SUPREME COURT OF ARKANSAS

No. 07-714

GARY DESPAIN AND JOY DESPAIN, APPELLANTS, VS. JAMES L. BRADBURN, M.D.; SOUNDTEC, INC. APPELLEES,	**Opinion Delivered** April 10, 2008 AN APPEAL FROM THE CIRCUIT COURT OF BENTON COUNTY, ARKANSAS, NO. CIV-2003-366-2, HONORABLE DAVID S. CLINGER, CIRCUIT JUDGE SUBSTITUTED OPINION ON GRANT OF REHEARING

TOM GLAZE, Associate Justice

On February 7, 2008, this court handed down its opinion reversing the circuit court's grant of summary judgment to appellee Soundtec, Inc.; in that opinion, we held that the Medical Device Amendment (MDA) to the federal Food, Drug, and Cosmetic Act did not preempt a state-law tort claim filed against the manufacturer of a medical device. *See Despain v. Bradburn*, ___ Ark. ___, ___ S.W.3d ___ (Feb. 7, 2008). Less than two weeks later, on February 20, 2008, the United States Supreme Court decided the case of *Riegel v. Medtronic, Inc.*, ___ U.S. ___, 128 S. Ct. 999 (2008). In *Riegel*, the Supreme Court held precisely the opposite — that is, the Court determined that claims against manufacturers of medical devices *are* preempted by the MDA.

In so holding, the Court noted first that the MDA expressly preempts only those state requirements that are "different from, or in addition to, any requirement applicable to [a medical] device" under federal law." Thus, the question was whether a device approved

under the MDA's premarket approval (PMA) procedure was subject to specific requirements, and, if so, whether common-law claims based upon state requirements with respect to the device are "different from, or in addition to," the federal ones, and that relate to safety and effectiveness. *Riegel*, 128 S. Ct. at 1006.

The Court concluded that the PMA process does, in fact, "impose[ ] 'requirements' under the MDA," and those requirements are device-specific. *Id*. at 1007. The Court noted that, "[u]nlike general labeling duties, premarket approval is specific to individual devices . . . [and] is focused on safety[.]" *Id*. Moreover, the Court pointed out that the Food and Drug Administration (FDA) "requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id*.

The Court then considered whether "tort duties" also constitute "requirements" under the MDA that are "'different from, or in addition to' federal requirements and that 'relate[ ] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.'" *Id*. In holding that they are, the Court wrote as follows:

> Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's "requirements" includes its common-law duties. As the plurality opinion said in *Cipollone* [*v. Liggett Group, Inc.*, 505 U.S. 504 (1992)], common-law liability is "premised on the existence of a legal duty," and a tort judgment therefore establishes that the defendant has violated a state-law obligation. *Id*. at 522. And while the common-law remedy is limited to damages, a liability award "can be, indeed is designed to be a potent method of governing conduct and controlling policy." *Id*. at 521.

> In the present case, there is nothing to contradict this normal meaning. To the contrary, in the context of this legislation excluding common-law duties from the scope of preemption would make little sense. State tort law that requires a manufacturer's [medical devices] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation.

Id. at 1108.

Following the Supreme Court's opinion, Soundtec filed its petition for rehearing, urging that the high court's interpretation of federal law is binding upon this court. *See*, *e.g.*, *Harper v. Virginia Dep't of Taxation*, 509 U.S. 86 (1993) (holding that, when the Supreme Court "applies a rule of federal law to the parties before it, that rule is the controlling interpretation of federal law, and must be given full retroactive effect in all cases still open on direct review"); *Rivers v. Roadway Express, Inc.*, 511 U.S. 298 (1994) (a "judicial construction [by the Supreme Court] of a statute is an authoritative statement of what the statute meant before, as well as after, the decision of the case giving rise to that construction").

