

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

**NOLAN WINKLER,
Plaintiff,**

v.

**BOSTON SCIENTIFIC CORPORATION,
Defendant.**

CIVIL ACTION NO. 5:17-274-KKC

OPINION AND ORDER

*** **

This matter is before the Court on Defendant Boston Scientific Corporation's motion to dismiss for failure to state a claim upon which relief can be granted. (DE 25). For the reasons stated below, Plaintiff's personal injury and breach of warranty claims are dismissed as time barred and Plaintiff's misrepresentation claims are dismissed for failing to meet the heightened pleading standards required by Federal Rules of Civil Procedure Rule 9(b).

I. Background

On July 17, 2007, Plaintiff Nolan Winkler had surgery at Baptist Health Richmond to treat deep venous thrombosis ("DVT"). (Compl. ¶ 20). During the procedure, Dr. Hameed Koury implanted a Boston Scientific Med-Tech Stainless Steel Greenfield Vena Cava Filter (Greenfield IVC Filter) at the L2 level of Winkler's vena cava vein. The surgery was performed in accordance with Boston Scientific instructions and procedures and occurred without complications. (Compl. ¶ 21-22). Winkler received post-operative treatment from Dr. Olubunmi M. Adegboyega, who observed on July 21, 2007 that the Greenfield IVC Filter had migrated to the L3-4 position of Winkler's vena cava vein. (Compl. ¶ 23). On July 29, 2007, Winkler was treated by Dr. Dough Smith, who diagnosed him with extensive lower-extremity

DVT and observed that his condition was not improved by implantation of the Greenfield IVC Filter. (Compl. ¶ 24). Over the next three years, Winkler also experienced inflammation around the Filter and was treated for leg swelling caused by DVT. (Compl. ¶ 25-26).

Winkler had a second operation on March 21, 2016 to revise the Greenfield IVC Filter. The complex surgery was prompted by clots burdening the common iliac vein, which cut off blood flow to the inferior vena cava (“IVC”) below the renal vein and which doctors considered life threatening. (Compl. ¶ 27). The next day, Winkler had surgery a third time. This procedure was an angioplasty with subsequent stenting of the IVC and common iliac veins, to again revise the filter. (Compl. ¶ 28). Subsequently, Winkler was diagnosed with chronic microvascular ischemia, a condition that an IVC filter is intended to prevent, and he experienced worsening of his right pleural effusion and right basilar airspace disease. (Compl. ¶ 29-30). Winkler’s Greenfield IVC Filter has been implanted for ten years, despite recent FDA warnings that physicians remove filters within two months of implantation or when issues of DVT and pulmonary embolism (“PE”) have diminished. (Compl. ¶ 32).

Plaintiff filed this products liability action in the Court of Common Pleas for Philadelphia County, Pennsylvania on April 4, 2017, alleging negligence, strict liability, breach of express and implied warranties, and fraudulent and negligent misrepresentation. The case was removed to the United States District Court for the Eastern District of Pennsylvania pursuant to 28 U.S.C. § 1441 by Defendant Boston Scientific Corporation on May 4, 2017. The parties stipulated that the proper venue for this case was the Eastern District of Kentucky and the case was transferred to this Court on June 21, 2017. (DE 7). Defendant has filed a motion to dismiss for failure to state a claim upon which relief can be granted. (DE 25). Plaintiff has filed a response in opposition, (DE 26), and Defendant has filed a reply, (DE 27). This matter is now ripe for consideration.

II. Standard of Review

When deciding a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure, this Court “must (1) view the complaint in the light most favorable to the plaintiff and (2) take all well-pleaded factual allegations as true.” *Tackett v. M & G Polymers, USA, LLC*, 561 F.3d 478, 488 (6th Cir. 2009) (citing *Gunasekera v. Irwin*, 551 F.3d 461, 466 (6th Cir. 2009)). Federal pleading standards require only “a short and plain statement of the claim showing that the pleader is entitled to relief” Fed. R. Civ. P. 8(a)(2). A complaint does not require “detailed factual allegations,” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), but “demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Merely offering “labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement.” *Id.* (internal quotation marks, citations, and alterations omitted) (quoting *Twombly*, 550 U.S. at 555, 557).

