UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

SOUTHERN DIVISION

KELLY J. KOCH, Plaintiff, vs. BREG, INC., a California corporation, Defendant.	)	CIV. 08-4193-KES ORDER DENYING IN PART AND GRANTING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Defendant, Breg, Inc., moves for summary judgment. Plaintiff, Kelly Koch, resists Breg's motion. Breg's motion is denied in part and granted in part.

BACKGROUND

In the light most favorable to Koch, the nonmoving party, the facts are as follow:

Breg manufactures the Breg Pain Care 3200 pump, commonly referred to as a pain pump. The pain pump was cleared by the FDA for sale to medical professionals for general surgery applications pursuant to the 510(k) process.[1] It uses a drip mechanism that infuses an anesthetic, such as

[1] The 510(k) process "imposes a limited form of review on every manufacturer intending to market a new device by requiring it to submit a 'premarket notification' to the FDA[.]" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). "If the FDA concludes on the basis of the § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis[.]" *Id.* at 478. The requirements of the 510(k) process are codified at 21 U.S.C. § 360(k). *See generally id.* (recognizing that § 360(k) "is also known as a '§ 510(k) process,' after the number of the

bupivacaine, at a rate of 4cc's per hour. It also allows the patient to administer a bolus[2] dose of the anesthetic.

In 1985, Nole et al. wrote an article that explained the toxicity of local anesthetics to articular cartilage. Roberta Nole, et al., Bupivacaine and Saline Effects on Articular Cartilage, *Arthroscopy: The Journal of Arthroscopy and Related Surgery* (1985). Breg designed the pain pump so that bupivacaine, an anesthetic, could be dispensed in the shoulder's joint space, or intra-articularly, where the bupivacaine would come into direct contact with the cartilage in the shoulder. Breg also told doctors to insert the pain pump in the shoulder's joint space, or intra-articularly. Breg did not warn about the potential damage to the cartilage that might result from having the pain pump administer the bupivacaine directly into the shoulder's joint space.

On August 8, 2005, Koch underwent arthroscopic surgery of his right shoulder. After the surgery, a high volume pain pump manufactured by Breg was inserted in his shoulder's joint space. The pain pump was used for purposes of alleviating Koch's pain by administering bupivacaine. Approximately six months after the surgery, Koch began experiencing pain and stiffness in his right shoulder. Koch was subsequently diagnosed with

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section in the original [Medical Device Amendments of 1976] Act").

[2] A bolus is defined as a "single, relatively large quantity of a substance[.]" *Stedman's Medical Dictionary* 239 (28th ed. 2006).

glenohumeral chondrolysis.[3] Koch brought suit against Breg, alleging various strict liability and negligence claims. Breg moves for summary judgment.

STANDARD OF REVIEW

Summary judgment is proper "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The burden is initially placed on the moving party to establish the absence of a genuine issue of material fact and that the party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) ("[A] party seeking summary judgment always bears the initial responsibility of . . . demonstrat[ing] the absence of a genuine issue of material fact." (internal quotations omitted)).

Once the moving party has met its initial burden, the nonmoving party "may not rely merely on allegations or denials in its own pleading[.]" Fed. R. Civ. P. 56(e)(2). Rather, the nonmoving party must, "by affidavits or as otherwise provided in this rule[,] set out specific facts showing a genuine issue for trial." *Id.* For purposes of summary judgment, the facts, and inferences drawn from those facts, are "viewed in the light most favorable to the party opposing the motion." *Matsushita Elec. Indus. Co. v. Zenith Radio*

[3] Glenohumeral means "[r]elating to the glenoid cavity and the humerus." *Stedman's Medical Dictionary* at 811. Chondrolysis is the "[d]isappearance of articular cartilage as the result of disintegration or dissolution of the cartilage matrix and cells." *Id.* at 369.

Corp., 475 U.S. 574, 586 (1986) (quoting *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962)).

