Skinner v. Small Bone Innovations Incorporated et al Doc. 17

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Richard Skinner,

Plaintiff,

v.

Small Bone Innovations Incorporated, et al.,

Defendants.

No. CV-23-01051-PHX-MTL

ORDER

Pending before the Court is Defendant Small Bones Innovations Incorporated's ("SBI") Motion to Dismiss Plaintiff Richard Skinner's Complaint. (Doc. 10.) The Motion is fully briefed.[1] (Doc. 10; Doc. 15; Doc. 16.) For the following reasons, the Court will grant the Motion.

I. BACKGROUND

The following facts are taken from the allegations in the Complaint, which the Court accepts as true and construes in the light most favorable to Plaintiff. *North Star Int'l. v. Arizona Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983).

In October of 2013, Plaintiff required surgery for his ankle and received a Scandinavian Total Ankle Replacement ("STAR"), the medical device at issue in this action. (Doc. 1 ¶ 6.) Subsequently, Plaintiff experienced symptoms of pain and instability in his affected ankle. (*Id.* ¶ 7.) Defendant SBI is a Pennsylvania corporation that

[1] The request for oral argument is denied, as both parties have fully briefed the issues and oral argument would not have significantly aided the Court's decisional process. *See Partridge v. Reich*, 141 F.3d 920, 926 (9th Cir. 1998); *see also* LRCiv 7.2(f); Fed. R. Civ. P. 78(b).

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"designed, manufactured, tested inspected, warranted and marketed the STAR ankle replacement." (*Id.* ¶¶ 2, 12.) On October 11, 2019, an unidentified entity issued a safety communication, advising the public that parts of the STAR device "were fracturing with loss of mechanical properties" and "occurring substantially more often than with comparable total ankle replacements." (*Id.* ¶ 8.) The Federal Drug Administration also issued a safety alert to the same effect. (*Id.* ¶ 9.) Plaintiff asserts that he became aware of the STAR's defects on June 13, 2022, after he received a CAT scan and was informed that the STAR product degraded and was shedding plastic into his body. (*Id.* ¶ 10.) On June 7, 2023, Plaintiff filed a Complaint with this Court, alleging strict product liability and negligence claims against Defendant SBI for its defective STAR device. (*Id.* ¶¶ 11-26.) In response, Defendant filed the pending Motion to Dismiss, arguing that Plaintiff's Complaint fails to state a claim for relief. (Doc. 10.)

II. STANDARD OF REVIEW

Dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) may be based on either a "'lack of a cognizable legal theory' or 'the absence of sufficient facts alleged under a cognizable legal theory.'" *Johnson v. Riverside Healthcare Sys., LP*, 534 F.3d 1116, 1121–22 (9th Cir. 2008) (quoting *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990)). In determining whether a complaint states a claim under this standard, the allegations in the complaint are taken as true and the pleadings are construed in the light most favorable to the nonmovant. *Knievel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005). A pleading 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). But "[s]pecific facts are not necessary; the statement need only give the defendant fair notice of what . . . the claim is and the grounds upon which it rests." *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (internal quotation omitted). To survive a motion to dismiss, a complaint must state a claim that is "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *see Bell Atlantic 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." *Iqbal*, 556 U.S. at 678.

Generally, when deciding a Rule 12(b)(6) motion, the court looks only to the face of the complaint and documents attached thereto. *Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002); *Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1990). If a court considers evidence outside the pleading, it must convert the Rule 12(b)(6) motion into a Rule 56 motion for summary judgment. *United States v. Ritchie*, 342 F.3d 903, 907–08 (9th Cir. 2003). A court may, however, consider documents incorporated by reference in the complaint or matters of judicial notice without converting the motion to dismiss into a motion for summary judgment. *Id.*

III. DISCUSSION

A. Judicial Notice

In addition to its Motion, Defendant asks the Court to take judicial notice of various documents, including Defendant's initial Premarket Approval ("PMA") records from the Food and Drug Administration's ("FDA") website (Doc. 10, Ex. 1), a May 27, 2009 PMA letter from the FDA (Doc. 10, Ex. 2), and three PMA supplemental applications (Doc. 10, Ex. 3–5.) All these documents are publicly available. (Doc. 10 at 5–7.) These additional facts establish that Defendant SBI's STAR device is a Class III medical device that underwent the FDA's comprehensive PMA process in December 2005, and was approved by the FDA on May 27, 2009. (*Id.*; Doc. 10, Ex. 1–2.) Plaintiff has not objected to Defendant's request for judicial notice. (*See* Doc. 15.)

