UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

RAYMOND RAMLJAK, *Plaintiff*, v. BOSTON SCIENTIFIC CORPORATION and AMERICAN MEDICAL SYSTEMS, LLC a/k/a AMS, *Defendants*.	No. 20 C 1903 Judge Thomas M. Durkin

MEMORANDUM OPINION AND ORDER

Plaintiff Raymond Ramljak filed this products liability action against defendants Boston Scientific Corporation ("BSC") and American Medical Systems LLC seeking relief for injuries he sustained in connection with an AMS 700 Series penile prosthetic. BSC moves to dismiss the claims against it under Federal Rule of Civil Procedure 12(b)(6). R. 11. For the following reasons, that motion is denied.

Standard

A Rule 12(b)(6) motion challenges the "sufficiency of the complaint." *Berger v.Nat. Collegiate Athletic Assoc.*, 843 F.3d 285, 289 (7th Cir. 2016). A complaint must provide "a short and plain statement of the claim showing that the pleader is entitledto relief," Fed. R. Civ. P. 8(a)(2), sufficient to provide defendant with "fair notice" of the claim and the basis for it. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). This standard "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

While "detailed factual allegations" are not required, "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.The complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (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.'" *Boucher v. Fin. Sys. of Green Bay, Inc.*, 880 F.3d 362, 366 (7th Cir. 2018) (quoting *Iqbal*, 556 U.S. at 678). In applying this standard, the Court accepts all well-pleaded facts as true and draws all reasonable inferences in favor of the non-moving party. *Tobey v. Chibucos*, 890 F.3d 634, 646 (7th Cir. 2018).

Background

BSC manufactures and sells medical devices. R. 1 ¶ 8. At issue in this case is BSC's AMS 700 LGX, a penile implant used to treat erectile disfunction, and one of the models in the AMS 700 Series of inflatable penile prosthetic devices. *Id.* ¶¶ 9, 17. The AMS 700 Series devices are fully implanted in the patient. *Id.* ¶ 10. To inflate the device, the patient squeezes a pump implanted inside his scrotum to fill the inflatable cylinders from a fluid-filled reservoir that is implanted in the patient's abdomen. To deflate the device, the patient presses a deflation button located in the scrotum. *Id.* ¶¶ 12-14.

The AMS 700 LGX is a Class III medical device subject to the Food and Drug Administration's ("FDA's") premarket approval process. *Id.* ¶ 15. To be certified as a

Class III device, BSC was required to submit the manufacturing procedures and device specifications for the AMS 700 LGX for FDA approval. *Id.* BSC is obligated to follow all specifications approved by the FDA. *Id.* ¶¶ 16.

On June 20, 2018, Plaintiff had an AMS 700 LGX surgically implanted. *Id.* ¶ 18. At a follow-up appointment about one month later, Plaintiff's surgeon was unable to deflate the device after inflating it properly. The surgeon's efforts caused Plaintiff great pain. *Id.* ¶ 20. Plaintiff's surgeon determined that the deflation button on the device would not depress. *Id.* ¶ 21. When the device still was not deflating properly the following month, Plaintiff's surgeon determined that Plaintiff may need a "take back surgery," during which the device would be removed and replaced due to its mechanical failure. *Id.* ¶ 23. In the meantime, Plaintiff continued to suffer from severe pain associated with his inability to fully deflate the device. *Id.* ¶ 24.

On September 5, 2018, Plaintiff underwent "take back surgery." *Id.* ¶ 25. After removing the faulty device, the surgeon determined that the spring mechanism did not function properly. *Id.* ¶ 26. BSC representatives then examined the faulty device, and concluded consistent with Plaintiff's surgeon that the pump had a misaligned spring. *Id.* ¶¶ 27-28. The faulty device and second surgery caused Plaintiff great pain. *Id.* ¶¶ 18, 29.

Plaintiff alleges two Illinois state law claims against BSC premised on an alleged manufacturing defect: (1) strict liability, based on the theory that Plaintiff's device "was manufactured in such a way that it did not conform to the specifications submitted to and approved by the FDA during the pre-market approval process;" and

(2) negligence, based on the theory that (among other things) the defendants failed to comply with 21 C.F.R. 820.80(c) and/or (d). *See generally id.* The complaint expressly alleges that neither claim is preempted under 21 U.S.C. § 360k (described further below) because both turn on BSC's failure to manufacture the device in accordance with federal requirements. BSC moves to dismiss both claims.

