UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

ASHLEY L. JOZWIAK,

Plaintiff,

-vs- **Case No. 6:09-cv-1985-Orl-19GJK**

STRYKER CORPORATION, STRYKER SALES CORPORATION, McKINLEY MEDICAL, LLC, MOOG, INC., and CURLIN MEDICAL, INC.

Defendants.

ORDER

This case comes before the Court on the following:

1. Motion to Dismiss Plaintiff's Amended Complaint by Defendants McKinley Medical, LLC, Moog, Inc., and Curlin Medical, Inc. (Doc. No. 32, filed Jan. 29, 2010);

2. Motion to Dismiss Plaintiff's Amended Complaint by Defendants Stryker Corporation and Stryker Sales Corporation (Doc. No. 33, filed Feb. 2, 2010);

3. Motion for Extension of Time to Serve Response to Defendants' Motion to Dismiss by Plaintiff Ashley L. Jozwiak (Doc. No. 34, filed Feb. 12, 2010);

4. Response to McKinley Medical, LLC, Moog, Inc., and Curlin Medical, Inc.'s Motion to Dismiss the Amended Complaint by Plaintiff Ashley L. Jozwiak (Doc. No. 35, filed Feb. 16, 2010);

5. Response to Stryker Corporation and Stryker Sales Corporation's Motion to Dismiss the Amended Complaint by Plaintiff Ashley L. Jozwiak (Doc. No. 36, filed Feb. 16, 2010); and

6. Motion for Leave to File a Reply Memorandum to Plaintiff's Response to Defendants' Motion to Dismiss by Defendants Stryker Corporation and Stryker Sales Corporation (Doc. No. 37, filed Feb. 23, 2010).

Background

I. Plaintiff's Allegations[1]

This case concerns an allegedly defective pain pump installed in the shoulder of Plaintiff Ashley L. Jozwiak during a surgery performed on March 23, 2005. (Doc. No. 28 ¶ 17, filed Jan. 8, 2010.) Jozwiak asserts that the defective pain pump was manufactured, marketed, distributed, sold, or promoted by Defendants Stryker Corporation, Stryker Sales Corporation, McKinley Medical, LLC, Moog, Inc., and Curlin Medical, Inc. (collectively, "Defendants"). (*Id.* ¶ 15.) Jozwiak also maintains that the defective pain pump was filled with anesthetic pain medication pursuant to the Defendants' instructions for use and that the pain pump delivered anesthetic into Plaintiff's shoulder join for an extended length of time. (*Id.* ¶ 17.) The pain pump allegedly caused the cartilage in Plaintiff's shoulder joint to disintegrate, resulting in a severe, disabling condition known as gleno-humeral chondrolysis. (*Id.* ¶¶ 18-19.)

Jozwiak alleges that the instructions for use accompanying the pain pump contained no warning or cautionary statement regarding the risk of cartilage injury. (*Id.* ¶ 20.) She further asserts

[1] The facts presented in this Order are derived from the allegations of the Amended Complaint. These facts are included only to provide context and should not be construed as findings of fact.

that: (1) Defendants knew or should have known that continuous exposure to large doses of anesthetic pain medication was toxic to cartilage; (2) Defendants conducted no pre-market testing to evaluate the safety of their pain pump when used during orthopedic surgery; (3) Defendants failed to conduct testing to evaluate the effect of continuous exposure to large doses of anesthetics on articular cartilage; and (4) Defendants represented that their pain pump was cleared for use in orthopedic surgery when in fact the FDA denied approval of the pain pump for such use. (*Id.* ¶¶ 22-25.)

II. Procedural History

Plaintiff filed an three-count complaint alleging the following claims against all Defendants: (1) negligence (*id.* at 5-7); (2) strict liability for defective design (*id.* at 7-8); and (3) strict liability for failure to warn (*id.* at 8-10). On January 29, 2010, Defendants McKinley Medical, LLC, Moog, Inc., and Curlin Medical, LLC ("McKinley Defendants") moved to dismiss the Amended Complaint for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6). (Doc. No. 32.) On Feburary 2, 2010, Defendants Stryker Corporation and Stryker Sales Corporation ("Stryker Defendants") filed a Motion to Dismiss. (Doc. No. 33.) On February 12, 2010, the day that a response to the McKinley Defendants' Motion to Dismiss was due, Plaintiff filed a Motion for Extension of Time to Respond. (Doc. No. 34.) Counsel for the McKinley Defendants did not oppose granting an extension of time on the condition that Jozwiak file her response by February 16, 2010. (*Id.* at 1-2.) On February 16, 2010, Plaintiff filed her Responses to both Motions to Dismiss. (Doc. Nos. 35-36.) On February 23, 2010, the Stryker Defendants moved for leave to file a reply to Plaintiff's response. (Doc. No. 37.)