Generally, when assessing the sufficiency of a complaint under Rule 12(b)(6), courts may not consider material outside the pleadings. *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001); *see also* Fed. R. Civ. P. 12(d) (explaining that if a court considers matters outside the pleadings, the Rule 12 motion "must be treated as one for summary judgment under Rule 56"). There are, however, two exceptions to this rule: (1) the incorporation-by-reference doctrine, and (2) judicial notice under Federal Rule of

Evidence 201. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018). Rule 201 of the Federal Rules of Evidence permits a court to notice an adjudicative fact if it is "not subject to reasonable dispute." *Id.* (citing Fed. R. Evid. 201(b)). A fact is "not subject to reasonable dispute" if it is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Id.*

Because these exhibits are matters of public record and not subject to reasonable dispute, the Court grants Defendant's request for judicial notice. *See Stengel v. Medtronic, Inc.*, 676 F.3d 1159, 1167 (9th Cir. 2012), *rev'd en banc on other grounds*, 704 F.3d 1224 (9th Cir. 2013) (affirming district court's judicial notice of FDA's grant of PMA); *Arvizu v. Medtronic Inc.*, 41 F. Supp. 3d 783, 785 n.3 (D. Ariz. 2014) (granting request for judicial notice of documents related to the PMA process).

B. The Medical Device Amendments and Federal Preemption

Prior to the passage of the Medical Device Amendments ("MDA"), "the introduction of new medical devices was left largely for the States to supervise as they saw fit." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–16 (2008). But in 1976, Congress enacted the MDA to the Federal Food, Drug and Cosmetic Act ("FDCA"), imposing an exclusive, federal regime of oversight for medical devices. *See* 21 U.S.C. § 360c *et seq.*; *Riegel*, 552 U.S. at 316–17. The MDA established a hierarchy of three categories of medical devices, each with different levels of regulatory scrutiny according to their risk. 21 U.S.C. § 360c.

Medical devices in Class I pose the lowest risk to health and safety, and thus, are subject to "general controls" such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A); *Riegel*, 552 U.S. at 316. Class II devices pose a higher risk and are subject to "general" and "specific controls," such as performance standards and postmarket surveillance measures. 21 U.S.C. § 360c(a)(1)(A). Class III devices pose the greatest risk, and therefore, receive the most extensive federal oversight. *Id.* § 360c(a)(1)(C). Class III devices are "subject . . . to premarket approval" which is a process designed "to provide reasonable assurance of [the device's] safety and effectiveness." *Id.*; *see also* 21 U.S.C.

§ 360e (describing the procedure for obtaining premarket approval). The application for premarket approval must include, among other things, "reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective" and "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of such device." *Id.* § 360e(c)(1)(A), (c)(1)(C). If a Class III device receives PMA—such as the STAR medical device in this action—the manufacturer cannot make any changes to the medical device affecting safety or effectiveness without a supplemental application for approval.[2] *Id.* § 360e(d)(5)(A)(i). The manufacturer must also report any information learned after receiving PMA that the device "may have caused or contributed to a death or serious injury," or that the device malfunctioned and a similar device would likely cause or contribute to a death or serious injury. *Id.* § 360i(a)(1); *see also* 21 C.F.R. § 803.50(a).

Congress enacted the MDA to sweep "back some state obligations and impose[] a regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. To achieve this, the MDA includes an express preemption provision, stating:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a); *see also* 21 C.F.R. § 808.1(d). Courts applying Section 360k use a two-prong test to determine whether a state law claim is expressly preempted. *Riegel*, 552

[2] There are exceptions to this rule. A manufacturer may modify a device if the change is consistent with a predetermined change control plan approved under 21 U.S.C. § 360e-4, or if the change is a modification of manufacturing procedure and the holder of the PMA submits written notice to the Secretary. 21 U.S.C. § 360e(d)(5)(A)(i).

