Legal Backgrounder

WLF Washington Legal Foundation

Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Vol. 26 No. 7 March 25, 2011

U.S. SUPREME COURT PREEMPTION TRILOGY: THE SEQUEL

by
Eric G. Lasker

In its 2010-2011 Term, the United States Supreme Court granted certiorari to three cases in which defendants asserted federal preemption defenses in response to state common law tort claims in products liability litigation. The Court's focus on federal preemption of product liability claims follows closely on the heels of its similar consideration in its 2008-2009 Term of three cases that likewise addressed the scope of the preemption defense in such litigation. However, while the Court's first preemption trilogy in its 2009-2010 Term offered the promise of some much-needed guidance on the preemption doctrine and highlighted significant philosophical divisions in the Court over the virtues or demerits of preemption in securing public health and safety, the 2010-2011 sequel – as is so often the case with sequels – is not living up to the same billing. With two of the three 2010-2011 preemption cases now decided, the Court appears resigned to a case-by-case approach to preemption in which rulings will be narrowly decided based on the specific facts of each federal statute and regulatory regime at issue.

This LEGAL BACKGROUNDER will first review the philosophical debate that dominated the Court's 2008-2009 preemption rulings. It will then turn to the Court's narrower approach to date in its preemption rulings in its 2010-2011 Term and discuss what these rulings portend for the future of the preemption defense.

The Supreme Court's First Preemption Trilogy: **Riegel, Kent,** ***and*** **Levine**. In 2008, after having issued a handful of difficult-to-reconcile preemption rulings over the prior 25 years, the United States Supreme Court appeared intent on providing clearer guidance on the scope of federal preemption in products liability litigation, granting certiorari in cases involving prescription drugs, medical devices, and tort reform statutes including fraud on the FDA exceptions. The Court's rulings, however, were a mixed bag – with one win each for pro- and anti-preemption advocates and a 4-4 summary affirmance in the remaining case. *See Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (rejecting preemption in prescription drug case); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (finding preemption in Class III medical device case); *Warner Lambert v. Kent*, 552 U.S. 440 (2008) (4-4 summary affirmance in statutory fraud on the FDA preemption case). Notably, the rulings exposed the deep division among the Justices on the underlying policy questions surrounding the product liability preemption debate.

Eric G. Lasker is a partner in the Washington, D.C. law firm Hollingsworth LLP.

In the Court's first preemption ruling written by Justice Scalia in *Riegel*, a 7-2 Court held that an express preemption provision in the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a), precluded state common law claims of negligence, strict liability, and implied warranty brought against the manufacturer of a Class III medical device. While the Court's reasoning centered on the plain language of the MDA preemption clause, Justice Scalia's opinion was bolstered by his belief that a contrary interpretation of the MDA "would make little sense" because of the strong policy arguments supporting preemption:

> 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. … A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.

Riegel, 552 U.S. at 325. While the Court expressly disavowed any intention in *Riegel* to resolve the separate question of implied preemption of state tort law claims involving prescriptions drugs (which was then pending before the Court in *Wyeth v. Levine*), *see id.* at 326, Justice Scalia's public policy argument seemed equally applicable to state tort law prescription drug claims, which disrupt an FDA federal regulatory scheme that is in many ways substantively identical to that governing Class III medical devices. In her dissenting opinion, Justice Ginsburg took direct aim at Justice Scalia's public policy analysis, arguing that "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection" and that "[p]reemption of all [state tort liability] claims would result in the loss of a significant layer of consumer protection." *Id*. at 337 (citation omitted).