To survive a Rule 12(b)(6) motion to dismiss, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is *plausible* on its face.’” *Id.* (emphasis added) (quoting *Twombly*, 550 U.S. at 570). A claim is facially plausible if “the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). The plausibility standard identified in *Twombly* and *Iqbal* is not a “probability requirement but it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Id.* (citing *Twombly*, 550 U.S. at 556). If a plaintiff merely pleads facts consistent with liability, the complaint fails to state an entitlement to relief and will not survive a motion to dismiss. *Id.* (citing *Twombly*, 550 U.S. at 557).

III. Analysis

1. Personal injury claims

Boston Scientific argues that Winkler's personal injury claims are time-barred. When sitting in diversity, federal courts "must apply the law of the forum state in determining statute of limitations questions." *Swanson v. Wilson*, 423 Fed. App'x 587, 592 (6th Cir. 2011). Kentucky law therefore applies. Kentucky imposes a one-year limitations period on personal injury claims. Ky. Rev. Stat. § 413.140(a)(1). That period of limitations applies to both negligence and strict liability actions involving personal injury. *See Michaels v. Baxter Healthcare Corp*, 289 F.3d 402, 406 (6th Cir. 2002) (upholding summary judgment of strict liability and negligence claims brought outside Kentucky's one-year statute of limitations). Under Kentucky's "discovery rule, a cause of action will not accrue until the plaintiff discovers (or in the exercise of reasonable diligence should have discovered) not only that he has been injured, but also that this injury may have been caused by the defendant's conduct." *Fluke Corp. v. LeMaster*, 306 S.W.3d 55, 60 (Ky. 2010). The discovery rule applies in cases where "the fact of injury or offending instrumentality is not immediately evident or discoverable with the exercise of reasonable diligence, such as in cases of medical malpractice or latent injuries or illnesses." *Id.*

Winkler's negligence and strict liability claims (Counts I-III) are personal injury claims. This action was commenced on April 6, 2017, the date when the Philadelphia Court of Commons pleas issued a summons for Boston Scientific. Ky. Rev. Stat. § 413.250. Even applying Kentucky's discovery rule, Winkler's personal injury claims are time-barred. As set forth in his complaint, Winkler was implanted with a Greenfield IVC Filter on July 17, 2007. (Compl. ¶ 20). Doctors observed migration of the filter on July 21, 2007, (Compl. ¶ 21), and that his condition had not improved on July 29, 2007, (Compl. ¶ 24). CT scans in 2008 and 2010 revealed inflammation around the Greenfield IVC Filter. (Compl. ¶ 25). Winkler was

treated for swelling caused by DVT on June 10, 2010. (Compl. ¶ 26). And Winkler underwent additional surgeries to revise the filter, dealing with clots and lack of blood flow to his renal vein allegedly caused by the filter, on March 21 and 22, 2016. (Compl. ¶ 27, 28). Winkler claims that he suffers “possible risk of migration of the filter to the other parts of the vena cava, heart or other organs, DVT, blood clots, fracture or breakage of the filter and other complications.” (Compl. ¶ 33). Winkler knew by 2007 that his Greenfield IVC Filter had migrated. Winkler was aware by 2010 that he continued to suffer complications from DVT. By March 2016, when Winkler underwent his two revision surgeries, he knew, based on Dr. Kumar’s diagnosis, that his “inferior vena cava and common iliac veins . . . had been occluded as a result of the Greenfield IVC Filter blockage.” (Compl. ¶ 28). Thus, at the very latest, Winkler’s personal injury claims accrued on March 22, 2016, and therefore his personal injury claims are time-barred.