ANALYSIS

I. Koch's Negligence Claims

Koch alleges that Breg "knew or reasonably should have known that the pain pump and the anesthetic medication used in it could cause serious injury to patients when used in the joint space as directed." Docket 1 at 5. Koch also alleges that Breg failed, in various ways, to disclose and warn about the dangers of the intra-articular use of the pain pump in the shoulder. Docket 1 at 5-6. Koch also alleges that Breg negligently designed the pain pump to be inserted "directly into the shoulder joint, which infused commonly used medications that were associated with damage to articular cartilage." Docket 1 at 6. Breg argues that there is no evidence that Breg knew or should have known, prior to Koch's surgery, that its pain pump could injure patients.

Koch's complaint raises two distinct negligent product liability claims: (1) negligent failure to warn; and (2) negligent design. As a general rule, "[f]oreseeability for purposes of establishing a duty . . . relates to the time when the act or omission occurred." *See Peterson v. Spink Elec. Co-op., Inc.*, 578 N.W.2d 589, 592 (S.D. 1998) (internal quotations and citations omitted). Specifically, a negligent failure to warn claim requires evidence that "the manufacturer *knew or reasonably should have known* that the product was

dangerous or was likely to be dangerous when used in a reasonably foreseeable manner[.]" *Burley v. Kytec Innovative Sports Equip., Inc.*, 737 N.W.2d 397, 410 (S.D. 2007) (emphasis added). A negligent design claim requires a plaintiff to "show that the defendant failed to use the amount of care in designing . . . the product that a reasonably careful designer . . . would use in similar circumstances to avoid exposing others to a foreseeable risk of harm." *Burley*, 737 N.W.2d at 407 (citing Restatement (Second) Torts § 395). "To determine whether the designer . . . used reasonable care, one must balance what the designer . . . *knew or should have known* about the likelihood and severity of potential harm from the product against the burden of taking safety measures to reduce or avoid the harm." *Id.* (emphasis added) (citing Restatement (Second) Torts § 395). Thus, while there are two distinct types of negligence claims, each negligence claim requires evidence that Breg knew or reasonably should have known that the pain pump was dangerous, was likely to be dangerous, or created a foreseeable risk of harm. *See Burley*, 737 N.W.2d at 407, 410.

Breg argues that it could not have breached its duty because "no one—not one pain pump manufacturer, pharmaceutical manufacturer, orthopedic surgeon, anesthesiologist, medical researcher, or scientist—reported before plaintiff's surgery any suspicion of a potential risk associated with continuous infusion of local anesthetics in the shoulder joint space." Docket 88 at 11. There is evidence, however, that the first report

about "the toxicity of local anesthetics[, including bupivacaine,] to articular cartilage dates back to 1985 by Nole et al." Docket 105, Ex. 73 at 7. There is also evidence that Breg designed and intended for the pain pump to be used in the joint space of a patient's shoulder where the bupivacaine would come in direct contact with cartilage. Docket 109, Ex. 22 at 8. As Dr. Busfield explains in his expert report when discussing the Nole et al. report, "[i]t stands to reason that this toxicity of a single injection performed repeatedly over two to three days by a continuous infusion pain pump with optional additional bolus could demonstrate massive cumulative toxicity beyond which recovery was not biologically possible." Docket 105, Ex. 73 at 7. This evidence is sufficient to create a material issue of fact as to whether it was reasonably foreseeable to Breg prior to Koch's surgery that a pain pump that dispenses bupivacaine directly into the shoulder's joint space could cause permanent damage to the cartilage. Therefore, the court rejects Breg's argument that it had no duty as a matter of law.

In support of its argument that Breg could not have breached its duty, Breg relies on evidence that the scientific community had not demonstrated any association or explicit connection between pain pumps and chondrolysis. Specifically, Breg identifies the following question and answer given by Dr. Busfield during his deposition:

> Q. To your knowledge, Dr. Busfield, is there anything in any scientific or medical circles or journals or studies or research to suggest to anyone anywhere in the world prior to 2005 that a

> continuous flow of anesthetic may be potentially associated with a condition called "PAGCL" [post-arthroscopic glenohumeral chondrolysis]?
>
> A. No, there was not.

