Brenda Griffin TOOLE, Plaintiff-Appellee-Cross-Appellant,

v.

BAXTER HEALTHCARE CORPORATION, Defendant-Appellant-Cross-Appellee.

No. 99-15019.

United States Court of Appeals,

Eleventh Circuit.

Dec. 14, 2000.

Appeal from the United States District Court for the Northern District of Alabama, (No. 94-13559-CV-P-S), Sam C. Pointer, Jr., Judge.

Before CARNES and BARKETT, Circuit Judges, and POLLAK,[*] District Judge.

BARKETT, Circuit Judge:

Baxter Healthcare Corporation ("Baxter") appeals a final judgment based on a jury verdict in favor of Brenda Toole for injuries she suffered as a result of breast implants manufactured by Heyer-Schulte Corporation, Baxter's predecessor corporation.

In 1987, several years after receiving the implants, Ms. Toole began to experience capsular contracture, a hardening of the breast due to scar tissue around the implant compressing down on the implant. Her physician performed a "closed capsulotomy"[1] to correct the contracture. Ms. Toole's pain continued, leading to surgery which revealed that both implants had ruptured. The implants were replaced. Approximately one year after the replacement surgery, Ms. Toole discovered a lump in her breast and was forced to undergo the first of multiple surgical procedures to remove what turned out to be silicone granulomas.[2] Ms. Toole became increasingly ill, experiencing difficulty concentrating, oral ulcers, hair loss, dry skin, and fatigue. As time passed, she had increasing pain in the form of arthralgias and myalgias. While disagreeing as to the etiology of the disease, the parties do not dispute that her symptoms were real.

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[*]Honorable Louis H. Pollak, U.S. District Judge for the Eastern District of Pennsylvania, sitting by designation.

[1]In performing a closed capsulotomy, the physician attempts to break the scar capsule by manually exerting direct, extreme pressure upon it. At the time, closed capsulotomy was the treatment of choice for contracture.

[2]A granuloma is the human body's encapsulation of small amounts of a foreign substance, in this case silicone.

Ms. Toole filed this tort action against Baxter.[3] Two jury trials were held in this lawsuit. At the first trial, she was awarded $350,000 in compensatory damages and $5,000,000 in punitive damages. Ms. Toole accepted a remittitur of the compensatory damages to $275,000 and punitive damages to $2,000,000, and the trial court denied Baxter's motions for Judgment as a Matter of Law ("JNOV"). After Baxter appealed, this Court found that the evidence presented at the first trial was insufficient to support an award of punitive damages, reversed the compensatory damages based upon an evidentiary issue,[4] and remanded the case for a new trial. *Toole v. McClintock,* 999 F.2d 1430 (11th Cir.1993) (hereinafter "*Toole I* ").

In the second trial, the jury awarded $2,500,000 in compensatory damages and $3,500,000 in punitive damages to Ms. Toole. The trial court granted Baxter's Motion for JNOV as to punitive damages and denied Baxter's Motion for a New Trial on compensatory damages conditioned on Ms. Toole's acceptance of a remittitur of the compensatory damage amount to $1,000,000. Ms. Toole originally rejected the remittitur and the case was restored to the docket for trial. However, prior to trial, Ms. Toole filed, and the trial court granted, a motion to withdraw her earlier rejection of the remittitur and accept the reduced amount of $1,000,000 in compensatory damages. Baxter then filed its "renewed" post-trial motions which were denied. Baxter now appeals those denials, and Ms. Toole cross-appeals the punitive damages issue.

DISCUSSION

Baxter argues on appeal that the judgment against it must be reversed because the trial court: (1) failed to properly instruct the jury on the duties of a medical device manufacturer; (2) erroneously admitted expert testimony that the implants caused Ms. Toole's injury; (3) erroneously admitted evidence of prior complaints against the manufacturer about product failures that Baxter asserts were irrelevant and prejudicial; (4) erred in allowing Ms. Toole to accept a remittitur which she had originally rejected; and (5) once having entered judgment upon Ms. Toole's acceptance of the remittitur, erred in failing to grant Baxter a new trial under F.R.C.P. 60(b) based on intervening scientific and legal developments relating to breast implants. Ms. Toole cross-appeals, claiming that the trial court erred in vacating the award of punitive damages. We address each claim in turn.