In his response to the motion to dismiss, Winkler argues that he did not know his injuries were caused by the malfunctioned Greenfield IVC Filter until April 10, 2016—a date not mentioned in his complaint. This argument is unavailing. As discussed above, Winkler alleged in his complaint that Dr. Kumar diagnosed him on March 22, 2016 with occlusion resulting from Greenfield IVC Filter blockage. Winkler cannot plausibly claim that, as of that date, he did not know, or was not able to discover through reasonable due diligence, that his Greenfield IVC Filter was the cause of his alleged injuries.

Winkler also references April 2017 as the date that he was informed his filter was a Greenfield brand IVC filter, rather than a filter manufactured by another company. But he does not argue that his claim accrued on this date. Nor could he, for the reasons stated above, and because he admits to having retained counsel on April 9, 2016 to pursue these claims. Moreover, even assuming Winkler did not know the brand of his filter at the time of his second revision surgery, he was placed on notice at that time that his filter was causing his

alleged injuries and, through reasonable due diligence, could have discovered the manufacturer by having his implant label retrieved, as he ultimately did.

2. Breach of warranty claims

Winkler also alleges breach of express and implied warranties in Counts IV, V, VI of his complaint. Kentucky law provides a four year statute of limitations for express and implied warranty claims. Ky. Rev. Stat. § 355.2-725(1) (“An action for breach of any contract for sale must be commenced within four (4) years after the cause of action has accrued.”). Breach of warranty claims “accrue[] when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach.” *Id.* at § 355.2-725(2). Accordingly, Kentucky’s discovery rule is inapplicable to Winkler’s breach of warranty claims. These claims accrued on July 17, 2007, the date that Winkler’s Greenfield IVC Filter was implanted. Because Winkler did not file suit until nearly ten years later, his breach of warranty claims are time-barred. *See Imes v. Touma*, 784 F.2d 756, 757 (6th Cir. 1986) (finding breach of warranty claims time barred when allegedly defective metal plate was surgically implanted more than four years before commencement of the action).

3. Misrepresentation claims

In Counts VII and VIII of his complaint Winkler alleges claims of fraudulent and negligent misrepresentation. When alleging fraud, plaintiffs are subject to a heightened pleading standard. Rule 9(b) requires a party bring such a claim to “state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). To survive Rule 9(b)’s heightened pleading standard, the Sixth Circuit requires the allegations “(1) to specify the allegedly fraudulent statements; (2) to identify the speaker; (3) to plead when and where the statements were made; and (4) to explain what made the statements fraudulent.” *Republic Bank & Trust Co. v. Bear Stearns & Co., Inc.*, 683 F.3d 239, 247 (6th Cir. 2012) (citing *Ind. State Dist. Council of Laborers and Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*,

583 F.3d 935, 942-43 (6th Cir. 2009)). Both Kentucky's cause of action for fraudulent misrepresentation and negligent misrepresentation are subject to Rule 9(b)'s heightened pleading standard. *Id.* at 247-48. A claim for fraudulent misrepresentation under Kentucky law requires a plaintiff to establish six elements:

(1) the defendant made a material representation to the plaintiff; (2) the representation was false; (3) the defendant knew the representation to be false or made it with reckless disregard for its truth or falsity; (4) the defendant intended to induce the plaintiff to act upon the misrepresentation; (5) the plaintiff reasonably relied upon the misrepresentation; and (6) the misrepresentation caused injury to the plaintiff.

Giddings & Lewis, Inc. v. Indus. Risk Insurers, 348 S.W.3d 729, 747 (Ky. 2011) (citing *Flegles, Inc. v. TruServ Corp.*, 289 S.W.3d 544, 549 (Ky. 2009)). For claims of fraudulent misrepresentation, Kentucky has adopted the approach identified in the Restatement (Second) of Torts:

(1) One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

(2) Except as stated in Subsection (3), the liability stated in Subsection (1) is limited to loss suffered

(a) by the person or one of a limited group of persons for whose benefit and guidance he intends to supply the information or knows that the recipient intends to supply it; and

(b) through reliance upon it in a transaction that he intends the information to influence or knows that the recipient so intends or in a substantially similar transaction.

