UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

TAMMIE L. WILLIAMS, *et al.*,

Plaintiffs,

v.

Case No.: 2:08-cv-910
JUDGE SMITH
Magistrate Judge Kemp

BAUSCH & LOMB COMPANY, *et al.*,

Defendants.

OPINION AND ORDER

This matter is before the Court on Defendants Bausch & Lomb Company and pSivida US Inc.'s Motion to Dismiss the Non-Statutory Product Liability Causes of Action in Plaintiffs' Complaint (Doc. 5 and 24).[1] Plaintiffs Tammie and Charles Williams (collectively "Plaintiffs") bring this action against Defendants Bausch & Lomb Company, pSivida US Inc.,[2] David G. Callanan, M.D., Texas Retina Associates, and two John Does. Plaintiffs assert claims for strict liability, negligence, breach of implied warranty, breach of express warranty, negligent misrepresentation, intentional infliction of emotional distress, and loss of consortium.

Plaintiffs initiated this case on September 26, 2008. Defendant Bausch & Lomb filed its Motion to Dismiss on October 20, 2008 (Doc. 5), and Defendant pSivida filed its Motion to

[1] Defendants David G. Callanan, M.D. and Texas Retina Associates moved the Court to dismiss for lack of personal jurisdiction, which was granted on August 28, 2009 (Doc. 38).

[2] Defendant pSivida states that it is incorrectly identified in Plaintiffs' Complaint as pSivida USA, Inc. and pSivida Company.

Dismiss on January 15, 2009 (Doc. 24). Plaintiffs have filed their responses and the Motions are now ripe for review. For the reasons that follow, this Court **GRANTS** Defendant Bausch & Lomb's Motion to Dismiss and **GRANTS** Defendant pSivida's Motion to Dismiss.

I. FACTS

Plaintiffs Tammie and Charles Williams are residents of Columbus, Ohio. Defendant Bausch & Lomb Company has its principal place of business in Rochester, New York and is in the business of designing, manufacturing and distributing optometric devices, including the Retisert Intravitreal Fluocinolone Acetonide Implant (the "Implant") at issue in this case. Defendant pSivida has its principal place of business in Watertown, Massachusetts and is in the business of designing, manufacturing and/or distributing the Implant. Defendant David G. Callanan is a medical physician who acted as an agent, principal investigator, and study doctor for Bausch & Lomb by surgically placing the Implant in Plaintiff Tammie Williams' eye. Defendant Texas Retina Associates is the association for which Defendant Callanan was working at the time of the implant surgery. John Doe Defendants A and B, are or were suppliers, distributors and/or manufacturers of the Implant and were agents, officers and representatives of Defendant Bausch & Lomb and were acting in their individual and official capacities.

On or about May 21, 2001, Plaintiff Tammie Williams agreed to participate in a clinical research study sponsored by Defendant Bausch & Lomb. Plaintiff agreed to have the Implant surgically implanted into her right eye for the treatment of Uveitis affecting the posterior segment of the eye. The Implant releases an anti-inflammatory drug to reduce the swelling of certain tissues in the eye (uveitis). Plaintiff was advised that the Implant could safely remain in her eye permanently. Plaintiff signed a consent form on May 21, 2001, permitting the Implant to be

placed in her eye, and the surgery was performed that day by Defendant David G. Callanan, M.D. at his office in Arlington, Texas.

Defendant Bausch & Lomb contends, and Plaintiffs deny, that Ms. Williams was presented with a second consent form on or about November 6, 2003, approximately 30 months after having the Implant surgery. The second consent form indicates that "a separation of the cup" (which holds the drug pellet) from the "strut" (which holds the Implant in place in the back of the eye) has been observed in a few study patients that had the implants for over 18 months. The second consent form further stated that "if this does occur, it is unlikely that the eye would feel any discomfort nor should you anticipate any serious or otherwise severe affects to occur."

On or about October 6, 2006, the Implant in Plaintiff's eye separated causing her pain, blurred vision, and discomfort. Ms. Williams had to undergo surgery to remove the broken Implant. On or about October 9, 2006, immediately after the removal of the broken Implant from Plaintiff's eye, she suffered the complete loss of all vision in her eye and continues to experience total blindness in her right eye. Prior to the breakage of the Implant, Plaintiff had vision in her right eye.

