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No. 11-3726

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
Aug 10, 2012
LEONARD GREEN, Clerk

RACHEL KRUMPELBECK,	)	
	)	
Plaintiff-Appellant,	)	
	)	
v.	)	ON APPEAL FROM THE UNITED
	)	STATES DISTRICT COURT FOR THE
BREG, INC., et al.,	)	SOUTHERN DISTRICT OF OHIO
	)	
Defendants-Appellees.	)	
	)	

Before: GUY and DONALD, Circuit Judges, and O'MEARA, District Judge.*

BERNICE BOUIE DONALD, Circuit Judge. This appeal arises from a product liability action against medical device manufacturer Breg, Inc., for injuries allegedly resulting from Rachel Krumpelbeck's use of a Breg pain pump. Krumpelbeck's complaint asserted seven claims against Breg: (1) strict liability - design defect; (2) strict liability - warning defect; (3) strict liability - nonconformance with representations; (4) negligence; (5) breach of express warranty; (6) breach of implied warranty; and (7) negligent misrepresentation and fraud. Breg filed a motion for summary judgment in which it argued that it was reasonably unaware of the risk of injury that Krumpelbeck sustained, and therefore, that it had no duty to warn. Alternatively, Breg argued that Krumpelbeck could not show that a failure to warn caused her injury. The district court granted Breg's motion for

* The Honorable John Corbett O'Meara, United States District Court for the Eastern District of Michigan, sitting by designation.

summary judgment and dismissed Krumpelbeck's complaint. Krumpelbeck timely appealed. While we find no error in the district court's dismissal of Krumpelbeck's common law claims and her statutory claim of nonconformance with representations, we find that, construing the evidence in the light most favorable to Krumpelbeck, there are genuine disputes of fact that could allow a reasonable jury to find in her favor on her statutory claims of defective design and inadequate warning or instruction. Accordingly, we **AFFIRM** in part, **REVERSE** in part, and **REMAND** for further proceedings.

I. BACKGROUND

On March 3, 2005, Plaintiff-Appellant Rachel Krumpelbeck, then seventeen years old, underwent arthroscopic surgery on her shoulder. Her surgeon, Dr. Paul Favorito, used a Breg pain pump device to administer a local anesthetic to Krumpelbeck's shoulder for four days following her surgery. Dr. Favorito inserted the pain pump catheter directly into Krumpelbeck's shoulder joint to deliver the prescribed pain medication. In the months following her surgery, Krumpelbeck experienced extreme pain, and worsening stiffness, clicking, and popping in her shoulder joint. In December 2007, Krumpelbeck was diagnosed with glenohumeral chondrolysis, a painful condition involving the permanent destruction of articular cartilage in the shoulder joint. According to her doctor, Krumpelbeck's prognosis is poor, and she will likely require several complete shoulder replacements during her lifetime.

On February 6, 2009, Krumpelbeck filed a seven-count complaint against Breg, the manufacturer of the pain pump; Orthofix International NV, Breg's parent corporation; and Advanced

Technology, a wholesale distributer of medical equipment, including the Breg pain pump.[1] The complaint alleged strict liability for defective design, inadequate warnings, and failure of the pump to conform to representations. The complaint also asserted claims for negligence, breach of express and implied warranty, negligent misrepresentation, and fraud.

On October 15, 2010, Breg filed a motion for summary judgment, arguing that at the time of Krumpelbeck's surgery neither Breg nor Krumpelbeck's treating physician had knowledge of any risk associated with the continuous intra-articular infusion of anesthetic and, in particular, any link to chondrolysis. Breg also argued that all common law claims Krumpelbeck asserted were barred by the April 2005 amendment to the Ohio Products Liability Act ("OPLA"), which expressly abrogated all common law causes of action sounding in products liability. Krumpelbeck filed a response under seal on November 5, 2010, arguing that there were disputed facts regarding the foreseeability of harm that precluded summary judgment. On November 22, 2010, Breg filed a reply.

