United States Court of Appeals,

Fifth Circuit.

No. 96-30307.

Dorothy Marie REEVES, Plaintiff-Appellee-Cross-Appellant,

Randy J. Ungar, Intervenor,

v.

ACROMED CORP. et al., Defendants-Appellants-Cross-Appellees.

Jan. 20, 1997.

Appeal from the United States District Court for the Eastern District of Louisiana.

Before KING, JOLLY and DENNIS, Circuit Judges.

DENNIS, Circuit Judge:

This is the second appeal arising from a products liability action filed by the plaintiff-appellee, Dorothy Marie Reeves ("Reeves"), alleging that a metal bone implant manufactured and marketed by the defendant-appellant, AcroMed Corporation ("AcroMed") aggravated and compounded her back injuries. In the first appeal this court vacated the district court's judgment in favor of Reeves based on a jury verdict awarding her damages of $475,000 against AcroMed and remanded the case for retrial. *Reeves* v. *AcroMed Corporation,* 44 F.3d 300 (5th Cir.1995), *cert. denied,* --- U.S. ----, 115 S.Ct. 2251, 132 L.Ed.2d 258 (1995)("*Reeves I*"). After retrial, the district court rendered judgment in favor of Reeves against AcroMed and Dr. Arthur Steffee ("Steffee"), chairman of AcroMed and inventor of the metal bone implant, implementing a

jury award to Reeves of $318,000 in damages. We affirm the judgment against AcroMed but reverse it insofar as it affects Steffee. Reeves' unreasonably dangerous per se claim is not preempted by the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act. 21 U.S.C. § 360k(a). Under the law of this case established in *Reeves I* we will not reexamine whether Reeves' unreasonably dangerous per se claim should have been presented to the jury. Steffee was not a manufacturer of the metal bone implant because he personally did not place the product on the market or introduce it into the stream of commerce.

BACKGROUND

In December 1985, the plaintiff-appellee, Dorothy Marie Reeves, seriously injured her back. She was diagnosed as having spinal stenosis. To alleviate this condition, her neurosurgeon attempted a complicated procedure that entailed fusing grafts of bone from Reeves' hip into her spine at four different levels of her vertebrae. As part of this surgery, metal bone plates and screws manufactured by the appellant, AcroMed, were implanted into Reeves' back to secure the fusion. Reeves' condition initially improved after surgery. However, six months after the surgery, Reeves began to suffer from back pain that had not existed prior to the surgery. Reeves continued to suffer from this pain and in December 1991, filed suit against AcroMed alleging that AcroMed's products implanted in her back were defective. Reeves based her

cause of action on several theories of recovery including, failure to warn, defective design, defective manufacturing, and the "unreasonably dangerous per se" category of products liability. *Reeves I,* at 308; See *Halphen v. Johns-Manville Sales Corp.,* 484 So.2d 110, 113-115 (La.1986). The jury returned a verdict in favor of Reeves, but did not specify upon which legal theory the verdict was based.

In *Reeves I,* this court held that the failure to warn theory was preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.,* and that Reeves failed to produce sufficient evidence to recover on her defective design and manufacturing theories. Accordingly, we vacated the judgment of the district court and remanded for retrial of Reeves' action predicated solely on the unreasonably dangerous per se theory. However, in *Reeves I* we found that Reeves presented sufficient evidence to have her unreasonably dangerous per se claim submitted to the jury, including the questions of whether the medical device was an unreasonably dangerous per se product and, if so, whether this product condition caused the exacerbation of Reeves' back injury. *Id.* at 308.