1. Evidentiary Rulings

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[3]The original complaint also contained medical malpractice allegations against Ms. Toole's physician, but the jury determined that the doctor was not liable.

[4]This evidentiary issue did not arise in the second trial.

A. Admission of expert witness testimony

Baxter claims that admitting the testimony of Drs. Schneider, Tiliakos, Gaston and Espinosa, each of whom testified to support Ms. Toole's contention that the breast implants that she received caused her disease, constituted an abuse of discretion. Baxter likewise claims that the district court erred in admitting the testimony of Drs. Shanklin, Smalley and Batich, who did not testify to causation directly, but described a disease process based on the human body's reaction to silica and/or the degradation of silicone into silica, which related to the effects of the residual silicone in Ms. Toole's body from the rupturing of her breast implants during the closed capsulotomy.

Ms. Toole first responds that Baxter did not properly preserve this issue, arguing that objections which had been made in limine were not renewed at trial and that objections to certain questions posed to the expert witnesses during trial were insufficient to preserve their *Daubert* objections. Based on the record, we are satisfied that Baxter appropriately preserved this issue. Baxter submitted three motions in limine, objecting to the expert testimony of Drs. Shanklin, Smalley and Batich, respectively. As to the other experts, Baxter lodged objections in the course of the experts' testimony based on a lack of foundation for the opinion. The district court overruled the objections and admitted the testimony. On this record we are satisfied that the objections were sufficient to preserve the issue.

We review a trial court's evidentiary rulings on the admission of expert witness testimony for abuse of discretion. *General Electric Co. v. Joiner,* 522 U.S. 136, 142, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997); *see also Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 142, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). Scientific evidence or testimony must not only be relevant, but also reliable. *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 589, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Accordingly, we grant the district court the same broad latitude when deciding how to determine the reliability of expert testimony as it enjoys in determining whether the testimony is reliable. *Kumho Tire Co.,* 526 U.S. at 142, 119 S.Ct. 1167.

Under Federal Rule of Evidence 702 and *Daubert,* expert testimony is admissible if (1) the expert is qualified to testify competently, (2) the expert has used sufficiently reliable methodology in reaching a conclusion, and (3) the testimony will assist the trier of fact. *See City of Tuscaloosa v. Harcros Chems., Inc.,* 158 F.3d 548, 562 (11th Cir.1998). Based upon their testimony, the trial court found Ms. Toole's expert witnesses to be qualified and their testimony to be sufficiently reliable, as they had conducted research,

published in peer-reviewed journals and treated hundreds of patients with silicone gel implants. We have read and carefully considered the testimony of the experts in this case. We are also mindful of the Supreme Court's directive that "it is very much a matter of discretion with the court whether to receive or exclude the evidence," and that an "appellate court will not reverse ... unless the ruling is manifestly erroneous." *Joiner,* 522 U.S. at 141, 118 S.Ct. 512. Based on our careful review of the testimony presented, we cannot say that the trial court abused its discretion in admitting the expert testimony. *See In re Rasbury,* 24 F.3d 159, 168 (11th Cir.1994) ("An abuse of discretion standard differs from a de novo standard of review" because "the abuse of discretion standard allows a range of choice for the district court, so long as that choice does not constitute a clear error of judgment.") (citation and internal quotations omitted).

B. Admission of prior complaints into evidence

Baxter also asserts that 92 complaints/reports submitted to Heyer-Schulte from the period 1979-1980 were admitted erroneously into evidence, as only thirteen concerned implants ruptured by a closed capsulotomy. Ms. Toole responds by noting that the admitted complaints were only a subset of the complaints Heyer-Schulte received during the two-year period and only dealt with rupture and bleed—both issues before the jury. Ms. Toole also claims that Baxter previously raised this issue on appeal in *Toole I,* and their claim was dismissed.