In *Wyeth v. Levine*, the Court reversed tack and rejected preemption of state tort law prescription drug claims. Unlike *Riegel*, *Wyeth* addressed an implied preemption defense, a distinction that was likely central to some of the justices' decision to switch sides (particularly Justice Thomas, who has traditionally been the strongest Court opponent of implied preemption arguments). Once again, however, the Court's majority and dissent dueled over the policy arguments that underpin the preemption debate. Now writing for the majority, Justice Ginsburg returned to the same theme expressed in her *Riegel* dissent, contending that state tort law claims provide a necessary separate layer of consumer protection:

> [I]t appears that the FDA traditionally regarded state law as a complementary form of drug regulation. … State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. … Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

Levine, 129 S. Ct. at 1202. The dissent (in which Scalia joined) in turn repeated its contrary argument that had won the day in *Riegel*: "By their very nature, juries are ill-equipped to perform the FDA's cost-benefit-balancing function. As we explained in *Riegel*, juries tend to focus on the risk of a particular product's design or warning label that arguably contributed to a particular plaintiff's injury, not to the overall benefits of that design or label." *Id.* at 1229-30.

The Preemption Trilogy Take Two: **Bruesewitz, Williamson, *and* Mensing**. Flash forward two years and the Supreme Court once again is grappling with three cases involving preemption of products liability claims. With the first two cases now decided, however, it appears that the Court has largely abandoned the big theme policy debate over preemption and has resigned itself instead to a narrow, case-by-case approach to the preemption defense. *See Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011); *Williamson v. Mazda Motor of Am., Inc.*, 2011 U.S. LEXIS 1711 (Feb. 23, 2011); *Pliva, Inc. v. Mensing*, 131 S. Ct. 817 (2010) (granting cert).

On February 22, 2011, the Court issued a 6-2 opinion in *Bruesewitz* (with Justice Kagan recusing) holding that design defect claims against vaccine manufacturers are preempted by the National Childhood Vaccine Injury Act (NCVIA). If ever there was a case that called for an opinion staking out a strong public policy in favor of preemption, *Bruesewitz* is surely that case. Congress enacted the NCVIA in 1986 specifically to address a litigation-created crisis in which vaccine manufacturers were being driven out of business by the risk of tort liability. Recognizing the vital importance of vaccines to the public health, Congress set up a two-part statutory scheme that (1) protected vaccine manufacturers from tort liability through, *inter alia*, an express preemption provision and (2) set up a no-fault regulatory claims process to provide allegedly injured claimants with an alternative venue to seek monetary relief. As the United States explained in its *amicus* brief in support of preemption, the express preemption provision in the NCVIA was specifically intended and necessary to enhance the public health: "Congress enacted the Vaccine Act … in significant part to alleviate the large and potentially unknowable tort liability that vaccine manufacturers faced. That exposure had increasingly led manufacturers to cease production of vital vaccines, which in turn threatened vaccine shortages and the resurgence of preventable diseases." *See Amicus* Brief for the United States, *Bruesewitz v. Wyeth LLC*, No. 09-152, at 7 (filed July 30, 2010). As explained by in the United States' *amicus* brief, a holding in favor of preemption in this case was literally a holding necessary to save lives.

Rather than building off this strong public policy foundation, however, Justice Scalia (again writing for the majority) went out of his way to disavow any reliance on the reasoning he expressed in *Riegel*. *See Bruesewitz*, 2011 WL 588789, at *8 & n.63 (holding that it was reasonable for Congress to "leave complex epidemiological judgments about vaccine design to the FDA" but noting that "[l]eaving [such judgments] to the jury may (or may not) be reasonable as well; *we express no view*") (emphasis added). Instead, Justice Scalia focused on a detailed, and in some places almost impenetrable, grammatical parsing of the statutory language of the NCVIA preemption provision that centered, *inter alia*, on the meaning of the word "unavoidable," the "subtle distinction" between the words "because" and "despite," and his reading of a key clause in the preemption provision as a "concessive subordinate clause." *Id.* at *6 & n.43. While Justice Sotomayor, writing for the dissent, appeared more interested in engaging in the public policy debate, *see id.* at *22, the majority's focus on narrow statutory interpretation issues required her to devote the bulk of her argument to responding in kind.

