COLORADO COURT OF APPEALS

Court of Appeals No. 09CA0224
City and County of Denver District Court No. 06CV11778
Honorable Morris B. Hoffman, Judge

Kerry O'Connell and Anne O'Connell,

Plaintiffs-Appellants,

v.

Biomet, Inc., an Indiana corporation; EBI, L.P., an Indiana limited partnership; and John Kyger, an individual,

Defendants-Appellees.

JUDGMENT AFFIRMED

Division II
Opinion by JUDGE CASEBOLT
Carparelli and Richman, JJ., concur

Announced March 18, 2010

Lasater & Martin, P.C., J. Scott Lasater, Christopher J. Shannon, Janet B. Martin, Highlands Ranch, Colorado, for Plaintiffs-Appellants

Tucker, Ellis & West, LLP, Patricia A. Fennelly, Charles Q. Socha, Denver, Colorado, for Defendants-Appellees

In this action against a medical device manufacturer and its sales representative, plaintiffs, Kerry O'Connell (O'Connell) and Anne O'Connell, appeal the summary judgment in favor of defendants, Biomet, Inc., EBI, L.P., and John Kyger, on their claims of negligence and strict liability failure to warn. We conclude that the trial court correctly applied the "learned intermediary" doctrine in the context of the failure to warn claim and correctly held that product warnings need be given only to O'Connell's physician. We further conclude that the trial court correctly applied the "captain of the ship" doctrine. We decline to address plaintiffs' claim that there is a genuine issue of material fact that precludes summary judgment on the adequacy of the warning, because they did not present to the trial court the argument they now assert on appeal. Accordingly, we affirm.

I. General Background

O'Connell fractured his elbow. His physician, Dr. Christopher Brian, recommended surgery to repair the fracture. To provide range of motion for the affected joint during the healing process, Dr. Brian decided to use an external elbow fixator called the EBI

OptiROM, manufactured by EBI, a wholly-owned subsidiary of Biomet.

The fixator, a medical device regulated by the federal Food and Drug Administration, may only be sold by or upon the order or prescription of a physician. EBI provided a package insert and a surgical technique manual with the fixator describing installation techniques, risks, and potential adverse events in the use and application of the device. During the surgery, EBI's sales representative, John Kyger, who physically delivered the fixator, was present in the operating room.

Dr. Brian applied the fixator to O'Connell's humerus using bone screws, during which the drill bit or the bone screw pierced his radial nerve, wound it up, and tore a section of it out of his arm, resulting in permanent injury. After the surgery, Dr. Brian wrote a letter to Biomet and EBI regarding O'Connell's surgical injury and recommended revisions to the surgical technique manual in an effort to prevent future occurrences of that type of injury.

Plaintiffs asserted and settled a claim against Dr. Brian. Plaintiffs released Dr. Brian, his surgical assistant, his practice group, and all of Dr. Brian's "agents." Plaintiffs later filed this

action, asserting negligence, strict liability failure to warn, design defects, breach of implied warranty, and loss of consortium.

Defendants moved to dismiss the negligence claim against Kyger, asserting that he was one of Dr. Brian's "agents" under the "captain of the ship" doctrine and was therefore covered under the terms of the release. They also moved for partial summary judgment on the failure to warn claim, asserting that the warnings and instructions in the package insert and surgical technique manual were adequate as a matter of law. Treating the motion to dismiss as a motion for summary judgment, the trial court granted the motions. It subsequently granted summary judgment on the remaining claims. This appeal followed.

II. Standard of Review

Summary judgment is appropriate only when the pleadings and supporting documents clearly demonstrate that there are no genuine issues of material fact, and that the moving party is entitled to judgment as a matter of law. C.R.C.P. 56(c); *Cotter Corp. v. American Empire Surplus Lines Ins. Co.*, 90 P.3d 814, 819 (Colo. 2004). Factual disputes will not defeat summary judgment if the

disputed facts are not material to the outcome of the case. *Svanidze v. Kirkendall*, 169 P.3d 262, 264 (Colo. App. 2007).

In the determination of a summary judgment motion, "[t]he nonmoving party is entitled to the benefit of all favorable inferences that may be drawn from the undisputed facts, and all doubts as to the existence of a triable issue of fact must be resolved against the moving party." *Martini v. Smith*, 42 P.3d 629, 632 (Colo. 2002).