On December 2, 2010, after the pleadings were fully ripe for review, Krumpelbeck filed as a stand-alone docket entry the expert report of Dr. Suzanne Parisian, which was taken in a similar pain-pump case pending in another district. On December 23, 2010, seven weeks after filing her memorandum, Krumpelbeck filed an additional 2,827 pages of deposition transcripts, also as independent docket entries, which included the deposition of Dr. Parisian.

[1] Orthofix and Advanced Technology are no longer parties to the case.

On December 27, 2010, the district court entered an order granting Breg's motion for summary judgment. *Krumpelbeck v. Breg, Inc.*, 759 F. Supp. 2d 958 (S.D. Ohio 2010). The court agreed that "[a]s of the time of Plaintiff's surgery, the now-purported association between chondrolysis and anesthetic infusion in the shoulder joint was unknown to Defendant, and, indeed, to the entire scientific community," and "[t]herefore, Defendant breached no duty, and the [pain pump] was not defective for inadequate warnings or instructions." *Id.* at 974. The court rejected Krumpelbeck's design defect claim for the same reason—because there was no evidence that Breg knew or should have known of the risk, Krumpelbeck could not show that "the foreseeable risks associated with [the product's] design . . . exceeded the benefits." *Id.* at 975. The district court dismissed Krumpelbeck's complaint in its entirety.

On January 17, 2011, Krumpelbeck filed a motion to alter and/or obtain relief from judgment. In the motion, counsel posited that, for some reason "not known to Plaintiff," the Court "overlooked" Dr. Parisian's testimony in granting Breg's motion for summary judgment. Krumpelbeck argued that Dr. Parisian's report and deposition "directly state[] that there was ample medical literature and other evidence in existence at the time of Plaintiff's surgery that Breg knew or should have known of the risk of harm from using pain pumps inside the joint space prior to March 2005." Krumpelbeck urged the district court to "now consider these documents and expert testimony as they are representative of that which will be presented at the trial of this matter . . . and it directly addresses those omissions in the record that led the Court to grant the Defendant's motion for summary judgment." Krumpelbeck also argued for the first time that her common law claims were not pre-empted by the OPLA because her injury occurred before the effective date of the April 2005 amendment.

The district court denied Krumpelbeck's motion,[2] citing Southern District of Ohio Local Rule 7.2(d), which provides that "all evidence then available shall be discussed in, and submitted no later than, the *primary* memorandum of the party relying upon such evidence." (emphasis added). In light of that rule, and given the fact that Dr. Parisian's deposition and report were not "newly discovered evidence," the court stated that it would not consider Dr. Parisian's report or deposition, nor any of the other late-filed documents that Krumpelbeck submitted. The court pointed out that, apart from being untimely, Krumpelbeck's "supplementary exhibits" were filed without any explanation as to how they supported her memorandum in opposition. The district court stated that it could not "infer arguments from exhibits that are not referenced in the pleadings nor be expected to analyze 27,000 [sic] pages of facts without any direction," and chastised counsel for failing "to synthesize those facts and present them to the Court in a comprehensive fashion." The district court made clear, however, that even if it were to consider these documents, they were insufficient on their face to establish the existence of a triable issue.

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[2] Krumpelbeck's motion sought relief pursuant to both Rule 59(e) and Rule 60(b) of the Federal Rules of Civil Procedure. Rule 59(e) was amended effective December 1, 2009, to allow parties twenty-eight days after entry of judgment to file a motion to alter or amend. The district court, citing an older version of Rule 59(e), erroneously stated that Krumpelbeck's motion to alter or amend was untimely because it was filed more than ten days after the entry of judgment. Therefore, the court only considered Krumpelbeck's motion under the much higher standard required for granting a Rule 60(b) motion for relief from judgment.

Although the district court undeniably erred in stating that Krumpelbeck's Rule 59(e) motion was untimely, Breg correctly notes that Krumpelbeck's counsel has not presented this issue for review in the present appeal, which makes assignments of error only with regard to the district court's summary judgment analysis. Accordingly, we limit our review to those issues. We note, however, that Krumpelbeck is not prejudiced by this limitation, as her Rule 59(e) motion essentially raised the same objections to the district court's summary judgment analysis that Krumpelbeck now raises on appeal.

