SIMPSON THACHER

REPORT FROM WASHINGTON

Supreme Court Bars State Common Law Claims Challenging Medical Devices with FDA Pre-Market Approval

March 6, 2008

TO VIEW THE SUPREME COURT'S DECISION IN *RIEGEL V. MEDTRONIC, INC.* — S.CT. — NO. 06-179 (2008), PLEASE CLICK HERE.

On February 20, 2008, the Supreme Court affirmed 8 - 1 the Second Circuit's decision in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008). The Court held that when a medical device is given pre-market approval from the Food and Drug Administration ("FDA"), the preemption clause of the Medical Device Amendments of 1976 ("MDA") bars several state common law claims challenging the device's safety or effectiveness. Such claims are preempted because they are based on state "requirements" that are "different from, or in addition to" the corresponding federal requirements, and are related to the safety and effectiveness of the device at issue. The Court thereby stripped plaintiffs of one means of challenging companies that manufacture defective medical devices. Although the decision is unlikely to have a direct impact on the viability of common law claims against drug manufacturers, the majority opinion left open the possibility of preemption in drug cases, and an appeal currently pending before the Supreme Court squarely presents this issue.

BACKGROUND

The *Riegel* appeal arose from a Second Circuit case captioned *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006). Plaintiffs brought suit against Medtronic after one of its catheters ruptured in Mr. Riegel's coronary artery during heart surgery. The catheter was a Class III device that had received pre-market approval from the FDA, a "rigorous" process involving the submission of studies relating to the device's safety and effectiveness, samples or device components, and proposed labeling. Plaintiffs alleged that the catheter was designed, labeled, and manufactured in a way that violated New York state common law and that the defects caused Mr. Riegel to suffer severe and permanent injuries. Petitioners brought common law claims for (1) negligence in the design,

The *Report From Washington* is published by the Washington, DC office of Simpson Thacher & Bartlett LLP.

testing, inspection, manufacture, distribution, labeling, marketing, and sale of the catheter; (2) strict liability; (3) breach of express warranty; (4) breach of implied warranty; and (5) loss of consortium.

The district court had held that Petitioners' strict liability and breach of implied warranty claims, and all claims of negligence other than the manufacturing claim, were preempted by the MDA. The claim for loss of consortium was preempted by the MDA to the extent it was derivative of the preempted claims. The lower court relied primarily on the Supreme Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which it interpreted as requiring three elements for a determination of preemption under the MDA: (1) a specific federal requirement governing the device at issue; (2) a specific state requirement relating to the safety of the device; and (3) a difference in, or addition to, the obligations between the state and federal law requirements. The district court later dismissed plaintiffs' remaining breach of express warranty and negligent manufacturing claims on other grounds.

The Second Circuit affirmed the district court's rulings. Like the district court, the Second Circuit analyzed *Lohr* and noted two 5-4 splits within the Supreme Court's decision. The first split resulted in a majority finding that only federal device-specific requirements could give rise to preemption, while the remaining Justices believed even general federal requirements could result in preemption. The second 5-4 split favored a finding that a state "requirement" as used in the MDA preemption clause could derive from state "common law," with the minority believing a state "requirement" only arose from state statutes and regulations. The Second Circuit stated that, since *Lohr*, a majority of circuits have held that common law tort actions relating to pre-market approved medical devices are preempted by the MDA, with only the Eleventh Circuit reaching the opposite conclusion. The Second Circuit then applied *Lohr* using a two-step process that considered (1) whether a device that obtains pre-market approval is subject to a federal device-specific requirement and (2) whether there is a conflict between the device-specific requirement and any liability basis of the state-law tort claims.

"State tort law that requires a manufacturer's catheters 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."

JUSTICE SCALIA
(opinion of the Court)

THE SUPREME COURT'S DECISION

In the opinion of the Court, delivered by Justice Scalia and joined by Chief Justice Roberts and Justices Kennedy, Souter, Thomas, Breyer, and Alito, the Supreme Court affirmed the Second Circuit's decision dismissing several of plaintiffs' state common law claims against the device maker. The Court held that the MDA preempts certain state common law claims challenging the safety or effectiveness of a medical device that has pre-market approval from the FDA.

At the outset of its analysis, the Court stated that the MDA "expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law." The Court then laid out a two-step process for answering the question before it: first, determine whether the federal government has established requirements applicable to defendant's catheter, and second, if so, determine if plaintiffs' common law claims are based upon state law requirements that are "different from, or in addition to," the federal requirements, and are related to safety and effectiveness.

For the first part of the analysis, the Court looked to its previous decision in *Lohr*, where the Court had determined that the MDA's preemption provision was "substantially informed" by the FDA regulation at 21 CFR § 808.1(d), which states that state requirements are preempted "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device . . . ." Applying this provision, the Court held in Lohr that certain federal manufacturing and labeling requirements, which applied to almost all medical devices, did not preempt common law negligence and strict liability claims, because those requirements were not specific to the device in question. The Court distinguished the present case, stating that FDA pre-market approval possessed the necessary attributes absent from the federal requirements at issue in *Lohr*: the approval is specific to individual devices and focuses on safety. Accordingly, the Court found that FDA pre-market approval imposes "requirements" under the MDA.

Having answered the first question in the affirmative, the Court turned to whether plaintiffs' common law claims relied upon "any requirement" of state law that was "different from, or in addition to" federal requirements and that related "to the safety or effectiveness of the device." The Court stated that "safety and effectiveness are the very subjects of [plaintiffs'] common law claims, so the critical issue is whether New York's tort duties constitute 'requirements' under the MDA." The Court then stated that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties." As the Court explained, "[s]tate tort law that requires a manufacturer's catheters 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." As a result, the Court held that "a provision pre-empting state 'requirements' pre-empted common-law duties," and thus plaintiffs' claims were preempted by the MDA.