Analysis

BSC makes two principal arguments in support of dismissal. Specifically, that: (1) Plaintiff's claims are preempted; and (2) Plaintiff fails to state a plausible claim for relief. In addition to addressing the merits of BSC's arguments, Plaintiff contends that a Rule 12(b)(6) motion is not the proper vehicle for BSC's preemption argument. The Court addresses this argument first.

I. Rule 12(b)(6) Motion as a Vehicle for Preemption

Plaintiff argues that the Court should deny BSC's motion because preemption is an affirmative defense, and as such, may be raised only in a Rule 12(c) motion for judgment on the pleadings after an answer is filed. R. 17 at 3. Plaintiff is correct that ordinarily "[a]ffirmative defenses do not justify dismissal under Rule 12(b)(6); litigants need not try to plead around defenses." *Doe v. GTE Corp.*, 347 F.3d 655, 657 (7th Cir. 2003)). Indeed, the Seventh Circuit "has repeatedly cautioned that the proper heading for such motions is Rule 12(c), since an affirmative defense is external to the complaint." *Brownmark Films, LLC v. Comedy Partners*, 682 F.3d 687, 690 n.1 (7th Cir. 2012). Nevertheless, courts in this District have regularly "[decided] Rule 12(b)(6) motions on the basis of affirmative defenses and [the Seventh Circuit] has

affirmed" those decisions. *Id.*; *see also Tillman v. Smith & Nephew, Inc.*, 2013 WL 3776973, at *5 (N.D. Ill. July 18, 2013) (denying Rule 12(b)(6) motion to dismiss plaintiff's claims on the merits of preemption arguments); *Gravitt v. Mentor Worldwide, LLC*, 289 F. Supp. 3d 877, 884 (N.D. Ill. 2018) (dismissing plaintiff's FDA noncompliance claims as preempted under § 360k(a) on defendant's 12(b)(6) motion). Moreover, little rides on the distinction, because "[a] motion for judgment on the pleadings under Rule 12(c) . . . is governed by the same standards as a motion to dismiss for failure to state a claim." *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1029 (N.D. Ill. 2016) (quoting *BBL, Inc. v. City of Angola*, 809 F.3d 317, 325 (7th Cir. 2015)). Accordingly, "[w]hen a plaintiff's complaint . . . sets out all of the elements of an affirmative defense, dismissal under Rule 12(b)(6) is appropriate." *Indep. Tr. Corp. v. Stewart Info. Servs. Corp.*, 665 F.3d 930, 935 (7th Cir. 2012). Plaintiff's complaint does just that, having identified the exact provision that BSC's preemption argument rests upon (21 U.S.C. § 360k), and alleging that his claims are not preempted by that provision. R. 1 ¶¶ 40-41, 52-53. Therefore, Plaintiff cannot now argue that BSC's motion should be denied because he was not required to anticipate it, and the Court turns to the merits of BSC's arguments.

II. Preemption

A bit of background is necessary to understand the parties' preemption arguments. Congress granted the FDA sole authority to regulate medical devices and created a "regime of detailed federal oversight" through the Medical Device Amendments Act of 1976, 21 U.S.C. § 360 (the "MDA"), which amended the Food,

Drug, and Cosmetics Act ("FDCA"). *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327-30 (2008). The MDA divides medical devices into three categories based on the risk they pose to the public: (1) Class I devices, which present no unreasonable risk of illness or injury; (2) Class II devices, which present a greater potential for danger and thus warrant more stringent controls; and (3) Class III devices, like the AMS 700 LGX at issue here, which "present[ ] a potential unreasonable risk of illness or injury," and are therefore subject to the most regulation. 21 U.S.C. § 360c(a)(1)(A)-(C). As Plaintiff's complaint alleges, Class III devices generally are required to undergo a "rigorous" premarket approval ("PMA") process. *Riegel*, 552 U.S. at 317. During that process, a manufacturer submits detailed information concerning the safety and efficacy of its device—typically in the form of a multivolume application—which the FDA then spends an average of 1,200 hours reviewing. *Id.* at 317-18. Once such a device has received premarket approval, the MDA prohibits the manufacturer from making changes that would impact the safety or effectiveness of the device without FDA permission. *Id.* at 319.

According to BSC, the FDA's approval of the AMS 700 LGX through this process means that Plaintiff's claims against it are expressly preempted under Section 360k of the MDA.[1] That section preempts state claims when: (1) the federal government has established specific requirements applicable to the device; and (2) the common law claims are based on state requirements that are "different from, or

[1] Without elaborating, BSC also contends that Plaintiffs' claims are impliedly preempted under 21 U.S.C. § 337. But because BSC fails to develop this argument, the Court does not consider it here.

in addition to the federal ones" and relate to the device's safety and effectiveness. *Riegel*, 552 U.S. at 322 (citing 21 U.S.C. § 360k(a)).