II. ANALYSIS

On appeal, Krumpelbeck argues that the district court applied the wrong version of the OPLA, thereby erroneously determining that her common law claims were barred by the April 2005 amendments to the Act. Krumpelbeck also argues that the district court erred in dismissing without discussion or analysis certain claims that were pleaded in her complaint but which Breg did not address in its motion for summary judgment. Finally, Krumpelbeck maintains that summary judgment was improper on her claims of defective design, defects due to inadequate warning or instruction, and defects due to nonconformance with representations because she put forth sufficient evidence from which a reasonable jury could find in her favor.

A. Standard of review

We review a district court's order granting summary judgment de novo. *Int'l Union v. Cummins, Inc.*, 434 F.3d 478, 483 (6th Cir. 2006). A motion for summary judgment should be granted if the evidence before the court shows that there is no dispute of material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *see Celotex Corp v. Catrett*, 477 U.S. 317, 322 (1986). The moving party has the burden of showing the absence of genuine disputes over facts which, under the substantive law governing the issue, might affect the outcome of the action. *Celotex*, 477 U.S. at 323. The party opposing the motion may not rest upon the allegations set forth in the pleadings; rather, it must show that there is some evidence, more than a mere scintilla, establishing a genuine issue for trial. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

B. Applicable version of the OPLA

The district court did not address the merits of Krumpelbeck's argument that the pre-amendment version of the OPLA—the version in effect at the time of her March 2005 surgery—should govern this case rather than the post-amendment version in effect at the time her cause of action arose. Because Krumpelbeck failed to timely raise this argument below, we find no error in the district court's dismissal of Krumpelbeck's common law claims.

C. Notice of risk

The thrust of Breg's motion for summary judgment, and the primary basis on which the district court granted the motion, was that Breg was reasonably unaware of the risk of chondrolysis at the time of Krumpelbeck's surgery in March 2005 and, thus, had no duty to warn of this risk. On appeal, Krumpelbeck argues that there is a genuine dispute of fact as to whether the information available to the scientific community as of March 2005 was sufficient to put Breg on notice of the risk of harm from the intra-articular use of its pain pumps. She also contends that the FDA's repeated refusal to clear Breg's device for orthopedic and/or intra-articular use should have placed Breg on notice of a risk of harm of the nature that Krumpelbeck suffered. Moreover, Krumpelbeck points out that several of her claims do not have a notice requirement—in particular, her claims for strict liability for nonconformance with representations, breach of express warranty, and breach of implied warranty. Thus, to the extent that the district court granted summary judgment on these claims based on Breg's lack of notice, Krumpelbeck argues that the court erred.

It is clear from her complaint that Krumpelbeck asserted two distinct categories of claims: those that require notice of a foreseeable risk and those that are premised on a material

misrepresentation.[3] Having determined that Krumpelbeck's common law claims are barred, we address the merits of Krumpelbeck's arguments only with respect to those claims that are cognizable under the OPLA.

1. Claims that include a notice requirement

The claims that Krumpelbeck asserted in her complaint that require notice of a risk of harm before liability can be imposed are: strict liability for defective design; strict liability for inadequate warning or instruction; and negligence. Of these claims, two have statutory counterparts under the OPLA as amended: products defective in design or formulation, found in Ohio Revised Code § 2307.75, and products defective due to inadequate warning or instruction, found in Ohio Revised Code § 2307.76.[4] Because genuine disputes of fact exist that could allow a reasonable jury to find for Krumpelbeck on the statutory claims, we find that summary judgment was not appropriate.

a. Applicable OPLA provisions

A product is defective in design or formulation if the foreseeable risks associated with its design or formulation exceed the benefits. Ohio Rev. Code § 2307.75(A). The foreseeable risks associated with a product's design are determined by considering factors, including, but not limited to, the likely awareness of product users of the risk of harm; the likelihood of the design or

[3] Krumpelbeck also correctly observes that the district court's order focused solely on the former category of claims (those that require notice of a foreseeable risk) and did not address the merits of her claims based on a material misrepresentation, despite granting summary judgment in favor of Breg on those claims.