After trial on remand, the jury awarded Reeves $318,000 finding that AcroMed's medical device was unreasonably dangerous per se and this product condition caused the aggravation and compounding of Reeves' back injuries. On remand Reeves also

brought a cause of action based on the unreasonably dangerous per se theory of recovery against Dr. Arthur Steffee, the inventor of the metal bone plates and screws implanted in Reeves' back and the chairman of the board of AcroMed.[1] Before the commencement of Reeves' jury trial, the parties stipulated that if the jury returned a verdict in favor of Reeves, the judge would rule on Steffee's liability. After the jury rendered a verdict in Reeves' favor, the trial judge determined that Dr. Steffee was personally liable. We conclude that Reeves' unreasonably dangerous per se claim is not preempted, the law of the case doctrine mandates that we not reconsider the sufficiency of the evidence and causation issues with respect to Reeves' unreasonably dangerous per se claim against AcroMed, and the jury acted reasonably in awarding Reeves $318,000. However, we conclude that the district court erred in part by holding Steffee liable.

STANDARD OF REVIEW

We employ a three-tiered standard of review in this case. A court's findings of fact are reviewed for clear error and conclusions of law are reviewed de novo. *Peaches Entertainment v. Entertainment Repertoire,* 62 F.3d 690, 693 (5th Cir.1995). In reviewing a jury's findings of fact, we apply the standard set out

[1]In *Reeves I,* Reeves also brought a claim against Dr. Steffee, but the parties apparently agreed not to submit the claim against Dr. Steffee to the jury because AcroMed's insurance would cover any judgment. However, Dr. Steffee was never dismissed as a party.

in *Boeing Co. v. Shipman* 411 F.2d 365 (5th Cir.1969): "[A] jury verdict will not be overturned unless the facts and inferences point so strongly and overwhelmingly in favor of one party that the court believes that reasonable [jurors] could not arrive at a contrary verdict."

DISCUSSION

I. Reeves' Claim Against AcroMed

AcroMed first asserts that Reeves' state law unreasonably dangerous per se claim is preempted by the Medical Device Amendments of 1976 (MDA or Act) to the Food, Drug, and Cosmetic Act. 90 Stat. 539. 21 U.S.C. § 301, *et. seq.* In light of the Supreme Court's decision in *Medtronic, Inc. v. Lohr,* 518 U.S. ----, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), this argument is not persuasive.

Congress enacted the MDA to give the FDA authority to regulate medical devices. *Lohr,* 518 U.S. at ----, 116 S.Ct. at 2246. In *Lohr,* the Supreme Court explained the critical provisions of the MDA as background for its preemption analysis.

Medical devices are divided into three classes. Class III devices present potential unreasonable risks and are subject to the most intensive regulation. *Id.* The metal bone plates and screws implanted in Reeves' back are Class III devices. In order for a new Class III device to be marketed, the manufacturer of the device must provide the FDA with a reasonable assurance that the device is

both safe and effective. *Id.* (citing 21 U.S.C. § 360e(d)(2)). This process, known as the "premarket approval" (PMA) process, is quite rigorous in that the FDA spends an average of 1200 hours on each submission. *Id.* at ---- - ----, 116 S.Ct. at 2246-47.

There are two exceptions to the PMA requirement. First, the statute grandfathers in all pre-1976 devices and allows those devices to remain on the market until the FDA initiates and completes a PMA. *Id.* at ----, 116 S.Ct. at 2247 (citing 21 U.S.C. § 360e(b)(1)(A)). Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure rapid introduction of improvements, the Act also permits devices that are "substantially equivalent" to preexisting devices to be marketed without the rigorous PMA review. *Id.* (citing 21 U.S.C. § 360e(b)(1)(B)).

However, all "substantially equivalent" devices are subject to the requirements of 21 U.S.C. § 360(k). That section imposes a limited form of review on every manufacturer intending to market a new device by requiring it to submit a "premarket notification" to the FDA. This process is also known as the "§ 510(k) notification or process," after the number of the section in the original act. We will use it hereinafter to avoid confusion between 21 U.S.C. § 360(k)(§ 510(k) notification or process) and 21 U.S.C. § 360k(a)(preemption provision). If the FDA concludes on the basis of the § 510(k) notification that the device is "substantially

equivalent" to a pre-existing device, it can be marketed until the FDA initiates the PMA process for the underlying pre-1976 device to which the new device is "substantially equivalent." *Id.* In contrast to the rigorous PMA process, the § 510(k) process averages only 20 hours instead of 1200. *Id.*

