IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge William J. Martínez

Civil Action No. 1:10-cv-1797-WJM-CBS

BLAINE W. KLINGEMANN,

Plaintiff,

v.

BREG, INC.,

Defendants.

ORDER DENYING MOTIONS FOR SUMMARY JUDGMENT

In this product liability action, Plaintiff Blaine W. Klingemann brings claims against Defendant Breg, Inc. arising out of Plaintiff's 2003 shoulder surgery. Before the Court are the following: (1) Defendant's Motion for Summary Judgment (ECF No. 87) on all claims; and (2) Plaintiff's Motion for Partial Summary Judgment (ECF No. 96). For the reasons set forth below, Plaintiff's Motion is denied and Defendant's Motion is granted in part and denied in part.

I. LEGAL STANDARD

Summary judgment is appropriate only if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Henderson v. Inter-Chem Coal Co., Inc.*, 41 F.3d 567, 569 (10th Cir. 1994). Whether there is a genuine dispute as to a material fact depends upon whether the evidence presents a sufficient

disagreement to require submission to a jury or conversely, is so one-sided that one party must prevail as a matter of law. *Anderson v. Liberty Lobby*, 477 U.S. 242, 248-49 (1986); *Stone v. Autoliv ASP, Inc.*, 210 F.3d 1132 (10th Cir. 2000); *Carey v. U.S. Postal Service*, 812 F.2d 621, 623 (10th Cir. 1987).

A fact is "material" if it pertains to an element of a claim or defense; a factual dispute is "genuine" if the evidence is so contradictory that if the matter went to trial, a reasonable party could return a verdict for either party. *Anderson*, 477 U.S. at 248. The Court must resolve factual ambiguities against the moving party, thus favoring the right to a trial. *Quaker State Mini-Lube, Inc. v. Fireman's Fund Ins. Co.*, 52 F.3d 1522, 1527 (10th Cir. 1995); *Houston v. Nat'l General Ins. Co.*, 817 F.2d 83, 85 (10th Cir. 1987).

II. FACTUAL BACKGROUND

The relevant facts are as follows:

Plaintiff Blaine Klingemann underwent arthroscopic surgery on his left shoulder on October 10, 2003. (ECF No. 96-1.) Plaintiff's orthopedic surgeon was Dr. John D. Papilion, M.D. (ECF No. 96-3.) To manage Plaintiff's post-operative pain, Dr. Papilion placed a catheter for Defendant's Pain Care 3000 pain pump into Plaintiff's shoulder. (ECF No. 96-1.) The pain pump injected an anesthetic into Plaintiff's shoulder on a continuous basis for the first few days following his surgery. (*Id*.)

Plaintiff began to notice a gradual loss of motion, pain, and inability to use his left arm. (ECF No. 96-2.) On a follow-up visit with Dr. Papilion in November 2005, x-rays showed significant narrowing of the glenohumeral (shoulder) joint and collapse of the joint

space. (ECF No. 96-5.) Dr. Papilion believed that Plaintiff was suffering from a condition known as chondrolysis and progressive degenerative osteoarthritis in the glenohumeral joint. (*Id*.) Chondrolysis is the rapid loss of joint cartilage following some chemical, mechanical, infectious, immunological, or thermal insult. (ECF No. 87 at 3.)

To rectify this condition, Plaintiff underwent a second surgery on his shoulder in January 2006. (ECF No. 96-11.) A third surgery was performed in August 2006. (ECF No. 96-8.) During this procedure, Dr. Papilion noted that Plaintiff's humeral head was "completely devoid of any cartilage circumferentially." (*Id*.) Plaintiff's shoulder condition significantly impairs his ability to lead a normal life and it is anticipated that Plaintiff will need additional shoulder surgeries in the future. (ECF No. 96-4 at 19.)

