

[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 15-12243

D.C. Docket No. 1:13-cv-20742-JLK

SANDRA WITT,

Plaintiff - Appellant,

versus

STRYKER CORPORATION OF MICHIGAN,
HOWMEDICA OSTEONICS CORP.,

Defendants - Appellees.

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

(April 20, 2016)

Before MARCUS, DUBINA, and MELLOY,* Circuit Judges.

* Honorable Michael J. Melloy, United States Circuit Judge for the Eighth Circuit, sitting by designation.

MARCUS, Circuit Judge:

Plaintiff-Appellant Sandra Witt brought this diversity action against Defendant-Appellee Howmedica Osteonics Corp. (“HOC”), the manufacturer of a prosthetic knee implant that she alleges was defectively designed, for strict liability and negligence. She appeals from the district court’s denial of her motion for leave to file a third amended complaint, the denial of her motion to enlarge time for discovery, the grant of HOC’s motion to exclude the expert testimony of Dr. Jerry Lubliner, and finally, an order granting final summary judgment to HOC. After thorough review and having the benefit of oral argument, we affirm.

I.

The essential facts are these. On June 21, 2006, Witt injured her right knee when she tripped and fell at work. After two surgeries failed to alleviate her pain, Dr. Richard Levitt operated a third time on April 18, 2008, and implanted into Witt’s right knee the EIUS Unicompartmental Knee System, which was developed, manufactured, and distributed by HOC. Dr. Levitt testified that he expected the device to function properly for ten to fifteen years. However, Witt continued to suffer severe pain and swelling in her right knee, which would occasionally slip out of place and lock out of position. Dr. Levitt performed another surgery on

April 17, 2009, to remove the EIUS device. He noted that the femoral component of the EIUS device was loose on probing and removed without difficulty.

In 2010, two National Joint Replacement Registries reported that the EIUS device was associated with significantly higher than usual revision rates. The 2010 Annual Report of the National Joint Replacement Registry of the Australian Orthopaedic Association reported an 18.5% revision rate for EIUS at five years post implantation, compared to 8.6% for other unicompartmental devices. HOC's parent company, Stryker UK, issued a recall notice on September 21, 2011, alerting customers of the problem.

This tort action was commenced in Florida's courts on January 28, 2013, and subsequently removed to the United States District Court for the Southern District of Florida. After her initial and amended complaint were dismissed without prejudice for lacking sufficient factual allegations, Witt filed her Second Amended Complaint on January 17, 2014. This Complaint broadly alleged two claims: the first for strict liability defective design, and the second for simple negligence. On January 31, 2014, Witt moved the district court for leave to file still a Third Amended Complaint, which added a count for "Products Liability - Failure to Warn." The district court denied this motion.

The court entered a detailed scheduling order on April 22, 2014, setting the course for trial and enumerating several pretrial deadlines. The deadline for

completing discovery was set at February 25, 2015. At a status conference held on September 2, 2014, the district court remarked that “there does not appear to have been much activity or any activity in the file.” Because the case was “coming up on two years old,” the court sought to ensure that all of the deadlines that had been set the previous spring would be met. Indeed, the district court specifically warned the litigants about the discovery cut-off date, urged them to pursue discovery diligently, and observed that the discovery timeline was set carefully to avoid any need for an extension.

On October 29, 2014, the parties jointly moved the trial court to extend the defendant’s expert disclosure deadline from January 1, 2015, to January 29, 2015, in order to allow for staggered expert disclosure deadlines (Witt’s deadline remained January 1, 2015). The parties specifically observed, however, that they were not seeking any modification of the discovery cut-off, the dispositive motion deadline, or the trial date. The motion was granted on October 30. The parties subsequently negotiated reciprocal extensions to the expert report deadlines, extending Witt’s expert disclosure deadline to January 21, 2015, and HOC’s expert disclosure deadline to February 11, 2015. On February 23, just two days before the cut-off date for all discovery, Witt moved the district court to enlarge the deadlines for completing discovery and for filing motions; the court denied the application.