In *Toole I,* Baxter appealed the trial court's decision to admit 270 complaints into evidence on a number of grounds, including the assertion that the prior complaints were not substantially similar to Ms. Toole's situation. This Court found that this claim of evidentiary error lacked merit. *Toole I,* 999 F.2d at 1433 n. 7 (vacated and remanded on other grounds). Under the law-of-the-case doctrine, an issue decided at one stage of a case is binding at later stages of the same case. *United States v. Escobar-Urrego,* 110 F.3d 1556 (11th Cir.1997). Given that Baxter makes the same claim on prior complaints evidence in this case, Baxter's claim is foreclosed. Moreover, we again find that it was not an abuse of discretion for the trial court to admit the prior complaints for the purpose of showing that Baxter had notice of the fragility of its product.

2. Jury instructions on learned intermediary doctrine and duties of manufacturer

Baxter argues that the jury instructions erroneously characterized the applicable law as stating that the manufacturer's duty to warn depends on the knowledge of the patient, rather than on the knowledge of

the physician.[5] We examine jury instructions as a whole to determine whether they fairly and adequately addressed the issue and correctly stated the law. *Christopher v. Cutter Laboratories,* 53 F.3d 1184, 1190 (11th Cir.1995). "A district court has broad discretion in formulating jury instructions.... Motions for new trial on the basis of erroneous and prejudicial jury instructions are committed to the discretion of the trial court and reviewed to ascertain whether there has been a clear abuse of that discretion." *Id.* at 1190 (citations omitted).

In cases involving complex products, such as those in which pharmaceutical companies are selling prescription drugs, the learned intermediary doctrine applies. *See Stone v. Smith, Kline & French Labs.,* 731 F.2d 1575, 1579-1580 (11th Cir.1984). Under the learned intermediary doctrine, a manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product. *Id.* This standard is "an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products." *Id.* at 1579 (internal citation omitted). As such, we rely on the expertise of the physician intermediary to bridge the gap in special cases where the product and related warning are sufficiently complex so as not to be fully appreciated by the consumer. In *Toole I,* we held that "[u]nder the 'learned intermediary doctrine,' the adequacy of Baxter's warning is measured by its effect on the physician, ... to whom it owed a duty to warn, and not by its effect on Ms. Toole." 999 F.2d at 1433.

Here, in addressing Question (1)(a)[6] of the special verdict, the trial court offered the following instructions with regard to Alabama Extended Manufacturers Liability Doctrine:

> [a] product is considered unreasonably dangerous if it has hazards or risks that would be unappreciated and unknown by the consumer when it's used in its intended manner ... [a]nd in determining whether something is unreasonably dangerous, you consider the extent to which the manufacturer or the distributor was aware of or reasonably should have been aware of some dangers and hazards that would not have been known and appreciated by the ordinary consumer.

The trial court then added:

> [i]f there are any, then the manufacturer can, in effect, prevent itself from being held liable by giving appropriate and adequate warnings of those risks so that then someone using the product is adequately warned about the kinds of problems to be expected.

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[5]Ms. Toole argues that Baxter did not properly object to the jury instructions on the learned intermediary doctrine. Although Baxter's objection was not expressed particularly well, upon reviewing the trial transcript, we find that the objection was sufficient to preserve the issue for appeal.

[6]Question (1)(a) was as follows: Has Brenda Toole established by a preponderance of the evidence that she has been injured as a proximate result of ... Heyer-Schulte's distributing breast implants that were unreasonably dangerous for their intended use?

In the next sentence, the trial court provided the following instruction on the learned intermediary doctrine and its application to this case:

> With products such as breast implants, this obligation of a manufacturer to give appropriate warnings of things that would not be appreciated by the consumer may be discharged by giving appropriate warnings to the physicians who are going to be using the product, taking into account the type of knowledge that one would expect physicians to have as a result of their professional training and experience, and providing them with additional information, supplemental information, that would help those physicians to assess the proper use of that product and to understand the types of risks, if any, that would be associated with that.

