

High Court Clarifies Tort Law But Skirts Broad Claims

By **Allison Grande**

Law360, New York (July 6, 2011) -- In significant rulings this term, the U.S. Supreme Court tightened the standards for bringing product liability cases against companies, but showed that it will continue to interpret the intent of a statute when determining whether state tort claims are preempted by federal law or barred by jurisdictional restraints, attorneys say.

The high court took a slightly manufacturer-friendly tilt in their consideration of tort claims this past term, handing wins to generics makers, the childhood vaccine industry, and foreign manufacturers accused of producing products that were defective due to labeling or design.

But the Supreme Court also found in favor of plaintiffs seeking to hold the automobile industry liable for failing to install lap-and-shoulder belts — a decision that showed the court's willingness to consider a preemption issue that many believed had been decided in an earlier case before the court — and sided with plaintiffs who challenged a federal judge's authority to stop a state court from certifying a class action over Bayer Corp.'s Baycol.

These rulings clarified which tort claims plaintiffs can lawfully bring against businesses in several industries and sent a message to both sides that it would be wrong to generalize about the high court's attitude toward these issues, especially preemption.

“Over the past several terms, the court has recognized the importance of preemption and accepted a steady stream of preemption cases,” Mayer Brown LLP Supreme Court and appellate partner Andy Tauber told Law360. “But the results haven't been uniformly pro-business or pro-plaintiff. Instead, they're always answered in the specific context of how the statute or regulation at issue interacts with the state law claims at issue.”

One of the most significant preemption cases of the term, which will severely hinder plaintiffs' ability to bring failure-to-warn claims against generic-drug makers, demonstrated this tendency to focus on the issues of the current case, rather than relying on prior case law.

On June 23, the high court in a 5-4 decision reversed Fifth Circuit and Eight Circuit decisions that allowed

state-law tort claims against Pliva Inc. and Activis Inc. in consolidated suits claiming they failed to warn consumers that generic versions of Wyeth Inc.'s Reglan were tied to the neurological disorder tardive dyskinesia.

This finding that federal law preempts state failure-to-warn claims against generic-drug manufacturers came just two years after the high court's decision in *Wyeth v. Levine*, which allowed such state claims to proceed against name-brand companies.

"Pliva was a bit surprising [in light of *Wyeth*], but it makes good sense when you understand the purpose behind the rules and regulations that govern generics," said Peg Donahue Hall, one of the leaders of SNR Denton's health and life sciences industry sector.

By holding that the consumers could not maintain their state law tort claims because they conflict with federal law requiring generic-drug labels to be the same as corresponding brand-name drug labels, the high court's decision was consistent with the Hatch-Waxman Act's intent to allow generic makers to bring drugs to consumers at a lower price without the cost of testing and analysis needed to meet labeling requirements, according to Hall.

The ruling also demonstrates that the manufacturer's ability to act independently could play a vital role in deciding preemption moving forward, Reed Smith LLP life sciences and health industry group partner Adam Masin said.

"The decision shows that the Supreme Court is not in the business of speculating what the [U.S. Food and Drug Administration] might do in a hypothetical situation," Masin said. "Just because the risks don't match up with the label that has been approved doesn't necessarily mean that the FDA would find it to be misbranded."

This finding might actually benefit brand name manufacturers by helping them stave off future claims alleging that they should have done something that they did not have the independent authority to do, Masin added.

Even though the recent decision will make it much more difficult for plaintiffs to seek relief against generics makers, Hall pointed out that other causes of action — including claims related to manufacturing problems and design defects — could still be brought, and agreed with Masin's point that the ruling didn't necessary toll the death knell for cases against generics makers.

"This decision merely addressed one particular claim that is preempted by the statute," Hall said. "The ruling gives manufacturers more tools to defend against product liability cases, but plaintiffs' lawyers are creative, and if there are legitimate claims, they will make their way into court."

The vaccine industry also received a favorable ruling during the past term, when the high court in February handed down a 6-2 decision in *Bruesewitz et al. v. Wyeth* that held that the National Childhood Vaccine Injury Act preempted state law claims against vaccine makers over alleged design defects.

As in the generics preemption case, the Supreme Court looked closely at the intent of the disputed statute, and concluded that Congress meant for the 1986 act to protect state law liability claims when companies' vaccines were properly manufactured but nevertheless injured a small percentage of people.

Holding otherwise, Justice Antonin Scalia wrote in the majority opinion, would not only torture the text of the statute itself, but would also violate the clear intent of the law, which was to ensure a reliable supply of vaccines by protecting their manufacturers from outsize jury awards.

"The Supreme Court looked to the plain language of the National Childhood Vaccine Injury Act, and to the purpose and objectives of Congress in setting up the act," Gibson Dunn & Crutcher LLP partner Daniel Thomasch said. "The court concluded that the policies promoted by the act – including saving the lives of children – would be furthered by allowing the [Department of Health and Human Services], not juries, decide how vaccines should be designed."