The basis of our earlier, unanimous opinion in this case was that the trial court erred in granting Soundtec's motion for summary judgment on the basis of federal preemption, because Soundtec did not provide evidence of any device-specific requirements related to the hearing device at issue. *Despain*, ___ Ark. at ___, ___ S.W.3d at ___. We further noted that we found nothing in the Despains' complaint that "would require a specific change in the way the hearing device was manufactured," and so their state common-law tort claim did not constitute a device-specific requirement that would be subject to preemption under the MDA. However, in light of the Supreme Court's conclusion in *Riegel*, *supra*, that state-law

tort claims are, in fact, preempted by the MDA, we are compelled to grant Soundtec's petition for rehearing and issue this substituted opinion whereby we affirm the trial court's order granting Soundtec's motion for summary judgment.[1]

HANNAH, C.J. AND BROWN, concur.

HANNAH, C.J., concurring. I concur. As the majority notes, in *Riegel v. Medtronic, Inc.*, ___ U.S. ___, 128 S. Ct. 999 (2008), the United States Supreme Court held that the State of New York's tort duties were preempted by the MDA. Therefore, our holding in the present case that Arkansas tort duties are not preempted must be reversed.

The United States Supreme Court is the court of last resort on questions of whether United States Congressional acts preempt state law. However, I must express my deep concern with the *Riegel* decision. Clearly the MDA preempts states from setting up regulatory systems that compete with the regulatory systems set up by the federal government under the MDA. The state's common law on tort is no such regulatory system. It does not compete with the MDA.

The core premise underlying the *Riegel* decision is that common-law tort damages constitute requirements preempted under the MDA because the award of damages may affect how medical devices are designed, manufactured, and sold. The fear is that changes made by medical device providers as a consequence of tort damage suits will be made based on what

[1] In our original opinion, we also held that the trial court erred in concluding that summary judgment was appropriate based on the "learned intermediary doctrine." However, because the Despains' complaint is now barred on federal preemption grounds, it is unnecessary to discuss this issue.

must be done to avoid future tort damages as opposed to increasing safety and effectiveness. The Court believes that the FDA is more reliable than juries in dealing with the issue of defective medical devices. I disagree.

No evidence was offered in *Riegel* to show that New York used its common-law tort damages as a means to set requirements for the safety and effectiveness of medical devices. Arkansas does not use common-law tort damages as a means to set requirements for the safety and effectiveness of medical devices. Arkansas has no special tort law that applies only to medical devices. The tort law that applies to medical devices in Arkansas applies to any other causes of action in tort.

Common-law negligence liability is based on a duty of care by a defendant to a plaintiff that the defendant has breached. *See Shannon v. Wilson*, 329 Ark. 143, 947 S.W.2d 349 (1997). The duty in common-law negligence arises from the relationship between the plaintiff and the defendant. *Id.* Compensatory damages redress the concrete loss that a plaintiff suffered from a defendant's wrongful conduct. *State Farm Mut. Ins. Co. v. Campbell*, 538 U.S. 408 (2003). In Arkansas, punitive damages are awarded only where the defendant's conduct is malicious or done with deliberate intent to injure another. *McCoy v. Montgomery,* 370 Ark. 333, ___ S.W.3d ____ (2007). Thus, neither form of damages constitutes a direct or indirect competing regulatory system in violation of the MDA. The common-law on tort is not preempted under the terms of the MDA.

I am also compelled to express my dismay at the summary abandonment of venerable principles of state common law that have been developed over many generations. By a

conclusory and incomplete analysis, our law is dismissed. In the place of well-reasoned judicial decisions reaching back to the England of Blackstone, injured plaintiffs are told that instead of looking to their common law for redress they must look to a regulatory agency that has no power to grant them any redress.

Further, the MDA, which was enacted to protect the public against defective and unsafe medical devices through federal regulation, is now turned on its head and instead grants immunity to the providers of medical devices. I believe that the United States Congress will step in to amend the MDA and heal the injury caused in this case; however, the injury done to the common law and principles of federalism will not be so easily healed.

BROWN, J., joins.