IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

DOVIE J. WILLIAMS PLAINTIFF

V.

CIVIL NO.: 1:13-cv-368-HSO-RHW

CIBA VISION CORPORATION;
AND JOHN AND JANE DOES A; B; C; D; E; AND F DEFENDANTS

MEMORANDUM OPINION AND ORDER GRANTING
DEFENDANT'S [27] MOTION TO DISMISS

BEFORE THE COURT is the Motion to Dismiss Plaintiff's Second Amended Complaint [27] filed by Defendant CIBA Vision Corporation. The Motion is now fully briefed. After due consideration of the Motion [27] and supporting Memorandum [28], Plaintiff's Response in Opposition [29] and supporting Memorandum [30], Defendant's Reply [31], the Second Amended Complaint [26], and relevant legal authorities, the Court finds that Defendant's Motion to Dismiss Second Amended Complaint [27] should be granted and that Plaintiff's claims against Defendant should be dismissed.

I. BACKGROUND

A. Factual Background

This products liability case arises out of injuries allegedly sustained by Plaintiff Dovie J. Williams to her left eye after receiving Defendant CIBA Vision Corporation's MemoryLens IOL / U940A, Lot S/N M381747 replacement lens during cataract surgery for her left eye on October 15, 1999. Sec. Am. Compl. [26] at 4.

Plaintiff also received a MemoryLens IOL / U940A, Lot S/N M402355 replacement lens to her right eye during this cataract surgery. *Id.* In the Second Amended Complaint, Plaintiff does not claim that she suffered injuries to her right eye as a result of receiving MemoryLens IOL / U940A, Lot S/N M402355.

Plaintiff alleges that although she was diligent in her follow-up with her treating physicians, she began to experience an assortment of problems with her left eye over the next couple of years. *Id.* Specifically, Plaintiff claims that over the next few years following the surgery she experienced inflammation, pain, infection, and the inability to see out of her left eye. *Id.* According to Plaintiff, the "symptoms" she suffered prevented her from "living a normal life and severely restricted her activity because of the pain and inability to see out of her left eye, including the ability to operate her vehicle." *Id.* at 5. Plaintiff was forced to live with "pain, discomfort, and the restrictions of her sight" for twelve years. *Id.* at 5-6.

On or about April 12, 2012, Plaintiff experienced "stabbing pain in her left eye" at which time her treating physician indicated that the MemoryLens IOL may need to be replaced. *Id.* at 4. On April 9, 2013, Plaintiff underwent an extraction of the MemoryLens from her left eye at the University Medical Center in Jackson, Mississippi. *Id.* at 5. Diagnostic testing on the extracted MemoryLens "confirmed a foreign substance on the extracted MemoryLens IOL / U940A, Lot S/N M381747." *Id.*

On September 20, 2013, Plaintiff filed suit. Compl. [1]. In her Second Amended Complaint, Plaintiff asserts that the injuries to her left eye were caused by a manufacturing defect in the MemoryLens IOL caused by Defendant's deviation from the manufacturing process pre-approved by the FDA. Sec. Am. Compl. [26] at 2-4. Plaintiff asserts that during the years 1999 through 2000 Defendant "deviated from the FDA pre-approved manufacturing process and mandated that the subject MemoryLens undergo a modified (buffered tumbling) manufacturing process." *Id.* at 2. According to Plaintiff, this modified process "allowed for biofilm formation within the lens causing opacification in a large majority of lenses," which caused patients to suffer "severe side effects" and led to a voluntary recall of the MemoryLens IOL / U940A and U940B. *Id.*

B. Procedural History

On September 20, 2013, Plaintiff filed her Complaint [1] naming CIBA Vision Corporation and John and Jane Does A, B, C, D, E, and F as Defendants. On October 31, 2013, Defendant filed a Motion to Dismiss [6] pursuant to Federal Rule of Civil Procedure 12(b)(6). On November 25, 2013, Plaintiff filed a Motion for Leave to File First Amended Complaint [9] and her Response in Opposition to the Motion to Dismiss [10]. In response, on December 9, 2013, Defendant filed its Notice of Withdrawal of Motion to Dismiss [12], in which Defendant stipulated that it had no objection to Plaintiff's Motion [9]. Plaintiff's unopposed request for leave

to amend was granted by Text Order dated December 10, 2013.

On December 10, 2013, Plaintiff filed her First Amended Complaint [13]. On December 23, 2013, Defendant filed its Renewed Motion to Dismiss [14]. On January 21, 2014, Plaintiff filed a Motion for Leave to File Second Amended Complaint [22]. By Order [25] dated September 15, 2014, Plaintiff was granted leave to file a second amended complaint and Defendant's motion for dismissal was denied as moot.