On March 2, 2015, HOC filed a motion in limine to exclude the expert testimony of Witt's witness Dr. Jerry Lubliner, the Director of New York Orthopaedics and Sports Medicine. After reviewing Witt's medical records and information regarding the EIUS device, Dr. Lubliner submitted a report that concluded "the looseness" identified in Witt's EIUS device established a mechanical failure that was the primary cause of her continued pain. Soon thereafter, on April 20, 2015, the court granted HOC's motion to exclude the opinions and testimony of Dr. Lubliner, which the court characterized as offering only an unreliable ipse dixit under Federal Rule of Evidence 702. The district court then granted HOC's motion for final summary judgment on April 20, 2015. Witt timely filed this appeal.

II.

A.

As for the first claim on appeal, the district court denied Witt's motion for leave to amend her complaint because it determined that justice did not require affording the plaintiff a fourth opportunity to file a complaint, and because permitting a Third Amended Complaint would be prejudicial to HOC. We affirm the district court's denial. This Court "will only reverse a district court's denial of a motion to amend in instances in which the district court has clearly abused its discretion." Oravec v. Sunny Isles Luxury Ventures, L.C., 527 F.3d 1218, 1231

(11th Cir. 2008). The district court “has discretion to deny leave to amend . . . when the moving party offers no adequate explanation for a lengthy delay.” In re Engle Cases, 767 F.3d 1082, 1119 (11th Cir. 2014). Witt’s motion was submitted a year after the action was initially filed and lacked any supporting explanation for why leave should have been granted. Her threadbare request failed to state why justice required the opportunity to submit a fourth version of her complaint. As we see it, the district court did not clearly abuse its discretion by denying leave to amend.

Moreover, Witt’s proposed amendment was futile. See Hubbard v. BankAtlantic Bancorp, Inc., 688 F.3d 713, 716 (11th Cir. 2012) (recognizing this Court “may affirm for any reason supported by the record.”) “Because justice does not require district courts to waste their time on hopeless cases, leave may be denied if a proposed amendment fails to correct the deficiencies in the original complaint or otherwise fails to state a claim.” Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1255 (11th Cir. 2008). We review de novo “the underlying legal conclusion that an amendment to the complaint would be futile.” SFM Holdings, Ltd. v. Banc of Am. Sec., LLC, 600 F.3d 1334, 1336 (11th Cir. 2010).

To establish strict liability for failure to warn under Florida law, the plaintiff must establish that the defendant (a) is a manufacturer or distributor of the product at issue, and (b) did not adequately warn of a particular risk that was known or

knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of the manufacture and distribution. See Griffin v. Kia Motors Corp., 843 So. 2d 336, 339 (Fla. Dist. Ct. App. 2003). In her Amended Complaint, Witt included a count for failure to warn. The district court dismissed that complaint without prejudice because:

The Amended Complaint does not allege any facts as to the content of any warnings given. It only states that Defendant failed to give proper warnings and that the warnings were “inadequate.” E.g. D.E. 16 at 9. Simply stating that the warnings were insufficient only recites the elements of this cause of action. The Amended Complaint contains insufficient details as to the facts surrounding these warning[s].

Witt’s proposed Third Amended Complaint alleged that “Howmedica had knowledge and information confirming the defective and dangerous nature of the EIUS Knee, including the possibility of the EIUS Knee loosening, resulting in failure of the Femoral Component once implanted in a patient.” Witt alleged that the defect was knowable precisely on account of two reports published in 2010 with data reporting significantly higher revision rates for the EIUS device, and a recall commenced by HOC in 2011. However, Witt’s EIUS device was implanted on April 18, 2008, before any of the reports had been published. Moreover, the proposed Third Amended Complaint does not indicate that HOC had any access to the revision data before it was published. Because HOC could not have warned Witt in 2008 about data that had been reported some two years later in 2010, Witt

has failed to allege a plausible set of facts to state a claim for failure to warn. We are left only with the bald allegation, asserted at the highest order of generality and unsupported by any factual claims. Thus, this pleading would have been insufficient to state a claim. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (“[A] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.”); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (A plaintiff must assert “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.”).

