COURT OF APPEALS DECISION DATED AND FILED

April 5, 2022

Sheila T. Reiff Clerk of Court of Appeals

NOTICE

This opinion is subject to further editing. If published, the official version will appear in the bound volume of the Official Reports.

A party may file with the Supreme Court a petition to review an adverse decision by the Court of Appeals. *See* WIS. STAT. § 808.10 and RULE 809.62.

Appeal No. 2020AP1454 STATE OF WISCONSIN Cir. Ct. No. 2018CV3317

IN COURT OF APPEALS DISTRICT I

NEIL J. RENNICK,

PLAINTIFF-APPELLANT,

V.

TELEFLEX MEDICAL INCORPORATED,

DEFENDANT-RESPONDENT,

WEA INSURANCE CORPORATION,

DEFENDANT.

APPEAL from an order of the circuit court for Milwaukee County: KEVIN E. MARTENS, Judge. *Reversed and cause remanded for further proceedings*.

Before Brash, C.J., Dugan and White, JJ.

Per curiam opinions may not be cited in any court of this state as precedent or authority, except for the limited purposes specified in WIS. STAT. RULE 809.23(3).

PER CURIAM. Neil J. Rennick filed this products liability suit against Teleflex Medical Inc. after experiencing complications following surgery in which Weck Hem-o-lok Polymer Ligation System clips manufactured, marketed, and sold by Teleflex were used. The circuit court granted summary judgment in favor of Teleflex and dismissed Rennick's complaint. Rennick now appeals, arguing that the circuit court erroneously applied the learned intermediary doctrine in order to dismiss his claims. For the reasons set forth below, we agree, and we reverse the order of the circuit court and remand this matter for further proceedings consistent with this opinion.

BACKGROUND

¶2 The following facts are undisputed. On April 17, 2015, Rennick underwent a laparoscopic partial nephrectomy on his left kidney to remove a cancerous tumor. Dr. Mark Waples, a urological specialist, performed the surgery, and as part of the surgery, Dr. Waples used Teleflex's Hem-o-lok clips in a technique referred to as sliding clip renorrhaphy.¹ Renorrhaphy is the process of suturing and closing up the kidney, and the purpose of the clips in the renorrhaphy was to reinforce and secure the sutures Dr. Waples used in Rennick's kidney and surrounding tissue. As Dr. Waples described, the clips are plastic "with an open jaw and they have a little lock on the end of it that you can lock it down and slide it," and he used the clips "as a bolster" to distribute the pressure of the sutures.

¹ The clips were allegedly provided by Aurora St. Luke's Medical Center to Dr. Waples for Dr. Waples to use in Rennick's surgery.

¶3 Following the surgery, Rennick experienced pain and other symptoms, such as internal bleeding. Dr. Waples conducted a renal ultrasound and sent Rennick to Dr. Antony Ruggieri, an oncologist. Rennick's symptoms worsened, and in March 2016, Rennick passed a closed clip while urinating. Eventually, Dr. Waples suggested further treatment from additional specialists, including a rheumatologist and a nephrologist, and in November 2016, Rennick underwent another operation in which Dr. Steve Weiner, Rennick's urologist, discovered a clip embedded in Rennick's kidney in a place that Dr. Waples indicated that he would not have put any clips during the surgery. Rennick's symptoms improved when his kidney was ultimately removed.

¶4 On April 16, 2018, Rennick filed a complaint against Teleflex, alleging four causes of action. In the first cause of action, Rennick asserted common law negligence for negligent product testing, design, manufacture, and sale, along with negligence for lack of product injury warnings, inadequate safety instructions, and inaccurate clip performance and safety claims. In the second cause of action, Rennick alleged a strict product liability claim under WIS. STAT. § 895.047 (2019-20),² for defective manufacture, design, and inadequate instructions or warnings. The third cause of action asserted a claim for strict liability misrepresentation under RESTATEMENT (SECOND) OF TORTS § 402(A).³ The fourth cause of action asserted a violation of WIS. STAT. § 100.18 for untrue, deceptive, or misleading advertising related to the clips. In short, Rennick alleged

 $^{^2}$ All references to the Wisconsin Statutes are to the 2019-20 version unless otherwise noted.

³ The complaint cites RESTATEMENT (SECOND) OF TORTS § 402(B); however, as Teleflex highlighted below, the correct cite seems to be RESTATEMENT (SECOND) OF TORTS § 402(A).

in his complaint that Teleflex's clips failed to stay permanently and securely attached where they were surgically implanted and failed to perform as Teleflex intended and advertised. Rennick alleged that Teleflex's clips were migrating and moving throughout his body, which was causing him pain, internal bleeding, and other injuries, and he alleged that Teleflex misrepresented that its clips were safe for use in laparoscopic surgeries and failed to provide any information about the risk of migration associated with using its clips.

