SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-3280-15T1

KEMUEL GOODSON,

Plaintiff-Appellant,

v.

C.R. BARD and DAVOL, INC.,

Defendants-Respondents.

Argued January 10, 2018 – Decided March 19, 2018

Before Judges Koblitz, Manahan, and Suter.

On appeal from Superior Court of New Jersey, Law Division, Atlantic County, Docket No. L-0826-13.

William L. Hurlock argued the cause for appellant (Mueller Law LLC and Mark R. Mueller (Mueller Law, PLLC) of the Texas bar, admitted pro hac vice, attorneys; William L. Hurlock and Mark R. Mueller, on the briefs).

Daniel K. Winters argued the cause for respondents (Reed Smith LLP, attorneys; Daniel K. Winters, of counsel and on the brief; Shana E. Russo, of counsel and on the brief).

PER CURIAM

This appeal requires our consideration of the Bard 3DMax Mesh (3DMax), a polypropylene mesh used for hernia operations that is manufactured, designed, and marketed by defendants C.R. Bard, Inc. and Davol, Inc. (collectively defendants). Plaintiff Kemuel Goodson alleges that the implantation of this medical device caused multiple complications that required extensive medical care, including numerous operations. Plaintiff alleged four causes of action: (1) defective design of the 3DMax under the New Jersey Product Liability Act; (2) defective design of the 3DMax Mesh under Georgia law; (3) negligence under Georgia law; and (4) fraud and misrepresentation under Georgia law.

Upon the completion of discovery, defendants filed a motion seeking summary judgment which was granted. Plaintiff appeals, arguing the trial court erred in granting summary judgment to defendants on plaintiff's claims of design defect and negligence. We affirm.

We discern the facts from the summary judgment record, viewing them in the light most favorable to plaintiff, the non-moving party. Globe Motor Co. v. Igdalev, 225 N.J. 469, 479 (2016); R. 4:46-2(c).

The 3DMax is a prescription, three-dimensional, synthetic, and implantable hernia mesh repair product made by defendants. It is an anatomically formed prosthesis used in laparoscopic groin

hernia repair. The mesh used in the 3DMax is made of knitted polypropylene monofilaments. Products that use polypropylene mesh are regulated by the FDA as Class II medical devices. Defendants have continued to be in compliance with the FDA requirements, and have never been requested by the FDA to remove 3DMax from the market.

Plaintiff is a Georgia resident who underwent a laparoscopic bilateral inguinal hernia repair using the 3DMax in December 2006. The surgery was performed by Dr. Mark Middleton in Hiram, Georgia. After the surgery, plaintiff experienced right groin pain and swelling of the right testicle. He continues to be in constant pain.

Dr. Middleton testified he was aware of the risks and benefits of using synthetic mesh, including the risks of chronic pain, infertility, and nerve ingrowth. Dr. Middleton also testified he discussed the risks of numbness and chronic pain with plaintiff prior to the surgery. Dr. Middleton stated he did not read the Instructions for Use (IFU) that came with the product. He specified he "had less problems with the 3DMax Mesh than any of the other mesh products that I've used . . . ." Dr. Middleton does not believe the 3DMax is the cause of plaintiff's medical complications.

After the surgery, plaintiff was referred to urologist Dr. James Cullison, due to complications causing pain and a swollen testicle. Dr. Cullison performed a right epididymectomy, spermatocelectomy, and hydrocelectomy on plaintiff, but the pain did not subside, which ultimately led to the removal of the right testicle. Afterwards, plaintiff continued to experience pain.

In January 2012, plaintiff was treated by Dr. John Galloway at Emory University Medical Center. Dr. Galloway performed a triple neurectomy, which included removing the 3DMax and replacing it with biologic mesh. Dr. Galloway offered no criticisms of the 3DMax used in the original hernia repair and stated he did not believe that the 3DMax was defective or unreasonably dangerous. Dr. Galloway further testified that "the mesh is considered standard of care and safe in inguinal hernia repairs."

In July 2015, due to continuing chronic pain, plaintiff underwent a third surgery with Dr. Bruce Ramshaw in Daytona Beach, Florida, who removed the biologic mesh and completed an exploration of the entire groin. Dr. Ramshaw found serious scarring and a nerve entrapped within the scar tissue. He believed those conditions were caused by the mesh removal surgery. Dr. Ramshaw testified he had no criticisms of Dr. Middleton's decision to use the 3DMax. During Dr. Ramshaw's deposition, the following colloquy ensued:

> Q. Was there any indication that [plaintiff] has some sort of unusual response to the mesh?
>
> A. No. It looked like there was scar tissue from prior surgery.