The day after issuing its pro-preemption opinion in *Bruesewitz*, the Court held in favor of the plaintiff in *Williamson*, ruling unanimously that a product liability claim against an automobile manufacturer for installing a rear seat lap seat belt rather than a lap-and-shoulder seat belt was not impliedly preempted by Federal Motor Vehicle Safety Standard 208, despite the Department of Transportation's express decision to leave manufacturer's with a choice as between such seat belts. As with *Bruesewitz*, *Williamson* teed up a number of fundamental preemption issues that could have resulted in a far reaching opinion, including whether (1) the Court would depart from its earlier holding in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000) that a regulatory decision expressly leaving a choice to a manufacturer was preemptive and (2) a federal decision based upon a cost-benefit analysis rather than a risk-benefit analysis could be preemptive. The Court, however, again refused to engage in these larger arguments and decided *Williamson* on narrower grounds. First, the Court reaffirmed its ruling in *Geier*, but held that the DOT decision to leave manufacturers a choice between seatbelts was not preemptive because "unlike *Geier*, we do not believe here that choice is a significant regulatory objective." *Williamson*, 2011 WL 611628, at *7. Second, the Court ruled narrowly on the

issue of cost-benefit preemption, holding that "[w]hile an agency could base a decision to pre-empt on its cost-effectiveness judgment, we are satisfied that the rulemaking record at issue here discloses no such preemptive intent." *Id.* at *8.

At the time of this LEGAL BACKGROUNDER's release, briefing has not yet been completed on *Mensing*, but the preemption issue in that case – whether the *Levine* preemption ruling should be extended to generic prescription drug manufacturers who are subject to much more exacting FDA limitations on what they can and cannot say on a drug label – seems destined for a narrow ruling as well.

Preemption Take III – What's Next? Thus far, the Court's second preemption trilogy provides a clear signal that future questions on whether particular federal regulatory or statutory schemes preempt state tort law will be resolved not on the basis of broad policy arguments but rather on a case-by-case analysis of specific statutory language, regulatory history, and federal decision-making. Ironically, however, this case-by-case approach may make it more important than ever that the parties litigating preemption issues highlight the policy arguments that informed the specific federal decisions at issue. It also places a premium on an early engagement on preemption issues well before litigation is filed.

While the Court went to great lengths in *Bruesewitz* and *Williamson* to explain its opinions on narrow grounds, the lack of any clear bright line preemption rule in those cases leads inevitably to the conclusion that success in preemption litigation will turn in the first instance on which party succeeds in defining the narrative through which a court will view its analysis. In *Bruesewitz*, for example, the Court's detailed grammatical dissection of the NCVIA's express preemption provision could not hide the fact that both sides' proposed statutory interpretations rendered parts of the statutory language superfluous. *See Bruesewitz*, 2011 WL 588789 at *7. The majority opinion may have had the better of this interpretive argument, but it is difficult to credit either side's view that Congress clearly expressed its intent through the at-best inartfully-worded express preemption provision. It is likewise difficult to believe that the important public health goals specifically furthered by preemption of vaccine design defect claims did not guide the Court in reaching the proper statutory interpretation conclusion. Even more so, in *Williamson*, the Court's determination that the implied preemption decision turns on the "significance" of the federal regulatory decision at issue sets the stage in future preemption cases for battles over whether the policies underlying particular regulatory decisions are sufficiently (or insufficiently) significant.

Bruesewitz and *Williamson* also demonstrate that preemption arguments will often be won or lost in the congressional and regulatory decision-making at the time the potentially preemptive federal decision is made. While the doctrine of preemption rests upon the broad constitutional principle that federal law is supreme over state law, the practice of litigating preemption claims rests upon the definition of what the federal law is and how that properly-defined federal law applies to a specific defendant in a specific case. This places a premium not only on parties engaging in the legislative and regulatory debate when federal law is enacted, but also on parties establishing a clear, documented record of the application of the federal law to the specific private party actions that may be at issue in future products liability litigation.

Finally, *Bruesewitz* and *Williamson* demonstrate – as does the now over 30 year history of Supreme Court preemption jurisprudence – that, absent some future significant reconfiguration of the Court, both side's hopes for a knockout victory on products liability preemption are in vain. Absent a directly applicable Supreme Court ruling, parties in product liability litigation must prepare anew for preemption arguments in each case.