The preemption provision of the MDA, 21 U.S.C. § 360k(a), reads as follows:

> § 360k. State and local requirements respecting devices
>
> (a) General rule
>
> Except as provided in subsection (b) of this section, no State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

In *Medtronic, Inc. v. Lohr,* 518 U.S. ----, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), petitioner Medtronic Inc.'s pacemaker was a Class III device found substantially equivalent under the § 510(k) process. Cross-petitioners Lohrs filed a state court suit in Florida alleging strict liability and negligence claims because of the failure of her Medtronic pacemaker. Medtronic removed the case to federal district court. That court dismissed the complaint as having been pre-empted by 21 U.S.C. § 360k(a) because it was based on state law claims which, if successful, would impose a

requirement different from or in addition to any requirement applicable to the device under the MDA relating to the safety or effectiveness of the device. The Eleventh Circuit Court of Appeals reversed in part and affirmed in part, concluding that the Lohrs' negligent design claims were not pre-empted, but that their negligent manufacturing and failure to warn claims were. *Lohr,* 518 U.S. at ----, 116 S.Ct. at 2249. The Supreme Court reversed in part, affirmed in part, and remanded, concluding that the MDA does not pre-empt the Lohrs' common law claims. *Id.* at ----, 116 S.Ct. at 2259.

Although the Supreme Court determined that it need not go beyond § 360k(a)'s pre-emptive language to determine whether Congress intended the MDA to pre-empt at least some state law, citing *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 517, 112 S.Ct. 2608, 2618, 120 L.Ed.2d 407 (1992), the Court concluded that the domain expressly pre-empted by that language must be identified. The Court further noted that its interpretation of the text is informed by the assumptions that the States' historic police powers cannot be superseded by a Federal Act unless that is Congress' clear and manifest purpose, citing *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947), and that any understanding of a pre-emption statute's scope rests primarily on "a fair understanding of *congressional purpose,*" quoting *Cipollone,* 505 U.S. at 530, 112 S.Ct. at 2624.

The Court determined that the Lohrs' design claims were not pre-empted because the FDA's "substantially equivalent" determination as well as its continuing authority to exclude a device from the market do not amount to a specific, federally enforceable design requirement that cannot be affected by the type of state law pressures imposed by those claims. Because the § 510(k) process is focused on *equivalence,* not safety, the Court observed, substantial equivalence determinations provide little protection to the public. Neither the statutory scheme nor legislative history suggests that the § 510(k) process was intended to do anything other than maintain the status quo, which included the possibility that a device's manufacturer would have to defend itself against state law negligent design claims. *Lohr,* 518 U.S. at ---- - ----, 116 S.Ct. at 2254-55.

The Supreme Court also held that the Lohrs' manufacturing and labeling claims are not pre-empted because § 360k(a) does not pre-empt state rules that merely duplicate the FDA's rules regulating manufacturing practices and labeling. That the state requirements may be narrower than the federal rules does not make them "different" under § 360k(a). *Id.* at ----, 116 S.Ct. at 2258. Nor does the presence of a damages remedy amount to an additional or different "requirement"; it merely provides another reason for manufacturers to comply with identical existing federal law "requirements." *Id.* The Court found that this view is supported by

the regulations of the FDA, to which Congress has delegated authority to implement the MDA. *Id.*

In the present case, we conclude, for the same reasons, that Reeves' unreasonably dangerous per se claim is not preempted by § 360k(a). As the Supreme Court noted, quoting the court below with approval, " "[t]he 510(k) process is focused on *equivalence,* not safety.' *Lohr v. Medtronic, Inc.,* 56 F.3d 1335, 1348 (11th Cir.1995). As a result, "substantial equivalence' determinations provide little protection to the public." *Lohr,* 518 U.S. at ----, 116 S.Ct. at 2254. " "These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective.' " *Id.* (quoting Adler, 43 Food Drug Cosm. L. J., at 516). The design of Medtronic's pacemaker, the Court remarked, as with the design of pre-1976 and other "substantially equivalent" devices, has never been formally reviewed under the MDA for safety or efficacy. *Id.*

In concluding its review with respect to the Lohrs' defective design claims, the Court stated:

> Thus, even though the FDA may well examine § 510(k) applications for Class III devices (as it examines the entire medical device industry) with a concern for the safety and effectiveness of the device ..., it did not "require" Medtronics' pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker,

> as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process.... There is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design.... [T]he Court of Appeals properly concluded that the "substantial equivalence" provision did not pre-empt the Lohrs' design claims.