Dr. Ramshaw could not definitively say what caused plaintiff's pain.

Plaintiff's expert, Dr. Robert Bendavid, was deposed. The doctor was not offered as a Food and Drug Administration (FDA) regulatory expert and did not opine as to the 3DMax specifically. Dr. Bendavid offered no opinion as to whether the 3DMax was appropriately marketed to physicians in the United States. Dr. Bendavid agreed that the 3DMax was appropriate to use in some cases, but not others. He opined that the use of synthetic polypropylene should be used "judiciously."

Next Dr. Vladimir Iakovlev, another plaintiff's expert, was deposed. Dr. Iakovlev, a pathologist, testified regarding his criticism of polypropylene products in general. Dr. Iakovlev did not offer opinions regarding the design of the 3DMax, an alternate design, or whether defendants complied with any applicable standard of care. In his report, Dr. Iakovlev concluded the 3DMax caused plaintiff's pain and testicular symptoms.

A third plaintiff's expert, Dr. Kevin Petersen, was also deposed. Dr. Petersen offered no criticism about the 3DMax and

had no opinion about whether the 3DMax was appropriately designed or manufactured. Dr. Peterson did not have an opinion about whether plaintiff would have experienced a different outcome if another mesh product was used. Dr. Petersen stated in his expert report that the 3DMax was the cause of plaintiff's complications, and that a hernia repair without mesh would have been the better, safer option and would have avoided the risks associated with the 3DMax.

On February 18, 2016, after hearing oral argument, the trial court granted summary judgment to defendants and dismissed plaintiff's complaint. The court explained the reasons for its ruling in a written opinion issued with its order. On the design defect claim, the court found that plaintiff produced no evidence that the 3DMax was defectively designed. As to defendant's claim of negligence, the court found plaintiff had presented no proof on the standard of care. In addition, the court held plaintiff did not demonstrate that the proximate cause of plaintiff's injury was the use of the 3DMax. Rather, the court held plaintiff's proofs supported the mere possibility, rather than a reasonable probability, that the 3DMax proximately caused plaintiff's injuries.

Plaintiff raises the following issues on appeal:

POINT I

THE LAW DIVISION ERRED IN GRANTING SUMMARY JUDGMENT TO DEFENDANTS ON PLAINTIFF'S DESIGN DEFECT CLAIM.

1. Plaintiff Established Specific Factual Disputes about the Existence of a 3DMax Mesh Design Defect.

2. Plaintiff Established Specific Factual Disputes Material to Plaintiff's Proof of Proximate Causation.

POINT II

THE LAW DIVISION PLAINLY ERRED IN GRANTING SUMMARY JUDGMENT ON PLAINTIFF'S NEGLIGENCE CLAIM.

1. The Law Division Erred in Holding That Plaintiff Cannot Satisfy the Standard of Care Element as Matter of Law.

2. The Law Division Erred in Holding That Plaintiff Cannot Satisfy the Proximate Cause Element for Negligence as Matter of Law.

We first address plaintiff's arguments regarding the design defect claim. Pursuant to the agreement of the parties, as did the trial court, we apply Georgia law.

"An appellate court reviews an order granting summary judgment in accordance with the same standard as the motion judge." Bhagat v. Bhagat, 217 N.J. 22, 38 (2014) (citing W.J.A. v. D.A., 210 N.J. 229 237-38 (2012)). We "must review the

competent evidential materials submitted by the parties to identify whether there are genuine issues of material fact and, if not, whether the moving party is entitled to summary judgment as a matter of law." Ibid. (citing Brill v. Guardian Life Ins. Co., 142 N.J. 520, 540 (1995)); see also R. 4:46-2(c).

We consider all facts in the light most favorable to plaintiff, the non-movant, Robinson v. Vivirito, 217 N.J. 199, 203 (2014), keeping in mind "[a]n issue of fact is genuine only if, considering the burden of persuasion at trial, the evidence submitted by the parties on the motion, together with all legitimate inferences therefrom favoring the non-moving party, would require submission of the issue to the trier of fact." R. 4:46-2(c). "The practical effect of this rule is that neither the motion court nor an appellate court can ignore the elements of the cause of action or the evidential standard governing the cause of action." Bhagat, 217 N.J. at 38.