We review a grant of summary judgment de novo. *West Elk Ranch, L.L.C. v. United States*, 65 P.3d 479, 481 (Colo. 2002).

III. Failure to Warn Claim

Plaintiffs first contend that the trial court erred in applying the "learned intermediary" doctrine in holding that defendants had a duty to warn *only* Dr. Brian. They also contend that, even if the court correctly applied that doctrine, there are nevertheless genuine issues of material fact as to whether defendants provided adequate warnings and instructions to surgeons about the dangers and installation of the elbow fixator. We conclude that the trial court correctly applied the learned intermediary doctrine. We decline to address the contention that genuine issues of material fact are present here because we conclude that plaintiffs failed to assert

before the trial court the argument they make in their opening brief, and the argument they made in the trial court is not asserted on appeal.

A. General Law

A failure to warn adequately can render a product, which is otherwise free of defect, defective for purposes of strict liability recovery. *Barton v. Adams Rental, Inc.*, 938 P.2d 532, 539 (Colo. 1997); *Hiigel v. General Motors Corp.*, 190 Colo. 57, 63, 544 P.2d 983, 987 (1975); *see* Restatement (Second) of Torts § 402A cmt. j (1965) ("In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use.").

The plaintiff has the burden of proving that the manufacturer gave an inadequate warning of the danger that caused the injury. *Peterson v. Parke Davis & Co.*, 705 P.2d 1001, 1004 (Colo. App. 1985).

B. Nature of the Duty

Ordinarily, a manufacturer has a duty to warn all foreseeable ultimate users of dangers inherent in its products. *See Hiigel*, 190 Colo. at 63, 544 P.2d at 987; Restatement (Second) of Torts § 388.

However, where prescription drugs are concerned, the manufacturer's duty to warn has been limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974). The physician is trained to assess the risks and benefits of the drug as applied clinically to a particular patient. *See id.* This principle is the learned intermediary doctrine. *See Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).

No Colorado appellate opinion has addressed the learned intermediary doctrine directly. However, in *Peterson*, 705 P.2d at 1003, the division, in analyzing the propriety of a product misuse defense, noted that the warnings contained in a prescription drug manufacturer's package insert were addressed to the physician. *See also Hamilton v. Hardy*, 37 Colo. App. 375, 387, 549 P.2d 1099, 1110 (1976) (indicating that drug manufacturer's duty is to give adequate warnings to the medical profession), *overruled on other grounds by State Board of Med. Examiners v. McCroskey*, 880 P.2d 1188 (Colo. 1994).

In *Caveny v. CIBA-GEIGY Corp.*, 818 F. Supp. 1404, 1406 (D. Colo. 1992), the federal district court in a diversity case, applying

Colorado law, addressed an inadequate warning claim concerning a drug available only by prescription from a physician. The court held that a warning is adequate when it explains to the physician the risk that the plaintiff asserts is associated with the drug and that caused the injury, stating that "[i]t is the responsibility of the physician as a learned intermediary to assess the risks and benefits of a particular course of treatment." *Id.*

The Restatement (Third) of Torts: Products Liability § 6(d) (1998), treats prescription drugs and medical devices together and provides that a medical device is not reasonably safe if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings. Comment b to section 6, describing the rationale for directing warnings only to health-care providers, notes:

> [O]nly health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.

Comment e to that section also notes that "the learned intermediary rule is generally accepted," and that a manufacturer "fulfills its legal obligation to warn by providing adequate warnings to the health-care provider."

Courts in other jurisdictions have applied the learned intermediary doctrine in cases involving medical devices. *See Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1280 (11th Cir. 2002) (applying Georgia law); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1367-68 (S.D. Fla. 2007) (collecting cases) (applying Florida law); *Pumphrey v. C.R. Bard, Inc.*, 906 F. Supp. 334, 337 (N.D. W. Va. 1995) ("the learned intermediary doctrine[] is nearly universal") (applying West Virginia law).

Based on the above authorities, we are persuaded that the learned intermediary doctrine should apply to failure to warn claims in the context of a medical device installed operatively when it is available only to physicians and obtained by prescription, and the doctor is in a position to reduce the risks of harm in accordance with the instructions or warnings.