U.S. at 321–23. Under the first prong, a court considers whether the FDA has established requirements applicable to the device at issue. *Id.* If so, then the court considers whether the claims in the case attempt to impose state requirements relating to safety and effectiveness that are different from, or in addition to, the federal requirements. *Id.* If the answer to both questions is yes, then the claims are preempted by Section 360k. *Id.* The Ninth Circuit has explained that "for a state law claim regarding a Class III medical device to survive express preemption by the MDA, a plaintiff must establish that the defendant violated an FDA requirement." *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1111 (9th Cir. 2019).

A state law claim that avoids express preemption by Section 360k may still be impliedly preempted if the claim is not based on "traditional state tort law" and instead only attempts to enforce federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001). Claims premised solely on violations of federal regulations are preempted because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration." *Id.* at 348. Therefore, private litigants may not file suit against a manufacturer merely for its noncompliance with the FDA's medical device provisions. *Id.* at 349 n. 4; *see also* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.")

Consequently, a state law claim must fit the "narrow gap" between express and implied preemption. *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013). To avoid preemption, "[t]he plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* State law claims that parallel a federal law duty under the MDA or FDCA fit this narrow gap and are not preempted. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013); *see also Lawrence v. Medtronic*, 791 F. App'x 679, 680 (9th Cir. 2020) ("To avoid preemption, a plaintiff bringing a state tort claim must allege that

the state-law duty at issue parallels a federal requirement.").

C. SBI's Motion to Dismiss

In its Motion, Defendant contends that dismissal is warranted because Plaintiff's claims are: (1) expressly preempted by 21 U.S.C. § 360k; and (2) otherwise fail to state a claim for relief. (Doc. 10 at 7–11.) In his Response, Plaintiff argues that Defendant's Motion is premature because he should have the opportunity to investigate whether Defendant complied with federal laws,[3] that Plaintiff has alleged viable tort claims, and that Plaintiff's claims are not preempted. (Doc. 15 at 1–2.) Specifically, as to preemption, Plaintiff argues that the presumption against preemption applies, that Plaintiff's claims for failures in "testing, inspecting, warranty, marketing, lack of warnings, and packaging, each provide a basis of Arizona tort relief that is not expressly preempted," and that Plaintiff has alleged parallel claims to avoid preemption. (*Id.* at 8–10.)

i. The Presumption Against Preemption

Before addressing Plaintiff's strict liability and negligence claims, the Court first addresses his fleeting presumption against preemption argument. (*Id.* at 8.) The United States Supreme Court has recognized that where there is "an express pre-emption clause,"—such as Section 360k here—courts do not invoke any presumption against preemption and instead "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Puerto Rico v. Franklin California Tax-Free Tr.*, 579 U.S. 115, 125 (2016) (internal citation omitted); *see also Buckman*, 531 U.S. at 347–48 (holding that "no presumption against pre-emption obtains in this case" where the claims were based on fraudulent statements to the FDA). Therefore, and pursuant to *Puerto Rico*, the presumption against preemption does not apply here. *See also Jacob v. Mentor Worldwide, LLC*, 393 F. Supp. 3d 912, 923 (C.D. Cal. 2019), *aff'd sub nom. Nunn v. Mentor Worldwide, LLC*, 847 F. App'x 373 (9th Cir. 2021) (applying *Puerto Rico* and holding that the presumption against preemption does

[3] Plaintiff is subject to the pleading requirements of Federal Rules of Civil Procedure 8(a) and 12(b)(6). The Court finds that Defendant's Motion, challenging the legal sufficiency of the Complaint under Rule 12(b)(6), is not premature.

not apply where the MDA expressly preempts state tort law).

ii. Count I: Strict Liability

Plaintiff first asserts a claim of strict product liability against Defendant under Ariz. Rev. Stat § 12-681 *et seq.* (Doc. 1 ¶¶ 11–17.) Plaintiff avers that the "STAR ankle replacement was defective, unreasonably dangerous and unfit for its intended use and purposes because of its design, manufacture, testing, inspection, warranty, marketing, lack of warnings and packaging" at the time of Plaintiff's surgery. (Doc. 1 ¶ 15.) Specifically, Plaintiff asserts that the STAR device was "subject to material degradation of the polyethylene component . . . causing the plastic within the device [] to fracture." (*Id.* ¶ 15.) Plaintiff alleges that because Defendant manufactured and designed the STAR device, and Plaintiff's injuries were a direct and proximate result of the device's defects, it is strictly liable for Plaintiff's injuries. (*Id.* ¶¶ 11–17.)