Plaintiff filed her Second Amended Complaint [26] on October 8, 2014. Plaintiff advances state law claims for damages for negligence, gross negligence, strict liability, breach of implied warranty, breach of express warranty, and negligent infliction of emotional distress. Sec. Am. Compl. [26] at 6-12. On October 27, 2014, Defendant filed its Motion to Dismiss Plaintiff's Second Amended Complaint [27], arguing that on the face of the pleading, Plaintiff's claims are barred by the applicable statutes of limitations and preempted by federal law. On November 10, 2014, Plaintiff filed her Response in Opposition to Motion to Dismiss [29]. Defendant filed its Reply [31] on November 20, 2014.

II. DISCUSSION

A. Legal Standard

When presented with a motion to dismiss pursuant to Rule 12(b)(6), a court "must assess whether the complaint contains sufficient factual matter, accepted as

true, to state a claim for relief that is plausible on its face . . . ." *Spitzberg v. Houston Am. Energy Corp.*, 758 F.3d 676, 683 (5th Cir. 2014)(citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Hale v. King*, 642 F.3d 492, 498-99 (5th Cir. 2011)). A court must accept all well-pleaded facts as true and view those facts in the light most favorable to the plaintiff. *Varela v. Gonzales*, 773 F.3d 704, 707 (5th Cir. 2014) (citation omitted). This tenet, however, is inapplicable to legal conclusions. *Id.* (citation omitted). "A statute of limitations may support dismissal under Rule 12(b)(6) where it is evident from the plaintiff's pleadings that the action is barred and the pleadings fail to raise some basis for tolling or the like." *Jones v. Alcoa, Inc.*, 339 F.3d 359, 366 (5th Cir. 2003).

Generally, "[i]n considering a motion to dismiss for failure to state a claim, a district court must limit itself to the contents of the pleadings, including attachments thereto." *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000) (citing FED. R. CIV. P. 12(b)(6)). Documents attached to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to the plaintiff's claim. *Id.* at 498-99.

A district court has complete discretion whether to consider materials outside the pleadings when adjudicating a motion to dismiss pursuant to Rule 12(b)(6) and, when the district court's order clearly indicates that it did not consider any

materials outside the pleadings, the appellate court treats the decision as one under Rule 12(b)(6). *Griffith v. Johnston*, 899 F.2d 1427, 1433 n.2 (5th Cir. 1990) (citation omitted); *see, e.g., Stahl v. United States Dep't of Agric.*, 327 F.3d 697, 701 (8th Cir. 2003) (citing 5A Wright & Miller, *Federal Practice and Procedure* §1366, at 491 (2d ed. 1990); *Casazza v. Kiser*, 313 F.3d 414, 417-18 (8th Cir. 2002)); *see also Ware v. Associated Milk Producers, Inc.,* 614 F.2d 413, 414-15 (5th Cir. 1980) (the wording of the dismissal order affirmatively shows the court refused to consider materials outside the pleadings). If matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Federal Rule of Civil Procedure 56. *Griffith,* 899 F.2d at 1433 n.2; *see, e.g.*, FED. R. CIV. P. 12(d). In the present case, the Court has not relied upon any evidence outside the pleadings.

B. Preemption

Defendant's Motion to Dismiss asserts first that Plaintiff's claims are barred by the applicable statutes of limitations and second that Plaintiff's claims are preempted by federal law. Although this Court agrees that Plaintiff's claims are time barred, the Court will address whether Plaintiff has sufficiently alleged any parallel state law claim that would survive federal preemption under both express preemption, 21 U.S.C. §360k(a), and implied preemption, 21 U.S.C. § 337(a).

In response to Defendant's Motion, Plaintiff acknowledges that her state law

claims are subject to federal preemption, as follows:

> [d]efendant's MemoryLens IOL is a Class III device that was subject to premarket approval by the United States Food and Drug Administration ("FDA"). As a result, there are federal requirements specific to the devise regarding its design, manufacture, and labeling. *Reigel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Put simply, this creates federal preemption. The only case in which state law claims regarding a Class III medical device are not preempted is where the claims are "parallel" to the federal requirements reflected in FDA's pre-market approval of the device. *Id*. at 330. That is, the state law claims must be "premised entirely on violation of applicable federal requirements." *Bass v. Stryker Corp.*, 669 F.3d 501, 509 (citing *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770 (5th Cir. 2011)).