Standard of Review

I. Motion for an Extension of Time

Pursuant to Rule 6(b)(1)(A) of the Federal Rules of Civil Procedure, a court may grant an extension of time for good cause shown if a motion is made before the original time expires. The diligence of the moving party should be considered in determining whether there is good cause to extend a deadline. *See Sosa v. Airprint Systems, Inc.*, 133 F.3d 1417, 1418 (11th Cir. 1998) ("The good cause standard precludes modification unless the schedule cannot be met despite the diligence of the party seeking the extension.") (internal quotations omitted).

II. Motion to Dismiss

When ruling on a motion to dismiss for failure to state a claim upon which relief may be granted under Federal Rule of Civil Procedure 12(b)(6), a court must limit its consideration to the complaint, the written instruments attached to it as exhibits, "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007); *GSW, Inc. v. Long County, Ga.*, 999 F.2d 1508, 1510 (11th Cir. 1993). In determining the merits of the motion, a court must "accept all factual allegations in the complaint as true." *Tellabs, Inc.*, 551 U.S. at 323. However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, __ U.S. __, 129 S. Ct. 1937, 1949 (2009). Thus, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

Once a court "identif[ies] pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth," the court must next determine whether the well-pled facts "'state

a claim to relief that is plausible on its face.'" *Id.* at 1949-50 (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 1949 (citing *Twombly*, 550 U.S. at 556). "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 1950 (citation omitted). As the United States Supreme Court explained:

> The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Id. at 1949 (quotation marks and internal citations omitted) (quoting *Twombly*, 550 U.S. at 557). On a Rule 12(b)(6) motion to dismiss, when a court considers the range of possible interpretations of the defendant's alleged conduct, if the "more likely explanations" involve lawful, non-actionable behavior, the court should find that the plaintiff's claim is not plausible. *Id.* at 1950-51.

Analysis

I. Motion to Extend Time

The McKinley Defendants moved to dismiss the Amended Complaint on January 29, 2010, and thus Plaintiff's response was due by February 12, 2010. *See* Local Rule 3.01(b) (providing fourteen days to serve a response in opposition to a motion). On February 12, 2010, Plaintiff moved to extend the deadline for filing a response to the McKinley Defendants' Motion to Dismiss, which was unopposed. (Doc. No. 34.) Because Plaintiff's Motion to Extend was filed within the deadline for filing a response, the Court may grant an extension of time upon a showing of good cause. Fed. R. Civ. P. 6(b)(1)(A).

Jozwiak's counsel averred that he was nearing completion of the response to the motion to dismiss on the afternoon of February 12, 2010, when a power surge caused his computer to re-boot and the unsaved response to be lost. (Doc. No. 34 at 1.) In the absence of any opposition or contrary facts, the Court finds that Jozwiak's counsel was diligent and that there is good cause to extend the deadline for filing a response to the McKinley Defendants' Motion to Dismiss until February 16, 2010. *Sosa*, 133 F.3d at 1418. Thus, Jozwiak's response was timely filed.

II. Motion for Leave to File Reply

The Stryker Defendants moved for leave to file a reply to Jozwiak's Response to their Motion to Dismiss, seeking an opportunity to further address the legal standards under which the Motions to Dismiss must be considered. (Doc. No. 37 at 2.) The legal standards under Rule 12(d) and (f) raised by the Defendants' Motions to Dismiss are well-settled and will be addressed by the Court herein. *See infra* part III.A. Therefore, a reply brief is not necessary, and the Court will proceed to the merits of the instant Motions to Dismiss.

III. Motions to Dismiss

The McKinley Defendants argue that the Amended Complaint should be dismissed against them for failure to state a claim because: (1) Jozwiak fails to sufficiently plead her claims of negligence and strict liability by failing to allege any facts that plausibly establish the identify the manufacturer of the pain pump at issue (Doc. No. 32 at 8-10); and (2) an email from Plaintiff's counsel states that Plaintiff's treating physician told Plaintiff's counsel that he exclusively used Stryker pain pumps ("Email") (Doc. No. 32 at 11; Doc. No. 32-1 at 1). The Stryker Defendants argue that the Amended Complaint should be dismissed against them for failure to state a claim because: (1) Jozwiak alleges that both the Stryker Defendants and the McKinley Defendants

manufactured the pain pump that caused Plaintiff's injuries and because only one the defendant groups could have manufactured the pain pump at issue; (2) Jozwiak does not plead facts that plausibly establish each element of her claims of negligence and strict liability. (Doc. No. 33 at 3-5.) Jozwiak asserts that she has sufficiently pled each of her three claims against the Defendants. (Doc. No. 35 at 5-7.)