Id. at 744-745 (quoting *Restatement (Second) of Torts* § 552 (1997)).¹

¹ Kentucky also recognizes claims of fraudulent omission, *id.* at 747, but Winkler does not argue fraud by omission, and refutes Boston Scientific's invocation of the doctrine in his response brief as a misstatement of his claims. (DE 26, at 18 ("Additionally, Defendant in his Motion only takes part of the entirety of Plaintiff's complaint and allegation for fraudulent and negligent misrepresentation and tries to pass it off as a failure to state an omission [*sic*]."))

Winkler's misrepresentation claims do not meet the heightened pleading standards of Rule 9(b). Winkler's fraud claim, in pertinent part, states that "Defendants . . . misrepresented and omitted material information regarding [Greenfield IVC Filters] by failing to disclose the known risks of their Greenfield Filters and predecessor devices." (Comp. ¶ 100). Winkler does not identify specific fraudulent statements, the speaker, or the dates of those statements at any point in his complaint.

In his response brief, Winkler argues that Boston Scientific overlooks other sections of his complaint which provide this information. That is not the case. While Winkler's complaint does allege the specific date of his implantation surgery, (Compl. ¶ 20-22), it does not sufficiently alleged that, on that date, Boston Scientific fraudulently or negligently made misrepresentations concealing alleged defects of the filter. Nothing cited by Plaintiff supports such allegations. Paragraphs 17-19 of the Complaint merely identify warnings issued by the FDA in 2010 and claims that Boston Scientific was aware of the risks that prompted those warnings at the time of his surgery. Paragraph 21 states the implantation surgery was done "in accordance with Defendant's specific instructions, guidelines, and directives" but does not specifically identify any statements made in those instructions. In paragraphs 60, 61, and 71, Winkler alleges that Boston Scientific failed to adequately warn that the filter created a risk of serious harm, that the warnings given did not accurately reflect that risk, and that the filter lacked adequate post-market warnings. But Winkler does not identify any specific warnings which he believes were false.

The closest Winkler comes to meeting the heightened Rule 9(b) pleading standard are paragraphs 101 and 106. In paragraph 101, Winkler claims that Boston Scientific "engaged in unfair and deceptive consumer-oriented acts" which "misrepresented to the medical community, the FDA, and consumers, including the Plaintiff and her [*sic*] health care providers, that its Greenfield IVC Filters had been adequately tested in clinical trials and

was found to be safe and effective.” (Compl. ¶ 101). In paragraph 106, Winkler claims that Boston Scientific made misrepresentations that the “product had been tested, and found to be safe and effective for its stated purposes.” (Compl. ¶ 106). Again, however, Winkler does not identify specific statements, the speaker, or the date on which these alleged statements were made.

Winkler requests that the Court grant him leave to amend his complaint under Rule 15(a)(2), which provides that “[t]he court should freely give leave [to amend pleadings] when justice so requires.” Fed. R. Civ. P. 15(a)(2). But Winkler provides no basis for amendment except that “[t]he issues here are far too complex to suggest that denial of leave to amend . . . would be either fair or appropriate.” (DE 26, at 19). He does not indicate that he possesses additional fact which, if incorporated into the complaint, would meet Rule 9(b)’s heightened pleading standard. Accordingly, Winkler’s fraudulent and negligent misrepresentation claims are denied for failure to state a claim.

IV. Conclusion

For the reasons set forth above, the Court **HEREBY ORDERS** that:

- (1) Defendant Boston Scientific Corporation’s Motion to Dismiss is **GRANTED**;
- (2) Plaintiff Nolan Winkler’s claims against Defendant are **DISMISSED** for failure to state a claim upon which relief can be granted;
- (3) a judgment consistent with this Order shall be entered contemporaneously.

Dated March 26, 2018.



Karen K. Caldwell

KAREN K. CALDWELL, CHIEF JUDGE
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY