

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION at LEXINGTON

CIVIL ACTION NO. 10-391-KSF

CHERYL WHALEN

PLAINTIFF

v.

OPINION & ORDER

STRYKER CORPORATION AND
STRYKER SALES CORP.

DEFENDANTS

* * * * *

Currently before the Court is the motion of the defendants, Stryker Corporation and Stryker Sales Corporation (collectively “Stryker”), to dismiss the plaintiff’s complaint for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. This motion is fully briefed and is ripe for review.

I. FACTUAL AND PROCEDURAL BACKGROUND

On June 29, 2006, the plaintiff, Cheryl Whalen (“Whalen”) underwent arthroscopic shoulder surgery at UK Healthcare Good Samaritan Hospital in Lexington, Kentucky. During surgery, her orthopedic surgeon inserted a Stryker pain pump that injected local anesthetic products into her shoulder joint on a continuous basis for up to 72 hours or more following the surgery. Although Whalen continued to seek medical care for her shoulder through 2010, she contends that she was not aware, nor could she have reasonably discovered through the exercise of reasonable diligence, that she had been injured and was suffering from various injuries related to or caused by the Stryker pain pump.

Whalen alleges that she did not learn of the alleged association between the Stryker pain pump and a condition known as glenohumeral chondrolysis until November 13, 2009, when the Food and Drug Administration (“FDA”) published its Postmarket Drug Safety Bulletin. According to Whalen, she then learned that the pain pump works by bathing the surgical site with a constant source of local anesthetic which is delivered via a “soaker” catheter implanted during surgery. Whalen contends that the anesthetic delivered by the pain pump is toxic to the cartilage which makes up the articular surfaces in the shoulder, known as the chondral cartilage. Once the anesthetic kills the chondrocytes (the cells that make up the chondral cartilage), the shoulder is irreparably damaged and will not regenerate - a process known as glenohumeral chondrolysis which results in constant pain and loss of full use of the shoulder and/or arm. There is no effective treatment for glenohumeral chondrolysis, and that many patients ultimately require shoulder replacements.

Whalen contends that Stryker knew or should have known about the correlation between its pain pumps and glenohumeral chondrolysis, and still promoted, sold, advertised, and marketed the use of the pain pumps for use after shoulder surgery. She now claims that as a result of her use of the pain pump, she has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, loss of shoulder mobility and range of motion and loss of use of the shoulder.

On November 11, 2010, Whalen filed this products liability action in this Court [DE #1]. Her Complaint asserts the following claims: (1) negligence; (2) strict products liability; (3) breach of express warranty; (4) breach of implied warranties; (5) fraudulent misrepresentation; (6) fraudulent concealment; (7) negligent misrepresentation; (8) fraud and deceit; and (9) violation of state consumer fraud and deceptive trade practices act. Although this action was filed more than four

years after her surgery, Whalen contends that the statute of limitations has been tolled because she first learned that she had suffered a wrongful injury, separate and apart from her underlying pre-existing shoulder injury, on November 13, 2009 when the FDA published its Postmarket Drug Safety Bulletin. Additionally, Whalen contends that Stryker's fraudulent concealment of the association between the use of its products and chondrolysis acted to toll the statute of limitations. Stryker has now filed its motion to dismiss, arguing that Whalen's Complaint fails to state a claim upon which relief can be granted.

II. ANALYSIS

A. MOTION TO DISMISS STANDARD

To withstand a motion to dismiss, a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 547 (2007).

While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.

Id. at 555(citations and quotation marks omitted). *See also Association of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 548 (6th Cir. 2007). In ruling upon a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, all of a plaintiff's allegations are presumed true, and the complaint is construed in the light most favorable to the plaintiff. *Hill v. Blue Cross and Blue Shield of Michigan*, 409 F.3d 710, 716 (6th Cir. 2005).