B.

We also review the district court’s discovery rulings for an abuse of discretion, not de novo. See Josendis v. Wall to Wall Residence Repairs, Inc., 662 F.3d 1292, 1306 (11th Cir. 2011). The Federal Rules of Civil Procedure require a district court to issue a scheduling order limiting the time for parties to complete discovery. Fed. R. Civ. P. 16(b)(3)(A). In this case, the district court fastidiously and timely issued a detailed scheduling order setting forth, among other things, a cut-off for discovery, the timing for filing expert reports, a date for a final pretrial conference, and a date certain for trial. This schedule “may be modified only for good cause and with the judge’s consent.” Fed. R. Civ. P. 16(b)(4). “[W]e have often held that a district court’s decision to hold litigants to the clear terms of its scheduling orders is not an abuse of discretion.” Josendis, 662 F.3d at 1307. Thus,

for example, in Goodman-Gable-Gould Co. v. Tiara Condo. Ass'n, 595 F.3d 1203, 1209 n.21 (11th Cir. 2010), we held that the district court did not abuse its discretion in denying the defendant's motion to extend the discovery deadline when there was at least six months to conduct discovery.

Here, the district court clearly set forth a reasonable discovery schedule, then warned the litigants that discovery appeared to be proceeding slowly and that the court was not disposed to grant any extensions. Indeed, the parties had more than ten months to complete discovery after the scheduling order was announced. Witt waited over four months to submit her first document requests. The district court permitted the parties to extend the deadlines for expert disclosures, although the parties jointly and expressly said that they “**do not** request a modification of the discovery cut-off” (emphasis in original). Because Witt received ample time to pursue discovery, the district court's decision to hold the litigants to the clear terms of a reasonable scheduling order was not an abuse of discretion.

C.

“Rulings on the admissibility of evidence are reviewed for abuse of discretion.” City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 556 (11th Cir. 1998). But “when the district court misinterprets the Federal Rules of Evidence or controlling case law, our review is plenary.” Id. “Discretion means the district court has a range of choice, and that its decision will not be disturbed as

long as it stays within that range and is not influenced by any mistake of law.” Betty K Agencies, Ltd. v. M/V Monada, 432 F.3d 1333, 1337 (11th Cir. 2005) (quotation omitted). “Indeed, the deference that is the hallmark of abuse-of-discretion review requires that we not reverse an evidentiary decision of a district court unless the ruling is manifestly erroneous.” United States v. Frazier, 387 F.3d 1244, 1258 (11th Cir. 2004) (en banc) (citation and quotations omitted).

The admissibility of testimony by an expert witness is governed by Federal Rule of Evidence 702, which provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Rule 702 assigns “to the trial judge the task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands.” Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597 (1993). The

burden of establishing the qualification, reliability, and helpfulness of the proffered expert testimony rests with the proponent of the expert opinion. Frazier, 387 F.3d at 1260. When evaluating the reliability of expert testimony, “the abuse of discretion standard thrives.” United States v. Brown, 415 F.3d 1257, 1266 (11th Cir. 2005). In Frazier, we recognized that if the witness is relying primarily on his experience, “then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court’s gatekeeping function requires more than simply ‘taking the expert’s word for it.’” 387 F.3d at 1261 (quoting Fed. R. Evid. 702 advisory committee’s note (2000 amends.)) (emphasis in original). “If admissibility could be established merely by the ipse dixit of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong.” Id.