- ¶5 Teleflex filed a motion for summary judgment on December 9, 2019, and it argued that Rennick could not "establish that any alleged act or omission by Teleflex caused his alleged injuries." Teleflex pointed to the learned intermediary doctrine as a means of limiting any assumed duty it had to warn of the risks associated with the clips to Dr. Waples, and then argued that Rennick could not establish cause because Dr. Waples would not have altered his decision to use the clips had Teleflex provided a warning to Dr. Waples about a risk of clip migration. It additionally argued that Rennick's fourth claim alleging a violation of Wis. STAT. § 100.18 must be dismissed because it was filed after the statute of limitations had expired and Rennick was unable to identify an actionable misrepresentation.
- The circuit court held a hearing on December 10, 2019, at which the parties discussed the briefing schedule. Rennick raised an argument that Teleflex filed its motion for summary judgment in advance of the deadline for dispositive motions and the close of discovery, and he requested further discovery before responding to Teleflex's motion. Teleflex opposed conducting further discovery in the interest of efficiency and to avoid unnecessary expense, and it maintained that no further discovery was required should the learned intermediary doctrine apply. The circuit court set a briefing schedule and also ordered Teleflex to

participate in depositions of Teleflex's sales employees and hospital representatives from Aurora Healthcare Inc. before Rennick's deadline to file his response.

Rennick filed his response on April 27, 2020. In his response, Rennick did not dispute that he was required to prove that an act or omission by Teleflex caused his injuries as an element of his claims, but rather, he argued that the learned intermediary doctrine did not apply. He also argued that there were genuine issues of material fact that precluded summary judgment and that summary judgment was premature because he was unable to complete the discovery necessary to support his claims. As Rennick described, Teleflex refused to participate in the depositions ordered by the circuit court following the December 10, 2019 hearing and generally refused to engage in discovery, rendering summary judgment inappropriate at that time.⁴

Rennick also provided several items that he contended supported the fact that Teleflex knew or should have known of the risk of clip migration and included warnings about this post-surgery risk. Specifically, he provided forty-nine articles from medical journals from 2006 to 2020 discussing the risk of clip migration, a June 2000 news release, an article posted on Teleflex's website by Dr. Sam B. Bhayani—the alleged creator of the sliding clip renorrhaphy technique—about the use of Teleflex's clips in the technique, a Teleflex internal corporate report dated May 2014 that discusses clip migration, a premarket notification from a staff member at the U.S. Food and Drug Administration

⁴ Prior to the summary judgment proceedings, the circuit court had granted a motion to compel and ordered Teleflex to respond to certain discovery requests issued by Rennick.

(FDA), an FDA "Medwatch" product problems report, and various other marketing materials used to promote Teleflex's clips for medical use. Rennick additionally provided his own affidavit opining as to the medical cause of his symptoms, the possibility of clip migration, and how he would have altered his behavior to avoid his injuries had he known about the risk he was undertaking in deciding to have surgery.⁵ Rennick argued that these documents at the very least provided sufficient evidence of a genuine issue of material fact to render summary judgment inappropriate.

The circuit court granted Teleflex's motion for summary judgment and dismissed Rennick's complaint. In its decision, the circuit court found that there were no genuine issues of material fact and Rennick could not prove that any act or omission by Teleflex caused his injuries. In reaching this decision, the circuit court reasoned that the learned intermediary doctrine applied and limited Teleflex's duty to warn of any risk of clip migration to Dr. Waples. Because the circuit court found that Dr. Waples would have used the clips in the surgery even if he had received such a warning from Teleflex, the circuit court found that Rennick could not prove the cause element of his claims. The circuit court did not address Teleflex's arguments related to Rennick's WIS. STAT. § 100.18 claim, nor did it address Rennick's argument that discovery was incomplete and rendered summary judgment inappropriate at that time.

¶10 Rennick now appeals.

⁵ As Rennick avers, he is a doctor with his own medical practice and claims that he is qualified as an expert and able to provide an opinion as to the medical cause of the symptoms he experienced following his surgery. We express no opinion on Rennick's status as his own medical expert.