Since the grant of summary judgment calls for a review of the "trial court's interpretation of the law and the legal consequences that flow from established facts," the trial court's decision is "not entitled to any special deference," and is subject to de novo review. Manalapan Realty, LP v. Twp. Comm., 140 N.J. 366, 378 (1995) (citation omitted).

Plaintiff argues that summary judgment was improperly granted as to his design defect claim and the court improperly weighed the competing evidence presented. Plaintiff contends his experts opined that the risks of the 3DMax outweighed the benefits, and thus plaintiff satisfied his burden of proof. We disagree.

Under Georgia law, the three types of product defects are manufacturing, design, and marketing/packaging defects. S K Hand Tool Corp. v. Lowman, 479 S.E.2d 103, 106 (Ga. Ct. App. 1996). To recover on a design defect claim, the plaintiff must establish: (1) the product's design is defective, and (2) the defective design caused the plaintiff's injuries. In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig., 711 F. Supp. 2d 1348, 1364 (M.D. Ga. 2010). The standard the trier of fact uses to determine defectiveness in design defect cases, under a strict liability cause of action, is a "risk-utility" test. S K Hand Tool Corp., 479 S.E.2d at 106. The "risk-utility" test "set[s] out a non-exhaustive list of factors for a jury to consider in a balancing analysis of whether a product is defective." Ibid. Essentially, the test is a balancing test where the risks inherent in the product design are weighed against the benefits. Banks v. Ici Ams., 450 S.E.2d 671, 673-74 (Ga. 1994); Dean v. Toyota Indus. Equip. Mfg., 540 S.E.2d 233, 237 (Ga. Ct. App. 2000). Therefore,

> [t]his risk-utility analysis incorporates the concept of "reasonableness," i.e., whether the manufacturer acted reasonably in choosing a particular product design, given the probability and seriousness of the risk posed by the design, the usefulness of the product in that condition, and the burden on the manufacturer to take the necessary steps to eliminate the risk.
>
> [Banks, 450 S.E.2d at 673.]

An important factor to consider in the balancing test is the availability of alternative designs that may be safer. Id. at 674. Other factors, although not exclusive, include:

> the usefulness of the product; the gravity and severity of the danger posed by the design; the likelihood of that danger; the avoidability of the danger, i.e., the user's knowledge of the product, publicity surrounding the danger, or the efficacy of warnings, as well as common knowledge and the expectation of danger; the user's ability to avoid danger; the state of the art at the time the product is manufactured; the ability to eliminate danger without impairing the usefulness of the product or making it too expensive; and the feasibility of spreading the loss in the setting of the product's price or by purchasing insurance.
>
> [Id. at 675 n.6.]

Factors that concern the beneficial aspects of the product include: "the appearance and aesthetic attractiveness of the product; its utility for multiple uses; the convenience and extent of its use . . . ; and the collateral safety of a feature other than the one that harmed the plaintiff." Ibid.

"In general, weighing the risk-utility factors is left to the jury." In re Mentor, 711 F. Supp. 2d at 1365. Thus, "[t]o prevail at summary judgment, a defendant must 'show plainly and indisputably an absence of any evidence that a product as designed is defective.'" Ibid. (alteration in original) (quoting Ogletree v. Navistar Int'l Transp. Corp., 522 S.E.2d 467, 470 (Ga. 1999)).

In the instant case, none of the experts specifically opined that the 3DMax is defective and that this defective design caused the medical complications complained of by the plaintiff. Instead, plaintiff's three experts gave general opinions about the various medical risks of the product that can cause complications. This is not enough to overcome the summary judgment standard. See Brill, 142 N.J. 520 (1995).

In addition, no expert presented an alternative, feasible design for the 3DMax. As previously stated, this is one of the determining factors in a defective design case. Banks, 450 S.E.2d at 674. For instance, Dr. Iakovlev testified:

> Q: And you're not going to say that if there had been some different design for the 3DMax Product, that a patient would have had a different clinical outcome, correct?
>
> A: That's correct.

Further, Dr. Petersen testified:

> Q: You are not offering anything about how tissue-based products are better in general, are you?
>
> A: No.
>
> Q: And you are actually not offering any specific opinions about some sort of adjustment or change in the specific design of the PerFix Plug that would have avoided a risk of what you considered to be chronic disabling pain, correct?
>
> A: Yes.
>
> Q: You're not doing that?
>
> A: I'm not doing that.
>
> Q: . . . For the 3DMax product, you're not offering any opinion that there was some change in the design or configuration of the product that would have avoided or minimized the risk of what you think is chronic or disabling pain, correct?
>
> A: Correct.