Plaintiff does not contest that the first prong of the *Riegel* test is met, and nor could he; as stated, the AMS 700 LGX is a Class III device certified under the PMA process. But the parties dispute whether Plaintiff's claims involve state requirements that are "different from, or in addition to" the federal requirements such that preemption applies. 21 U.S.C. § 360k(a). And that matters, because "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330.

In considering the parties' arguments on preemption, two principles guide the Court's analysis: first, the presumption against the preemption of state police power, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); and second, that Congress's purpose "is the ultimate touchstone in every preemption case." *Id.* at 485. With that, the Court turns to the parties' arguments on each claim.

Strict liability. BSC argues that Plaintiff's strict liability claim fails because a plaintiff cannot bring a strict liability manufacturing defect claim that is based on a violation of plans approved through the PMA process. BSC is correct on the law. *See Tillman v. Smith & Nephew, Inc.*, 2012 WL 6681698, at *3 (N.D. Ill. Nov. 1, 2012) (a plaintiff's claim is preempted if it is based on an alleged defect that is intrinsic to the product as approved through the PMA process). But the problem for BSC is that Plaintiff's contention is not that the manufacturing process approved through the

PMA process led to the defect, but rather that the defect was caused by manufacturing procedures that *did not conform* with the FDA's requirements. *See* R. 1 ¶ 35 (alleging that "[t]he device was manufactured in such a way that did not conform to the specifications submitted to and approved by the FDA during the pre-market approval process"). Such a theory directly tracks that of a parallel claim. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010) ("if [plaintiff] can prove those allegations of harm caused by violations of federal law, her claims under state law would not impose on defendants any requirement 'different from, or in addition to, any requirement' imposed by federal law"); *see also Elmore v. Smith & Nephew, Inc*, 2013 WL 1707956, at *3 (N.D. Ill. Apr. 19, 2013) ("Medical device manufacturers that receive PMA are protected from civil liability to the extent that they comply with federal law, but this protection does not foreclose claims based on violations of federal law.").

BSC also argues that Plaintiff's strict liability claim is preempted for failure to "allege a violation of *any* specific FDA regulation." R. 12 at 8. But this argument is foreclosed by *Bausch*, where the Seventh Circuit expressly held that the district court erred in dismissing the plaintiff's original complaint on the basis that it did not "specify the precise defect or the specific federal regulatory requirements that were allegedly violated." *Bausch*, 630 F.3d at 560; *see also id.* ("Although the complaint would be stronger with such detail, we do not believe the absence of those details shows a failure to comply with Rule 8 of the Federal Rules of Civil Procedure or can

support a dismissal under Rule 12(b)(6)."). Plaintiff's strict liability claim thus survives BSC's preemption argument.

Negligence. The same is true for Plaintiff's negligence claim, which is based upon "the contention that the Defendants' product was in violation of federal regulations and requirements," including certain Current Good Manufacturing Practice ("CGMP") requirements set forth in 21 C.F.R. 820.80(c) and (d). R. 1 ¶¶ 48-50. Just as they are required to comply with device-specific requirements approved through the PMA process, manufacturers of Class III medical devices also are required to comply with CGMPs, which are "intended to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." 21 C.F.R. § 820.1(a)(1); *see also Bausch*, 630 F.3d at 555. Among other things, CGMPs govern the "methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1).

But BSC argues that a violation of a CGMP "do[es] not support a parallel claim" because CGMPs are "vague and generic." R. 12 at 9. BSC cites only to cases outside this Circuit in support. *Id.* And that makes sense, because the Seventh Circuit in *Bausch* explicitly held that CGMPs are "obviously vital to producing safe and effective medical devices" even though they are "not concrete or product-specific," and that state claims based on their violation are therefore *not* preempted. *Bausch*, 630 F.3d at 555 ("We do not see a sound legal basis for defendants' proposal to distinguish between general requirements and 'concrete, device-specific' requirements."); *see also*

Tillman v. Smith & Nephew, 2013 WL 3776973, at *3 (N.D. Ill. July 18, 2013) (holding that negligence and strict liability claims based on CGMPs, including 21 C.F.R. § 820.80, not preempted); *Elmore*, 2013 WL 17077956 at *2-3 (same). As such, Plaintiff's negligence claim also is a parallel claim that survives preemption.

III. Sufficiency of Plaintiff's Complaint

Next, BSC argues that even if Plaintiff's claims are parallel claims, Plaintiff's complaint fails to allege sufficient facts to make those claims plausible. The Court takes each claim in turn.

