[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
APR 14, 2011
JOHN LEY
CLERK

No. 10-13529
Non-Argument Calendar

D.C. Docket No. 1:08-cv-00655-WS-N

JUDITH HUGHES,

Plaintiff - Appellant,

versus

STRYKER CORPORATION,

Defendant,

STRYKER SALES CORPORATION,
HOWMEDICA OSTEONICS CORP.,
d.b.a. Stryker Orthopaedics,

Defendants - Appellees.

Appeal from the United States District Court
for the Southern District of Alabama

(April 14, 2011)

Before MARCUS, MARTIN and KRAVITCH, Circuit Judges.

PER CURIAM:

Judith Hughes appeals the district court's denial of her motion for reconsideration of its order granting summary judgment in favor of Stryker Sales Corporation ("Stryker Sales") and Howmedica Osteonics Corp ("Howmedica") on Hughes's products liability and negligence claims relating to the failure of a hip prosthesis designed, manufactured, and marketed by the defendants.[1] After thorough review of the record and the parties' briefs, we affirm.

I.

Hughes first argues that the district court erred in granting summary judgment on her products liability claims under the Alabama Extended Manufacturer Liability Doctrine ("AEMLD"). Although the notice of appeal only indicates that Hughes seeks review of the district court's denial of her motion for reconsideration, we construe such notices as an appeal from the underlying order or judgment regarding which reconsideration is sought. See Kicklighter v. Nails by Jannee, Inc., 616 F.2d 734, 738–39 n.1 (5th Cir. 1980).[2] "This Court reviews

[1] Hughes's complaint originally named a third defendant, Stryker Corporation, who is not a party to this appeal because the district court entered an earlier order granting Hughes's request to voluntarily dismiss without prejudice her claims against Stryker Corporation under Federal Rule of Civil Procedure 41(a)(1).

[2] In Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), we adopted as binding precedent all decisions of the former Fifth Circuit handed down before the close of business on September 30, 1981.

de novo summary judgment rulings and draws all inferences and reviews all evidence in the light most favorable to the non-moving party." Moton v. Cowart, 631 F.3d 1337, 1341 (11th Cir. 2011). Summary judgment is appropriate only if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "The moving party may meet its burden to show that there are no genuine issues of material fact by demonstrating that there is a lack of evidence to support the essential elements that the non-moving party must prove at trial." Moton, 631 F.3d at 1341. "We review the denial of a motion for reconsideration for an abuse of discretion." Richardson v. Johnson, 598 F.3d 734, 740 (11th Cir. 2010).

Hughes argues that the "evidence raised genuine issues of material fact that the Trident acetabular cup implanted in her hip was unreasonably dangerous as manufactured because it contained residues that impeded biologic fixation."

> To establish a prima facie case against a manufacturer under the AEMLD, a plaintiff must show that (1) the defendant manufacturer sold a defective product, (2) the defect was the cause in fact of the plaintiff's injury and is traceable to the defendant, and (3) the product reached the plaintiff without substantial modification to the condition in which it was sold.

Goree v. Winnebago Indus., Inc., 958 F.2d 1537, 1541 (11th Cir. 1992). Under Alabama law, "[t]he fact of an injury . . . does not establish the presence of a

defect." Sears, Roebuck & Co. v. Haven Hills Farm, Inc., 395 So. 2d 991, 995 (Ala. 1981) (quotation marks omitted). Instead, a plaintiff must show "that the product's failure of performance is causally related in fact to the product's defective condition at the time of its sale." Id. "[O]rdinarily, expert testimony is required [to prove that the product was defective and that the defect caused the injury] because of the complex and technical nature of the commodity." Id. But expert testimony is not required if the inference "that the defective condition of the product is the cause of the product's failure and the plaintiff's resultant injury . . . . may be reasonably made from the product's failure of performance under all the attendant circumstances." Id.

Because Hughes failed to disclose any expert testimony as required by Federal Rule of Civil Procedure 26(a)(2), the district court considered whether the non-expert evidence Hughes offered was sufficient to allow a jury to infer from the failure of the Trident acetabular cup to achieve biological fixation that the product was defective and that the defect caused the product's failure and Hughes's injury.[3] As the district court observed, Hughes pointed to four pieces of

[3] In Hughes's response to the defendant's motion for summary judgment, she requested leave to belatedly designate expert witnesses. On appeal, she does not challenge the district court's denial of this request, so we consider this issue abandoned. See Greenbriar, Ltd. v. City of Alabaster, 881 F.2d 1570, 1573 n.6 (11th Cir. 1989) (holding that issues not argued on appeal are deemed abandoned).

evidence: (1) medical records showing that she received a total right hip replacement on September 14, 2007, at which time a prosthetic hip device manufactured by the defendants was implanted in her body; (2) a hospital record stating that on or about July 1, 2008, her treating physician determined that she "had suffered a hardware failure involving the acetabular cup with migration of the cup," such that she would need a second surgical procedure called a "[r]evision of right total hip arthroplasty;" (3) a March 15, 2007 "Warning Letter" sent from the United States Department of Health and Human Services to a company called Stryker Ireland, Ltd., Orthopaedics in Cork, Ireland, which states that an inspection of the manufacturing facility in the fall of 2006 had revealed several violations of regulations promulgated under the Federal Food, Drug, and Cosmetic Act; and (4) a January 24, 2008 letter from Stryker Orthopaedics recalling all Trident Hemispherical and PSL Shells manufactured at the company's Cork, Ireland facility between January 2000 and December 2007 because "the average level of manufacturing residuals in some cases exceeded Stryker Orthopaedics self imposed conservative acceptance criteria," creating "[t]he potential hazard . . . that the device may not achieve biological fixation," but noting that "failure to achieve biological fixation may result from many factors unrelated to the device."