There is no error in these instructions. The learned intermediary doctrine is an exception to general manufacturer liability law, and we find no abuse of discretion in outlining general manufacturer's liability law and then describing the learned intermediary doctrine. Further, given that the learned intermediary doctrine applies in cases in which the product is particularly complex, it was not an abuse of discretion for the trial court to describe such complex products as "things that would not be appreciated by the consumer." In examining the jury instructions as a whole, we find that the jury instructions on Question (1)(a) both fairly stated the issue and correctly stated the law.

On Question (1)(c),[7] the negligence claim, the trial court offered the following instruction:

> Negligence is the key in this question ... that is, did Heyer-Schulte do something that a reasonable manufacturer would not have done or did it fail to do something that a reasonable manufacturer would have done under the same circumstances with respect to warnings to people who had already gotten breast implants or to their physicians.... Did Heyer-Schulte fail to do something a reasonable manufacturer would have done under that same or similar circumstances, with respect to giving warnings to implant recipients or to their physicians concerning possible risks or consequences of closed capsulotomy?

The instructions to Question (1)(c) followed the jury instructions on the learned intermediary doctrine. Moreover, the trial judge made two references to the duty to warn physicians in the instruction on Question (1)(c). Therefore, viewing the challenged instructions to Question (1)(c) as part of the entire charge, we find no abuse of discretion on the part of the trial court. *Johns v. Jarrard,* 927 F.2d 551, 554 (11th Cir.1991) (quoting *National Distillers & Chem. Corp. v. Brad's Mach. Prod., Inc.,* 666 F.2d 492, 497 (11th Cir.1982) ("[We] view the challenged instructions as part of the entire charge, in view of the allegations of the complaint, the evidence presented, and the arguments of counsel, to determine whether the jury was misled and whether the jury understood the issues.") (internal quotations omitted)).

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[7]Question (1)(c) was as follows: Has Brenda Toole established by a preponderance of the evidence that she has been injured as a proximate result of ... Heyer-Schulte's negligence in the adequacy of warnings it provided to physicians after February 1981 and before February 1988 about the risk and possible consequences of closed capsulotomies?

3. Acceptance of the previously rejected remittitur

Baxter next claims that the trial court erred in entering judgment for Ms. Toole after she previously rejected a remittitur, a new trial was ordered, and four years of legal and scientific developments created important issues for trial. We review the trial court's ruling reinstating the remittitur to determine whether the trial court erred as a matter of law. *Gallimore v. Missouri Pacific R. Co.,* 635 F.2d 1165 (5th Cir. Unit A Feb.1981).[8]

"There is no sound reason why the court may not reconsider its ruling (granting) a new trial.... Since an order granting a new trial is an interlocutory order, the district court has plenary power over it and this power to reconsider, revise, alter or amend the interlocutory order is not subject to the limitations of Rule 59." *Id.* at 1171-72 (quoting 6A James W. Moore, *Moore's Federal Practice* ¶ 59.13(1), at 59-257 (2d ed.1979)). *See Hardin v. Hayes,* 52 F.3d 934, 938 (11th Cir.1995) (endorsing the holding in *Gallimore* and the language of *Moore's Federal Practice*); *McIsaac v. Didriksen Fishing Corp.,* 809 F.2d 129, 135 (1st Cir.1987) ("[t]he trial court also has discretion to revoke its order for a new trial and reinstate the judgment."). In this case, the court's order for a new trial was an interlocutory order, and therefore the trial court had the power to revoke it and reinstate the judgment.