Defendant Breg first sought approval from the Food and Drug Administration ("FDA") to market a pain pump in 1998. (ECF No. 96-11.) Breg sought approval for updated versions of its pain pumps in subsequent years. (ECF Nos. 96-16 & 96-17.) Each of these devices was approved for use in general surgery; none was approved for use in orthopedic surgery or in the intra-articular[1] space. (ECF Nos. 96-16; 96-17; 96-19.) However, Breg marketed its pain pumps, including the Pain Care 3000 used following Plaintiff's surgery, to orthopedic surgeons. (ECF No. 96-56.)

Plaintiff alleges that Defendant's Pain Care 3000 pain pump inserted directly into the intra-articular space following his October 2003 surgery caused his chondrolysis. Plaintiff brings this action to recover damages for his injuries.

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[1] "Intra-articular" means "[w]ithin the cavity of a joint". Stedmans Medical Dictionary (27th ed. 2000).

III. ANALYSIS

Plaintiff's Amended Complaint brings the following causes of action: (1) negligence; (2) negligent misrepresentation; (3) fraud; (4) strict product liability; (5) strict product liability—failure to warn; and (6) breach of implied warranty. (ECF No. 73.) Plaintiff seeks compensatory and punitive damages, as well as other relief. (*Id.*) Defendant moves for summary judgment on all claims and on Plaintiff's request for punitive damages. Plaintiff moves for summary judgment on his strict liability and breach of implied warranty claims.

The Court will address each in turn below.

A. Breach of Implied Warranty

Defendant moves for summary judgment on Plaintiff's breach of implied warranty claim and argues that it is barred by a three year statute of limitations. (ECF No. 87 at 20-21.) Plaintiff does not dispute the fact that a three year statute of limitations applies or that his claim was filed more than three years after his injury. Instead, Plaintiff argues that his limitations period should be equitably tolled so that his action is timely. (ECF No. 107 at 31-32.) Because whether a limitations period should be equitably tolled is a question of law, this issue is appropriate for summary disposition by the Court. *Hall v. U.S. Dep't of Labor*, 198 F.3d 257 (10th Cir. 1999).

Equitable tolling is a extraordinary remedy that is to be used sparingly by the courts. *Montoya v. Chao*, 296 F.3d 952, 957 (10th Cir. 2002). The Supreme Court has held that equitable tolling may be appropriate "where the claimant has actively pursued his judicial remedies by filing a defective pleading during the statutory period, or where

the complainant has been induced or tricked by his adversary's misconduct into allowing the filing deadline to pass." *Irwin v. Dep't of Veterans Affairs*, 498 U.S. 89, 96 (1990).

Plaintiff contends that Defendant intentionally withheld information from him and, therefore, his limitations period should be tolled. However, the accrual of a breach of warranty cause of action does not depend on the injured party's knowledge. In Colorado, a breach of warranty claim accrues at the time delivery is made, "regardless of the aggrieved party's lack of knowledge of the breach." Colo. Rev. Stat. § 4-2-725(2). Because the Colorado legislature explicitly stated that the three year limitations period begins to run regardless of whether the injured party is aware of the breach, the Court is not compelled to toll Plaintiff's limitations period simply because Defendant withheld information from Plaintiff.

Moreover, Plaintiff has presented no evidence that Defendant intentionally misled him into allowing the limitations period to run. Plaintiff's allegations of fraud and deceit by Defendant are generalized as to the public at large; there is no allegation that Defendant intentionally and actively induced or tricked Plaintiff in any manner. *See Wallace v. Kato*, 549 U.S. 384, 396 (2007). The lack of alleged wrongdoing directed specifically at Plaintiff weighs against finding that equitable tolling applies here.

In sum, the Court does not find that the facts of this case are so extraordinary as to merit the exceptional relief of equitable tolling. Accordingly, the Court finds that Plaintiff's claim for breach of implied warranty is time-barred. Plaintiff's Motion for Summary Judgment is denied and Defendant's Motion for Summary Judgment is granted as to the breach of implied warranty claim.