Id. at ---- - ----, 116 S.Ct. at 2254-55.

Applying these principles to the present case, we conclude that the "substantial equivalence" provision did not pre-empt Reeves' unreasonably dangerous per se claim. When Reeves' claim arose, Louisiana and many other jurisdictions recognized that a product may be unreasonably dangerous because of its design for reasons very similar to those underlying the unreasonably dangerous per se claim. This widely recognized defective design theory accrued when "[a] reasonable person would conclude that the danger-in-fact, whether foreseeable or not, outweighs the utility of the product." *Halphen v. Johns-Manville Sales Corp.,* 484 So.2d at 114. *See also Elmore v. Owens-Illinois, Inc.,* 673 S.W.2d 434 (Mo.1984); *Turner v. General Motors Corp.,* 584 S.W.2d 844 (Tex.1979); *Carter v. Johns-Manville Sales Corp.,* 557 F.Supp. 1317 (E.D.Tex.1983); Prosser and Keeton on Torts, p. 699 (5th Ed.1984); Keeton, Torts, Annual Survey of Texas Law, 1981, 35 Sw.L.J. 1, 9 (1981); Keeton, The Meaning of Defective in Products Liability Law, 45 Mo.L.Rev. 579, 592 (1980). "This is the same

danger-utility test applied in determining whether a product is unreasonably dangerous per se." *Id.* The design of AcroMed's metal bone implant, as with the design of pre-1976 and other "substantially equivalent" devices, has never been formally reviewed under the MDA for safety or efficacy. Thus the FDA did not "require" AcroMed's medical device to take any particular form for any particular reason; the metal bone implant was simply allowed by the agency, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process. As the Supreme Court took notice with regard to Lohr's pacemaker, there is no suggestion that the § 510(k) process was intended to do anything other than maintain the marketing status quo, and that status quo included the possibility that AcroMed, the manufacturer of the metal bone implant, would have to defend itself against state-law claims of unreasonably dangerous products liability claims, including strict liability defective design and unreasonably dangerous per se claims. *Accord: Moore v. Kimberly-Clark Corporation,* 867 F.2d 243 (5th Cir.1989)(Louisiana strict liability claims based on defective design, construction and composition of tampon were not preempted by § 360k(a) of MDA).

This court's decision in *Feldt v. Mentor Corp.,* 61 F.3d 431 (5th Cir.1995) fully anticipated the reasoning and holding of *Lohr* that we now apply. In *Feldt,* we decided that the MDA does not

preempt Texas design defect and implied warranty claims against the manufacturer of a pump-activated inflatable penile prosthesis. This court noted that there was no regulation relating specifically to design quality of the prosthesis approved for marketing based on substantial equivalence to prior devices. *Id.* at 436-438. Moreover, we noted that "[t]he FDA ... may approve an unreasonably dangerous device so long as the device has the same technological characteristics or, if the device has different technological characteristics, is as safe and effective as the predicate device. 21 U.S.C. § 360c(i). To say that a new device is as safe as its predicate thus indicates nothing, absolutely, about how safe either product is; a new device may be as safe as a predicate device that itself is unreasonably dangerous." *Id.* at 438, n. 12.

Considering the background behind the "substantial equivalence" exemption, the fact that the purpose of Congress is the ultimate touchstone in every pre-emption case, *Lohr,* 518 U.S. at ----, 116 S.Ct. at 2256, and the presumption against pre-emption, *id.,* we conclude that the "substantial equivalence" provision did not pre-empt Reeves' unreasonably dangerous per se claim.