The Court declined to address plaintiffs' argument that the lawsuit raised "parallel" claims not preempted by the MDA, because plaintiffs failed to raise this argument in their Second Circuit briefs or their petition for certiorari. The Court noted, however, that the MDA "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."

Dissenting from the majority opinion, Justice Ginsburg asserted that the MDA preemption clause was enacted to respond to state regulation of medical devices created during an absence of FDA regulation, not to address state common law claims. She stated, "state premarket regulation of medical devices, not any design to suppress tort suits, accounts for Congress' inclusion of a preemption clause in the MDA; no such clause figures in earlier federal laws regulating drugs and additives, for States had not installed comparable control regimes in those areas." Justice Ginsburg also stated that the MDA's failure to create any federal compensatory remedies suggests that Congress did not intend to broadly preempt common law suits. Finally, Justice Ginsburg suggested that, because manufacturers could present regulatory compliance as a defense in court, a holding that the MDA failed to preempt state common law claims would not render the

"[S]tate premarket regulation of medical devices, not any design to suppress tort suits, accounts for Congress' inclusion of a preemption clause in the MDA; no such clause figures in earlier federal laws regulating drugs and additives, for States had not installed comparable control regimes in those areas."

JUSTICE GINSBURG
(dissenting)

FDA's pre-market approval of devices irrelevant.

Justice Stevens concurred with the Court's judgment, but wrote separately to state that, while he agreed with Justice Ginsburg regarding the overall purpose of the MDA's preemption clause, "the language of the provision reaches beyond such regulatory regimes to encompass other types of 'requirements.'"

IMPLICATIONS

The Court's decision in *Riegel* precludes would-be plaintiffs from bringing several state common law claims challenging the safety or effectiveness of "medical devices" that have received pre-market approval from the FDA. In its analysis, the Court reaffirmed the two-step analysis for determining whether particular state law requirements are preempted by the MDA: first, determine whether the federal government has established requirements applicable to the medical device at issue, and second, if so, determine whether the state law requirements are "different from, or in addition to," the federal requirements and are related to safety and effectiveness. Furthermore, by adopting a broad definition of "state law requirements," the Court extended the reach of the MDA's preemption clause.

The Court's decision, however, does not leave injured claimants without any remedy against device manufacturers. The Court was careful not to comment on the viability of state common law claims not specifically at issue in plaintiffs ' suit. Moreover, the decision applies only to those devices that undergo FDA pre-market approval review, and not those that enter the market via the less exacting 510(k) process. And for devices that receive FDA pre-market approval, plaintiffs may still bring state tort claims based on a manufacturer's deviation from the standards set forth in the device's pre-market approval application.

Finally, although only common law claims against device manufacturers were at issue in plaintiffs' suit, both the majority opinion and the dissent touched briefly on the issue of common law claims against drug manufacturers. Justice Ginsburg noted that courts have "overwhelmingly held that FDA approval of a new drug application does not preempt state tort suits," while the majority asserted that "[i]t has not been established (as the dissent assumes) that no tort lawsuits are pre-empted by drug or additive approval under the FDCA." The specific basis of the Court's decision is unlikely to have a direct impact on the viability of state common law claims against drug manufacturers, as the Court's opinion rests largely on the language of the MDA's preemption clause, and the Food, Drug and Cosmetic Act ("FDCA"), unlike the MDA, does not contain such a clause. However, this issue is squarely presented in an appeal currently pending before the Supreme Court in *Wyeth v. Levine*, No. 06-1249. In *Levine*, the Supreme Court granted Wyeth's petition for certiorari from a decision of the Vermont Supreme Court rejecting the defense that the FDA's approval for the drug Phenergan preempted state common law product liability claims, despite the FDA having recently promulgated a "preemption preamble" to its FDCA regulations to the effect that state common law product liability design and warning claims should be preempted by an FDA new drug application approval.

For further information about this case, please feel free to contact the following Members of the Firm:

New York City:

Roy Reardon
212-455-2840
rreardon@stblaw.com

David Ichel
212-455-2563
dichel@stblaw.com

Mark Cunha
212-455-3475
mcunha@stblaw.com

Robert Bourque
212-455-3595
rbourque@stblaw.com

Mary Elizabeth McGarry
212-455-2574
mmcgarry@stblaw.com

Joseph McLaughlin
212-455-3242
jmclaughlin@stblaw.com

Lynn Neuner
212-455-2696
lneuner@stblaw.com

Palo Alto

George Newcombe
650-251-5050
gnewcombe@stblaw.com

Washington DC:

Peter Thomas
202-220-7735
pthomas@stblaw.com

Arman Oruc
202-220-7799
aoruc@stblaw.com

UNITED STATES

New York
425 Lexington Avenue
New York, NY 10017-3954
212-455-2000

Washington, D.C.
601 Pennsylvania Avenue, N.W.
North Building
Washington, D.C. 20004
202-220-7700

Los Angeles
1999 Avenue of the Stars
Los Angeles, CA 90067
310-407-7500

Palo Alto
2550 Hanover Street
Palo Alto, CA 94304
650-251-5000

EUROPE

London
Citypoint
One Ropemaker St.
London EC2Y 9HU England
+44-20-7275-6500

ASIA

Beijing
3119 China World Tower One
1 Jianguomenwai Avenue
Beijing 100004, China
+86-10-5965-2999

Hong Kong
ICBC Tower
3 Garden Road
Hong Kong
+852-2514-7600

Tokyo
Ark Mori Building
12-32, Akasaka 1-Chome
Minato-Ku, Tokyo 107-6037, Japan
+81-3-5562-6200

www.simpsonthacher.com