A. Whether to Consider the Email

The McKinley Defendants assert that the Email attached to their Motion to Dismiss proves that they did not manufacture the pain pump used in Jozwiak's surgery and thus could not be liable for her injuries. (Doc. No. 32 at 11; Doc. No. 32-1 at 1.) Plaintiff asserts in response that the email attached to the McKinley Defendants' Motion to Dismiss should not be considered by this Court for purposes of the instant Motions to Dismiss because discovery concerning the manufacturer of the pain pump at issue is ongoing and because the McKinley Defendants failed to meet their initial disclosure obligation under Federal Rule of Civil Procedure 26, which, if properly met, would have identified the manufacturer of the pain pump. (Doc. No. 35 at 2-5.)

Pursuant to Rule 12(d) of the Federal Rules of Civil Procedure, if matters outside the pleadings are presented on a Rule 12(b)(6) motion to dismiss, the Court may either exclude such materials or treat the motion as one for summary judgment under Rule 56. *See Prop. Mgmt. & Invs., Inc. v. Lewis*, 752 F.2d 599, 604 (11th Cir. 1985) ("The court has discretion as to whether to accept material beyond the pleading that is offered in conjunction with a 12(b)(6) motion."). However, a motion to dismiss should only be treated as one for summary judgment if the record is fully developed and the non-moving party was given adequate notice of the court's decision. *See Artistic Entm't, Inc. v. City of Warner Robins*, 331 F.3d 1196, 1202 (11th Cir. 2003) (noting that granting

summary judgment without notice is only proper if "a legal issue has been fully developed, and the evidentiary record is complete"); *Trustmark Ins. Co. v. ESLU, Inc.*, 299 F.3d 1265, 1267 (11th Cir. 2002) ("The district court is required to notify the parties that the motion has been converted, and give the parties 10 days in which to supplement the record. . . . This Circuit has consistently interpreted the notice rules strictly." (internal citations omitted)); *Burton v. City of Belle Glade*, 178 F.3d 1175, 1203-04 (11th Cir. 1999) ("A district court possesses the power to enter summary judgment sua sponte provided the losing party was on notice that she had to come forward with all of her evidence. . . . [T]his notice provision is not an unimportant technicality, but a vital procedural safeguard to a party's right to offer the best defense to any challenge.") (internal quotations omitted).

Because the evidentiary record has not been fully developed on the issue of the identity of the manufacturer of the pain pump used in Jozwiak's surgery and because discovery related to that issue has recently commenced, it would be inappropriate to consider the Email at this stage of the proceedings, and the instant Motions to Dismiss will not be converted into motions for summary judgment under Rule 56. *See Pierson v. Orlando Reg'l Healthcare Sys., Inc.*, 619 F. Supp. 2d 1260, 1282 n.35 (M.D. Fla. 2009) (excluding a self-serving, exculpatory affidavit on a motion to dismiss); *Estate of Miller v. Toyota Motor Corp.*, No. 6:07-cv-1358-Orl-19DAB, 2007 WL 4482589, at *3 (M.D. Fla. Dec. 18, 2007) (excluding an affidavit on a motion to dismiss because the issue it concerned was fact-intensive and would likely require some degree of discovery). Thus, for purposes of the pending Motions to Dismiss, the Court will only consider the factual allegations in the Amended Complaint, the written instruments attached to it as exhibits, documents incorporated into the Amended Complaint by reference, and matters of which the Court may take judicial notice. *Tellabs, Inc.*, 551 U.S. at 323.

B. Count I: Negligence

Jozwiak asserts a claim of negligence against the Defendants arising out of the design, manufacture, sale, distribution, and promotion of the pain pump installed during her surgery. (Doc. No. 28 at 5-7.) The Defendants argue that this claim should be dismissed because Plaintiff does not allege facts plausibly establishing which of the Defendants manufactured the pain pump at issue. (Doc. No. 32 at 8-9; Doc. No. 33 at 3-4.)