B. Negligence and Strict Liability

Defendant moves for summary judgment on Plaintiff's negligence and strict liability claims arguing that chondrolysis was not a foreseeable injury at the time of Plaintiff's surgery in 2003. (ECF No. 87 at10.) What Defendant knew or could have known about the possibility of the injury that Plaintiff suffered is key to both Plaintiff's negligence and strict product liability claims. With respect to negligence, the Colorado Supreme Court has held: "When a manufacturer or seller knows or should know of unreasonable dangers associated with the use of its product . . ., it has a duty to warn of these dangers; and a breach of this duty constitutes negligence." *Palmer v. A.H. Robins Co., Inc.*, 684 P.2d 187, 198 (Colo. 1984). For a product liability claim, "the focus of the inquiry is whether the defendant failed to warn of particular risks that were known or knowable in light of the generally recognized and prevailing scientific and technical knowledge available at the time of manufacture and distribution." *Fibreboard Corp. v. Fenton*, 845 P.2d 1168, 1175 (Colo. 1993). Thus, to defeat Defendant's summary judgment motion, Plaintiff must show a genuine dispute of fact as to whether Defendant knew or should have known that there was a risk of chondrolysis if its pain pump was inserted directly into the intra-articular space at the time of Plaintiff's October 2003 surgery.

Defendant contends that the risk of chondrolysis as a result of the use of its pain pump was not known or knowable in light of the scientific literature published in 2003. (ECF No. 87 at 11-12.) The Court disagrees. While the medical literature may not have explicitly linked the particular condition of chondrolysis to pain pumps until 2006 or

2007, publications dating back to at least 1985 linked direct application of anesthetics and other fluids to deterioration of cartilage. (ECF No. 107-6 at 2-3.) Upon consideration of the medical literature, a reasonable juror could find that Defendant knew or should have known that there was a risk of injury to the cartilage if a pain pump was inserted directly into the joint space. (*Id*.; ECF No. 107-2 at 51-52.)

Additionally, Defendant breached its duty as a manufacturer of medical equipment if it did not exercise reasonable care in marketing, selling, and labeling its product. *See Mile High Concrete v. Matz*, 842 P.2d 198, 202 (Colo. 1992). Defendant is held to the standard of care of a reasonably prudent medical device manufacturer under the same or similar circumstances. *See Palmer v. A.H. Robbins, Co., Inc.*, 684 P.2d 187, 210 (Colo. 1984). Plaintiff has presented evidence showing that Defendant was repeatedly informed by the FDA that it would approve Defendant's pain pump only for use in general surgery. (ECF Nos. 107-7 at 30-71; 107-11 at 67-68; 107-16; 107-33.) The FDA made Defendant remove all references to orthopedic surgery or use of the pain pump in the intra-articular space on its applications for at least three different medical devices. (*Id*.) Despite the lack of approval, Defendant routinely marketed its devices to orthopedic surgeons and recommended that its pain pumps be used intra-articularly. (ECF Nos. 107-36 at 8, 11.) The Court finds that this evidence creates a genuine dispute of fact as to whether Defendant breached its duty in the manner in which it marketed and promoted its pain pumps.

In its Motion, Defendant relies heavily on *Pavelko v. Breg*, No. 1:09-cv-1461-PAB-KMT, 2011 WL 782664 (D. Colo. Feb. 28, 2011), in which United States District Judge Philip A. Brimmer granted Breg's Motion for Summary Judgment. The Court

notes that it is not bound by the decision in *Pavelko*. *See B.T. ex rel. G.T. v. Santa Fe Public Sch.*, 506 F.Supp.2d 718, 727 (D.N.M. 2007) (principle of *stare decisis* does not apply to decisions of other district court judges). However, such authority can oftentimes be persuasive. *Id*.

