LJN'S
Product Liability
Law & Strategy®

LJN LAW JOURNAL NEWSLETTERS

An ALM Publication

Volume 30, Number 7 • January 2012

PRACTICE TIP

Pliva, Inc. v. Mensing

Does It Reopen the Door For Targeted Preemption Arguments?

By Eric Lasker

In 2009, the United States Supreme Court issued a 6-3 opinion rejecting the argument that FDA approval of brand-name prescription drug labeling preempts state tort law claims in pharmaceutical product liability litigation premised on the alleged inadequacy of those same labels. *See Wyeth v. Levine*, 129 S. Ct. 1187 (2009). In so ruling, the Court relied on the FDA's "changes being effected" or CBE regulations, whereby brand name prescription drug manufacturers are permitted to make certain changes to their labels before receiving the FDA's approval. *Id*. at 1196. The Court also held that, at least based on the facts presented in that case, the imposition of state tort law liability against the prescription drug manufacturer did not frustrate federal objectives in the regulation of prescription drugs. *Id*. at 1204.

An Open Door?

While *Levine* shut the door on the argument that FDA regulation constitutes a *per se* bar to state tort law prescription drug product liability claims, the opinion appeared to leave the door open for some more targeted preemption arguments:

- The Court's focus on the CBE regulations governing brand-name prescription drugs, *see Id*. at 1199, suggested that a different preemption ruling might apply to generic drug manufacturers that do not have CBE authority but, rather, are required to use labeling identical to that in the corresponding brand-name drugs.
- The Court suggested that preemption might be appropriate if there were evidence that the FDA would have rejected stronger label warnings with respect to the alleged health risk at issue. *See Id*. at 1988 ("absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements").
- The Court expressly refused to address the question whether negligent marketing claims — *i.e.*, claims that a drug manufacturer should not have marketed a drug at all — were preempted by FDA approval of the drug as safe and effective. *See Id*. at 1194 (we "need not decide whether a state rule proscribing intravenous administration would be pre-empted").
- The Court distinguished, and therefore indicated its continued adherence to, the holding in *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), that claims alleging fraud on the FDA were preempted. *Id*. at 1195 n.3.

The Courts and *Levine*

In the two years following *Levine*, however, aside from the fraud-on-the-FDA preemption argument that continues to have its own *Buckman* Supreme Court imprimatur, *see, e.g.*, *In re Aredia & Zometa Prods. Liab. Litig.*, Nos. 08-5573, 09-5574, 08-5575, 2009 WL 4072074 (6th Cir. Nov. 24, 2009), lower courts have repeatedly read *Levine* broadly as leaving no room whatsoever for preemption arguments in prescription drug product liability litigation. *See Gaeta v. Perrigo Pharms. Co.*, 630 F.3d 1225, 1230 (9th Cir. 2011) (holding that "while not dispositive, *Levine* does foreshadow a similar disposition" in cases involving generic drugs and rejecting preemption); *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010) (same); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 607 (8th Cir. 2009) (same); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 393-396 (7th Cir. 2010) (holding that the long history of FDA rejection of stronger suicide warnings on SSRI drug labels was not sufficient for preemption under *Levine*); *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142, 1159 (C.D. Cal. 2010) (same); *Baumgardner v. Wyeth Pharms.*, 2010 WL 3431671, *1 (E.D. Pa. Aug. 31, 2010) (same); *Aaron v. Wyeth Pharms.*,

Eric Lasker, a member of this newsletter's Board of Editors, is a partner in the Washington, DC, law firm Hollingsworth LLP, where he specializes in pharmaceutical product liability, toxic tort, environmental, and Alien Tort Statute litigation. Mr. Lasker is the Chair of the Toxics and Hazardous Substances Committee of the International Association of Defense Counsel.

2010 WL 653984, at *6 (W.D. Pa. Feb. 19, 2010). It was thus notable, and somewhat surprising, given the uniform holdings of the circuit courts, that the U.S. Supreme Court reached out again to address prescription drug preemption in 2011 in the context of generic drug manufacturers.

Pliva, Inc. v. Mensing

The Court's ruling in *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) — which was fully addressed last month in an article by Steven Glickstein — rejected the anti-preemption holdings in the Fifth, Eighth, and Ninth Circuits. The Court made clear that the focus placed in *Levine* on the CBE regulation for brand-name drugs was in fact dispositive, and that the lack of such a regulation allowing label changes for generic drug manufacturers required that state common law claims against those manufacturers be preempted. *Mensing* does not address the question of whether the other potential openings in *Levine* for prescription drug preemption arguments are likewise broader than subsequent lower court opinions would suggest. As set forth below, however, there is language in the *Mensing* opinion written by Justice Thomas, as well as in Justice Sotomayer's dissenting opinion in that case, which suggests that the Court might be similarly receptive to these other prescription drug preemption arguments as well.