Plaintiff's Memorandum [30] at 5; *see* Sec. Am. Compl. [26] at 2.

1. Express Preemption

In determining whether Plaintiff's claims are expressly preempted pursuant to the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug and Cosmetic Act (FDCA), *see* 21 U.S.C. §360c, *et seq*., a court must determine (1) whether the federal government has established requirements pertaining to the device, and (2) whether the plaintiff's common law claims are based on state requirements that are different from, or in addition to, the federal requirements and relate to safety and effectiveness, as set forth in 21 U.S.C. §360k(a). *Bass v. Stryker Corp*., 669 F.3d 501, 506-07 (5th Cir. 2012)(citing *Reigel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008)). Specifically,

> . . . [n]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any

> requirement -- (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a); *Ledet v. Medtronic, Inc.*, No. 1:13CV200, 2013 WL 6858858 at *2 (S.D. Miss. Dec. 30, 2013).

Pre-market approval of an individual Class III medical device is specific to the individual device. *Riegel,* 552 U.S. at 323; *Ledet,* 2013 WL 6858858 at *3**.** Since the MemoryLens IOL at issue received pre-market approval, the first prong of the express preemption analysis is automatically satisfied in the present case. *Bass,* 669 F.3d at 507.

Under the second prong of the express preemption test, this Court must determine whether Plaintiff's claims are based upon state requirements that are "different from, or in addition to" the federal requirements. *Riegel,* 552 U.S. at 321-22; *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 768 (5th Cir. 2011). Under the second prong of the express preemption analysis, a manufacturer is not protected from state tort liability when the claim is based on the manufacturer's violation of applicable federal requirements. *Hughes*, 631 F.3d at 767 (citation omitted). A parallel claim is one that is based upon a damages remedy provided by state law for a manufacturer's violation of the applicable federal requirements provided that the state law imposes no additional or different duties than those imposed by the applicable federal requirements. *Riegel*, 552 U.S. at 330.

2. Implied Preemption

Implied preemption bars a plaintiff's claims if the claims are based solely upon a violation of federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (citing 21 U.S.C. § 337(a)).

> The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: "All such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a).

Id. The MDA can only be enforced by the Federal Government pursuant to 21 U.S.C. § 337(a). *Id.* at 352. For Plaintiff to avoid implied preemption, Plaintiff's claims must be premised upon "state-law tort claims rather than any duties independently created" by the FDCA or the FDA regulations. *Bass*, 669 F.3d at 513-14.

In sum, in order to survive both express and implied preemption, the claim must be premised upon conduct that (1) violated the FDCA and (2) would give rise to recovery under state law even in the absence of the FDCA. *Ledet,* 2013 WL 6858858 at *3 (citation omitted).

3. Discussion

To overcome preemption, Plaintiff's Second Amended Complaint must not only state a parallel claim, but must state the parallel claim with sufficient facts to support a claim for relief that is legally cognizable. *Funk v. Stryker Corp.*, 631 F.3d

777, 782 (5th Cir. 2011). Conclusory allegations and unwarranted deductions of fact are not admitted as true by a motion to dismiss. *Associated Builders, Inc., v. Ala. Power Co.,* 505 F.2d 97, 100 (5th Cir. 1974).

Plaintiff admits in her Second Amended Complaint [26] and her Memorandum [30] that the MemoryLens IOL / U940A received pre-market approval. To overcome both express and implied preemption and survive a motion to dismiss, the Plaintiff's Second Amended Complaint must have stated "the existence of a manufacturing defect caused by a violation of federal regulations and allegations connecting a defect in the manufacture of the specific device to the plaintiff's specific injury." *Bass*, 669 F.3d at 511-12 (citation omitted); *see Timberlake v. Synthes Spine, Inc.*, No. V-08-4, 2011 WL 711075 at *9 (S.D. Texas, Feb. 18, 2011) (a plaintiff must plead the specific way in which the defendant's manufacturing process differed from that approved by the FDA in order to show that a manufacturing defect claim is truly parallel).

As set forth in Paragraph 21 of the Second Amended Complaint, all of Plaintiff's claims regarding the design, manufacture, testing, advertising, warning, marketing, and sale of the MemoryLens IOL rely upon her basic premise that Defendant: (1) deviated from the FDA's pre-approved manufacturing process; and thereafter (2) failed to warn of the possible adverse side effects caused by the new manufacturing process; (3) failed to conduct adequate testing of the new

manufacturing process; (4) failed to provide adequate information to medical providers concerning the possible side effects of the new manufacturing process; (5) failed to warn consumers and medical providers of a known defect due to the new manufacturing process; and (6) failed to notify prescribing physicians that the product was defective. Plaintiff advances claims for negligence, gross negligence, strict liability, breach of implied warranty, breach of express warranty, and negligent infliction of emotional distress.

