UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Patricia A. Reid,

Plaintiff,

v.

Wright Medical Technology, Inc.;
Wright Medical Group, Inc.;
Zimmer Biomet Holdings, Inc.;
Zimmer US, Inc.; and
Zimmer, Inc.,

Defendants.

File No. 19-cv-1471 (ECT/HB)

OPINION AND ORDER

Michael D. Stinson and Ian A. Blodger, Dorsey & Whitney LLP, Minneapolis, MN, for Plaintiff Patricia A. Reid.

William L. Moran, HKM Law Group, St. Paul, MN, and Anne A. Gruner and Dana J. Ash, Duane Morris LLP, Philadelphia, PA, for Defendant Wright Medical Technology, Inc.

Defendant Wright Medical Technology, Inc. ("WMT") produces component parts used in hip replacement surgeries. In 2019, Plaintiff Patricia A. Reid commenced this case against WMT and others, alleging that she sustained injuries from artificial hip components produced by Defendants that were implanted during her hip replacement surgery in December 2012. WMT seeks to dismiss Count I of Reid's Amended Complaint under Federal Rule of Civil Procedure 12(b)(6), though only to the extent that it alleges a strict liability claim based on a manufacturing defect. Mot. to Dismiss [ECF No. 17]. WMT's partial motion to dismiss will be denied because Reid's allegations describing significant

deviations from the components' expected performance are enough to plead a plausible strict liability manufacturing defect claim.

I

In December 2012, doctors at Abbott Northwestern Hospital in Minneapolis performed a total right hip arthroplasty, i.e., hip replacement surgery, on Reid. Am. Compl. ¶ 15 [ECF No. 1-1]. During the surgery, doctors implanted five artificial hip components designed, manufactured, marketed, distributed and sold by Defendants. *Id.* ¶¶ 16–17, 48, 50, 74, 76. Specifically, doctors implanted two components produced by Zimmer (the Zimmer Trilogy Cup and Longevity Liner) and three components produced by WMT (a metal femoral head, the Profemur cobalt-chromium neck, and the Profemur Plasma Z femoral stem). *Id.* ¶ 17. Reid expected the components to last for at least 20 years without any need for revision or replacement. *Id.* ¶ 26.

In 2015, Reid sought medical treatment for pain in her right hip. *Id.* ¶ 29. Reid's doctor determined that she was suffering from an "adverse local tissue reaction," possibly related to "metallosis" or corrosion from the implant. *Id.* ¶¶ 30–31. In May 2016, Reid's doctor performed a revision of her surgery. *Id.* ¶ 32. Reid's doctor replaced the neck and head components produced by WMT and the liner produced by Zimmer, observing during that surgery the existence of corrosion and "particulate wear debris . . . throughout the entire joint." *Id.* ¶¶ 33–35, 39–40. In December 2016, the FDA issued a recall of WMT's metal femoral head based on increased rates of revision surgeries and the risk of a tissue reaction. *Id.* ¶¶ 41–42. The FDA determined that the cause of the recall was "defective

design." *Id.* ¶ 43. The recall specifically identified the serial number of the metal femoral head used in Reid's initial surgery. *Id.* ¶ 41.

In May 2019, Reid commenced this action by serving Defendants with a Complaint claiming that she sustained injuries caused by the artificial hip components produced by Defendants. *See* Def. Notice of Removal ¶¶ 1–2 [ECF No. 1]; Mem. in Opp'n at 3 [ECF No. 27]; Minn. R. Civ. P. 3.01(a). One month later, Reid provided an Amended Complaint to Defendants, asserting strict liability, negligence, and breach of warranty claims.[1] Defendants removed the case to federal court, invoking this Court's diversity jurisdiction. Def. Notice of Removal ¶¶ 7–24. In June 2019, the Parties filed a stipulation of voluntary dismissal of all claims against Defendants Wright Medical Group, Inc. and Zimmer Biomet Holdings, Inc. and of Count VI (Breach of Warranty) against all remaining Defendants. Stip. of Dismissal [ECF No. 15]. This Court subsequently issued an order approving the Parties' stipulation and dismissing those claims without prejudice. Order re Stip. [ECF No. 25].