To maintain an action for negligence, a plaintiff must establish that the defendant owed the plaintiff a duty, that the defendant breached that duty, and that this breach proximately caused the plaintiff damages. *Fla. Dep't of Corrs. v. Abril*, 969 So. 2d 201, 204 (Fla. 2007). Whether a duty of care exists is a threshold question of law. *Wallace v. Dean*, 3 So. 3d 1035, 1046 (Fla. 2009). "The duty element of negligence focuses on whether the defendant's conduct foreseeably created a broader 'zone of risk' that poses a general threat of harm to others." *McCain v. Fla. Power Corp.*, 593 So. 2d 500, 502 (Fla. 1992). "Where a product is defective . . . and that defect rises to the level of a dangerous condition, the manufacturer or designer has created a zone of risk to all parties who may come in contact with the product." *Stazenski v. Tennant Co.*, 617 So. 2d 344, 346 (Fla. 1st DCA 1993). Thus, the manufacturer or designer of a product has "a duty to use reasonable care to design a product that is reasonably safe for its intended use and for other uses which are foreseeably probable." *Vincent v. C.R. Bard, Inc.*, 944 So. 2d 1083, 1085 (Fla. 2d DCA 2006) (quoting *Light v. Weldarc Co.*, 569 So. 2d 1302, 1303 (Fla. 5th DCA 1990)).

Plaintiff plausibly establishes that the Defendants owed her a duty to use reasonable care by alleging that "[e]ach of the [Defendants] designed, manufactured, marketed, distributed, sold, or

promoted the pain pump" that was installed in her shoulder during surgery. (Doc. No. 28 ¶ 15.)[2] Finding no factual allegations in the Amended Complaint[3] to the contrary, both the Stryker Defendants and the McKinley Defendants are alleged to have owed Plaintiff a duty.

Plaintiff sufficiently pleads breach of that duty by alleging that the Defendants: (1) failed to conduct adequate pre-market testing to ensure its pain pumps were safe when used as intended; (2) failed to conduct adequate pre-market testing to evaluate and identify the toxic effect on cartilage of continuous exposure to large quantities of commonly used anesthetic pain medication when exposed over extended periods of time; (3) failed to identify and warn physicians and consumers of the substantial risk of placing the pain pump catheter inside a patient's joint; (4) failed to warn physicians and consumers of the potential risk of joint destruction if a pain pump was placed intra-articularly following surgery; (5) failed to make open and complete disclosure to the FDA about the true intended use and marketing of pain pumps so that proper pre-market evaluation and testing would be required; (6) failed to market the pain pump solely for its intended use; (7) failed to conduct adequate post-marketing testing and surveillance to identify the risks posed to consumers; (8) failed to recall its pain pumps at the earliest date that it became known that the pain pumps were dangerous and defective; (9) represented that the pain pumps were safe when used for their intended purpose when, in fact, they were unsafe; and (10) concealed and misrepresented information from

[2] Paragraphs 1-28 of the Amended Complaint are incorporated by reference into each of the three Counts. (Doc. No. 28 ¶¶ 29, 38, 45.)

[3] The Stryker Defendants argue that the Amended Complaint should be dismissed because both they and the McKinley Defendants could not have manufactured the pain pump at issue and thus they both could not have owed her a duty. (Doc. No. 33 at 4.) This argument is not proper at this stage of the proceedings because it assumes facts not alleged in the Amended Complaint or referenced or incorporated therein. *Tellabs, Inc.*, 551 U.S. at 323.

the Plaintiff, healthcare professionals, and the public concerning the severity of risks and dangers of intra-articular pain pumps. (Doc. No. 28 ¶ 33.)

Finally, Plaintiff plausibly establishes that these breaches caused her damages by alleging that the she has sustained severe and permanent injuries as a result of the Defendants' manufacture, marketing, advertising, off-label promotion, distribution, and sale of pain pumps and the installation of one such pain pump into her shoulder. (*Id.* ¶¶ 17-18, 26.) Accordingly, Plaintiff has sufficiently pled each element of a claim of negligence against Defendants.

C. Counts II and III: Strict Liability for Design Defects and Failure to Warn

Plaintiff asserts in Counts II and III that the Defendants are strictly liable for design defects in the pain pump installed in her shoulder and for failing to warn her about the dangers of the pain pump. (*Id.* at 7-10.) The Defendants argue that Jozwiak fails to sufficiently plead either claim of strict liability because she does not allege facts plausibly establishing the relationship between each manufacturer and the pain pump installed in her arm. (Doc. No. 32 at 9; Doc. No. 33 at 5.) The Court will address the sufficiency of each claim of strict liability separately.