In the pending Motion, Defendant argues that Plaintiff's strict liability claim is legally insufficient because Plaintiff has not adequately pleaded a design defect, manufacturing defect, or negligent manufacturing claim under Arizona law. (Doc. 10 at 7–8.) Defendant also contends that Plaintiff's strict liability claims seek to impose additional design, manufacturing, or labeling requirements that are "different from or additional to" the FDA's requirements. (*Id.* at 9–10 (quoting 21 U.S.C. § 360k(a)(1)).) Because Plaintiff has not alleged any parallel claims to survive preemption, Defendant argues that Plaintiff's strict liability claim is expressly preempted by Section 360k. (*Id.*) Plaintiff argues that the Complaint adequately alleges a strict liability claim under Arizona law and is not preempted. (Doc. 15 at 5–6, 8–10.)

To the extent Plaintiff alleges a design defect claim, that claim is expressly preempted by Section 360k. *See Arvizu*, 41 F. Supp. 3d at 792. In *Arvizu*, the plaintiffs brought strict liability claims against defendant manufacturers, alleging that an "Infuse Device," a Class III device that received premarket approval from the FDA, was defectively designed. *Id.* at 785. The court explained that to prevail on this claim, the plaintiffs would need to show that the Infuse Device should have been designed in a

manner different from what the FDA approved, and this "would impose requirements that are different from or in addition to federal law." *Id.* at 792. Because this showing would violate Section 360k, the court determined that the design defect claim was expressly preempted. *Id.* Similarly here, a design defect claim would require finding that the STAR device should have been designed differently than what was approved by the FDA. Because this would impose requirements that are "different from" or "in addition to" the MDA, Plaintiff's strict liability claim based on a design defect is expressly preempted. *See* 21 U.S.C. § 360k(a).

Other courts have held that a design defect claim is not expressly preempted if a plaintiff alleges that the design approved by the FDA in the PMA process was not the same design used in production. *See In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (explaining that design-defect claims against a medical device approved by the FDA through the PMA process must "alleg[e] that the product sold . . . was not the product design approved in the PMA Supplement"); *Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) ("To properly plead parallel claims that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation.") (internal quotation marks and citation omitted). But the present Complaint is devoid of comparable allegations sufficient to escape preemption. (*See* Doc. 1.)

To the extent Plaintiff alleges a manufacturing defect claim, that claim is also expressly preempted by Section 360k for the same reasons the design defect claim fails. *See Riegel*, 552 U.S. at 325; *Scovil v. Medtronic, Inc.*, 995 F. Supp. 2d 1082, 1095 (D. Ariz. 2014) (dismissing the plaintiffs' manufacturing and design defect claims as preempted by Section 360k). A plaintiff, however, may avoid preemption if he or she alleges that the defendant "deviated from a particular pre-market approval or other FDA requirement applicable to the Class III medical device." *Weber*, 940 F.3d at 1112. A plaintiff "cannot simply demonstrate a defect or a malfunction and rely on *res ipsa*

loquitur to suggest only . . . that the thing speaks for itself." *Id.* (citation and internal quotation marks omitted). Here, however, Plaintiff has not alleged that Defendant failed to comply with federal requirements either during the PMA process or after. (*See* Doc. 1.) As such, Plaintiff has failed to allege a state law claim that fits the "narrow" exception to avoid preemption by Section 360k. *Perez*, 711 F.3d at 1120.