Strict liability. To state a strict liability claim based on a manufacturing defect under Illinois law, a plaintiff must allege: (1) "a condition of the product that results from manufacturing;" (2) that the condition "made the product unreasonably dangerous;" (3) that the condition "existed at the time the product left the defendant's control;" (4) that "the plaintiff suffered an injury;" and (5) that "the injury was proximately caused by the condition." *Salerno v. Innovative Surveillance Tech., Inc.*, 932 N.E.2d 101, 109 (Ill. App. Ct. 2010). According to BSC, Plaintiff's complaint contains only conclusory allegations, and impermissibly "leaves to the imagination how the deflation mechanism was defective;" is "devoid of any non-conclusory allegations tying Plaintiff's alleged defect in manufacture to his alleged injuries;" and "asks the Court to assume that the deflation issue was necessarily the result of a manufacturing issue, rather than an issue that arose after the device left BSC's control." R. 12 at 21-22.

But "[t]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular." *Bausch*, 630 F.3d at 558. In fact, the Seventh Circuit has recognized "how difficult it is to plead such a claim sufficiently to survive a motion to dismiss," and has cautioned district courts to "keep in mind" in reviewing 12(b)(6) motions that "much of the product-specific information about manufacturing needed to investigate such a claim is kept confidential by federal law." *Id.* Contrary to BSC's representations, Plaintiff's complaint alleges a specific defect with the AMS 700 LGX; that is, a misaligned spring within the pump, which was identified by both Plaintiff's surgeon and BSC as the issue that made it difficult to deflate the device. R. 1 ¶¶ 26-28. Plaintiff also alleges that the device had a manufacturing defect and did not conform with FDA approvals, and that the defect was present when it left BSC's control. *Id.* ¶¶ 32, 35, 36. Finally, Plaintiff specifically alleges that his and his surgeon's inability to inflate the device caused him great pain. *Id.* ¶¶ 20-21, 24. That is sufficient to plausibly allege that a manufacturing defect was the source of his troubles and allow Plaintiff to proceed to discovery. *See Bausch*, 630 F.3d at 558 ("[f]ormal discovery" is usually "necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim").

Negligence. To state a negligence claim, a plaintiff must allege: (1) the existence of a duty of care owed by the defendant to the plaintiff; (2) a breach of that duty; and (3) an injury proximately caused by the breach. *Bajwa v. Metro. Life Insur. Co.,* 804 N.E.2d 519, 526 (Ill. 2004). BSC argues that Plaintiff's negligence claim fails

because it does not sufficiently allege a "causal link" between the "alleged violations of 21 C.F.R. § 820.80(c) and (d) . . . and his injuries." R. 12 at 11. However, the complaint specifically alleges that BSC failed to identify, capture and/or correct the discrepancy in the deflation mechanism in violation of those regulations, and that those failures resulted in severe pain and a second surgery. R. 1 ¶¶ 48(c)-(g), 49, 54. That is more than enough at this stage.[2] *See Bausch*, 630 F.3d at 554 ("plaintiffs could not be expected to plead their claims with greater specificity without discovery to obtain access to confidential government and company documents").

* * * * *

Finally, BSC argues that discovery in this case would be futile, as "the publicly available information" shows that the FDA has not taken any "compliance enforcement action or assessed any violations with respect to the device" that would "support a parallel claim." R. 12 at 12; R. 18 at 10. And in its reply brief, BSC attempts to distinguish this case from *Bausch* on the basis that the plaintiff in that case had identified past FDA violations for the product at issue (whereas here, Plaintiff has not and indeed cannot). But Plaintiff is not required to take BSC's word that any issues with the AMS 700 LGX would necessarily be reflected in its publicly available materials, and it is unreasonable to suggest that just because a defect may not have been recognized in the past, one could not be uncovered and acknowledged now.

[2] BSC also argues that Plaintiff's negligence claim "fails for the same reasons as Plaintiff's strict liability manufacturing defect claim." R. 12 at 22. But because the Court already concluded that Plaintiff's strict liability claim was sufficiently plead, it reaches the same conclusion with respect to his negligence claim.

Moreover, *Bausch* in no way requires such an allegation to proceed to discovery. And that makes sense, because imposing that obligation would foreclose suit for all persons injured by recently-approved medical devices for which there is little to no manufacturing history. BSC's motion to dismiss is denied.

Conclusion

For the foregoing reasons, BSC's motion to dismiss, R. 11, is denied. A status hearing is set for April 14, 2021 at 9:00 a.m. The parties are directed to file a proposed discovery schedule by April 12, 2021.

ENTERED:

Honorable Thomas M. Durkin
United States District Judge

Date: March 31, 2021