

experience a substantial amount of pain. Although Stieglitz has sought medical treatment for her conditions, she is permanently disabled and will continue to incur medical costs for her conditions.

Stieglitz filed suit in this Court, asserting causes of action under South Carolina law for strict liability, breach of express and implied warranties, and negligence. On October 9, 2015, Stryker moved to dismiss. In its motion, Stryker argued Stieglitz had failed to allege facts sufficient to state a claim for relief under any of her asserted causes of action. On November 6, Stieglitz filed a response in opposition, and, while not conceding that her original complaint was inadequate, also asked for leave to file an amended complaint that would address Stryker's criticisms of her original pleading. On November 16, Stryker filed a reply in support of its motion to dismiss; and on the following day, Stryker filed a response in opposition to Stieglitz's motion to amend. On November 30, Stieglitz filed a reply in support of her motion to amend. Finally, with the Court's permission, Striker filed a sur-reply on December 22, 2015. Accordingly, both motions are now ripe for consideration.

STANDARD OF REVIEW

The two motions before the Court involve a common scenario: defendant moves to dismiss the complaint for failure to state a claim; plaintiff seeks leave to file an amended complaint; and defendant contends the amendment would be futile. In such a scenario, the question of whether "justice . . . requires" the court to grant leave to amend, Fed. R. Civ. P. 15(a)(2), becomes a matter of deciding whether the proposed amended complaint adequately states a claim for relief. *See Woods v. Boeing Co.*, 841 F. Supp. 2d 925, 930 (D.S.C. 2012) ("If an amendment would fail to withstand a motion to dismiss, it is futile. Thus, if the well-pleaded facts in the proposed new complaint do not amount to a showing that the plaintiff is entitled to

relief, the court should deny a motion for leave to amend.” (citations and quotation marks omitted)).

A complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). Our courts use a “two-pronged approach” to assess the legal sufficiency of a complaint. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). First, the court must accept as true all of the facts alleged in the complaint and construe all reasonable inferences in favor of the plaintiff. *E.g.*, *E.I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d 435, 440 (4th Cir. 2011); *see also Iqbal*, 556 U.S. at 678 (“[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.”). Then, it determines whether those presumed-true allegations “contain sufficient factual matter . . . to ‘state a claim to relief that is plausible on its face.’” *Iqbal*, 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “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.* (citing *Twombly*, 550 U.S. at 556).

In this case, a proposed amended pleading was submitted while the motion to dismiss the original pleading was still pending. A defendant is “not required to file a new motion to dismiss simply because an amended pleading was introduced while [its] motion was pending.” *Tao of Sys. Integration, Inc. v. Analytical Servs. & Materials, Inc.*, 299 F. Supp. 2d 565, 570 (E.D. Va. 2004) (citing 6 Charles Alan Wright *et al.*, *Federal Practice and Procedure* § 1476 (2d ed. 1990)). Where, as here, “some of the alleged defects raised in the original motion remain in the amended pleading, the court will consider the motion as being addressed to the amended pleading.” *Id.*

ANALYSIS

Under South Carolina law, a “products liability case may be brought under several theories, including negligence, strict liability, and warranty.” *Rife v. Hitachi Constr. Mach. Co.*, 609 S.E.2d 565, 568 (S.C. Ct. App. 2005) (citations omitted). Regardless of the particular theory, a plaintiff must allege facts showing “(1) that he was injured by the product; (2) that the product, at the time of the accident, was in essentially the same condition as when it left the hands of the defendant; and (3) that the injury occurred because the product was in a defective condition unreasonably dangerous to the user.” *Allen v. Long Mfg. NC, Inc.*, 505 S.E.2d 354, 356 (S.C. Ct. App. 1998) (citation and internal quotation marks omitted).

Stryker’s numerous criticisms of the amended complaint boil down to two arguments: Stieglitz has not specified what made her hip replacement defective, and she has not shown a causal connection between the alleged defect and her injuries.² Both of those arguments relate to the third basic element of a product liability claim, as stated in *Allen*.