Alternatively, Baxter claims that, even if the district court had the power to reinstate the remittitur, the exercise of that power was an abuse of discretion, because, in effect, it allowed Ms. Toole to observe legal and scientific developments over a four-year period and then accept the remittitur because the developments were adverse to her case. While we agree that an unusually long period of time had elapsed, a review of the record does not lead us to conclude that accepting the remittitur in 1999 was an abuse of discretion. First, in issuing its final judgment, the trial court noted the "prolonged period of delay" was "primarily caused by awaiting the completion of research and depositions of neutral experts appointed by the court." In addition, Ms. Toole requested that the district court set a new trial date several years earlier. Based on the circumstances of this case, including the fact that the delays were not caused by Ms. Toole, we cannot say that the trial court erred as a matter of law by permitting her to accept the remittitur in 1999.

4. Rule 60(b) motion

Finally, Baxter argues that newly discovered scientific evidence and legal developments over the

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

past four years justify a new trial under either Federal Rule of Civil Procedure 60(b)(2) or 60(b)(6). We review the trial court's denial of Baxter's Rule 60(b) motion for abuse of discretion. *Scutieri v. Paige,* 808 F.2d 785, 793 (11th Cir.1987).

"A motion for a new trial under Rule 60(b)(2) is an extraordinary motion and the requirements of the rule must be strictly met." *Id.* at 793. In order for the court to grant such a motion, Baxter must meet the following five-part test: (1) the evidence must be newly discovered since the trial; (2) due diligence on the part of the movant to discover the new evidence must be shown; (3) the evidence must not be merely cumulative or impeaching; (4) the evidence must be material; and (5) the evidence must be such that a new trial would probably produce a new result. *Id.* Similarly, a Rule 60(b)(6) motion, by which a court has discretion to grant a new trial for "any other reason justifying relief from the operation of the judgment," is intended "only for extraordinary circumstances." *Frederick v. Kirby Tankships, Inc.,* 205 F.3d 1277, 1288 (11th Cir.2000).

Both parties acknowledge that new scientific evidence is continually emerging. The science surrounding breast implants is continuing to evolve and will do so even after this case has concluded. The District of Columbia Court of Appeals has elucidated the problems presented by new scientific evidence produced after a trial court judgment:

> Although science is a constantly evolving process, the law depends upon a high level of certainty once an outcome has been determined. A trial can be no more than a resolution of an immediate dispute on the basis of present knowledge; its outcome must turn upon the teachings of science as understood at the time of trial as best can be discerned through the presentations of the parties. Where scientific facts are at issue, it is not unexpected, given the nature of the process, that the passage of time will bring forth further scientific data and inquiry relating to the ultimate scientific fact at issue. To reopen the trial's determination of scientific truth, however, runs squarely into the fundamental principle of certainty.

Merrell Dow Pharm., Inc. v. Oxendine, 649 A.2d 825, 831 (D.C., 1994).[9]

For these reasons, we are reluctant to prolong a case that has already been in the courts for ten years. Nonetheless, we are obliged to review a denial of a Rule 60(b) motion for abuse of discretion. Although there may be circumstances in which the emergence of new scientific evidence would warrant a new trial, we find no abuse of discretion in the district court's determination to deny this motion. The record reflects sufficient

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[9]Notwithstanding the *Oxendine* court's recognition that "[t]he ends of the litigation process would be subverted if ... a jury's determination of a scientific fact after a full trial ... could be the subject of potentially endless re-examination except in the most unusual of circumstances," *Id.* at 832, the court remanded the case to the trial court for reconsideration. It did so because the trial court had "refus[ed] to consider at all" the proffered new scientific evidence. *Oxendine,* 649 A.2d at 832.

evidence indicating that the trial court considered the new scientific evidence.[10] Morever, while some of this new evidence supports Baxter's position, the new evidence is not exclusively in Baxter's favor. This implicates the requirement under Rule 60(b)(2) of demonstrating that the new evidence probably would have produced a different result. *See Scutieri,* 808 F.2d at 793. Additionally, the new evidence offered by Baxter would be cumulative or impeaching, which is the type of evidence for which a Rule 60(b)(2) motion cannot be granted. *See Taylor v. Texgas Corp.,* 831 F.2d 255, 259 (11th Cir.1987). Therefore, we find no abuse of discretion in the denial of Baxter's motion under Rule 60(b)(2).