It appears that the crux of Plaintiff's claims for damages is that Defendant deviated from the manufacturing process that had been pre-approved by the FDA for the MemoryLens IOL / U940A and utilized a "modified (buffered tumbling) manufacturing process" which resulted in a "biofilm formation within the lens causing opacification in a large majority of the lenses." Sec. Am. Compl. [26] at 2-4. Plaintiff contends that the lenses were adulterated. *Id*. at 3.

Plaintiff does assert the basic legal elements of a parallel claim, that Defendant deviated from the pre-approved manufacturing process which in turn caused a defect in the lens which in turn caused her injury. However, Plaintiff has not stated any facts to support the conclusory allegation that the alleged "buffered tumbling process" violated the pre-approved manufacturing process or any requirement specific to the MemoryLens IOL.

Plaintiff's "belief" that Defendant deviated from the pre-approved

manufacturing process, unsupported by any fact specific to the MemoryLens IOL, resembles the allegations contained in a plaintiff's complaint which was dismissed by the district court pursuant to a Rule 12(b)(6) motion in *Funk v. Stryker Corp.*, 631 F.3d 777 (5th Cir. 2011). In affirming the dismissal, the Fifth Circuit held that plaintiff's allegations that a "hip prostheses contained a manufacturing defect in that it was manufactured in such a manner that impurities, residues and bacteria remained on the prosthesis in violation of the FDA standards and requirements and in violation of the manufacturing processes and design approved by the FDA" were "impermissibly conclusory and vague" and that the complaint failed to specify the manufacturing defect or tell "how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process." *Id.* at 782 (citation omitted); *see In re Medtronic, Inc.*, 623 F.3d 1200, 1206-07 (8th Cir. 2010) (dismissal was appropriate where plaintiffs failed to identify any specific federal requirement in the PMA approval that could form the basis of an unpreempted parallel claim; further, the district court did not abuse its discretion in denying plaintiffs' motion to reconsider the dismissal order and grant their belated request for discovery to see if they could find such a basis).

The current case is distinguishable from *Bass v. Stryker Corp.*, 669 F.3d 501 (5th Cir. 2012), in which the Fifth Circuit overturned the district court's dismissal of a manufacturing defect claim. In *Bass,* the plaintiff alleged that: "(1) he received

a Shell implant [during hip replacement surgery]; (2) the FDA had previously warned Stryker [the defendant] of bioburden in excess of FDA regulations in its final rinse of the Shells; (3) after Bass's surgery, Stryker ultimately voluntarily recalled those Shells, including the Shell specifically used in Bass's implant; (4) Bass suffered from a loose Shell due to a lack of bony ingrowth; and (5) the lack of bony ingrowth is a known effect of an excess of bioburden and manufacturing residuals on Shells." *Id.* at 510. The *Bass* Court held that plaintiff had stated sufficient facts to go forward on his manufacturing defect claim because he had stated "that the FDA warned Stryker of excess contaminant in the manufacture of its Shells; that the Shells, including the Shell implanted into Bass's hip, were ultimately recalled because of contamination issues; and that Bass's Shell caused the type of injury that is consistent with excess contamination." *Id.* at 510-11.

Unlike *Bass*, because all of Plaintiff's claims in this case are premised upon the unadorned conclusory allegation that Defendant failed to follow the FDA's pre-approved manufacturing process, Plaintiff has not articulated a parallel state law claim. Plaintiff's claims are therefore preempted.

C. Statute of Limitations

Even if Plaintiff's claims were not preempted, her state law claims are barred by the applicable statutes of limitations under Mississippi law. The three-year statute of limitations for Plaintiff's negligence and strict liability claims found at

Mississippi Code Annotated §15-1-49 expired in 2002, and the six-year statute of limitations for her warranty claims set forth at Mississippi Code Annotated §75-2-725 expired in 2005, long before Plaintiff filed suit on September 20, 2013.

Plaintiff's reliance upon Mississippi Code Annotated §15-1-49(2) for the proposition that she is entitled to the benefit of the discovery rule is misplaced in that Plaintiff did not suffer a latent injury. Mississippi Code Annotated §15-1-49(2) provides that: "[i]n actions for which no other period of limitation is prescribed and which involve latent injury or disease, the cause of action does not accrue until the plaintiff has discovered, or by reasonable diligence should have discovered, the injury." This discovery rule is limited to latent injuries. *PPG Architectural Finishes, Inc. v. Lowery*, 909 So. 2d 47, 50 (Miss. 2005) (if a latent injury is not present the discovery rule does not apply).