[4] The third claim, negligence, is a common law claim that has been abrogated by the OPLA.

formulation to cause harm in light of the product's intended or reasonably foreseeable uses; and the extent to which the design or formulation is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner. *Id.* at § 2307.75(B). A product is defective due to inadequate warning or instruction if "the manufacturer knew, or in the exercise of reasonable care, should have known about a risk that is associated with the product" and the manufacturer "failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk." *Id.* at § 2307.76(A)(1).

b. Medical literature

According to Breg, Krumpelbeck's claims "rest on a fundamentally flawed premise: that Breg knew or reasonably should have known that continuous administration of anesthetic in the joint space could cause chondrolysis." In its motion for summary judgment, Breg averred that "no one in the medical science community as of March 2005 had hypothesized that continuous intra-articular infusion of anesthetic into the shoulder joint could cause chondrolysis." Breg further argued that "[t]his premise, still hotly disputed today, had not an iota of support in the collective literature and knowledge of the medical scientific community when [Krumpelbeck's] shoulder surgery was performed."[5]

[5] In fact, it is undisputed that it was not until March 23, 2006—one year after Krumpelbeck's surgery—at the annual meeting of the American Academy of Orthopedic Surgeons that Dr. Brent Hansen discussed, for the first time, the development of chondrolysis and a possible connection to pain pumps used in the intra-articular space. In July 2007, Dr. Hansen and his colleague Dr. Beck published the first peer reviewed article discussing the possible link between pain pumps and chondrolysis.

Although liability based on defective design involves balancing the foreseeable risks against the purported benefits, Breg's argument fails to acknowledge the many statutory factors that a court must consider in determining what those foreseeable risks are. *See* Ohio Rev. Code § 2307.75(B). One of these factors is the so-called "consumer expectation" test, which considers "[t]he extent to which [the product's] design or formulation is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner." *Id.* at § 2307.75(B)(5). This is the primary basis on which Krumpelbeck argues that Breg's pain pump was defective in design. The district court's order makes only passing reference to this test, describing it as "Plaintiff's theory" of defective design. The district court apparently did not associate the consumer-expectation test with the OPLA; it found that Krumplebeck's "design-defect claims fail for the same reason [she] cannot prove her warnings claims - there is no evidence that [Breg] knew or had reason to know of a purported risk associated with intra-articular infusion of anesthetics." The focus of the consumer-expectation test, however, is not the risks known to the manufacturer, but rather, the consumer's understanding and appreciation of the dangers associated with use of the product. Because the district court did not discuss the statutory factors listed in § 2307.75(B), including the consumer-expectation test, we find that it misapplied the law in determining the "foreseeable risks" for the purposes of Krumpelbeck's claim for defective design.

Moreover, we find that the district court's order frames the issue too narrowly. While the medical literature as of March 2005 was insufficient to put Breg on notice of the risk of chondrolysis specifically, Krumpelbeck pointed to numerous articles and published studies prior to that time that found a link between infusion of chemicals into the joint space and harm of the same general nature

as that Krumpelbeck suffered—damage and destruction of the cartilage. The district court correctly noted that this literature does not establish that Breg had actual notice of the risk of chondrolysis prior to her surgery. A reasonable jury could conclude, however, that it was sufficient to put Breg on notice of the risk of harm to the cartilage generally when its device was used to inject anesthetics directly in the joint space. Similarly, the literature could be sufficient to put a reasonable manufacturer on notice of the need for testing to explore the potential risks inherent in such use.