Here, HOC and the district court do not challenge Dr. Lubliner’s qualifications as an expert. Rather, the district court determined that his terse report and opinion were unreliable ipse dixit, resting on an utterly insufficient evidentiary foundation. Dr. Lubliner’s two-paragraph analysis is reproduced here in its entirety:

On 04/18/2008, the patient had an EIUS partial knee replacement inserted into the right knee. The patient continued to complain of pain and symptomatology and it was noted that a year later, in surgery, that this system appeared to be loose on probing and removed without difficulty. This shows that there was failure in the mechanical operation of the EIUS device in the right knee of Sandra Witt. The

patient had this revised to a total knee replacement and had more surgery as described.

I feel that the mechanical failure of the EIUS Stryker components was the competent producing cause for the need for surgery on 04/17/2009 and for a revision arthroplasty to a total knee replacement. I feel that the mechanical failure of the EIUS System installed on 04/18/2008 was a competent cause for the need for subsequent surgeries on 03/30/2011 and on 01/17/2012.

Dr. Lubliner's deposition testimony was hardly better. Indeed, he explicitly disclaimed having any expert opinion about why the EIUS design was defective. Besides broadly referencing the likelihood that the device suffered some mechanical failure, Dr. Lubliner offered no explanation for why the defect was one of design and not of manufacture. The district court determined that this expert opinion lacked any explanation, foundation, or support, and therefore had to be excluded because of its unreliability. As we see it, the district court did not abuse its considerable discretion by finding that Dr. Lubliner's expert testimony was insufficient under Rule 702. Plainly, his sparse report and subsequent deposition do not explain how the looseness of the device is related to the failure of its mechanical operation, nor did the expert report so much as consider any alternative explanation. Because Dr. Lubliner's opinion regarding Witt's EIUS device could reasonably be termed undeveloped and unreliable, the decision to exclude his testimony fell well within the district court's exercise of discretion as a gatekeeper.

D.

We review a district court's grant of summary judgment de novo. "Summary judgment is proper if the movant shows 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" Chapman v. Procter & Gamble Distrib., LLC, 766 F.3d 1296 (11th Cir. 2014) (quoting Fed. R. Civ. P. 56(a)). A fact is "material" if it may determine the outcome under the applicable substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The nonmoving party must show specific facts to support that there is a genuine dispute. Id. at 256. On a motion for summary judgment, the court must view the evidence and resolve all inferences in the light most favorable to the nonmoving party. Id. at 255. In reviewing the record evidence, the court may not undertake the jury's function of weighing the evidence or undertaking credibility determinations. Latimer v. Roaring Toyz, Inc., 601 F.3d 1224, 1237 (11th Cir. 2010).

Under Florida law, "[i]n order to hold a manufacturer liable on the theory of strict liability in tort, the user must establish the manufacturer's relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal connection between such condition and the user's injuries or damages." West v. Caterpillar Tractor Co., 336 So. 2d 80, 87 (Fla. 1976). To prove her claim for negligent design, Witt must show

that HOC owed her a duty, that HOC breached the duty, that the breach was the proximate cause of her injuries, and that she suffered damages resulting from those injuries. See Murray v. Traxxas Corp., 78 So. 3d 691, 693 (Fla. Dist. Ct. App. 2012).

Witt's primary argument on appeal is that the district court erred by ignoring the claim Witt allegedly brought for a manufacturing defect, and thus summary judgment, if appropriate, must be limited to the defective design claim. Witt's operative Second Amended Complaint presents only two claims: Strict Liability Defective Design and Negligence. Witt alleged, "At all relevant times hereto, Howmedica was engaged in the development, testing, manufacturing, marketing and sales of the EIUS Knee. Howmedica designed, manufactured, marketed, and sold the EIUS Knee to medical professionals knowing the device would be implanted for knee replacements." HOC moved for summary judgment on March 2, 2015, "against Plaintiff's claims." HOC explained, "Plaintiff alleges two design defect claims: a claim for strict liability defective design (Count I) and a claim for negligence (Count II)." It argued that "Defendants are entitled to summary judgment on all of Plaintiff's claims." In her summary judgment response, Witt said, "On January 17, 2014, Plaintiff filed her Second Amended Complaint which alleged two counts, both premised on design defect: Count I (Strict Liability Defective Design) and Count II (Negligence)."

