further surgery. (Pl's Opp. Ex. B.) There is clearly evidence that the defect caused injury, and a genuine issue remains for trial as to the extent of the injury.

CONCLUSION

All theories of liability or recovery other than manufacturing defect are preempted by the Medical Devices Amendment to the Food, Drug, and Cosmetics Act. AMO is entitled to judgment on those theories as a matter of law. However, genuine issues of material fact remain for trial on the manufacturing defect claim.

Accordingly,

IT IS ORDERED that the defendant's Motion for Summary Judgment (Doc. 18) is **DENIED** in part, and **GRANTED** in part.

New Orleans, Louisiana this the 12th day of January, 2007.

CARL J. BARBIER
UNITED STATES DISTRICT JUDGE