1. Design Defects

In order to hold a manufacturer strictly liable for a design defect, the plaintiff must establish: (1) the manufacturer's relationship to the product in question; (2) a defect in the product; and (3) proximate cause between the defective product and the plaintiff's injury. *West v. Caterpillar Tractor Co., Inc*., 336 So. 2d 80, 87 (Fla. 1976). In addition, the defect in the product must exist both at the time of the accident and at the time the product was within the possession of the manufacturer. *Jones v. Heil Co.*, 566 So. 2d 565, 567 (Fla. 1st DCA 1990); *Builders Shoring and Scaffolding Equip. Co., Inc. v. Schmidt*, 411 So. 2d 1004, 1006 (Fla. 5th DCA 1982).

As to the first element, Jozwiak plausibly establishes the Defendants' relationship to the pain pump at issue by alleging that "[e]ach of the [Defendants] designed, manufactured, marketed, distributed, sold, or promoted the pain pump" that was installed during her surgery. (Doc. No. 28 ¶ 15.) Jozwiak sufficiently pleads the second element, that the pain pump had a design defect, by alleging that the pain pump "was designed to continuously deliver large doses of anesthetic pain medication, over long durations," directly to her joints and that the Defendants knew or should have known that anesthetic pain mediation is toxic to cartilage. (*Id.* ¶¶ 22, 43.) Jozwiak plausibly establishes the third element, proximate causation, by alleging that the one of Defendants' defective pain pumps was filled with anesthetic pursuant to Defendants' instructions for use and installed in Plaintiff's shoulder, which resulted in gleno-humeral chondrolysis. (*Id.* ¶¶ 17-19, 44.) Finally, Jozwiak sufficiently pleads that the defect existed both at the time of the accident and at the time the product was within the possession of the manufacturer by alleging that pain pump was installed in her shoulder "without substantial change affecting its condition from the time it left the Defendant's possession." (*Id.* ¶ 27.) Accordingly, Plaintiff states a strict liability claim against Defendants in Count II for a defective design upon which relief can be granted.

2. Failure to Warn

To establish strict liability for failure to warn, a plaintiff must prove that: (1) defendant is a manufacturer or distributor of the product at issue; (2) defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of the manufacture and distribution; and (3) the existence of the proximate causal connection between the failure to warn and the plaintiff's

injuries or damages. *West*, 336 So. 2d at 87; *Ferayorni v. Hyundai Motor Company*, 711 So. 2d 1167, 1172 (Fla. 4th DCA 1998).

As to the first element, Jozwiak sufficiently pleads that the Defendants manufactured or distributed the pain pump at issue by alleging that "[e]ach of the [Defendants] designed, manufactured, marketed, distributed, sold, or promoted the pain pump" that was installed during her surgery. (Doc. No. 28 ¶ 15.) Jozwiak's plausibly establishes the second element, a failure to warn of a known or knowable risk, by alleging that Defendants placed no warning on the pain pump knowing that the continuous delivery of large doses of pain medication into a shoulder joint by the pain pump was toxic to cartilage and by alleging that Defendants sought and were denied FDA approval for such use of pain pumps in orthopedic surgery. (*Id.* ¶¶ 21-23, 47.) Finally, Jozwiak sufficiently pleads that the failure to warn proximately caused her injuries by alleging that the intended use of Defendants' pain pump during her surgery resulted in gleno-humeral chondrolysis, that Jozwiak's doctor would have explained to her any warnings placed on the pain pump, and the pain pump would not have been installed in Jozwiak's shoulder had she been warned. (*Id.* ¶¶ 47-50.) Accordingly, Jozwiak has properly stated a strict liability claim for failure to warn against Defendants in Count III.

Conclusion

Based on the foregoing, it is **ORDERED** and **ADJUDGED** that:

1. The Motion for Leave to File a Reply Memorandum to Plaintiff's Response to Defendants' Motion to Dismiss by Defendants Stryker Corporation and Stryker Sales Corporation (Doc. No. 37) is **DENIED**.

2 The Motion for Extension of Time to Serve Response to Defendant's Motion to Dismiss by Plaintiff Ashley L. Jozwiak (Doc. No. 34) is **GRANTED**.

3. The Motion to Dismiss Plaintiff's Amended Complaint by Defendants McKinley Medical, LLC, Moog, Inc., and Curlin Medical, Inc. (Doc. No. 32) and the Motion to Dismiss Plaintiff's Amended Complaint by Defendants Stryker Corporation and Stryker Sales Corporation (Doc. No. 33) are **DENIED**.

DONE and **ORDERED** in Chambers in Orlando, Florida on February 26, 2010.

PATRICIA C. FAWSETT, JUDGE
UNITED STATES DISTRICT COURT

Copies furnished to:

Counsel of Record