DISCUSSION

¶11 Summary judgment "shall be rendered if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." WIS. STAT. § 802.08(2). We review a summary judgment determination *de novo*, using the same methodology as the circuit court. *See Green Spring Farms v. Kersten*, 136 Wis. 2d 304, 315, 401 N.W.2d 816 (1987). Here, we review the matter on which Teleflex moved for summary judgment—whether Teleflex was entitled to judgment as a matter of law because there is no genuine issue as to any material fact surrounding whether its failure to include a warning about the risk of clip migration caused any of Rennick's injuries.

I. Application of the Learned Intermediary Doctrine

¶12 On appeal, Rennick argues that the circuit court erroneously relied on the learned intermediary doctrine, granted summary judgment in favor of Teleflex, and dismissed all of his claims for lack of an ability to show cause. Rennick contends that, even if Wisconsin follows the learned intermediary doctrine, the circuit court misapplied the doctrine because Teleflex failed to provide any warnings about the risk of clip migration. As Rennick argues, the doctrine is an exception to a manufacturer's general duty to warn consumers directly and it applies only after a manufacturer provides a warning to the physician of the risk involved. Therefore, because Teleflex failed to provide any warning at all to Dr. Waples about the risk of migration, the threshold requirement has not been met and the doctrine does not apply here. As a result, Teleflex had a duty to warn Rennick and Dr. Waples, and there are genuine issues of material fact

presented by Dr. Waples' deposition testimony and Rennick's own affidavit as to whether Teleflex's failure to warn caused his injuries.

¶13 Teleflex argues that there is but one issue before this court—namely, whether Rennick can show that Teleflex caused any of his injuries by its failure to warn Dr. Waples of the risk of post-surgical clip migration in what Teleflex argues was an "off-label" use of its product.⁶ In this regard, Teleflex argues that the circuit court properly applied the learned intermediary doctrine to Rennick's claims to limit its duty to warn to Dr. Waples. Teleflex further argues that the circuit court properly found that Rennick could not show cause because Dr. Waples would not have changed his decision to use the clips if Teleflex had in fact provided a warning about the risk of clip migration.

¶14 Teleflex supports its argument by pointing to deposition testimony from Dr. Waples in which Dr. Waples indicated that he learned the sliding clip renorrhaphy technique, not from anything Teleflex provided, but by reading medical literature and learning the technique from other physicians. Teleflex further supports its argument saying that Dr. Waples indicated that he would still have used the clips if he had received a warning about the risk of migration because of the overall positive experience he has had and the inability to perform this type of surgery without the clips. Indeed, as Teleflex argues, Dr. Waples has

⁶ Teleflex argues that Dr. Waples' use of its clips in the sliding clip renorrhaphy technique was an off-label use because its clips are only approved by the FDA for use in ligation of vessels or tissue structures in which a clip is placed around a vessel or tissue and then closed to close off the vessel or structure as opposed to how it describes the use of its clips here as "used to close the incision to [Rennick's] kidney." The example provided by Teleflex in its brief of an intended use is closing a clip around a vessel to stop the flow of blood. We need not decide today whether Dr. Waples' use of the clips in this instance was an off-label use.

continued to use the clips in the sliding clip renorrhaphy technique even after becoming aware of Rennick's post-surgery experience and possible clip migration.

- ¶15 As a general rule in Wisconsin, a manufacturer or supplier of a product has a duty to warn consumers directly of the known or knowable dangers associated with the use of its product. *See Strasser v. Transtech Mobile Fleet Serv., Inc.*, 2000 WI 87, ¶58, 236 Wis. 2d 435, 613 N.W.2d 142; *see also Tanner v. Shoupe*, 228 Wis. 2d 357, 367-68, 596 N.W.2d 805 (Ct. App. 1999). This includes "the duty to warn of dangers inherent in a use not intended by the manufacturer [] if such unintended use is reasonably foreseeable by the manufacturer." *Strasser*, 236 Wis. 2d 435, ¶58 (alteration in original) (quoting WIS JI—CIVIL 3242).
- ¶16 The learned intermediary doctrine at issue here operates as an exception to this general rule in the case of a prescription drug or medical device. The doctrine "holds that the manufacturer of a prescription drug or medical device fulfills its duty to warn of the product's risks by informing the prescribing physician of those risks." *In re: Zimmer, NextGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 751 (7th Cir. 2018). Thus, if the doctrine applies, it defeats a claim that a manufacturer had a duty to warn the patient directly of any risks associated with its product. *Id.* at 750-51.
- ¶17 Wisconsin has yet to adopt this doctrine, and Teleflex relies on a case from the Seventh Circuit Court of Appeals that predicted that Wisconsin would adopt this doctrine if given the opportunity to do so. *See id.* at 752. Based on this prediction, the Seventh Circuit concluded that "to the extent that [the patient's] defective-warning claim is based on Zimmer's duty to warn *him*, it is foreclosed by the learned-intermediary doctrine." *Id.* Thus, Teleflex argues that

we should apply this doctrine and limit any duty that it had to warn of a risk of clip migration to Dr. Waples and limit the analysis to how Dr. Waples would have altered his behavior had he received a warning from Teleflex.