Plaintiffs allege that the consent form and documentation regarding the Implant did not provide any warning or make any mention of the Implant's susceptibility to breakage, nor the harmful affects of breakage or separation of the Implant while in the eye. Plaintiff also alleges that the Implant was not adequately tested.

Plaintiffs assert seven claims in their Complaint: 1) strict liability; 2) negligence; 3) breach of implied warranty; 4) breach of express warranty; 5) negligent misrepresentation; 6) intentional infliction of emotional distress; and 7) loss of consortium.

II. STANDARD OF REVIEW

When considering a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a court must construe the complaint in the light most favorable to the plaintiff and accept all well-pleaded material allegations in the amended complaint as true. *See Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974); *Roth Steel Prods. v. Sharon Steel Corp.*, 705 F.2d 134, 155 (6th Cir. 1983). A 12(b)(6) motion to dismiss is directed solely to the complaint and any exhibits attached to it. *Roth Steel Prods.*, 705 F.2d at 155. The merits of the claims set forth in the complaint are not at issue on a motion to dismiss for failure to state a claim. Consequently, a complaint will be dismissed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure only if there is no law to support the claims made, or if the facts alleged are insufficient to state a claim, or if on the face of the complaint there is an insurmountable bar to relief. *Rauch v. Day & Night Mfg. Corp.*, 576 F.2d 697, 702 (6th Cir. 1978). Rule 12 (b)(6) must be read in conjunction with Rule 8(a) of the Federal Rules of Civil Procedure which provides that a pleading for relief shall contain "a short and plain statement of the claim showing that the pleader is entitled to relief." 5A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1356, at 296 (2d ed. 1990). The moving party is entitled to relief only when the complaint fails to meet this liberal standard. *Id.*

Although the court must apply a liberal construction of the complaint in favor of the party opposing the motion to dismiss, a court will not accept conclusions of law or unwarranted inferences of fact cast in the form of factual allegations. *See Blackburn v. Fisk Univ.*, 443 F.2d 121, 124 (6th Cir. 1971); *see also Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955,

1964-65 (2007)[3]. A plaintiff's obligation to provide the "grounds" of their entitlement to relief requires more than labels and conclusions or a formulaic recitation of the elements of the cause of action. *See LULAC v. Bredesen*, 2007 U.S. App. LEXIS 20556 at *3-4 (6th Cir. 2007) (*citing Bell Atlantic Corp. v. Twombly*, 127 S. Ct. at 1964-65). The factual allegations, assumed to be true, must do more than create speculation or suspicion of a legally cognizable cause of action; they must show entitlement to relief. *Id.*

Defendants have also moved to dismiss pursuant to Rule 12(f) of the Federal Rules of Civil Procedure which provides that "[t]he court may strike from a pleading any insufficient defense or any redundant, immaterial, impertinent or scandalous matter."

III. DISCUSSION

Defendant Bausch & Lomb and pSivida have moved to dismiss Counts Two, Three, Four, Five and Six of Plaintiffs' Complaint. Defendants argue that these non-statutory claims fail to state a claim upon which relief may be granted. Specifically, Defendants argue that Ohio's comprehensive product liability statutes, Ohio Revised Code Sections 2307.71 through 2307.80, constitute Plaintiffs' exclusive remedy, as stated in Ohio Revised Code Section 2307.71, and any claims which fall outside that statutory structure must be dismissed.

Defendants argue that all of Plaintiffs' claims are product liability claims as defined in Ohio Revised Code section 2307.71(A)(13) and therefore subject to the exclusive remedies provided in

[3] In *Bell Atlantic Corp.*, the United States Supreme Court rejected the language previously used by the Court in *Conley v. Gibson*, providing that "[i]n appraising the sufficiency of the complaint we follow, of course, the accepted rule that a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." 355 U.S. 41, 45-46 (1957). *See Bell Atlantic Corp.*, 127 S.Ct. at 1969 (holding that the *Conley* "no set of facts" language "has earned its retirement" and "is best forgotten.").