Here, the fixator is only available to a patient through a qualified physician's prescription. Dr. Brian obtained the fixator

from Kyger and then surgically attached it to O'Connell's arm. Because it was the responsibility of Dr. Brian as a learned intermediary to assess the risks and benefits of surgically applying the fixator to O'Connell's arm, defendants' duty was to warn and provide adequate instructions to Dr. Brian.

Accordingly, the trial court did not err in applying the learned intermediary doctrine.

C. Did Biomet and EBI Satisfy Their Duty as a Matter of Law?

Plaintiffs contend that the trial court erred in granting summary judgment because there is a genuine issue of material fact as to whether the warnings and instructions to Dr. Brian about the elbow fixator were adequate, and the warnings and instructions are not adequate as a matter of law. We decline to address this contention.

Arguments never presented to, considered by, or ruled upon by a trial court may not be raised for the first time on appeal. *Brown v. Silvern*, 141 P.3d 871, 874 (Colo. App. 2005). Thus, when a party fails to assert an argument in the trial court but raises it for the first time on appeal, the assertion is deemed waived. *Id.*; *see*

Estate of Stevenson v. Hollywood Bar & Cafe, Inc., 832 P.2d 718, 722 n.5 (Colo. 1992).

Here, in its motion before the trial court, defendant presented the affidavit of an expert who opined that the warnings and materials defendants provided were adequate to warn physicians of the risks and dangers of the product. In response, plaintiffs argued, without providing their own expert affidavit, that the surgical technique manual was:

> obviously insufficient to adequately warn . . . Dr. Brian . . . of the dangers of plunge incisions. The jury should be permitted to consider whether the word "recommended" is adequate warning when compared to other terms such as "always" or "never."
> . . . .
> It is undisputed that an open incision was neither employed, nor suggested by anyone complicit in Mr. O'Connell's surgery. Instead, plunge incisions were made under the watch of both a six-year veteran operating room sales representative and an orthopedic surgeon.

Thus, plaintiffs focused in the trial court on the type of incision that Dr. Brian used, arguing that he should have been warned never to use a plunge incision, but always to use an open incision.

On appeal, however, plaintiffs have not asserted that argument. Instead, they argue in their opening brief and asserted

during oral argument that "while warnings were made for one configuration of the device, no warnings at all were made relative to the configuration of the device actually used in the surgery." Stated differently, plaintiffs now assert that it was the failure to provide warnings about the configuration of the device that rendered the product defective and unreasonably dangerous. This argument was not presented in the trial court; plaintiffs assert this new argument for the first time on appeal. We therefore decline to address the issue further.

IV. Negligence Claim

Plaintiffs contend that the trial court erred in granting defendants' motion to dismiss their negligence claim. Specifically, plaintiffs assert the court erred in applying the "captain of the ship" doctrine and in determining, as a matter of law, that Kyger was an agent of Dr. Brian. Plaintiffs argue that the doctrine applies only to hospital employees working under the supervision of the surgeon.

Defendants contend that the doctrine applies to everyone in the operating room working under the surgeon's supervision, regardless of their actual employer, and that Kyger was such a person.

We conclude that the doctrine, as currently articulated in this state, not only includes hospital personnel such as nurses and orderlies, but also includes nonmedical persons present in the operating room upon the request and authorization of the physician, where the physician has the right to control and supervise the activities of the nonmedical persons. Accordingly, we conclude that the trial court correctly held that the captain of the ship doctrine applies here. We further conclude that, while there appear to be issues of fact as to what Kyger's role in the surgery was, nevertheless, these disputes are not germane to the application of the doctrine and therefore do not preclude summary judgment.

A. Law

The captain of the ship doctrine, which is grounded in respondeat superior principles, imposes vicarious liability on a surgeon for the negligence of hospital employees under his control and supervision during surgery. *Ochoa v. Vered*, 212 P.3d 963, 966 (Colo. App. 2009); *Spoor v. Serota*, 852 P.2d 1292, 1296 (Colo. App. 1992); *Young v. Carpenter*, 694 P.2d 861, 863 (Colo. App. 1984). The imposition of vicarious liability for negligent acts depends upon

the existence of a master-servant relationship. *Young*, 694 P.2d at 864. Consequently, to be held vicariously liable through such a master-servant relationship, the surgeon must exercise supervision and control over the alleged negligent act. *Adams v. Leidholt*, 195 Colo. 450, 453, 579 P.2d 618, 620 (1978).