Docket 81, Ex. 14 at 48.

There is evidence, however, that the phrase, "post-arthroscopic glenohumeral chondrolysis," did not exist until 2007. Docket 105, Ex. 73 at 8. And the fact that the phrase, "post-arthroscopic glenohumeral chondrolysis," was not developed and discussed in medical literature until after 2005 does not mean as a matter of law that Breg could not have reasonably known that its pain pump was likely to be dangerous. Simply put, a manufacturer's duty to manufacture a product that is not dangerous or likely to be dangerous does not depend on whether a specific name has been developed for the resulting injury at the time the product is made. Accordingly, Dr. Busfield's answer does not establish as a matter of law that Breg could not have known that its pain pump could cause harm to patients.

While Breg has identified evidence that supports its position that it could not have reasonably foreseen the alleged fact that its pain pumps cause chondrolysis, this is a motion for summary judgment, and the court must view the facts and draw all reasonable inferences in favor of the nonmoving party, Koch. *Matsushita*, 475 U.S. at 586. As explained above, there is evidence that bupivacaine was known in 1985 to be toxic to cartilage cells. And the jury could reasonably conclude that Breg should have reasonably

known that dispensing bupivacaine into the joint space of a person's shoulder for several days, and allowing the patient to administer a bolus dose, where the bupivacaine would come into direct contact with cartilage cells, would likely lead to the permanent and irreparable loss of cartilage. Thus, there is sufficient evidence to allow the jury to reasonably conclude that Breg knew or reasonably should have known at the time it manufactured the pain pump that it was dangerous, was likely to be dangerous, or created a foreseeable risk of harm. *See Burley*, 737 N.W.2d at 407, 410.

Breg alternatively argues that Koch cannot prove that the pain pump caused his chondrolysis. Koch has identified two experts who will testify about how pain pumps can cause chondrolysis and one expert who will testify that Koch's chondrolysis was caused by Breg's pain pump. Viewing the facts in favor of Koch, the court finds that there is sufficient evidence for the jury to conclude that Koch's chondrolysis was caused by Breg's pain pump. Accordingly, Breg's motion to dismiss Koch's negligence claims is denied.

II. Strict Liability Claims

Koch's complaint alleges two separate strict product liability theories: (1) Breg is strictly liable for Koch's chondrolysis because Breg failed to adequately warn about the potential danger of its pain pump; and (2) Breg is strictly liable for Koch's chondrolysis because Breg's pain pump was defectively designed. With regard to the failure to warn strict liability claim, Breg argues that it cannot be liable for Koch's injuries because his injuries

were not foreseeable and that there is no evidence that its pain pump caused Koch's chondrolysis. With regard to the design defect claim, Breg argues that there is no evidence that the pain pump itself causes chondrolysis.

" 'The issue under strict liability is whether the manufacturer's failure to adequately warn rendered the product unreasonably dangerous without regard to the reasonableness of the failure to warn judged by negligence standards.' " *Burley*, 737 N.W.2d at 409 (quoting *Peterson v. Safway Steel Scaffolds Co.*, 400 N.W.2d 909, 912 (S.D. 1987*).* "Where a manufacturer or seller has reason to anticipate that danger may result from a particular use of [the] product, and [the manufacturer] fails to give adequate warning of such a danger, the product sold without such warning is in a defective condition within the strict liability doctrine." *Id.* (alteration in original) (internal quotations and citations omitted). As the South Dakota Supreme Court recognized in *Safway Steel Scaffolds Co.*, "[t]he issue[] of 'unreasonably dangerous' under Section 402A . . . [is] an introduction of negligence concepts to strict liability theory." 400 N.W.2d at 913. Thus, whether a manufacturer's failure to adequately warn resulted in an unreasonably dangerous product is generally an issue for the jury. *See id.* (emphasizing that the "issue[] of reasonableness . . . in strict liability [is] usually [a] jury issue[]").