In rejecting this evidence, the district court made an impermissible factual determination that the evidence was not sufficient, stating that it was "particularly troubled by [Krumpelbeck's] failure to provide any expert testimony supporting counsel's bald conclusion that there was relevant literature available prior to March 2005." It is unclear why—at least, at the summary judgment stage—the court would require Krumpelbeck to produce an expert to testify that there was relevant literature when Krumpelbeck produced, instead, the literature itself. While a trial expert will almost certainly be required to explain the significance of the literature to a jury, the literature itself is evidence, more than a mere scintilla, sufficient to establish an issue for trial.

c. FDA

As additional support for her position, Krumpelbeck argues that there were other events and circumstances that put Breg on notice of the risk of harm—in particular, the Food and Drug Administration's ("FDA") refusal to approve Breg's pain pumps for orthopedic and/or intra-articular use. The FDA requires manufacturers, prior to marketing a medical device, to obtain either Premarket Approval (PMA) or Premarket Notification. The latter is sought under Section 510(k)

of the Federal Food, Drug, and Cosmetic Act, *see* 21 U.S.C. § 360(k), and is a significantly less rigorous option than PMA. It is available where the manufacturer seeks approval for a medical device that is substantially equivalent to another legally marketed, FDA-approved device. A limitation of Section 510(k) clearance is that the FDA will only approve a new device for the particular indications and uses for which the predicate device has been previously approved. Continuous-infusion pain pumps have been utilized in medical practice since the 1960s, but the evidence indicates that they have never been FDA-approved for orthopedic or intra-articular use.

On four occasions between 1998 and 2004, Breg applied for Section 510(k) approval for various pain-pump models and included in its applications references to intra-articular and orthopedic use. On each occasion, the FDA denied Breg's applications because of the references to intra-articular and/or orthopedic use, indications which had never before been approved for any of the predicate devices Breg cited in support of its applications. The FDA would not clear the device for these uses because Breg presented "no accompanying data to demonstrate that [the] device may be used safely and effectively [for such] use." Breg's applications for FDA clearance were approved only after all references to intra-articular/orthopedic use were deleted, and the pumps were subsequently cleared for general surgical use.

Contrary to Krumpelbeck's assertions, the FDA's rejection of Breg's § 501(k) application was not based on any *known* risks of intra-articular use of pain pumps but rather on the *absence* of any studies or data affirmatively establishing the safety of such use. Therefore, the FDA's rejection cannot give rise to a finding that Breg knew, or should have known, that its device was unsafe when

used in the joint space because the FDA's decision was not based on any finding that the pump was actually unsafe when so used.

However, whether the FDA's rejection did or should have put Breg on notice of the need to conduct testing of its pumps to establish their safety for orthopedic and intra-articular use is another question entirely. Had Breg elected to promote and market its pain pump only for those uses cleared by the FDA, perhaps Breg would have no duty to conduct such testing. But there is evidence in the record from which a jury could conclude that Breg actively marketed its products for off-label orthopedic and/or intra-articular use without conducting any relevant safety studies.

For instance, Plaintiff's Exhibit 57, submitted in support of Krumpelbeck's opposition to the motion for summary judgment, is a New Product Release for Breg's Pain Care 4200 pump, dated September 2002. This is an internal document, apparently directed to Breg's sales force, which describes the various components, features, benefits, and specifications of the 4200 pain pump. Under the heading "Indications," the document reads:

> Designed for local wound site infusion of non-narcotic medications for post-operative pain management:
>
> - Arthroscopic procedures
> - *Open Orthopedic procedures*
> - *Combination Arthroscopic and Open orthopedic procedures*
> - Iliac Crest bone graft harvest sites
> - General surgery
> - Plastic surgery

(emphasis added). The indications clearly list orthopedic procedures, a use that the FDA expressly informed Breg it would not approve due to Breg's lack of data supporting the safety of such use. A jury could conclude that a reasonable manufacturer would not market a product for a particular off-

label use without first conducting tests to establish the safety of such use. There is also Plaintiff's Exhibit 54, another of Breg's internal documents submitted in support of Krumpelbeck's opposition to Breg's motion. The relevant portion of this document describes placement of the pain pump catheter and indicates that it should be placed at the origin of the pain, including around the joint and/or directly into the joint cavity. (Sealed App. at 140.) This is further evidence from which a jury could find that Breg actively promoted the use of its pain pumps for off-label use directly in the joint space. Finally, Krumpelbeck's surgeon, Dr. Paul Favorito testified that "BREG did promote the use of intra-articular pain catheters. They never promoted them that I remember directly in the shoulder, but I know they promoted them in the knee."