Plaintiff asserts that she suffered a latent injury and that she was not put on notice of an injury to her left eye until "on or about April 12, 2012, when she suffered 'stabbing pain in her left eye' and when her treating physician indicated that the MemoryLens IOL may need to be replaced." Sec. Am. Compl. [26] at 4. However, the facts set forth in the Second Amended Complaint reflect chronic ongoing medical complaints which began almost immediately following the implantation of Plaintiff's replacement lens in her left eye during cataract surgery in 1999. Plaintiff experienced inflammation, pain, infection, and the inability to

see, which prevented her from living a normal life and severely restricted her activities including her ability to operate a vehicle. Finally, Plaintiff's statement that she had suffered from pain and loss of vision in her left eye for twelve years prior to the lens extraction that occurred on April 9, 2013, reflects that she experienced the pain and loss of vision in April 2001. Since the left eye replacement lens was implanted in October 1999, the pain and loss of vision suffered by Plaintiff occurred prior to the running of the three-year statute of limitations in 2002.

The record leads to the conclusion that Plaintiff knew or should have discovered through reasonable diligence that the replacement lens caused the injury to her left eye well within both the three- and six-year statutes of limitations. The sharp pain experienced by Plaintiff on April 12, 2012, did not establish a new cause of action. *Kemp v. G. D. Searle & Co.*, 103 F.3d 405, 408 (5th Cir. 1997) (Mississippi has long followed the rule that a tortious act gives rise to but a single cause of action and the limitations period begins to run when plaintiff can reasonably be held to have knowledge of the injury or disease); *Robinson v. Singing River Hosp. Sys.,* 732 So. 2d 204, 208 (Miss. 1999)(the cause of action accrues upon the occurrence of the traumatic injury, regardless of whether the full extent of the disability is known at the time).

Plaintiff's theory that she was required to have a medical opinion that causally linked her eye problems to the replacement lens before her cause of action

could accrue has been rejected based upon the plain language of Mississippi Code Annotated §15-1-49. "Under §15-1-49, a cause of action accrues when the plaintiff has knowledge of the injury, not knowledge of the injury and its cause." *Barnes ex. rel. Barnes v. Koppers, Inc.*, 534 F.3d 357, 361 (5th Cir. 2008). Additionally, neither absolute certainty nor an expert opinion is required for a plaintiff to assert a cause of action under Mississippi's products liability statute. *PPG Architectural Finishes,* 909 So. 2d at 52.

The Mississippi Supreme Court has held that:

> [t]he question of whether a statute of limitations is tolled by the discovery rule often turns on the factual determination of what the plaintiff knew and when. Thus, occasionally the question of whether the suit is barred by the statute of limitations is a question of fact for the jury; however, as with other putative fact questions, the question may be taken away from the jury if reasonable minds could not differ as to the conclusion.

Stringer v. Trapp, 30 So. 3d 339, 342 (Miss. 2010)(citation omitted*)*; *Ledet,* 2013 WL 6858858 at *6.

Based upon the facts contained on the face of the Second Amended Complaint, there can be no question that Plaintiff knew or reasonably should have known of her injury within three years following her October 1999 cataract surgery. The Court finds that reasonable minds could not differ as to the conclusion that Plaintiff's state law claims are barred by both the applicable three- and six-year statutes of limitations under Mississippi law. Plaintiff's Second Amended

Complaint should be dismissed with prejudice.

III. CONCLUSION

Based upon the facts alleged in the Second Amended Complaint, Plaintiff has not stated a plausible claim upon which relief can be granted in that her claims are preempted by federal law and are otherwise barred by the applicable statutes of limitations under Mississippi law. CIBA's Motion to Dismiss Plaintiff's Second Amended Complaint [27] should be granted, and this case will be dismissed with prejudice.

IT IS, THEREFORE, ORDERED AND ADJUDGED that, for the reasons stated herein, the Motion to Dismiss Plaintiff's Second Amended Complaint filed by Defendant CIBA Vision Corporation is **GRANTED**, and this case is **DISMISSED WITH PREJUDICE**.

SO ORDERED AND ADJUDGED, this the 27th day of April, 2015.

s/ Halil Suleyman Ozerden
HALIL SULEYMAN OZERDEN
UNITED STATE DISTRICT JUDGE