The remaining parties are of diverse citizenship—WMT is a Delaware corporation with its principal place of business in Tennessee, the Zimmer Defendants are Delaware corporations with their principal place of business in Indiana, and Reid is a citizen of Minnesota. Def. Notice of Removal ¶¶ 7–8, 11–12. Reid asserts exclusively state-law

[1] The Amended Complaint alleged six counts: (I) Strict Liability – Defective Design and Manufacture (Wright Defendants); (II) Strict Liability – Failure to Warn (Wright Defendants); (III) Strict Product Liability (Zimmer Defendants); (IV) Strict Product Liability – Failure to Warn (Zimmer Defendants); (V) Negligence (All Defendants); and (VI) Breach of Warranty (All Defendants). *See generally* Am. Compl. ¶¶ 47–120.

claims against Defendants, seeks compensatory damages "in an amount exceeding $50,000.00 to be proven at trial," alleges injuries that more likely than not establish an amount in controversy above the $75,000 jurisdictional threshold, and reserves the right to seek amendment to plead a claim for punitive damages against WMT. *See* Am. Compl. ¶ 46, 62 and Counts I–V; Def. Notice of Removal ¶¶ 14–24; *see also Bell v. Hershey Co.*, 557 F.3d 953, 956 (8th Cir. 2009) (stating defendant seeking to invoke federal jurisdiction through removal "has the burden to prove the requisite amount by a preponderance of the evidence" (quotation omitted)). Reid has not moved for remand or otherwise contested the valuation of her claims. Thus, this case is properly in federal court on the basis of diversity jurisdiction.

WMT has moved, pursuant to Rule 12(b)(6), to partially dismiss Count I of Reid's Amended Complaint. Count I asserts a strict liability claim against WMT under both defective design and defective manufacturing theories. Am. Compl. ¶¶ 47–62. WMT seeks to dismiss Count I only with respect to the strict liability claim based on a manufacturing defect. *See* Mem. in Supp. at 3 n. 2 [ECF No. 18].

II

In reviewing a motion to dismiss for failure to state a claim under Rule 12(b)(6), a court must accept as true all of the factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. *Gorog v. Best Buy Co.*, 760 F.3d 787, 792 (8th Cir. 2014) (citation omitted). Although the factual allegations need not be detailed, they must be sufficient to "raise a right to relief above the speculative level . . . ." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). The complaint must "state

a claim to relief that is plausible on its face." *Id.* 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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

A

"As this action is in federal court based on diversity of citizenship, state law governs substantive law issues." *Paine v. Jefferson Nat'l Life Ins. Co.*, 594 F.3d 989, 992 (8th Cir. 2010) (citation omitted); *see also Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). The Parties appear to agree that Minnesota law governs here as both parties cite to Minnesota law and neither party disputes its applicability. *See* Mem. in Supp. at 4; Mem. in Opp'n at 4. Accordingly, Minnesota law will be applied.

To recover under a theory of strict liability under Minnesota law, a plaintiff must establish "(1) that the defendant's product was in a defective condition unreasonably dangerous for its intended use, (2) that the defect existed when the product left the defendant's control, and (3) that the defect was the proximate cause of the injury sustained." *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 623 n. 3 (Minn. 1984) (citing *Lee v. Crookston Coca-Cola Bottling Co.*, 188 N.W.2d 426, 432 (Minn. 1971) (adopting Restatement (Second) of Torts § 402A)); *see also Yang v. Cooper Tire & Rubber Co.*, No. A13-0756, 2014 WL 502959, at *2 (Minn. App. Feb. 10, 2014) (applying strict liability standard in manufacturing-defect case). A product may be defective as a result of defective manufacture, inadequate directions or warnings, or defective design. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 232 (2011). "[T]he core of a manufacturing-defect case is

some manufacturing flaw—some deviation from a flawless product—that renders a product unreasonably dangerous." *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1147 (D. Minn. 2011); *see also Harrison ex rel. Harrison v. Harrison*, 733 N.W.2d 451, 454 n.2 (Minn. 2007) (quoting Restatement (Third) of Torts: Product Liability § 2(a) (1998)) (stating manufacturing defect exists when product "departs from its intended design"); *Bilotta*, 346 N.W.2d at 622 ("[I]n manufacturing-flaw cases, the defect is proved by focusing on the condition of the product."). In contrast, in a design-defect case, "the 'defect' lies in a consciously chosen design." *Bilotta*, 346 N.W.2d at 622; *see also* Restatement (Third) of Torts: Product Liability § 2 at cmt. d. ("A product asserted to have a defective design meets the manufacturer's design specifications but raises the question whether the specifications themselves create unreasonable risks.").

B

The Parties dispute the extent to which Reid must allege facts specific to the nature of the alleged defect. WMT argues that the factual allegations in Count I of the Amended Complaint assert only a strict liability claim based on a design-defect theory and that Reid has improperly combined design-defect and manufacturing-defect theories into a single cause of action in an attempt to avoid the necessity of pleading distinct facts that show a manufacturing defect. Mem. in Supp. at 4–5; *see also* Reply Mem. at 1–3 [ECF No. 32]. WMT contends that Reid must allege a specific deviation from the design specifications of the artificial hip components during the manufacturing process that rendered the components implanted in her defective and that she has failed to do so. Mem. in Supp. at 4–5; Reply Mem. at 1–3. Reid responds that she has properly pleaded a strict liability

claim premised on both design-defect and manufacturing-defect theories and that her factual allegations support reasonable inferences that WMT is liable for producing defective components under either or both theories. Mem. in Opp'n at 4–9. Reid contends that she is not required to plead specific details regarding the manufacturing process employed by WMT as she cannot possibly know the specifics of WMT's manufacturing processes without engaging in discovery. Mem. in Opp'n at 5–6.