¶18 We need not address the adoption of this doctrine in Wisconsin because we conclude that it does not apply to the facts of this case. As stated by the Seventh Circuit, the doctrine applies when the manufacturer has "inform[ed] the prescribing physician" of the risks associated with its product. See id. at 751. Here, it is undisputed that Teleflex provided no warning of any sort of the risk of post-surgery clip migration to Dr. Waples in the instructions for use booklet that came with the clips. Having provided no warning about this risk of migration, Teleflex has not met the threshold requirement for the application of the learned intermediary doctrine. Therefore, we conclude that the doctrine does not apply to the facts of this case, and we reject Teleflex's position that its duty to warn was limited to Dr. Waples. Rather, we conclude that Teleflex also had a duty to warn Rennick directly of known or knowable dangers associated with the use of the clips, consistent with the general rule. See Strasser, 236 Wis. 2d 435, ¶58. Having so concluded, we turn to the parties' arguments about cause, namely whether there is a genuine issue of material fact that Teleflex's failure to include a warning about the risk of migration caused Rennick's injuries.

II. Teleflex's Failure to Warn as a Cause of Rennick's Injuries

¶19 "In analyzing whether there are genuine issues of material fact, we draw all reasonable inferences in favor of the nonmoving party." *Id.*, ¶32. In this case, Dr. Waples provided deposition testimony that he learned the sliding clip renorrhaphy technique by watching Dr. Bhayani at Washington University in St. Louis and he visited the Cleveland Clinic multiple times, where he was also

able to learn more about the technique. Dr. Waples also described, "We haven't had any problems that I'm aware of, so it's something that basically has allowed us to do these partial nephrectomies. It's been a game-changer in terms of distributing the pressure and, you know, the doctor described doing this initially is it makes it a doable operation."

- ¶20 However, Dr. Waples also provided deposition testimony that he did not disclose this risk of clip migration to Rennick prior to surgery, but now that he is aware of the risk of clip migration, he stated that this risk might be something he should start disclosing when he discusses a laparoscopic partial nephrectomy surgery with a patient. Moreover, Dr. Waples indicated that he personally had thought about the risk of clip migration post-surgery, and while Teleflex points to this as evidence that Dr. Waples would not have altered his behavior, the full context of the deposition questioning is more ambiguous. In its context, it is unclear whether Dr. Waples would have treated his thought about the risk of clip migration more seriously if he had also received information from Teleflex, documenting a known risk of clip migration.
- ¶21 Drawing all reasonable inferences in Rennick's favor, we conclude that there is a genuine issue of material fact regarding whether a warning from Teleflex about the risk of migration would have caused Dr. Waples to alter his behavior to avoid Rennick's injuries. *See Kurer v. Parke, Davis & Co.*, 2004 WI App 74, ¶25, 272 Wis. 2d 390, 679 N.W.2d 867 ("A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury."). Had Dr. Waples received a warning from Teleflex, Dr. Waples may have altered his discussion with Rennick, and even altered his own thoughts about the risks associated with using the clips in the laparoscopic partial nephrectomy surgery,

and a reasonable jury could return a verdict for Rennick on this point. *See Strasser*, 236 Wis. 2d 435, ¶32. We, therefore, turn our attention to whether there is a genuine issue of material fact as it relates to Teleflex's duty to warn Rennick.

¶22 Attached to Rennick's brief opposing Teleflex's motion for summary judgment, Rennick submitted an affidavit in which he averred that he would have altered his conduct had he known about the risk of migration associated with the clips. Specifically, Rennick averred:

If I had been provided with the full Hem-O-Lok surgical details and device safety information before my 2015 surgery as I now possess regarding risks of Hem-O-Lok clip migration and implanted patient injury complications, I believe I would have conducted further pre-surgery research and I would have selected a surgical technique that did not require implantation of 29 to 33 Hem-O-Lok clips[.]

