

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

RICHARD KRYWOKULSKI,

Plaintiff,

v.

CASE NO: 8:09-CV-980-T-30MAP

**ETHICON, INC., a subsidiary of
Johnson & Johnson and
JOHNSON & JOHNSON OF
NEW JERSEY, INC.,**

Defendants.

ORDER

Before the court are Defendants Ethicon, Inc. (“Ethicon”) and Johnson & Johnson (“J&J”) **Joint Motion to Dismiss** (Dkt. 10) and Plaintiff’s response to this motion (Dkt. 12). The Court, having considered the motion and response, and being otherwise advised in the premises, determines that the motion should be granted in part.

Plaintiff alleges that Defendants are liable for Plaintiff’s injuries resulting from the installment and removal of Proceed Surgical Mesh Hernia Patches manufactured by Defendants. More specifically, Plaintiff alleges Defendants are liable pursuant to two tort theories: (1) strict liability and (2) negligence (Dkt. 2). Defendants move to dismiss the “Second Amended Complaint” pursuant to Rule 12(b)(6), Fed. R. Civ. P., arguing that the complaint is deficient because it makes only conclusory allegations and does not allege enough facts.

I. BACKGROUND

On or about October 19, 2004, Plaintiff underwent surgical repair of a ventral hernia at South Bay Hospital (Dkt. 2 at ¶ 4). Plaintiff's surgeon, Dr. Eli. N. Lerner, installed Proceed Surgical Mesh Hernia Patches to repair the ventral hernia (Id. at ¶ 5). The Proceed Surgical Mesh Hernia Patches ("patch") were manufactured and distributed by Defendants. Id. On or about February 24, 2006, Plaintiff complained to Dr. David Goldsberry that he was experiencing pain and swelling over the surgical site (Id. at ¶ 6). Dr. Goldsberry informed Plaintiff that he had an infected incisional hernia repair and that the patch must be removed (Id. at ¶¶ 7, 8). Plaintiff underwent surgery at the Tampa Veteran's Administration Medical Center to remove the infected patch on May 18, 2006 (Id. at ¶¶ 8, 9). Plaintiff alleges that the Proceed Surgical Mesh Hernia Patch used during his October 2004 surgery failed and was defective, causing Plaintiff to incur physical damage, bodily injury, infection, and additional surgery (Id. ¶ at 12).

II. STANDARD OF REVIEW

Although Rule 8(a)(2), Fed. R. Civ. P., requires a complaint to contain "a short and plain statement of the claim showing that the pleader is entitled to relief," the complaint must allege enough so that the defendant has fair notice of what the claim is and the grounds upon which it rests. Davis v. Coca-Cola Bottling Co. Consolidated, 516 F.3d 955, 974 (11th Cir. 2008) (citing Bell Atl. Corp v. Twombly, 550 U.S. 544, 555-56 (2007)). Thus, to survive Rule 12(b)(6), Fed. R. Civ. P., dismissal, a plaintiff must allege more than "labels and conclusions," and "a formulaic recitation of the elements of a cause of action will not do."

Bell Atl. Corp., 550 U.S. at 555 (2007). “Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement.” Ashcroft v. Iqbal, 129 S. Court. 1937, 1949 (2009) (internal quotations omitted). While the court views allegations of the complaint in the light most favorable to the plaintiff, takes plaintiff’s allegations to be true, and accept all reasonable inferences therefrom, the plaintiff must provide “enough facts to state a claim that is plausible on its face.” Bell Atl. Corp., 550 U.S. at 570. More simply, “conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts” will subject a complaint to dismissal. Davila v. Delta Air Lines, Inc., 326 F.3d 1183, 1185 (11th Cir. 2003).