There is evidence that at least one scientific article, which was published in 1985, demonstrated that bupivacaine and other local anesthetics were toxic to cartilage cells. Docket 105, Ex. 73 at 7. And there is

evidence that Breg designed and intended the pain pump to disperse bupivacaine into the joint space of a shoulder where the bupivacaine would come into direct contact with the cartilage. Docket 109, Ex. 22 at 8. Drawing all reasonable inferences based on the facts in the record in favor of Koch, the nonmoving party, a reasonable jury could conclude that the constant injection of bupivacaine in the shoulder's joint space for several days, along with bolus doses, would damage the cartilage to the point where it could not recover. A jury could therefore reasonably conclude that, prior to Koch's surgery, Breg should have anticipated the permanent destruction of cartilage in a patient's shoulder and warned about the danger accordingly. Breg has not identified evidence demonstrating that it warned about the potential danger of the pain pump destroying the cartilage in a patient's shoulder. Thus, there is sufficient evidence that Breg had "reason to anticipate that danger may result from a particular use of" the pain pump but "fail[ed] to give adequate warning of such danger[.]" *See Burly*, 737 N.W.2d at 409.

Breg alternatively argues that there is no evidence that pain pumps cause chondrolysis. This argument is rejected for the same reasons expressed above with regard to Breg's argument against the negligence claims. Thus, Breg's motion for summary judgment as to Koch's failure to warn strict liability claim is denied.

With regard to Koch's defective design strict liability claim, Breg argues that there is no evidence that the pain pump itself causes chondrolysis. Breg

has not, however, cited any authority to support the proposition that the product **itself** must cause the alleged harm. Indeed, such an argument is contrary to South Dakota law, which requires that the product must be the "proximate or legal cause." *Burley*, 737 N.W.2d at 409. *See also Peterson*, 400 N.W.2d at 911 (involving a plaintiff being hurt from a fall that was caused by allegedly defective clamps that gave way); *Klug v. Keller Indus., Inc.*, 328 N.W.2d 847, 848 (S.D. 1982) (involving a plaintiff being hurt from a fall that was caused by a defective ladder that gave way) (overruled on other grounds).

Here, there is no dispute that the pain pump dispensed bupivacaine into the joint space of Koch's shoulder. Docket 82 at 1. And there is sufficient evidence that bupivacaine causes chondrolysis and did in fact cause Koch's chondrolysis. Docket 105, Ex. 73 at 7-16. This evidence is sufficient to allow the jury to reasonably conclude that Breg's pain pump was the proximate or legal cause of Koch's chondrolysis. Thus, Breg's motion for summary judgment as to the defective design strict liability claim is denied.

III. Punitive Damages

Breg argues that summary judgment is appropriate with regard to Koch's punitive damages claim because there is no evidence that Breg acted with malice. Koch argues that there is sufficient evidence to create a material issue of fact as to whether Breg acted with malice.

SDCL 21-3-2 authorizes awards of punitive damages in tort "where the defendant has been guilty of oppression, fraud, or malice, actual or

presumed." "This statute limits punitive damages to cases in which oppression, fraud, or malice is claimed." *Dahl v. Sittner*, 474 N.W.2d 897, 900 (S.D.1991) (citations omitted) (analyzing SDCL 21-3-2). "Malice is an essential element of a claim for punitive damages[.]" *Id.* at 900 (emphasizing that "[a]s noted above, all punitive damages claims require a showing of either actual or presumed malice"). "[M]alice sufficient to support exemplary damages may be either actual, malice in fact, or presumed, legal malice." *Id.*

"Actual malice is a positive state of mind, evidenced by the positive desire and intention to injure another, actuated by hatred or ill-will toward that person." *Id.* Koch does not argue that Breg acted with actual malice. Moreover, there is no evidence that Breg had "the positive desire and intention to injure another[.]" *See id.* Thus, there is no actual malice that would allow an award of punitive damages.