Nor do we find any abuse of discretion in the denial of Baxter's motion under Rule 60(b)(6). Although Baxter argues that new or changed circumstances may justify relief under Rule 60(b)(6), Baxter does not provide evidence of "any other reason justifying relief" pursuant to Rule 60(b)(6) aside from the new scientific evidence already addressed under Baxter's Rule 60(b)(2) motion. This Court has held that "a Rule 60(b)(6) movant 'must persuade [the court] that the circumstances are sufficiently extraordinary to warrant relief.' Even then, whether to grant the requested relief is ... a matter for the district court's sound discretion." *Booker v. Singletary,* 90 F.3d 440, 442 (11th Cir.1996)(quoting *Ritter v. Smith,* 811 F.2d 1398, 1401 (11th Cir.), cert. denied, 483 U.S. 1010, 107 S.Ct. 3242, 97 L.Ed.2d 747 (1987)).

For all of the foregoing reasons, we AFFIRM the district court's ruling on each of Baxter's claims.

5. Cross-appeal on punitive damages

In her cross-appeal, Ms. Toole argues that the trial court erred in deciding that there was insufficient evidence of wanton conduct for the jury to have awarded punitive damages. The district court's grant of a motion for judgment as a matter of law vacating the punitive damage award is reviewed *de novo. Snapp v. Unlimited Concepts, Inc.,* 208 F.3d 928, 932 (11th Cir.2000).

In determining whether there was sufficient evidence of conduct warranting punitive damages, we apply Alabama substantive law. "Under Alabama law, to award punitive damages, the jury must have found, by clear and convincing evidence, that Baxter 'consciously or deliberately engaged in ... wantonness ... with regard to the plaintiff.' " *Toole I,* 999 F.2d at 1436 (quoting Ala.Code §§ 6-11-20 (Supp.1990)). "Wantonness" under Alabama law is "conduct which is carried on with a reckless or conscious disregard of the rights and safety of others." *Sears, Roebuck & Co. v. Harris,* 630 So.2d 1018, 1032 (Ala.1993).

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[10]Indeed, the fact that the delay in starting a third trial was caused primarily by awaiting the completion of research and depositions of neutral experts appointed by the court indicates that the district court was well aware of new developments in this field.

In *Richards v. Michelin Tire Corp.,* this Court stated that "[w]e have repeatedly held that the issue of punitive damages should not go to the jury when a manufacturer takes steps to warn the plaintiff of the potential danger that injured him; such acts bar a finding of wantonness." 21 F.3d 1048, 1058 (11th Cir.1994) (citing *Toole I,* 999 F.2d at 1436). In *Toole I,* we found that

> The Heyer-Schulte warning describes the main harms that Ms. Toole has actually suffered—capsular contracture, rupture, and granuloma-and the warning forecasted the way she came to suffer these harms—"treat[ment of] capsule firmness by forceful external stress." More could have been done or said, but Heyer-Schulte did not exhibit indifference toward safety. Baxter's conduct shows regard for recipients of its implants and cannot be viewed as "wanton." We conclude that there was insufficient evidence of wantonness in this case to permit the jury to award punitive damages.

Toole I, 999 F.2d at 1436.

On review of the record, we reaffirm our earlier view that while Heyer-Schulte could have done or said more, it did not exhibit wantonness as defined by Alabama law. Moreover, because essentially the same punitive damage case was presented at the second trial, Ms Toole's claim has been foreclosed by our earlier decision. *See Burger King Corp. v. Pilgrim's Pride Corp.,* 15 F.3d 166, 169 (11th Cir.1994) (under law of the case doctrine, "findings of fact and conclusions of law by an appellate court are generally binding in all subsequent proceedings in the same case in the trial or on a later appeal.") (citations omitted). Therefore, we affirm the district court's order granting Baxter's Motion for JNOV vacating the punitive damages**.**

Accordingly, the district court's rulings in all respects are

AFFIRMED.