In the absence of the requisite proof that the 3DMax was defectively designed, plaintiff's claim on this score fails. Given this failure of proof, it follows that plaintiff's proximate causation argument is rendered moot.

We next address plaintiff's negligence claim. Plaintiff asserts the court erred in holding plaintiff did not satisfy its burden of proof on his negligent warning claim. Plaintiff argues the court erred in weighing the evidence and that it applied the wrong standard of care. Specifically, plaintiff argues his experts

did not have to opine as to the standard of care because Georgia law does not require expert testimony as to defendants' standard of care. We disagree.

The court held that plaintiff's negligence claims failed as "[p]laintiff's experts d[id] not opine as to the standard of care owed by [d]efendants and thus whether they breached it . . . ." Similar to plaintiff's design defect claim, the court found that plaintiff provided insufficient evidence to support the negligent warning claim.

In order to establish a claim of negligence under Georgia law, the following elements must be met:

> (1) A legal duty to conform to a standard of conduct raised by the law for the protection of others against unreasonable risks of harm; (2) a breach of this standard; (3) a legally attributable causal connection between the conduct and the resulting injury; and (4) some loss or damage flowing to the plaintiff's legally protected interest as a result of the alleged breach of the legal duty.
>
> [Heston v. Lilly, 546 S.E.2d 816, 818 (Ga. Ct. App. 2001).]

Georgia law provides that in order to establish a failure to warn claim, plaintiff must show: "the defendant had a duty to warn, that the defendant breached that duty, and that the breach proximately caused the plaintiff's injury." Dietz v. Smithkline Beecham Corp., 598 F.3d 812, 815 (11th Cir. 2010) (citing Wheat

v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999)). "Within the context of prescription drugs [or medical devices], however, Georgia employs the learned intermediary doctrine, which alters the general rule that imposes liability on a manufacturer for failing to warn an end user of the known risks or hazards of its products." Ibid. (citing Wheat, 46 F. Supp. 2d at 1363). Under the learned intermediary doctrine, the manufacturer of:

> a . . . medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities.
>
> [McCombs v. Synthes, 587 S.E.2d 594, 595 (Ga. 2003).]

At the outset, we note that we are in agreement with the trial court that jurors would lack the requisite knowledge, training and experience to reach a determination relative to the standard of care absent expert testimony. Here, none of plaintiff's experts offered an opinion on the standard of care or whether that standard was breached. During his deposition, Dr. Iakovlev testified:

> Q: You're not going to offer any opinions about whether Davol complied with any standard of care applicable to a medical device manufacturer, are you?
>
> A: No, I'm not going to offer that opinion.

Although Dr. Petersen testified he believed the IFU should have contained information about chronic pain, he testified that his opinion on the IFU was general and could apply to any polypropylene mesh product. Dr. Bendavid similarly testified he was not offering an opinion of whether the instructions for the 3DMax were adequate or appropriate.

Concerning the issue of a learned intermediary, during Dr. Middleton's deposition, he testified:

> Q: Has any mesh manufacturer ever told you that infertility was a risk of implantation of mesh?
>
> . . . .
>
> A: A mesh manufacturer has never told me directly that infertility is a possibility. As part of my training in residency, I was made well aware that infertility was a possibility associated with this particular procedure.
>
> Q: Okay. How about the risk of dysejaculation?
>
> A: Yes.
>
> Q: From your training as well?
>
> A: Yes, the same.

> Q: Okay. Were you aware from any material from a manufacturer such as the instructions for use or the warnings that nerves would grow into the mesh and that could cause chronic debilitating pain?
>
> . . . .
>
> A: I've never directly read through the instructions of the manufacturer or anything, but I'm well aware that that is a possibility in this particular procedure in my training.
>
> Q: . . . Were you aware of these things that we've previously discussed, these risks before December of 2006?
>
> A: Yes.

Notwithstanding, Dr. Middleton testified he went over the risks of the mesh surgery with plaintiff prior to the surgery, including the risk of chronic pain, numbness, hematoma, and mesh infection.

As plaintiff's physician, Dr. Middleton was serving in the role of a learned intermediary. Despite the doctor's decision to not read the manufacturer's warnings, that decision does not alter his learned intermediary role nor does it impose liability on defendants for failure to warn.

Having considered the motion record in conjunction with our de novo standard of review, we discern no error in the holding that defendants were entitled to summary judgment.

Affirmed.