A licensed physician is the principal or master while performing medical services within a hospital, rather than an agent or a servant. *Kitto v. Gilbert*, 39 Colo. App. 374, 382, 570 P.2d 544, 549 (1977). Hospital personnel assisting under the surgeon's control are borrowed servants, and the surgeon is liable for their acts of negligence. *Id.* at 382, 570 P.2d at 549-50.

Several Colorado appellate opinions have specifically stated that "[o]nce the operating surgeon assumes control in the operating room, the surgeon is liable for the negligence of all persons working under the surgeon's supervision." *Krane v. Saint Anthony Hosp. Sys.*, 738 P.2d 75, 76 (Colo. App. 1987); *Kitto*, 39 Colo. App. at 382, 570 P.2d at 549-50. Indeed, in *Beadles v. Metayka*, 135 Colo. 366, 370-71, 311 P.2d 711, 713-14 (1957), the seminal "captain of the ship" case in which the supreme court first applied the doctrine, the

court quoted *Aderhold v. Bishop*, 94 Okla. 203, 207, 221 P. 752, 755 (1923), for this proposition:

> Necessarily the various agencies that enter into [a surgical operation] must be performed by different individuals, under the active supervision and direction of the operating surgeons in charge. If the operating surgeons were not made liable for the negligent performance of the duties of those working under them, the law in a large measure would fail in affording a means of redress for preventable injuries sustained from surgical operations.

Thus, contrary to plaintiffs' assertions, the cases have not limited the doctrine only to hospital employees. While most of the cases have dealt with acts of nurses, orderlies, or other hospital employees, *Kitto* held that the acts of an assisting physician, who was not an employee of a hospital, would be imputed under vicarious liability principles to the surgeon. *See Kitto*, 39 Colo. App. at 382, 570 P.2d at 549-50. Additionally, another division of this court has held that an attending physician could be vicariously liable for the professional negligence of a covering physician whose medical performance the attending physician has a right to control. *Hall v. Frankel*, 190 P.3d 852, 861 (Colo. App. 2008).

B. Application

Here, the trial court held that, because Dr. Brian was in control of the surgery, and therefore in control of any of Kyger's actions during the surgery, Kyger was Dr. Brian's agent during the surgery, and plaintiffs had waived their negligence claims against Kyger by settling their claims with Dr. Brian and releasing any of Dr. Brian's "agents."

The court also held:

> The sole purpose of Kyger being in the operating room was to provide Dr. Brian with information about the fixator, which information Dr. Brian then used to make his medical judgments. That is, Dr. Brian remained in control of the surgery vis-à-vis Kyger and all other non-physicians in the operating room. Because Dr. Brian remained in control of the surgery, anything Kyger might have done during that surgery, including any advice he allegedly gave or should have given to Dr. Brian, was done as a crew member, so to speak, of the surgical ship. Kyger was therefore at all times during the surgery acting as Dr. Brian's "agent" within the meaning of the settlement agreement Plaintiffs executed with Dr. Brian.

We agree with the trial court's conclusion.

Plaintiffs assert that there is a disputed issue of fact concerning the agency. We agree that there is a dispute as to the *role* that Kyger played in the surgery. In his deposition, Dr. Brian testified that Kyger provided technical expertise on the

implantation, use, and operation of the fixator, such that he was "helping to assemble that piece of equipment and being the technical background for how to put the thing on." Dr. Brian also testified that he consulted with Kyger regarding the placement of the alignment pin in putting the fixator on correctly. However, Kyger testified in his own deposition that he did not supervise or participate in the application of the fixator; instead, he stated that he was present and delivered the product, but that he did not assist in its application.

But this dispute does not relate to whether Dr. Brian had the *right to control and supervise* Kyger, which is the touchstone of vicarious liability in this situation. *Ochoa*, 212 P.3d at 966. There is no evidence that Kyger could or did act independently in the surgery.

Accordingly, we conclude that the court did not err in granting summary judgment on the negligence claim based on the captain of the ship doctrine, or in holding as a matter of law that Kyger was an agent under these circumstances.

In light of our disposition, we reject plaintiffs' argument that the cost award must be reversed.

The judgment is affirmed.

JUDGE CARPARELLI and JUDGE RICHMAN concur.