¶23 Teleflex argues that Rennick's affidavit does not create a genuine issue of material fact because Rennick cannot serve as his own expert. It also argues that what Rennick "might have done or not done is irrelevant." We are not persuaded by either argument. We have already dismissed the application of the learned intermediary doctrine, which would have limited the analysis to what Dr. Waples would have done. Therefore, what Rennick would have done if he was provided a warning about the risk of clip migration is relevant, and as it pertains to Teleflex's duty to warn Rennick, it is Rennick's own statement on how he would have altered his behavior that matters to our analysis. *See Kurer*, 272 Wis. 2d 390, ¶¶26-27 (analyzing what the patient would have done differently if provided a warning). Accordingly, we conclude that Rennick's affidavit creates a genuine issue of material fact as it relates to whether a warning from Teleflex would have caused Rennick to alter his behavior and avoid his injuries. *See id.*, ¶25.

III. Application of the Learned Intermediary Doctrine to Rennick's Additional Claims

¶24 Rennick further argues that it was error for the circuit court to apply the learned intermediary doctrine to his claims that were not premised on a failure to warn, and we agree. See **Zimmer**, 884 F.3d at 752 (applying the learned intermediary doctrine "to the extent" that the patient's claim was based on a duty to warn). Rennick's first claim for common law negligence also included claims as to negligence in product testing, negligence in product design, and negligence in providing adequate instructions and directions for safe use. Rennick's second claim for strict product liability under WIS. STAT. § 895.047 also included claims for defective manufacture and design. Rennick's third and fourth claims were also premised on Teleflex's marketing practices and representations related to its clips. The learned intermediary doctrine applies to claims predicated on a failure to warn and, as such, would not apply to these additional claims that Rennick brought that are not based on Teleflex's failure to provide a warning about the risk of clip migration. Thus, we conclude that the circuit court improperly applied the learned intermediary doctrine to these claims to grant summary judgment to Teleflex.

Moreover, we conclude that summary judgment was improperly granted because of the lack of discovery that Rennick contends was necessary to support his claims. Teleflex argues, for example, that Rennick is unable to present an alternative product design, expert testimony, and other materials to support his additional claims premised on product testing, design, and misrepresentation. As Rennick describes, however, Teleflex filed its motion for summary judgment prior to the close of discovery, prior to any deadlines to name expert witnesses, and prior to even participating in the depositions ordered by the court to be taken prior to Rennick filing his response to Teleflex's motion for summary judgment. "If

'for reasons stated,' that party cannot by affidavit present facts essential to justify its opposition, the court may refuse the motion for summary judgment or may order a continuance to permit such discovery to be had." *Racine Cnty. v. Oracular Milwaukee, Inc.*, 2010 WI 25, ¶26, 323 Wis. 2d 682, 781 N.W.2d 88 (quoting WIS. STAT. § 802.08(4)). Importantly, the depositions that the circuit court ordered in this case were never completed prior to Rennick's deadline to file his response to Teleflex's motion for summary judgment, and therefore, we conclude that there are genuine issues of material fact that preclude summary judgment on Rennick's additional claims as a result of the missing discovery items.

¶26 Teleflex argues that the circuit court did not address any claimed discovery deficiencies and thus, our review is limited to the learned intermediary doctrine. However, our review of a motion for summary judgment is *de novo*, reviewing the motion and supporting documents using the same method as the circuit court. *See Green Springs Farms*, 136 Wis. 2d at 315 ("[W]e are thus required to apply the standards set forth in the statute just as the trial court applied those standards."). Consequently, we reject Teleflex's argument on this point as we are not bound by the circuit court's reasoning in granting Teleflex's motion.

¶27 As a result of the lack of discovery, we also are unpersuaded by Teleflex's alternative argument for dismissal of Rennick's WIS. STAT. § 100.18 claim. We consider further discovery, and in particular, the court-ordered depositions of the activities of the Teleflex sales employees and Aurora's representatives necessary to resolve any argument regarding whether Rennick is able to identify an actionable misrepresentation to support his § 100.18 claim.

CONCLUSION

¶28 In sum, we conclude that the circuit court erroneously applied the learned intermediary doctrine to Rennick's case and dismissed his complaint. Teleflex has failed to meet the threshold requirements for the doctrine's application, and consequently, Teleflex had a duty to warn both Dr. Waples and Rennick of the risks associated with the clips. Furthermore, the deposition testimony of Dr. Waples and Rennick's affidavit create a genuine issue of material fact as to whether either would have altered their behavior had they received a warning from Teleflex. Accordingly, we reverse the circuit court's order, and we remand this matter to reinstate Rennick's complaint and for further proceedings consistent with this opinion.

By the Court.—Order reversed and cause remanded for further proceedings.

This opinion will not be published. *See* WIS. STAT. RULE 809.23(1)(b)5.