Factual allegations do not need to be in detail, but do demand more than “an unadorned, the-defendant-unlawfully-harmed-me accusation.” Ashcroft, 129 S. Court. at 1949 (2009). Sheer possibilities that the defendant acted unlawfully does not state a facially plausible claim for relief. Waters Edge Living, LLC v. Rsui Indem. Co., 2009 WL 4366031 at *3 (11th Cir. Dec. 3, 2009) (citing Ashcroft, 129 S. Court. at 1949). The factual allegations must permit a court reviewing a motion to dismiss “to draw the reasonable inference that the defendant is liable for the misconduct alleged” under some viable legal theory. Id. In addition, Rule 12(b)(6), Fed. R. Civ. P, authorizes a court to dismiss a claim on the basis of a dispositive issue of law. Neitzke v. Williams, 490 U.S. 319, 326-27 (1989); Marshall County Bd. of Educ. v. Marshall County Gas Dist., 992 F.2d 1171, 1174 (11th Cir. 1993).

III. DISCUSSION

A. Strict Liability Theory

Plaintiff alleges in Counts I and III that Defendants are strictly liable for Plaintiff's injuries resulting from the installation of the Proceed Surgical Mesh Patch. (Dkt. 2 at ¶¶ 14-17, 23-26). Defendants argue that Plaintiff fails to plead the requisite elements of strict liability and any factual allegations to support it.

Florida, which adopted the strict products liability standard from the Restatement 2d of Torts § 402 A, holds that a manufacturer of a defective product can be held liable if (1) the manufacturer made the product in question, (2) the product had a defect that renders it unreasonably dangerous, and (3) the unreasonably dangerous condition was the proximate cause of the plaintiff's injury. Jennings v. BIC Corp., 181 F.3d 1250, 1255 (11th Cir. 1999).

As to the first element, Plaintiff alleges that Ethicon and J&J manufactured and distributed the patch used in Plaintiff's surgical operation in October 2004 (Dkt. 2 at ¶ 5). Second, Plaintiff alleges that the product used in his operation contained "design, manufacture, and warning[]" defects (Id. at ¶ 15). More specifically, Plaintiff alleges that the defective patches delaminated and/or malfunctioned, thus making the patches unsafe and dangerous for use (Id. at ¶ 16). Finally, Plaintiff alleges that the defective patch was a direct and proximate result of injuries to the Plaintiff (Id. at ¶¶ 17, 26).

Defendants first argue that Plaintiff has failed to meet the requirements of a strict product liability claim, focusing on Plaintiff's failure to prove a defect and plead enough factual allegations to support his claims. Second, Defendants ask this Court to believe that

Twombly and Ashcroft placed a higher pleading burden upon plaintiffs to survive a Rule 12(b)(6), Fed. R. Civ. P., dismissal.

As noted above, Plaintiffs have met the pleading standard of Rule 8, Fed. R. Civ. P. Defendants believe that in addition to the elements of strict liability set out above, Plaintiff must also prove the existence of a product defect at the pleading stage of trial. As support, Defendants cite Rodriguez v. Nat'l Detroit, Inc., 857 So. 2d 199, 201 (Fla. 3d. DCA 2003); Cassisi v. Maytag Co., 396 So. 2d 1140, 1143 (Fla 1st. DCA 1981); and Griffin v. Kia Motors Corp., 843 So. 2d 336 (Fla. 1st DCA 2003). However, in each of these cases, the litigation had proceeded past the pleading stage and into the summary judgment or trial stage. In the instant case, only the pleadings have been filed and no evidence has been placed of record. If, at this current stage, Plaintiff failed to allege the existence of a defect or that the defect has led to an unreasonably dangerous condition, then Defendants would succeed in their motion to dismiss.

Moreover, Defendants contend that Plaintiff is required to provide more facts than currently alleged, including which defects Plaintiff's believe Defendants' product suffers from (product design, warning or manufacture). However, this is not a requirement at this stage of the litigation. As the Eleventh Circuit explains, "it would be difficult at such an early stage in the litigation for plaintiff to know whether a defect was due to a product's design or manufacture." Bailey v. Janssen Pharmaceutica, 288 Fed. Appx. 597, 605 (11th Cir. 2008) (affirming in part and reversing in part Bailey v. Janssen Pharmaceutica, 2006 WL 3665417 (S.D. Fla. Nov. 14, 2006)). Florida law does not require that a plaintiff be required

to plead design defect versus manufacturing defect during the complaint stage. Id. Plaintiff's allegation of a defect alone is sufficient, as mere knowledge of a defect gives defendant enough notice to produce a proper response which may include discussion of a manufacturing or design based defect. Id.