The Court has carefully reviewed *Pavelko* and finds it distinguishable because the record in this case is significantly more developed. For example, in *Pavelko*, Judge Brimmer found "that the risk of pain pumps to cartilage was not foreseeable to defendant at the time of plaintiff's surgery" in part because "plaintiff has provided no expert testimony explaining the significance" of the medical literature. *Id*. at *1, 6. In this case, Plaintiff has presented evidence from an expert who has reviewed the medical literature and opined that it "would and should have provided part of the basis for a reasonably prudent pain pump manufacturer to test for and warn of adverse effects of regional anesthetics on the cartilage." (ECF No. 107-6 at 2.)

With respect to the FDA approval process, in *Pavelko*, the plaintiff failed to present any admissible evidence showing that Breg's pain pump was not approved for intra-articular use or that Breg had been advised by the FDA that it was not approving its pain pump for intra-articular use due to the lack of safety data. 2011 WL 782664, at *7. Here, Plaintiff has provided a plethora of evidence regarding Breg's approval process with the FDA, including both a deposition of Irene Naveau, the FDA reviewer who oversaw the approval process, and an expert opinion that Breg's marketing and promotion of the device for intra-articular use after being denied approval by the FDA was unreasonable and violated a number of federal regulations. (ECF Nos. 96-9 & 96-

12.) Given the significant differences in the record between this case and *Pavelko*, the Court has little difficulty reaching a different conclusion.

Ultimately, whether a manufacturer of a product acted reasonably in the manner in which it designed, manufactured, marketed, or promoted its device is generally a question of fact that must be decided by the jury. *Hesse v. McClintic*, 176 P.3d 759, 765 (Colo. 2008). Many courts looking at the same or substantially similar evidence, including one judge in this District, have held that whether the risk of injury to cartilage from the intra-articular use of a pain pump was foreseeable issue at the time of the plaintiff's surgery is an issue that should be resolved by the jury. *See, e.g., Hackett v. Breg Inc.*, No. 1:10-cv-1437-RBJ-KMT, 2011 WL 4550186 (D. Colo. Oct. 3, 2011); *Staub v. Breg, Inc.*, 2012 WL 1078335, *9 (D. Ariz. March 30, 2012); *Creech v. Stryker Corp.*, 2012 WL 33360, *6 (D. Utah Jan. 6, 2012); *Kildow v. Breg*, 796 F.Supp.2d 1295, 1300 (D. Or. 2011).

For all of the reasons discussed above, the Court finds that Plaintiff has presented evidence showing a genuine dispute of fact as to whether Defendant knew or should have known about the risk of harm at issue here at the time of Plaintiff's surgery. Because there is evidence from which a reasonable juror could find in favor of Plaintiff on his negligence and strict product liability claims, Defendant's Motion for Summary Judgment is denied as to these claims. However, the Court finds that a reasonable juror could view the same evidence and find in favor of Defendant. Therefore, Plaintiff's Motion for Summary Judgment on these claims is also denied.

C. Fraud and Misrepresentation

Defendant moves for summary judgment on Plaintiff's fraud and misrepresentation claims. An essential element of both Plaintiff's fraud and negligent misrepresentation claims is that Plaintiff or his physician reasonably relied on false information provided by Defendant. *See Mehaffy, Rider, Windholz & Wilson v. Central Bank Denver, N.A.*, 892 P.2d 230, 236 (Colo. 1995). Concealment of a material fact also constitutes a tort. *Ackmann v. Merchants Mortgage & Trust Corp.*, 645 P.2d 7, 13 (Colo. 1982).

Defendant first argues that there is no evidence that Defendant made any representation to Plaintiff or his physician. (ECF No. 87 at 17.) Defendant's argument does not comport with the evidence. Dr. Papilion, Plaintiff's surgeon, testified that he got the idea for placing the catheter for the pain pump directly into the joint space from conversations that he had with Breg's representatives. (ECF No. 107-9 at 55.) Papilion also testified that the manner in which he used the device was "consistent with the way the Breg representatives taught or marketed the device." (*Id*. at 66.) Finally, Papilion testified that he reviewed literature that he was provided with Breg's pain pump and that literature informed him that the catheter should be placed in the joint space. (*Id*. at 40.)