"Presumed, legal malice . . . is malice which the law infers from or imputes to certain acts." *Id.* (citations omitted). "[W]hile the [defendant] may not act out of hatred or ill-will, malice may nevertheless be imputed if the [defendant] acts willfully or wantonly to the injury of the other." *Id.* (citation omitted). "In this context, however, . . . [m]alice as used in reference to exemplary damages is not simply the doing of an unlawful or injurious act, it implies that the act complained of was conceived in the spirit of mischief or of criminal indifference to civil obligations." *Id.* (internal quotations and citation omitted). Stated another way, "South Dakota requires more egregious conduct

than states which merely require proof of gross negligence and states which require proof of conduct more egregious than gross negligence, but which do not require proof of malice." *Bierle v. Liberty Mutual Ins. Co.*, 792 F. Supp. 687, 692 (D.S.D.1992) (citation omitted). "Thus, South Dakota is among the states having the most stringent conduct requirement." *Id.* at 692.

Koch argues that there is evidence that Breg improperly promoted the intra-articular use of its pain pumps for orthopedic surgeries. He also argues that there is evidence of Breg's failure to conduct additional tests with regard to the safety and efficacy of using its pain pumps.[4]

The South Dakota Supreme Court addressed the issue of punitive damages in a products liability situation in *Holmes v. Wegman Oil Co.*, 492 N.W.2d 107 (S.D.1992) (upholding jury's punitive damages award). *Holmes* involved claims of fraudulent concealment where the manufacturer recalled a defective water heater ten years after it learned that its water heaters would explode because of a defective knob. *Id.* at 113. The South Dakota Supreme Court has also explained in the context of a negligence claim that in order for there to be a successful punitive damages claim

> [t]here must be facts that would show that defendant . . . intentionally failed to do something which he should have done under the circumstances that it can be said that he consciously

[4] Koch also argues that Breg conducted "illegal 'field tests' on human subjects without their consent before it launched the pump line[.]" Docket 108 at 16. There is no evidence, however, that Koch was subjected to one of these "illegal 'field tests.' "

> realized that his conduct would in all probability, as distinguished from possibility, produce the precise result which it did produce and would bring harm to the plaintiff.

Berry v. Risdall, 576 N.W.2d 1, 9 (S.D. 1998) (quoting *Tranby v. Brodock*, 348 N.W.2d 458, 461 (S.D.1984)).

Here, Koch has not identified any evidence that Breg was aware that its pain pumps actually caused chondrolysis prior to Koch's surgery. In fact, Koch admits that "Breg was aware of chondrolysis in patients following [the] use of pain pumps at least as early as December 22, 2005[.]" Docket 109 at 11. Koch's surgery, however, was on August 8, 2005, over four months prior to the date that Breg arguably became aware of chondrolysis occurring in patients who had a Breg pain pump in the joint space of their shoulder. Docket 109 at 1. Therefore, unlike the case in *Holmes*, there is no evidence that Breg concealed or otherwise consciously failed to disclose that chondrolysis had occurred on a patient after Breg's pain pump administered an anesthetic directly into the shoulder's joint space. Nor is there sufficient evidence that Breg "realized that [its] conduct would in all probability, as distinguished from possibility," result in someone developing chondrolysis. *Berry*, 576 N.W.2d at 9. Thus, viewing the facts in the light most favorable to Koch, the nonmoving party, the court finds that Breg is entitled to summary judgment in its favor with regard to Koch's punitive damages claim in light of controlling South Dakota law. Accordingly, it is

ORDERED that Breg's motion for summary judgment (Docket 75) is denied with regard to Koch's negligence and strict liability claims.

IT IS FURTHER ORDERED that Breg's motion for summary judgment (Docket 75) is granted with regard to Koch's punitive damages claim.

Dated December 20, 2010.

BY THE COURT:

/s/ *Karen E. Schreier*
KAREN E. SCHREIER
CHIEF JUDGE