In support of her position, Reid points to *Bailey v. Janssen Pharmaceutica, Inc.*, 288 Fed. App'x 597 (11th Cir. 2008). In *Bailey*, the Eleventh Circuit, applying Florida law, determined that appellant's complaint wove "multiple defect theories under the rubric of strict liability" but concluded that doing so was not "fatal to having stated a valid cause of action." *Id.* at 607 ("Although it takes some piecing together, appellant established minimally sufficient factual allegations to support her claim for strict products liability under either a manufacturing or design defect avenue."). The court reasoned that "it would be difficult at such an early stage in the litigation for a plaintiff to know whether a defect was due to a product's design or manufacture" and that it was "not convinced that Florida law applies a rigid distinction among the various theories of recovery . . . such that a plaintiff would be required to expressly plead 'design defect' versus 'manufacturing defect' at the complaint stage." *Id.* at 605.

But this Court is not bound by *Bailey*, and Minnesota law does not take quite so permissive an approach. Rather, under Minnesota law, a strict liability claim based on a manufacturing defect is distinct from a strict liability claim based on a design defect. *See Bilotta*, 346 N.W.2d at 621–22; *Casso v. Ortho-McNeil Pharm., Inc.*, 2014 WL 1224581,

at *6 (N.D. Ohio Mar. 24, 2014) (applying Minnesota law in deciding motion for judgment on the pleadings). Accordingly, a plaintiff "must allege the product deviates from its design or other flawless products because of a manufacturing defect" to adequately plead a manufacturing-defect claim. *Casso*, 2014 WL 1224581, at *6; *see also Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 789 (D. Minn. 2009). A plaintiff is not required, however, to allege facts to support a claim of a manufacturing defect with a specificity that exceeds the requirements of the pleading standard in Rule 8(a). *See Hofts v. Howmedica Osteonics Corp*, 597 F. Supp. 2d 830, 837–38 (S.D. Ind. 2009) ("Manufacturing defect claims are not subject, for example, to the 'particularity' pleading requirements of Rule 9."). A plaintiff's allegation that "the product [] consumed was different from Defendants' design for it is a sufficient allegation to maintain [a] manufacturing defect claim." *Casso*, 2014 WL 1224581, at *6.

C

The adequacy of Reid's manufacturing-defect claim under Rule 8(a), therefore, turns on whether she has alleged facts plausibly showing that the artificial hip components implanted during her initial surgery differed from WMT's intended design. Reid's manufacturing-defect claim is largely premised on her expectation that WMT's artificial hip components would last for 20 years without a need for revision or replacement and the failure of the components to perform as expected. Am. Compl. ¶ 26; Mem. in Opp'n at 6–7. In her Amended Complaint, Reid alleges that, three years after her initial surgery, her doctor observed "particulate wear debris type material . . . throughout the entire joint" and "corrosion at the neck and stem junction." Am. Compl. ¶¶ 34–35. Reid also points to an

FDA recall[2] of the metal femoral head used in her initial surgery. *See* U.S. Food & Drug Administration, *Class 3 Device Recall Cobalt Chromium Heads*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=149548 (last updated Oct. 1, 2019). Though Reid acknowledges that the FDA-determined cause of the recall was "defective design," she points to the listed manufacturer reason for the recall as being potentially indicative of a manufacturing defect. Am. Compl. ¶ 42 ("Revision rate trends . . . show an increasing overall trend from 2009 to present and it was found that there was a specific hazard/harm for suspected tissue reaction to metal debris over one percent."). In essence, Reid alleges that WMT's artificial hip components were designed to be sustainable for two decades with typical use and that the degradation of the components in her hip implant evidences a deviation from that design. At this stage, Reid is not required to identify a particular flaw in the manufacturing process; she must allege only that a deviation occurred. Reid has alleged facts showing that WMT's artificial hip components failed, how they failed, and how the failure deviates from the components' expected performance, and these facts lead to a plausible inference that their failure is attributable, at least in part, to a manufacturing defect. Accordingly, Reid's allegations are sufficient to survive a Rule 12(b)(6) motion to dismiss.