Defendant also argues that, to the extent Plaintiff has shown that it made representations to Dr. Papilion, Plaintiff has not shown that such representations were false. (ECF No. 87 at 19.) Defendant points out the that pain pump was approved for general surgical use and, therefore, promotion of the pump for intra-articular use was not false. (*Id*.) While a reasonable juror could agree with Defendant, the Court finds

that a reasonable juror could also disagree. Defendant knew that the FDA repeatedly required it to remove any reference to orthopedic surgery from its indications for use. (ECF No. 96-12.) There is evidence that Breg's representatives did not inform Dr. Papilion that intra-articular use of the device—which Breg actively promoted—was not approved by the FDA. (ECF No. 107-9.)

Moreover, the Court has already found that there is a genuine dispute as to Defendant's knowledge of the risk of harm to the cartilage if the pain pump was inserted into the intra-articular space. The truth or falsity of Defendant's representations to Dr. Papilion is inextricably linked with the jury's finding on Defendant's knowledge. Therefore, whether Defendant made false representations to Dr. Papilion should likewise be decided by the jury.

In sum, the Court finds that Plaintiff has presented sufficient evidence to show a genuine dispute of fact as to the essential elements of his fraud and misrepresentation claims. Accordingly, Defendant's Motion for Summary Judgment is denied with respect to these claims.

D. Punitive Damages

Defendant moves for summary judgment on Plaintiff's claim that he is entitled to punitive damages. (ECF No. 87.) Colorado permits a plaintiff to recover punitive or exemplary damages in any case in which the jury finds that the defendant's acts constitute "fraud, malice, or willful and wanton conduct." Colo. Rev. Stat. § 13-21-102. "'Willful and wanton conduct' means conduct purposefully committed which the actor must have realized as dangerous, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, particularly the plaintiff." Id. §

13-21-102(1)(b). "Where the defendant is conscious of his conduct and the existing conditions and knew or should have known that injury would result, the statutory requirements of section 13-21-102 are met." *Coors v. Sec. Life of Denver Ins. Co.*, 112 P.3d 59, 66 (Colo. 2005); *see also Qwest Services Corp. v. Blood*, 252 P.3d 1071 (Colo. 2011) (restating and reaffirming this standard).

As discussed above, the Court has found that there is a genuine dispute of fact as to whether Defendant knew or should have known of the risk of injury if its pain pump was used intra-articularly. The standard for exemplary damages in Colorado also involves whether Defendant knew or should have known of the risk of injury. The similarity in these standards suggests that, because the Court has found a genuine dispute of fact as to Defendant's knowledge, there is likewise a dispute of fact as to whether exemplary damages are appropriate in this case. Accordingly, Defendant's Motion for Summary Judgment is denied as to Plaintiff's claim for punitive damages.

IV. CONCLUSION

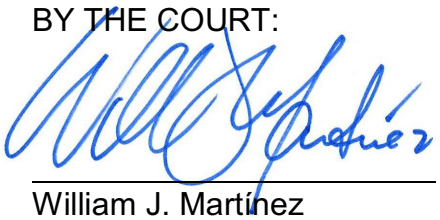
For the reasons set forth above, the Court ORDERS as follows:

1. Plaintiff's Motion for Partial Summary Judgment (ECF No. 96) is DENIED;
2. Defendant's Motion for Summary Judgment (ECF No. 87) is GRANTED IN PART and DENIED IN PART;
3. Judgment in favor of Defendant shall enter on Plaintiff's breach of implied warranty claim; and
4. The following claims shall proceed to trial by jury: (1) negligence; (2) negligent misrepresentation; (3) fraud; (4) strict product liability; and (5) strict product liability—failure to warn. Plaintiff shall also be permitted to pursue exemplary

damages against Defendant.

Dated this 20th day of April, 2012.

BY THE COURT:



William J. Martínez
United States District Judge