Finally, Defendants ask this court to apply the principles of two cases as evidence that in light of Twombly and Ashcroft, a higher pleading standard govern drugs and medical device cases. First, Defendants note Beale v. Biomet, Inc., No. 05-22941 (S.D. Fla. Aug. 16, 2006), requires that a plaintiff plead with particularity as to which defect his case rests on (warning, manufacture or design). However, as referenced above, Beale is no longer good law as Bailey merely requires the allegation of a defect, not which particular defect theory the plaintiff will prove at trial. Second, Defendants ask this court to apply the principles of Wolicki-Gables, et al. v. Arrow Int'l, Inc., et al., 2008 WL 2773721 (M.D. Fla. June 17, 2008). Wolicki-Gables is of no assistance to the Defendants. The Wolicki-Gables court dismissed plaintiff's complaint because it failed to expressly plead the existence of a product defect; the plaintiff only alluded to a defect in his allegations. Unlike Wolicki-Gables, Plaintiff has alleged the existence of a product defect as well as providing facts indicating the presence of a product defect. (See Dkt. 2, ¶¶ 10-12).

The Plaintiff's strict liability counts are plausible and thus will not be dismissed for failure to state a claim upon which relief can be afforded.

B. Negligence Theory

In Counts II and IV, Plaintiff alleges that Defendants are liable for Plaintiff's injuries because they knew or should have known of the defect in the Proceed Surgical Mesh Patch surgically placed in Plaintiff. (Dkt. 2 at ¶¶ 18-22, 27-31). Defendants argue that Plaintiff failed to allege a duty owed to the Plaintiff and a breach of what that duty might be.

“In the context of products liability, the basic elements of a negligence cause of action apply: (1) duty of care toward the plaintiff; (2) breach of that duty (or negligence); (3) proximate cause; [and (4)] ... the product was defective or unreasonably dangerous.” Marzullo v. Crosman Corporation, 289 F. Supp. 2d 1337, 1342 (2003) (citation omitted).

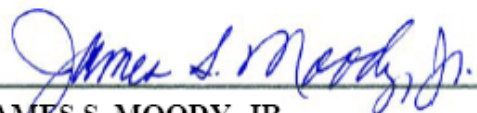
While the elements are similar to strict product liability theory, a plaintiff alleging negligence has the added burden of proving specific acts of negligence. Jennings, 181 F.3d at 1256-57.

In the instant case, Plaintiff has alleged the existence of a product defect and the proximate cause of the defect on the Plaintiff. However, Plaintiff has failed to allege the existence of a duty either Defendant owed the Plaintiff and a breach of what that duty might be. Failure to allege all the necessary elements of a negligent act in the context of products liability warrants dismissal for failure to state a claim upon which relief can be afforded. Gomez v. Pefizer, Inc., 2009 WL 4908937 at *2 (S.D. Fla. Dec. 21, 2009) (Court dismissed negligence claims because plaintiff failed to allege the existence of a duty); Bailey, 288 Fed. Appx. at 609 (Negligence count dismissed because plaintiff failed to explain each defendant's individual duty and breach in its production of the product in question). Therefore, Defendants' motion for dismissal is granted with regard to Counts II and IV.

It is therefore **ORDERED AND ADJUDGED** that:

- (1) Defendants' Joint Motion to Dismiss (Dkt. 10) is **GRANTED** in part and **DENIED** in part as set forth herein.
- (2) Plaintiff may file an Amended Complaint within 20 days of the date of this Order.

DONE and **ORDERED** in Tampa, Florida on January 21, 2010.



JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel/Parties of Record

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