WMT cites three decisions from the District of Minnesota to support its argument that Reid has not stated a plausible manufacturing-defect claim because she has not alleged

[2] The FDA recall is necessarily embraced by the pleadings as its contents are alleged in Reid's Amended Complaint and no party challenges its authenticity. *See Mattes v. ABC Plastics, Inc.*, 323 F.3d 695, 697 n.4 (8th Cir. 2003) (citation omitted).

a particular deviation in the manufacturing process, but each of these cases is distinguishable. In the first case, *Perry v. Boston Scientific Family*, the court applied both Florida and Minnesota law in considering a Rule 12(b)(6) motion and determined that the claim pleaded by the plaintiff—a pro se Florida state prisoner—was insufficient under both because he had not pleaded *any* facts that showed how his cardiac medical device was defective. No. 16-cv-137 (PJS/HB), 2016 WL 10637082, at *5 (D. Minn. Dec. 1, 2016). In the second case, *Riley*, the court focused primarily on the issue of preemption but reasoned that the plaintiff's manufacturing-defect claim must be dismissed even if it wasn't preempted because the plaintiff alleged only that the defendant violated FDA requirements but did not clearly allege that the violations resulted in any manufacturing failure. 625 F. Supp. 2d at 789. In the third case, *Adams v. Stryker Pain Pump Corp.*, the court determined that, even with a liberal reading of the complaint, which did not list specific causes of action, the pro se prisoner plaintiff had alleged only that his pain pump had delivered more anesthetic than he could absorb but had not alleged facts to show the pump was unreasonably dangerous or how the product had failed. Civ. No. 10-858 (MJD/LIB) 2010 WL 4909564 (Dec. 1, 2010), at *2. In contrast to these cases, Reid's allegations are neither cursory nor "threadbare" with respect to the existence of a manufacturing defect. *See id.*

WMT also asserts that Reid's Amended Complaint merely alleges that she suffered an injury as a result of the hip implant and argues that a manufacturing defect cannot reasonably be inferred simply because an injury occurred. Reply Mem. at 4–5. In support of this argument, WMT cites cases from other jurisdictions in which WMT is a party to litigation involving the same artificial hip components. *See Marcovecchio v. Wright Med.*

Grp., Inc., No. 2:18-cv-00274, 2019 WL 1406606, at *6–7 (D. Utah Mar. 28, 2019) (dismissing manufacturing-defect claim for a second time); *Jorgensen v. Wright Med. Grp., Inc.*, No. 2:18-cv-366 TS-EJF, 2018 WL 5792325, at *2 (D. Utah Nov. 5, 2018); *Schwartz v. Wright Med. Techn.*, No. EDCV 14-01615 JGB (SPx), 2014 WL 12603111, at *2–3 (C.D. Ca. Nov. 20, 2014). In these cases, WMT successfully moved to dismiss strict liability claims based on manufacturing defects pursuant to Rule 12(b)(6). For example, in *Jorgensen*, the plaintiff unsuccessfully argued that her manufacturing-defect claim was "sufficient because a properly functioning artificial hip would not have caused the damages she alleges she suffered." 2018 WL 5792325, at *2. Similarly, in *Marcovecchio*, the court determined that the "defects" alleged by plaintiff were actually "harms" caused by the artificial hip components and the allegation that a properly functioning artificial hip would not have resulted in the injury suffered was not adequate in lieu of alleging an actual defect. 2019 WL 1406606, at *7.

These cases are inapposite because they do not apply Minnesota law, but, even if they were instructive, they would not lead to a different conclusion. In fact, Reid cites to two additional cases of the same nature in which courts denied WMT's motions to dismiss. *See Gillan v. Wright Med. Tech., Inc.*, No. 4:18 CV 2012 CDP, 2019 WL 2450903 (E.D. Mo. June 12, 2019) (concluding allegation that "device differed from defendant's intended condition because it failed" was, "[a]t this early stage of litigation, . . . sufficient for the manufacturing defect claim to proceed."); *Simpson v. Wright Med. Grp., Inc.*, No. 5:17-cv-00062-KGB, 2018 U.S. Dist. LEXIS 55237, at *26–28 (E.D. Ark. Mar. 30, 2018) (determining allegation that "tolerances between the stem and neck components did not

comply with Wright's design specifications" such that they caused "motion, fretting and corrosion at the stem-neck juncture" was sufficient). It is true that "the mere fact of injury during use of the product usually is insufficient proof to show existence of a defect at the time defendant relinquished control." *Lee*, 188 N.W.2d at 432. But Reid has alleged more than the occurrence of an injury in her Amended Complaint; she has alleged a failure of the artificial hip components independent of any resulting harm. This failure is plausibly attributable to a deviation in the manufacturing process. As such, Reid has adequately pleaded a strict liability manufacturing-defect claim.

ORDER

Based on the foregoing, and all of the files, records, and proceedings herein, **IT IS ORDERED THAT** Defendant Wright Medical Technology, Inc.'s Partial Motion to Dismiss [ECF No. 17] is **DENIED**.

Dated: October 2, 2019

s/ Eric C. Tostrud
Eric C. Tostrud
United States District Court