A district court may not grant a Rule 12(b)(6) motion because it does not believe the complaint's factual allegations. *Wright v. MetroHealth Medical Center*, 58 F.3d 1130, 1138 (6th Cir. 1995). However, "[c]onclusory allegations or legal conclusions masquerading as factual

allegations will not suffice to prevent a motion to dismiss.” *Mezibov v. Allen*, 411 F.3d 712, 716 (6th Cir. 2005).

B. ANALYSIS

Although Stryker’s motion seeks a dismissal on all of Whalen’s claims, Whalen has agreed to voluntarily dismiss her claims for breach of express warranty, breach of implied warranty, and her claims based on the Kentucky Consumer Protection Act. Accordingly, the Court will dismiss these claims without any further analysis. Remaining before the Court, then, is Strkyer’s motion to dismiss Whalen’s claims for negligence and strict liability based on the statute of limitations, its motion to dismiss Whalen’s claims for fraud for failure to plead with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure, and its motion to dismiss Whalen’s claim for punitive damages for failure to show by clear and convincing evidence that Stryker acted with the requisite level of culpability.

1. WHALEN’S CLAIMS OF NEGLIGENCE AND STRICT LIABILITY ARE NOT BARRED BY THE STATUTE OF LIMITATIONS

Stryker contends that Whalen’s personal injury claims are barred by the one-year statute of limitations contained in Kentucky Revised Statute 413.140(1)(a), which provides “the following actions shall be commenced within one (1) year after the cause of the action accrued . . . (a) [a]n action for an injury to the person of the plaintiff. . . .” KRS 413.140(a). Here, Whalen alleges that her injury occurred when a Stryker pump was inserted into her shoulder joint during arthroscopic surgery on June 29, 2006. She did not file her lawsuit, however, until November 11, 2010, more than four years later. Whalen argues that the discovery rule tolled the statute of limitations in her case because she first learned of her injury on November 13, 2009 when the FDA issued its

Postmarket Drug Safety Bulletin on the use of pain pumps.

The Kentucky Supreme Court has described the discovery rules as follows:

A cause of action will not accrue under the discovery rule until the plaintiff discovers or in the exercise of reasonable diligence should have discovered not only that he has been injured but also that his injury may have been caused by the defendant's conduct.

Louisville Trust Co. v. Johns-Mansville Prods. Corp., 580 S.W.2d 497, 501 (1979). As further explained, “[t]he statute of limitations commences from the date the plaintiff knew or should have known not only (1) that he or she has been injured; but also (2) that his or her injury may have been caused by the defendant’s conduct.” *Blanton v. Cooper Industries, Inc.*, 99 F.Supp.2d 797, 801 (E.D.Ky. 2000).

Stryker argues that after Whalen’s surgery on June 29, 2006, she continued seeking medical care for her shoulder through 2010. However, because she failed to allege any effort to investigate the cause of her continuing problems, she should not be excused from failing to bring the suit within the limitations period. In support of their argument, Stryker relies on *Fluke Corp. v. LeMaster*, 306 S.W.3d 55, 64 (Ky. 2010). In *Fluke*, the plaintiffs were using a Fluke brand voltage meter to determine whether electricity was present in the area where they were working. The voltage meter malfunctioned, and the plaintiffs incorrectly believed that no electricity was present. They were injured in a subsequent explosion. The plaintiffs filed a timely action against several defendants, but later amended their complaint to name Fluke as a defendant, more than one year after the accident. The trial court granted summary judgment to Fluke based on the statute of limitation. However, on appeal, the Kentucky Court of Appeals reversed, finding instead that Fluke was equitably estopped from relying on the statute of limitations because it had failed to comply with a duty to report

consumer products hazards under the Consumer Product Safety Act. The Kentucky Supreme Court reversed, holding that the plaintiff's claims were barred by the statute of limitations "because the product's potential role in causing the accident that gave rise to this litigation was immediately evident from the accident itself, and the manufacturer's alleged failure to disclose product defects to government agencies did not excuse the plaintiffs' failure to exercise reasonable diligence to discover their cause of action and the identity of the tortfeasor within the time prescribed by the statute of limitations." *Fluke*, 306 S.W.3d at 56.