Ohio's Product Liability Statutes. The Ohio Product Liability Act applies to "recovery of compensatory [or punitive] damages based on a product liability claim." O.R.C. § 2307.72(A); *see also Delahunt v. Cytodyne Techs*, 241 F. Supp. 2d 827, 842 (S.D. Ohio 2003). A "Product liability claim" is defined as:

> a claim that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:
> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
> (c) Any failure of that product to conform to any relevant representation or warranty.

O.R.C. § 2307.71(A)(13).

Defendants further assert that the Court must look to the essential nature of the substantive allegations of Plaintiffs' claims and not the artificial label that Plaintiffs attach to the claims. *See Lawyer's Cooperative v. Muething*, 65 Ohio St.3d 273 (1992).

Plaintiffs argue that although Ohio Revised Code section 2307.71(B) is clear that the Legislature intended to abrogate all common law product liability claims, the allegations of the claims set out in their Complaint all fall within the statutory provisions of Ohio Products Liability law, as set out in Ohio Revised Code sections 2307.71 through 2307.80. Therefore, Plaintiffs argue that all their claims are authorized by the statute and are not subject to dismissal. Plaintiffs rely on *Stratford v. SmithKline Beecham Corp.*, 2008 WL 2491965 (S.D. Ohio 2008) in support of their argument. In *Stratford*, the court held that while certain claims were abrogated by the Ohio Products Liability Act, including a negligence claim, the allegations in those claims were

authorized by the Ohio Products Liability Act and could form the basis of claims under the Act.

Both parties agree that the Ohio Products Liability Act is applicable to Plaintiffs' claims in this case. Plaintiffs are seeking damages from a manufacturer for a physical injury that arose from the implant inserted into Mrs. Williams' eye. As a products liability claim, any recovery of compensatory damages is subject to sections 2307.71 through 2307.79 of the Ohio Revised Code. Effective April 7, 2005, section 2307.71 was amended to include the following:

> (B) Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability causes of action.

The amended version of the aforementioned code section applies to actions that arose after the effective date of the amendments. *See Luthman v. Minster Supply Co.*, 2008 Ohio 165 (Ohio Ct. App. Jan. 22, 2008) (applying the version of the Ohio Revised Code in effect at the time the cause of action accrued).

Plaintiffs' cause of action accrued on or about October 2006, at the time the Implant separated in Plaintiff's eye and had to be removed causing her severe pain and loss of vision. As the cause of action accrued after the effective date (April 7, 2005) of amended Ohio Revised Code section 2307.71, the amended version of the statute applied to the case at bar. Accordingly, all common law claims arising from damages in connection with product liability claims are abrogated by the Ohio Products Liability Act.

Plaintiffs argue that even if the Court finds that their claims are abrogated by the Ohio Products Liability Act, they should be dismissed without prejudice to allow them to be re-pled in accordance with the Act. Claims that are authorized by the Ohio Products Liability Act should be

pled with reference to the applicable provision of the Act. *See Delahunt*, 241 F. Supp. 2d at 844 (in order to avoid confusion with respect to product liability claims, the complaint should clarify which section of the OPLA governs each of the plaintiff's claims). The court in *Stratford* was faced with this same issue and dismissed the plaintiffs' claims without prejudice in order to plead the allegations pursuant to the Ohio Products Liability Act. Like the court in Stratford, this Court finds that the allegations set forth in Plaintiffs' claims for negligence, breach of implied warranty, breach of express warranty, negligent misrepresentation, and intentional infliction of emotional distress may be plead such that they are authorized under the Ohio Products Liability Act. Plaintiffs' claims for negligence, breach of implied warranty, breach of express warranty, negligent misrepresentation, and intentional infliction of emotional distress are therefore dismissed without prejudice to be re-pled pursuant to the Ohio Products Liability Act.

IV. DISPOSITION

Based on the foregoing analysis, Defendants Bausch & Lomb and pSivida's Motions to Dismiss are **GRANTED**. Plaintiffs' claims for negligence, breach of implied warranty, breach of express warranty, negligent misrepresentation, and intentional infliction of emotional distress are hereby dismissed without prejudice. Plaintiffs are granted leave to amend their Complaint in accordance with this Order.

The Clerk shall remove Documents 5 and 24 from the Court's pending motions list.

IT IS SO ORDERED.

/s/ George C. Smith
GEORGE C. SMITH, JUDGE
UNITED STATES DISTRICT COURT