Plaintiff's remaining allegations cannot rescue his strict liability claim. Plaintiff conclusively asserts that the Defendant is strictly liable because the STAR device is "unreasonably dangerous and unfit for its intended use and purposes because of its . . . warranty, marketing, lack of warnings and packaging." (Doc. 1 ¶ 15.) This is the only allegation in the Complaint relating to Defendant's warranty, marketing, lack of warnings, and packaging. (*See* Doc. 1.) As a conclusory allegation, Plaintiff has failed to state a claim for relief. *See Ashcroft*, 556 U.S. at 681 (holding that "bare assertions . . . amount[ing] to nothing more than a formulaic recitation of the elements . . . are conclusory and not entitled to be assumed true") (internal citations and quotations omitted).

iii. Count II: Negligence

Plaintiff also asserts a count of negligence against Defendant, alleging "Defendant SBI negligently designed, manufactured, tested, inspected, stored, marketed, warned about, distributed, repaired, maintained, prepared and packaged" the STAR device, which constituted a breach of the standard of care. (Doc. 1 ¶ 22.) Plaintiff claims that the STAR device was defective "[a]t the time Defendant SBI placed the subject implant into the stream of commerce," causing injury to Plaintiff. (*Id.* ¶¶ 18–26.) In the pending Motion, Defendant argues that these allegations are legally insufficient, and Plaintiff's negligence claim is expressly preempted by Section 360k. (Doc. 10 at 8–10.)

To the extent Plaintiff alleges Defendant was negligent in designing and manufacturing the STAR device, that claim is expressly preempted for the same reasons Plaintiff's strict liability claim is preempted. *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1044 (D. Ariz. 2014) (explaining that a claim based on negligent design or

manufacture is expressly preempted). In *Martin*, the plaintiffs sued defendant manufacturers for negligence, after they were allegedly injured by defendant's bone graft device—a Class III device that received PMA from the FDA. *Id.* at 1031–32. In dismissing the plaintiffs' negligence claim, the court explained that any claim "based on a failure to provide warnings . . . or based on any negligence in the design and manufacture of the [Class III device]" was expressly preempted because it would impose requirements different from or in addition to the FDA requirements. *Id.* at 1044. The same is true in this action. A claim that Defendant SBI negligently designed or manufactured the STAR device would necessarily require finding that Defendant breached a duty different from or in addition to what is required by the FDA. This is precisely what Section 360k prohibits.

Additionally, "[n]egligence in researching, manufacturing, selling, labeling, testing, distributing, and analyzing [] are claims preempted by federal law because they all address the safety of the device in ways that the FDA considers as part of the PMA process." *Scovil*, 995 F. Supp. 2d at 1096. Therefore, Plaintiff's claims that Defendant negligently tested, inspected, stored, distributed, repaired, maintained, prepared, and packaged the STAR device are also expressly preempted. Insofar as Plaintiff alleges Defendant was negligent in marketing the STAR device, Plaintiff has not provided more than conclusory allegations and thus, has failed to state a claim for relief. *Ashcroft*, 556 U.S. at 663. In sum, Plaintiff's negligence claim is dismissed.

D. Leave to Amend

Plaintiff has requested leave to amend his Complaint should this Court find it deficient. (Doc. 15 at 10.) Defendant argues that this request should be denied because leave to amend would be futile. (Doc. 16 at 9.)

Under Rule 15 of the Federal Rules of Civil Procedure, the Court "should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). The liberality of Rule 15(a)(2) does not apply, however, when the amendment would be futile. *See Doe v. United States*, 58 F.3d 494, 497 (9th Cir. 1995) (leave to amend should be freely given, "unless [the court] determines that the pleading could not possibly be cured by the

allegation of other facts").

In this case, leave to amend would not be futile as Plaintiff could potentially allege state law claims that parallel duties under the MDA or FDCA to avoid preemption. *See, e.g.*, *Jones v. Medtronic, Inc.*, 745 F. App'x 714, 717 (9th Cir. 2018) (finding that leave to amend should have been granted because "a properly alleged claim of manufacturing defect would not be preempted" nor would a claim based on misbranding); *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 1003 (D. Ariz. 2013) (holding that claims based on off-label promotion are not preempted by Section 360k). Accordingly, Plaintiff's request for leave to amend is granted.

IV. CONCLUSION

Accordingly,

IT IS ORDERED granting Defendant's Motion to Dismiss (Doc. 10).

IT IS FURTHER ORDERED that Plaintiff, if he chooses, shall file a First Amended Complaint no later than 21 days from the date of this Order.

Dated this 28th day of September, 2023.

Michael T. Liburdi

Michael T. Liburdi
United States District Judge