However, the high court came out with the opposite result when it applied this same analytical method to its ruling issued the following day in *Williamson v. Mazda Motor of America*.

In the Mazda case, the Supreme Court unanimously held that the Federal Motor Vehicle Safety Standard did not bar state tort claims over injuries from lap-only seatbelts.

This ruling contrasted with the high court's 2000 ruling in *Geier v. American Honda Motor Co.*, which held that federal regulations protected car companies from facing state law claims over their alleged failure to install air bags.

The high court differentiated the *Williamson* action from its earlier decision by holding that the disputed federal regulation governing the installation of lap-and-shoulder belts is not about choice but rather about setting a minimum safety standard, thereby allowing plaintiffs to seek relief for manufacturers' failure to go above and beyond that standard and sending a message to manufacturers that mere compliance with a federal minimum safety standard does not exempt a manufacturer from liability under state common law.

"The differing preemption findings in *Bruesewitz* and *Williamson* were very much driven by the importance of the product design choice at issue, and by the risks of allowing lay juries to have free reign over those product design choices," Thomasch said.

"Justice [Stephen] Breyer's opinion for the court in *Williamson* was premised on a finding that it was not a significant objective of the federal regulation at issue to prevent tort suits from restricting the freedom of manufacturers to choose between lap belts and lap-and-shoulder belts in middle rear car seats," Thomasch added. "In contrast, Justice Breyer's concurring opinion in *Bruesewitz* stressed his recognition that the statute at issue delegated responsibility for overseeing the safety of childhood vaccines to the Department of Health and Human Services, and that permitting design defect product liability suits would threaten a crisis in the supply of life-saving vaccines."

The past term also saw an opening for class action plaintiffs to bring product liability class actions, when the high court ruled June 16 in a unanimous finding in *Smith v. Bayer Corp.* that a Minnesota federal judge did not have the authority under the Anti-Injunction Act's relitigation exception to enjoin a West Virginia state court from considering certification of a class of Baycol consumers.

Even though that judge had denied certification in a similar product liability case over Baycol, “the federal court's resolution of one issue does not preclude the state court's determination of another,” the justices held.

“Class action litigation by its nature can be expensive, so this decision is not a positive for manufacturers because it allows plaintiffs to do some amount of forum shopping if they lost their case in federal court,” Hall said.

But plaintiffs will have a tougher time bringing their claims in state court against foreign manufacturers, after a pair of rulings issued by the court on June 27 found that these companies cannot be sued unless their allegedly defective products have a clear link to that jurisdiction.

In *Goodyear Dunlop Tires Operations SA v. Brown* and *J. McIntyre Machinery Ltd. v. Nicastro*, the high court reversed rulings by the Supreme Court of New Jersey and the Court of Appeals of North Carolina, concluding that the out-of-state corporate defendants' in-state contacts were not sufficiently “continuous and systematic” to justify the states' jurisdiction over claims unrelated to those contacts.

“At a time when globalization is pretty prominent and many companies have affiliates and sister companies that are foreign, these two cases on specific and general jurisdiction are helpful in clarifying and solidifying the type of conduct that will get companies hauled into court in a certain area,” Hall said. “A ruling against manufacturers could have had a real negative impact for U.S. consumers because foreign institutions would have been afraid of having their product come into the U.S.”

But while both rulings provided clarification on these issues, the *McIntyre* decision stopped short of deciding how these considerations should apply to an Internet marketing scheme that targets the entire country, but not any specific state, thereby leaving the door open for the court to decide in the future whether foreign manufacturers that rely on the Internet to market their products will be permitted to avoid state law product liability suits, Thomasch added.

The issue of preemption will also certainly come up again in future terms, with the high court already agreeing to hear one preemption case — *Kurns v. Railroad Friction Products*, which addresses whether the Locomotive Inspection Act bars product liability tort claims over asbestos exposure — in its next term.

“It will not be surprising if the court accepts several preemption cases for argument in the fall term,” Thomasch said. “Preemption issues are going to keep coming up because of pervasive government regulation of manufacturers. While the circumstances of each case will differ, businesses are going to continue to argue that juries should not be permitted to predicate tort liability on design or labeling choices that are the product of judgments made by expert federal agencies.”

While the courts newest members, Justices Elena Kagan and Sonia Sotomayor, have so far tended to side with the plaintiffs, their impact has not been significantly felt yet, and attorneys are also looking forward to seeing how their presence will impact the court in future terms.

“My take on Supreme Court justices is that their impact lies in their ability to persuade members of the court who don't share their ideology to come over to their side in a particular case, or their impact lies in their ability to surprise and end up on the side of the case where they weren't expected to land,” Masin said. “So in that sense that Justices Kagan and Sotomayor have so far been fairly predictable and haven't persuaded anyone, it's hard to predict what their real impact on the court will be.”

--Additional reporting by Erin Fuchs. Editing by Pamela Wilkinson and Chris Giganti.

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