In her amended complaint, Stieglitz alleges that Stryker sold the hip replacement system implanted in her and that the system “was defective and unreasonably dangerous and hazardous and unsafe for use. A screw in the acetabular component of the hip replacement system penetrates the acetabulum and pelvis which . . . caused Plaintiff pain and numerous falls.” (Am. Compl., ECF No. 9-1, at ¶ 5.) Stieglitz incorporates that allegation into all of her claims. (*See id.* at ¶¶ 5, 7, 11.) Similarly, Stieglitz alleges that “a screw in the acetabular component of the hip replacement system penetrates the acetabulum and pelvis which . . . caused Plaintiff’s

2. *See, e.g.*, Def.’s Resp. Opp’n Pl.’s Mot. Amend, ECF No. 12, at 3 (arguing the amended complaint’s allegations “fail to identify specific defects or violations sufficient to maintain a cause of action”); *id.* (arguing the amended complaint “does not allege any facts specifying *how* hip replacement system and acetabular screw was [sic] ‘unreasonably dangerous and unsafe for use.’”); Def.’s Reply Supp. Mot. Dismiss, ECF No. 11, at 2 (arguing the amended complaint “does not allege factual allegations to support a specific defect and does not allege facts that support a causal connection between her alleged injuries and her hip replacement system”).

injuries.” (*Id.* at ¶ 9.) Stieglitz incorporates that allegation into her claims for negligence and breach of warranties. (*See id.* at ¶¶ 9, 11.) Finally, in her negligence claim, Stieglitz alleges that “[a] screw and metal on the hip replacement . . . was [sic] defective and Plaintiff was required to undergo medical treatment” (*Id.* at ¶ 14.) These allegations of defect and causation are not conclusory, and thus the Court accepts them as true. *See Iqbal*, 556 U.S. at 679. By alleging those facts, Stieglitz has met her burden of sufficiently pleading the third element from *Allen*.

Stryker frames the issue as whether Stieglitz’s amended complaint complies with the basic pleading standards articulated in *Iqbal* and *Twombly*. However, a close examination of Stryker’s argument reveals that it is based on a very specific application of those standards. Stryker relies heavily upon three opinions: *Funk v. Stryker Corp.*, 631 F.3d 777 (5th Cir. 2011); *Wells v. Allergan USA, Inc.*, No. 6:12-cv-3509-TMC, 2014 WL 117773 (D.S.C. Jan. 13, 2014); and *Viserta v. St. Jude Medical, Inc.*, No. 8:11-cv-505-JMC, 2012 WL 667814 (D.S.C. Feb. 29, 2012). Importantly, the products at issue in those cases were classified by the FDA as Class III medical devices. *See Funk*, 631 F.3d at 779; *Wells*, 2014 WL 117773, at *2; *Viserta*, 2012 WL 667814, at *1. The Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.*, preempt most state-law products liability claims involving Class III medical devices. *See Walker v. Medtronic, Inc.*, 670 F.3d 569, 577 (4th Cir. 2012). The only type of claim not preempted is one alleging that the device deviated from the formal performance standards that the FDA has issued for the device. *Id.* Such claims are called “parallel claims.” *See id.* at 576. In *Funk*, *Wells*, and *Viserta*, the issue was whether the plaintiff had adequately alleged a parallel claim and thus could avoid preemption. *See Funk*, 631 F.3d at 781–82; *Wells*, 2014 WL 117773, at *3; *Viserta*, 2012 WL 667814, at *3. In each case, the court faulted the plaintiff for failing to plead facts alleging, to the degree of specificity required under *Iqbal* and *Twombly*, how the device in question

deviated from a specific FDA-imposed performance standard or the causal connection between that deviation and the plaintiff's injury. *See Funk*, 631 F.3d at 782; *Wells*, 2014 WL 117773, at *3; *Viserta*, 2012 WL 667814, at *3–4.

It has not escaped this Court that the FDA has classified certain hip replacement products as Class III devices and that preemption and parallel-claim issues have arisen frequently in hip replacement lawsuits. *See generally, e.g., Bass v. Stryker Corp.*, 669 F.3d 501 (5th Cir. 2012); *Funk, supra*; *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466 (W.D. Pa. 2012); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145 (S.D.N.Y. 2011); *White v. Stryker Corp.*, 818 F. Supp. 2d 1032 (W.D. Ky. 2011). However, neither party has made preemption an issue. Stieglitz does not allege in her amended complaint that her hip replacement system is a Class III medical device, and Stryker has not asserted that Stieglitz's claims are preempted. Thus, the Court has no occasion to consider whether Stieglitz's amended complaint meets the two specific pleading requirements in *Funk*, *Wells*, and *Viserta*—namely, violation of a particular FDA performance standard, and a causal connection between the violation and the injury. The precise issue here is whether Stieglitz has sufficiently pled product liability claims under South Carolina substantive law, not whether she has sufficiently pled an exception to a federal preemption statute. Accordingly, the Court rejects Stryker's arguments that Stieglitz has not sufficiently pled factual allegations regarding the acetabular screw.