While promoting an off-label use does not necessarily give rise to liability in itself, promoting a use for which the safety and long-term effects have never been tested or established might give rise to liability. Like the sufficiency of the medical literature, it is for a jury to decide whether a reasonable manufacturer in Breg's position would have conducted such testing prior to promoting an off-label use of its product.

2. Claims premised on a material misrepresentation

This same evidence of off-label marketing and promotion is relevant to Krumpelbeck's claims that are based on a material misrepresentation, which are: strict liability for nonconformance with representations; breach of express warranty; breach of implied warranty; negligent misrepresentation and fraud. The bases of all of these claims is that Breg made representations regarding the safety and quality of the pain pump and that the pain pump did not conform to these representations because it was not safe for all uses for which Breg marketed it.

Because they were abrogated by the 2005 amendment to the OPLA, as discussed *supra*, the district court properly granted summary judgment on Krumpelbeck's common law claims of breach of express warranty, breach of implied warranty, and negligent misrepresentation and fraud. However, the essence of these claims is actionable under § 2307.77 of the OPLA, which encompasses all product liability claims based on nonconformance with a manufacturers' representations. This provision provides that "[a] product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer." Ohio Rev. Code § 2307.77. The product may be defective even if the "manufacturer did not act fraudulently, recklessly, or negligently in making the representation." *Id.* To prevail on this claim, a plaintiff must prove that: 1) the defendant made a representation as to a material fact regarding the character or quality of its product; 2) the product failed to conform to the defendant's representation; 3) the plaintiff justifiably relied on the defendant's representation; and 4) such reliance directly and proximately caused the plaintiff's alleged injuries. *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 942 (S.D. Ohio 2010) (citations omitted).

As noted above, there is evidence in the record from which a jury could conclude that Breg actively promoted its device for use directly in the joint space. What the record lacks, however, is evidence that Breg's representatives made any express representations to Krumpelbeck—either directly or through Dr. Favorito—regarding the safety, efficacy, or FDA approval of such use. Krumpelbeck's complaint avers generally that Breg "made representations regarding the character or quality of the Breg Pain Pump, including representations that the Breg Pain Pump was safe" and that the device did not conform to these representations. Krumpelbeck also asserted in her response

to the motion for summary judgment that "Breg and the other manufacturers . . . falsely represent[ed] to physicians that the FDA had approved the pumps for joint space use." However, Krumpelbeck has failed to identify where, to whom, or by whom these alleged representations were made, nor has she pointed to any evidence to substantiate her allegations.

The only evidence in the record that would appear to speak to this issue is Dr. Favorito's deposition testimony. Dr. Favorito indicated that Breg did not warn him that intra-articular use was not cleared by the FDA and that, at the time he was using Breg's device in that manner, he did so with the belief that the device had been cleared by the FDA for such use. However, Dr. Favorito did not testify that a representative of Breg affirmatively told him that the pump had been FDA-approved for orthopedic and/or intra-articular use. Absent some evidence showing that Breg made an express representation to Krumpelbeck and/or her doctor regarding the safety or FDA approval of its pump for use in the joint space, summary judgment on this claim was appropriate.[6]

IV. CONCLUSION

For the foregoing reasons, we **AFFIRM** the district court's grant of summary judgment as to Krumpelbeck's claims of nonconformance with representations, negligence, breach of express warranty, breach of implied warranty, negligent misrepresentation and fraud. We **REVERSE** and **REMAND** for further proceedings as to Krumpelbeck's statutory claims for defective design and inadequate warning or instruction.

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[6] Aside from Krumpelbeck's failure to show that Breg made an express representation regarding a material fact, we note that the record is also lacking in evidence of other elements of this claim—namely, justifiable reliance and causation.