Alternatively, AcroMed asserts that the judgment of the district court should be reversed because there was not sufficient evidence from which a reasonable juror could find that the medical device was unreasonably dangerous per se and that this condition of

the product caused the aggravation of Reeves' injuries. In *Reeves I* this court concluded, however, that Reeves' evidence was sufficient to support submitting her unreasonably dangerous per se claim to the jury, including the questions of whether the product was unreasonably dangerous per se and whether that product condition caused the exacerbation of Reeves' back injuries. On this appeal these issues are controlled by the law of the case doctrine.

> Under the law of the case doctrine, we follow the prior decisions in a case as the law of that case. Thus, we will not reexamine issues of law addressed by a prior panel opinion in a subsequent appeal of the same case unless: "(i) the evidence on a subsequent trial was substantially different, (ii) controlling authority has since made a contrary decision of the law applicable to such issues, or (iii) the decision was clearly erroneous and would work a manifest injustice."

Alberti v. Klevenhagen, 46 F.3d 1347, 1351 n. 1 (5th Cir.1995)(quoting *North Mississippi Communications v. Jones,* 951 F.2d 652, 656 (5th Cir.1992), *cert. denied,* 506 U.S. 863, 113 S.Ct. 184, 121 L.Ed.2d 129 (1993)). Because none of the above enumerated exceptions apply to this case, we are governed herein by the decisions of legal questions by *Reeves I.* Therefore, under the law of this case there was sufficient evidence to support the submission of all elements of Reeves' unreasonably dangerous per se claim to the jury.

We find nothing improper or unreasonable regarding the jury's verdict with respect to the quantum of damages. In light of the deference that we are required to give, we cannot overrule the

jury's verdict in this case. The record indicates that the jury's award of compensatory damages to Reeves was within reasonable bounds.

II. Reeves' Claim Against Dr. Steffee

Finally, we address whether the district court erred in holding Steffee liable as the manufacturer or supplier of an unreasonably dangerous product. Under product liability theories of recovery, the plaintiff must establish that the defendant was the manufacturer or supplier of the defective product.[2] *See e.g. Halphen v. Johns-Manville Sales Corp.,* 484 So.2d 110, 113 (La.1986). A manufacturer or supplier is one who places a product on the market or introduces it into the stream of commerce. *See CNG Producing Co. v. Columbia Gulf Transmission,* 709 F.2d 959 (1983); *Heirs of Fruge v. Blood Services,* 506 F.2d 841 (5th Cir.1975); *Carney v. Marathon Oil Company,* 632 F.Supp. 1037 (W.D.La.1986); Restatement (Second) of Torts, § 402A comment f (1965). *Cf.* La.R.S. 9:2800.53(1) and (3). The facts that Steffee

[2]The Louisiana Supreme Court has recognized that professional vendors may also be subject to liability under product liability theories. *See e.g., Shortess v. Touro Infirmary,* 520 So.2d 389, 391 (La.1988); *Rowell v. Carter Mobile Homes, Inc.* 500 So.2d 748, 752 (1987); *Chappuis v. Sears Roebuck & Co.,* 358 So.2d 926, 930 (La.1978). In order to qualify as a professional vendor, one must do more than occasionally place a product in the stream of commerce; one must be in the business of selling the product. *See Rowell, supra* (where a bank which only occasionally sold mobile homes which it was forced to acquire in foreclosures was held not to be a professional vendor); *See also* Restatement (Second) of Torts, § 402A(1)(a) (1965).

invented the metal bone plates and screws and served as chairman of the board of AcroMed do not suffice to make him a manufacturer, supplier, or professional vendor. Steffee invented the bone implant, but he, in his capacity of an individual person, did not place the medical device on the market, introduce it into the stream of commerce, or act as a professional vendor of the product.

CONCLUSION

For the foregoing reasons, the judgment of the district court in favor of Reeves is affirmed insofar as it was rendered against AcroMed but it is reversed insofar as it affects Steffee. Accordingly, the judgment of the district court is AFFIRMED IN PART AND REVERSED IN PART.