However, the Court agrees with Stryker that other allegations in the amended complaint lack sufficient specificity. Stieglitz alleges that, in addition to the acetabular screw, “other defects,” “other nonconformities,” and “other things” in her hip replacement are harming her. (Am. Compl., ECF No. 9-1, at ¶¶ 5, 9, 14.) These catch-all allegations are too vague to give Stryker fair notice of what other defect theories Stieglitz might be pursuing against it. *See*

Spencer v. Earley, 278 F. App'x 254, 259 (4th Cir. 2008) (per curiam) (stating the purpose of Rule 8(a)(2) “is to provide the defendant with ‘fair notice of what . . . the claim is and the grounds upon which it rests.’” (quoting *Twombly*, 550 U.S. at 555)); *see also Twombly*, 550 U.S. at 558 (“[A] district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.” (quoting *Associated Gen. Contractors of Cal., Inc. v. Carpenters*, 459 U.S. 519, 528 n.17 (1983))). Because claims based on those vague allegations could, if asserted, be dismissed under Rule 12(b)(6), allowing Stieglitz to assert them would be futile.

As the above discussion illustrates, the Court faces a request for leave to file an amended complaint containing some claims that are facially plausible and some that are not. That creates some tension between Rule 8(a)(2) and Rule 15(a)(2). On one hand, because the amended complaint contains some facially plausible claims, letting Stieglitz file it would not be futile, and thus “justice . . . requires” this Court to give Stieglitz leave to amend. On the other hand, letting Stieglitz file an amended complaint with identified deficiencies would be inconsistent with Rule 8(a)(2). Further, as Stryker would likely file another motion to dismiss or strike those deficient allegations, letting Stieglitz file her amended complaint as-is would likely lead to additional time and money being spent on an issue the Court has already examined. *See Fed. R. Civ. P. 1* (providing that parties and courts are to construe, administer, and employ the Rules to secure the “just, speedy and inexpensive determination” of cases).

Although not explicitly stated in Rule 15(a)(2), district courts may condition leave to amend on the fulfillment of reasonable requirements. 6 Charles Alan Wright *et al.*, *Federal Practice and Procedure* § 1486 (3d ed. 1998); *see also United States v. Woods*, No. 5:07-cv-187-BR, 2008 WL 2115130, at *4 (E.D.N.C. May 16, 2008) (granting leave to assert facially viable

defenses, but denying leave to assert an inadequately pled counterclaim and other defenses that were irrelevant); *Spampinato v. M. Breger & Co.*, 176 F. Supp. 149, 151 (E.D.N.Y. 1958) (permitting amendment of complaint on condition that plaintiff withdraw from proposed amended complaint thirty-four paragraphs concerning previously adjudicated claims), *aff'd on other grounds*, 270 F.2d 46 (2d Cir. 1959). Accordingly, the Court grants Stieglitz's motion to amend on the condition that, within fourteen days of this order, she file an amended complaint that omits the "other defects," "other nonconformities," and "other things" allegations discussed above. In that same vein, the Court denies Stieglitz's request for leave to file a pleading that contains those vague allegations.

The filing of the amended complaint will moot Stryker's motion to dismiss the original complaint. *See Young v. City of Mount Ranier*, 238 F.3d 567, 573 (4th Cir. 2001) ("As a general rule, an amended pleading ordinarily supersedes the original and renders it of no legal effect." (citation and internal quotation marks omitted); *Eades v. Ark Holdings, Inc.*, No. 8:11-cv-1516-TMC-JDA, 2011 WL 6844534, at *1 (D.S.C. Nov. 23, 2011) ("[M]otions directed at the superseded pleading generally are to be denied as moot."), *report and recommendation adopted*, 2011 WL 6844457 (D.S.C. Dec. 29, 2011). The Court assumes Stieglitz will comply with the Court's conditions and file an amended complaint as prescribed above. Proceeding on that assumption, the Court denies Stryker's motion to dismiss, without prejudice to refile it if the Court's prediction proves to be inaccurate.

Lastly, Stryker argues that it is not the proper defendant for Stieglitz's claims. As Stryker acknowledges, however, its argument contravenes Stieglitz's allegation that Stryker designed, manufactured, sold, and distributed the hip replacement implanted in her. At this juncture, this Court must accept that allegation as true. Accordingly, the Court must reject Stryker's argument.

See Gross, 858 F. Supp. 2d at 478–49 (declining to consider affidavit accompanying motion to dismiss purporting to show, in contradiction to the complaint, that defendant was not a proper party). At this time, the Court expresses no opinion on whether Stryker is, in fact, a proper defendant.

CONCLUSION

Therefore, for the foregoing reasons, it is **ORDERED** that Stieglitz’s motion to amend is **GRANTED IN PART**, with the conditions mentioned above, and **DENIED IN PART**. It is **FURTHER ORDERED** that Stryker’s motion to dismiss is **DENIED** without prejudice.

AND IT IS SO ORDERED.



PATRICK MICHAEL DUFFY
United States District Judge

January 4, 2016
Charleston, South Carolina