Both parties clearly understood that Witt's action turned on an alleged defective design. The fact that Witt simply alleged in her operative complaint that HOC was the manufacturer of the EIUS device is not sufficient to state a claim for defective manufacture. If Witt believed the court had committed a mistake arising from oversight or omission by neglecting to discuss her supposed manufacturing defect claim, she could have sought relief by filing a motion under Fed. R. Civ. P. 60. But now it is too late. Even if this argument were not waived, it would still fail on the merits. Witt's Second Amended Complaint simply does not allege a manufacturing defect claim.

Witt also argues that the entry of summary judgment on her defective design claims was improper. "In order to prevail in a products liability action brought under a theory of either strict liability or negligence, a plaintiff must demonstrate that the injuries complained of were caused by a defective product whose defect existed at the time of injury and at the time in which the product left the manufacturer's control." Rodriguez v. National Detroit, Inc., 857 So. 2d 199, 201 (Fla. Dist. Ct. App. 2003) (citing Cassisi v. Maytag Co., 396 So. 2d 1140, 1143 (Fla. Dist. Ct. App. 1981)). Because the testimony of expert witness Dr. Lubliner was properly excluded, Witt is left with no admissible testimony establishing that her injuries were caused by a defective product.

Witt maintains, nevertheless, that expert testimony is not required because she benefits from the inference recognized by Cassisi. “In Florida strict product liability actions, a legal inference is created that the subject product was defective at both the time of injury and the time of sale when that product ‘malfunctions during normal operation.’” McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1258 (11th Cir. 2002) (citing Cassisi, 396 So. 2d at 1148). This inference is generally known as the Cassisi inference. Id. In Cassisi, the plaintiff brought a products liability action against the manufacturer of her clothes dryer after a fire alleged to have started in the dryer ravaged her house. 396 So. 2d at 1142. The court explained that it “considered that appellants’ evidence of a defect if one existed was attributable to a manufacturing flaw, and was not one of design.” Id. at 1146. Had the claim been for defective design, the court said, the inference would offer no benefit to the plaintiff:

A product’s malfunction may of course be caused by a design defect. However, for the purposes of the product defectiveness inference, which we are adopting *infra*, when the plaintiff’s evidence consists as here only of proof showing that a product malfunctioned during normal operation, it will be inferred that the defect was one of construction, rather than design, because a malfunction of a product is not a result ordinarily intended by the manufacturer.

Id. at 1146, n. 10. We are aware of no Florida case where the Cassisi inference has been applied in a defective design case. This sound distinction reflects the special difficulty in proving a claim for manufacturing defect. As illustrated in Cassisi

itself, where the plaintiff's dryer was consumed by fire, a manufacturing defect may often destroy critical evidence of the product's malfunction. When the claim is for defective design, on the other hand, the necessary evidence survives. The plaintiff need only point to model blueprints or other identical products on the market to establish the design of the product and its defective nature. Because Witt's claim was for defective design, the Cassisi inference is of no benefit to her. The design of her EIUS implant was easily ascertainable, and it is her burden to establish its defect.

What's more, we believe Witt has waived this issue by failing to raise Cassisi or the related inference before the district court. "This Court has repeatedly held that an issue not raised in the district court and raised for the first time in an appeal will not be considered by this court." Access Now, Inc. v. Sw. Airlines Co., 385 F.3d 1324, 1331 (11th Cir. 2004) (quotation omitted). None of the recognized exceptions to our waiver rule apply here. See id. at 1332.

In short, the district court did not reversibly err by denying Witt's motions to amend her complaint or to extend discovery, by excluding the testimony of Dr. Lubliner, or, finally, by granting final summary judgment in favor of HOC. Accordingly, we affirm.

AFFIRMED.