The district court correctly rejected Hughes's arguments premised on the recall letter because that letter, which states only that "in some cases" the level of manufacturing residuals exceeded the company's "self imposed conservative acceptance criteria," did not amount to an admission by the defendants that the Trident acetabular cup was defective, and in any event the recall letter was inadmissible as evidence of subsequent remedial measures used to show product defect. See Fed. R. Evid. 407 ("[E]vidence of . . . subsequent measures is not admissible to prove . . . a defect in a product . . . ."). Turning to the remaining evidence, the Warning Letter is insufficient to prove the existence of a defect because, while it describes the company's failure to establish and maintain certain general quality control procedures, it says nothing about the presence of residuals in any Trident acetabular cups. Nor is the medical record indicating a "hardware failure" enough to permit a jury to conclude that the product was defective because, under Alabama law, the "mere failure of a product does not presuppose the existence of a defect." Sears, Roebuck & Co., 395 So. 2d at 996. While a defect, and its causal relation to a plaintiff's injury, may be inferred "from the product's failure of performance under all the attendant circumstances," id. at 995, nothing about the circumstances of this case would permit such an inference. As the district court explained:

> [t]he interaction between a complex and technical medical device and the unique physiological and medical circumstances of the patient in which it is implanted is a subject on which no ordinary juror could rationally be expected to have knowledge. The net result is that, without the benefit of expert testimony, a reasonable jury could not possibly make a determination on this summary judgment record that Hughes'[s] injuries were caused by a maufacturing or design defect in the prosthetic hip.[4]

We decline to consider Hughes's argument that the evidence in the record demonstrates a genuine dispute as to causation because the medical records negate the possibility of alternate causes. Hughes failed to make this argument before the district court in her response to the defendants' motion for summary judgment, and that court did not abuse its discretion in refusing to consider the argument when Hughes presented it belatedly in her motion for reconsideration, which the district court properly treated as a motion to alter or amend the judgment under Federal

[4] We need not decide whether the defendants are correct that expert testimony is always necessary to prove product defect and breach of duty in products liability cases involving complicated medical devices because even if such testimony is not required, Hughes cannot survive summary judgment under the circumstances of this case.

Rule of Civil Procedure 59. See Green v. Drug Enforcement Admin., 606 F.3d 1296, 1299 (11th Cir. 2010) (noting that district courts have "almost without exception" treated motions for reconsideration as Rule 59 motions "*regardless* of their label" (quotation marks omitted)). We have explained that such "[m]otions to amend should not be used to raise arguments which could, and should, have been made before the judgment was issued." Case v. Eslinger, 555 F.3d 1317, 1329 (11th Cir. 2009) (quotation marks omitted). Hughes "cannot readily complain about the entry of a summary judgment order that did not consider an argument [she] chose not to develop for the district court at the time of the summary judgment motions." Id. (quotation marks omitted).

For all these reasons, we conclude that the district court did not err in granting summary judgment in favor of Stryker Sales and Howmedica on Hughes's products liability claims.

II.

Hughes next argues that the district court erred in granting summary judgment on her negligence claims.[5] A plaintiff's negligence claim is distinct

[5] Before the district court, Hughes pursued claims for both negligence and wantonness, but on appeal she argues only that the district court erred in granting summary judgment on her negligence claims. We conclude that she has therefore abandoned her wantonness claims. See Greenbriar, Ltd., 881 F.2d at 1573 n.6.

from a products liability claim under the AEMLD. See Vesta Fire Ins. Corp. v. Milam & Co. Constr., Inc., 901 So. 2d 84, 102 (Ala. 2004). "In a negligence action the plaintiff must prove (1) that the defendant owed the plaintiff a duty; (2) that the defendant breached that duty; (3) that the plaintiff suffered a loss or injury; and (4) that the defendant's breach was the actual and proximate cause of the plaintiff's loss or injury." QORE, Inc. v. Bradford Bldg. Co., 25 So. 3d 1116, 1123 (Ala. 2009) (quotation marks omitted). The district court concluded that Hughes failed to establish a genuine dispute as to causation.

Hughes argues that there is sufficient circumstantial evidence to permit a jury to find that the defendants' negligent manufacture of the Trident acetabular cup proximately caused the failure of the prosthesis in her hip replacement. We disagree. As the district court stated: "No evidence links the failure of that complex, technical medical device to any negligent or wanton conduct by defendants; to the contrary, it could have failed for myriad reasons totally unrelated to any negligent acts or omissions by defendants." Hughes argues that records from her treating physician negate alternative causes because the physician stated that the failure of the prosthesis was the result of "aseptic loosening." As explained above, we decline to consider this argument because it was not presented to the district court in response to the defendant's motion for summary

judgment, and the district court did not abuse its discretion in refusing to consider the argument when Hughes belatedly presented it in her motion to reconsider. See Case, 555 F.3d at 1329. Hughes also points again to the recall letter, but this would be inadmissible as evidence of negligence under Rule 407. See Fed. R. Evid. 407 ("[E]vidence of . . . subsequent measures is not admissible to prove negligence . . . .").

On this summary judgment record, a jury could only speculate as to why the prosthesis failed in this case, but "[s]peculation does not create a *genuine* issue of fact." Cordoba v. Dillard's, Inc., 419 F.3d 1169, 1181 (11th Cir. 2005). We therefore conclude that the district court did not err in granting summary judgment in favor of Stryker Sales and Howmedica on Hughes's negligence claims.

For all of these reasons, we affirm the district court's entry of summary judgment in favor of Stryker Sales and Howmedica.

AFFIRMED.