A careful reading of *Fluke*, however, confirms that it is distinguishable from this case. First, the court's ruling in *Fluke* was based on a motion for summary judgment filed after the benefit of discovery. Here, however, at the motion to dismiss stage, it remains unclear exactly what Whalen knew about her injury or the steps she took to discover the cause of her injury prior to November 13, 2009. Additionally, unlike the cause of the accident in *Fluke*, the cause of Whalen's injuries were not so readily apparent. This case is more analogous to the Kentucky Supreme Court's decision in *Wiseman v. Alliant Hospitals, Inc.*, 37 S.W.3d 709 (Ky. 2000). In *Wiseman*, the plaintiff brought a medical malpractice action against her doctor, a medical organization, and hospital for failure to remove a piece of surgical instrument from her body during surgery. The court held that the discovery rule tolled the statute of limitations in her case because she had no reason to know that the surgical instrument had been left in her body until a subsequent procedure to explore the area revealed the object. According to the court, "while Appellant may have suspected that something went wrong during the surgery, that in and of itself was insufficient to accrue a cause of action. One who possesses no medical knowledge should not be held responsible for discovering an injury based on the wrongful act of a physician." *Id.* at 712-13.

Like the plaintiff in *Wiseman*, there is no evidence here that Whalen had any medical knowledge or training. While Stryker has provided the Court with numerous medical articles analyzing the use of pain pumps like the one at issue here, the Court, at this stage of the proceedings, must accept her allegation that she had no reasonable basis to know that her injury may have been caused by the pain pump. Whalen did what any reasonable patient in her position would do - continue to follow up with her physician. Based on the allegations in her Complaint that she did not discover, nor could have reasonably discovered by the exercise of reasonable diligence, that she had been injured and was suffering from various injuries relating to the Stryker pain pump, her claim was tolled until issuance of the FDA bulletin on November 13, 2009. Her Complaint was then filed within the one year statute of limitations and thus her claims for negligence and strict liability are not time barred.

2. WHALEN'S CLAIMS FOR FRAUD SATISFY THE PARTICULARITY REQUIREMENTS OF RULE 9(b)

Stryker argues that Whalen's claims for fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraud and deceit, should be dismissed due to her failure to plead these claims with particularity as required by Rule 9(b). According to Stryker, Whalen's claims fail to specifically identify the pain pump made by Stryker, including what Stryker said, who made the alleged misrepresentations, or when the misrepresentations were made. Rather, Stryker contends that Whalen's Complaint only contains generic and vague allegations that fail to provide any concrete information required to sustain her claims.

When faced with a motion to dismiss for failure to plead fraud "with particularity" as required by Rule 9(b) of the Federal Rules of Civil Procedure, "a court must factor in the policy of

simplicity in pleading which the drafters of the Federal Rules codified in Rule 8” of the Federal Rules of Civil Procedure. *Michaels Bldg. Co. v. Ameritrust Co., N.A.*, 848 F.2d 674, 679 (6th Cir. 1988). Rule 8 requires a “short and plain statement of the claim,” and calls for “simple, concise, and direct” allegations. Thus, Rule 9(b)’s particularity requirement must be “read in harmony” with Rule 8. *Id.* The purpose of Rule 9(b)’s particularity requirement is to provide the defendant fair notice of the substance of the plaintiff’s claim in order that the defendant may prepare a responsive pleading.

Here, there has been no discovery in this action, and the alleged fraud occurred over an extended period of time, is within the knowledge and control of Stryker, and consisted of numerous acts; consequently, the specificity requirements of Rule 9(b) will be applied less stringently. *U.S. ex rel. Bledsoe*, 501 F.3d 493, 509-10 (6th Cir. 2007). Reviewing Whalen’s Complaint, the Court is convinced that the Complaint is sufficiently detailed to satisfy the notice requirement. Whalen’s Complaint, including the supporting factual allegations, specifies the parties and participants to the alleged fraud, the representations made, the nature in which the statements are alleged to be misleading or false, the fraudulent scheme, the fraudulent intent of the defendants, reliance on the fraud, and the injury resulting from the fraud. Specifically, Whalen alleges that Stryker possessed knowledge of an epidemiological correlation between pain pumps and glenohumeral chondrolysis [DE #1, ¶¶9-11]. She alleges that Stryker made false and fraudulent statements to her, her doctors, the public, and the FDA including statements that the pain pumps were safe for their intended use in the shoulder joints, despite studies and tests to the contrary. [DE #1, ¶¶ 80, 88-90, 96-97, 99, 121, 123-24, 129]. Whalen alleges that the statements were made over a period of time to the medical and healthcare community, to her, and to the FDA [DE #1, ¶¶28, 35, 80, 89-90, 96-97, 123-124,129].

To survive Stryker's motion to dismiss for failure to plead fraud with particularity, Whalen's Complaint does not need detailed factual allegations. *See Bell Atlantic v. Twombly*, 550 U.S. 555 (2007). The Court must take all well pleaded facts in her Complaint as true and view them in the light most favorable to her. *Jenkins v. McKeithen*, 395 U.S. 411, 421 (1969). Whalen's Complaint contains sufficient facts to support her claims of fraud; the process of discovery will provide her an opportunity to obtain further evidence in support of these facts, much of which may be in Stryker's possession and/or control.

3. WHALEN HAS SUFFICIENTLY PLED HER CLAIM FOR PUNITIVE DAMAGES

Finally, Stryker contends that Whalen cannot show by clear and convincing evidence that it acted with the requisite level of culpability for the imposition of punitive damages. Under Kentucky law, to recover punitive damages, a plaintiff must prove by clear and convincing evidence that a defendant acted with oppression, fraud or malice. K.R.S. § 411.184(2). Fraud is the only level of culpability described in the statute that is applicable to this action. The statute defines fraud as "an intentional misrepresentation, deceit, or concealment of material fact known to the defendant and made with the intention of causing injury to the plaintiff." K.R.S. §411.184(1)(b). Additionally, Kentucky law allows for punitive damages where "gross negligence" is shown. *Williams v. Wilson*, 972 S.W.2d 260, 262-65 (Ky. 1998). "Gross negligence" has been defined by Kentucky courts as a "wanton or reckless disregard for the safety of other persons." *Id.*

The Court finds that the Complaint alleges facts sufficient to support an award of punitive damages against Stryker. The Complaint alleges that Stryker's fraudulent conduct was intentional and made for the purpose of marketing a product known to be dangerous and defective [DE #1, ¶¶

79-110, 119-154]. Whalen further alleges that these intentional misrepresentations were made for the purpose of convincing the public that their pain pumps were fit and safe for use in shoulder joints. Taking all the allegations in the light most favorable to Whalen, the Court finds that Whalen has alleged facts that could give rise to an inference that Stryker's actions amount to "an intentional misrepresentation, deceit, or concealment of material fact" known to Stryker "and made with the intention of causing injury" to Whalen. *See* K.R.S. § 411.184 (2). Moreover, the allegations in Whalen's Complaint are sufficient to set out a claim for gross negligence. Therefore Stryker's motion to dismiss Whalen's claim for punitive damages will be denied.

III. CONCLUSION

For the reasons set forth above, the Court, being fully and sufficiently advised, hereby

ORDERS as follows:

- (1) Stryker's motion to dismiss [DE #9] is **GRANTED IN PART** and **DENIED IN PART** as follows:
 - (a) Stryker's motion to dismiss Whalen's claims for breach of express warranty, breach of implied warranty and for violation of the Kentucky Consumer Protection Act is **GRANTED**, and these claims are hereby **DISMISSED**; and
 - (b) Stryker's motion to dismiss Whalen's claims for negligence, strict liability, fraud, and punitive damages are **DENIED**,
- (2) this matter **REMAINS PENDING** on Whalen's claims for negligence, strict products liability, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, fraud and deceit, and punitive damages.

This March 8, 2011.



Signed By:

Karl S. Forester K S F

United States Senior Judge