Justice Thomas on Implied Preemption

As a matter of general preemption jurisprudence, *Mensing* is notable in that it appears to mark an evolution — or perhaps resolution — of Justice Thomas's thinking on implied preemption. Although his general position on the conservative wing of the Court might suggest to outsiders that he would be favorably inclined to preemption arguments, Justice Thomas has in fact been one of the stronger voices on the Court against implied preemption, which he has viewed as being inconsistent with the governing principles laid out in the U.S. Constitution. Thus, for example, in *Levine*, Justice Thomas not only joined the majority in opining that brand-name prescription drug product liability litigation was not *per se* preempted, but issued a separate concurring opinion because he could not "join the majority's implicit endorsement of far-reaching implied preemption doctrines." *Levine*, 129 S. Ct. at 1206 (Thomas, J. concurring). In particular, Justice Thomas stated that, in light of the limitations of federal power set forth in the constitutional principle of "enumerated powers" and the "constitutionally required bicameral and presentment procedures," he had become "increasingly reluctant to expand federal statutes beyond their terms through doctrines of implied preemption." *Id*. at 1206, 1207 (quoting his concurrence in part and dissent in part in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005)).

While Justice Thomas did not abandon those concerns in *Mensing*, he arrived at a new constitutional analysis of the preemption doctrine that appears to have provided him with a foundation upon which to find in favor of implied preemption arguments in the future. In a plurality portion of his opinion (joined by Justices Roberts, Scalia, and Alito), Justice Thomas focused on the text of the Supremacy Clause to the U.S. Constitution, which states that federal law shall be supreme, "any thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. Art. VI, cl. 2; *see Mensing*, 131 S. Ct. at 2579. Justice Thomas explained that the phrase "any [state law] to the Contrary notwithstanding is a *non obstante* provision," which 18th-century legislatures used "to specify the degree to which a new statute was meant to repeal older, potentially conflicting statutes in the same field." *Mensing*, 131 S. Ct. at 2579. As explained by Justice Thomas, the implications of the Constitution's use of a *non obstante* provision in the Supremacy Clause are quite significant.

First, the *non obstante* provision in the Supremacy Clause means that the "presumption against preemption" that has been invoked in prior implied preemption cases, *see, e.g.. Levine*, 129 S. Ct. at 1194 and n.3, is incorrect. As Justice Thomas stated, "a *non obstante* provision in a new statute acknowledged that the statute might contradict prior law and instructed courts *not* to apply the general presumption against implied repeals." *Mensing*, 131 S. Ct. at 2579 (emphasis added). "The *non obstante* provision in the Supremacy Clause therefore suggests that federal law *should be understood* to impliedly repeal conflicting state law." *Id*. at 2580 (emphasis added) Second, Justice Thomas explained that the non obstante provision "suggests that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law." *Id*. "A *non obstante* provision … was a useful way for legislatures to specify that they did not want courts distorting the new law to accommodate the old." *Id*. "The *non obstante* provision of the Supremacy Clause indicates that a court need look no further than the ordinary meaning of federal law, and should not distort federal law to accommodate conflicting state law." *Id*. (internal quotations omitted). Again, this conclusion appears to mark a departure from the Supreme Court's prior holdings, which argued for a higher standard of Congressional intent before holding state law impliedly preempted. *See, e.g., Levine*, 129 S. Ct. at 1195 (arguing that implied preemption should not be found "unless that was the clear and manifest purpose of Congress"). *See also Mensing*, 131 S. Ct. at 2591 (Sotomayor, J., dissenting) (characterizing Justice Thomas's *non obstante* analysis as "a direct assault" on the Court's preemption precedents").

Perhaps more notable even than the implications of this *non obstante* analysis is the fact that — as Justice Sotomayor noted in her dissent — this analysis was "advocated by no party or *amici* in these cases." *Mensing*, 131 S. Ct. at 2591-92 (Sotomayor, J., dissenting). Rather, the *non obstante* analysis appears to reflect Justice Thomas's own dissatisfaction with prior preemption jurisprudence and his independent efforts to find some new constitutional mooring for the implied preemption doctrine.

To the extent that *Mensing* thus marks an evolution of Justice Thomas's thinking about implied preemption, it could signal an important development in future implied preemption disputes, not only in brand-name prescription drug litigation, but also in all other areas as well. Prior to *Mensing*, there were three and possibly four Justices who could be counted on as likely "Yes" votes on implied preemp-

tion arguments (Justices Roberts, Scalia, and Alito, with Justice Kennedy perhaps somewhat less predictable). Justice Breyer was a potential fifth vote, but he was far more unpredictable. However, if Justice Thomas is now moving into the implied preemption camp, future preemption advocates before the Supreme Court will have a significantly stronger hand, and the possibility exists that a new voting block could form that would notably expand the reach of implied preemption moving forward.

Justice Sotomayor's Apparent Openness to Targeted Preemption Arguments

Given her rejection of the implied preemption argument for generic drug manufacturers, it is perhaps surprising that brand-name prescription drug manufacturers may wish to rely on Justice Sotomayor's dissenting opinion in *Mensing* to support implied preemption arguments in their cases. However, in the course of explaining why she did not believe a *per se* preemption rule was appropriate for generic drug manufacturers, Justice Sotomayor (and arguably the three other Justices who joined her dissent, Justices Ginsburg, Breyer, and Kagan) appeared to go further than the majority had in *Levine* to signal an openness to targeted prescription drug preemption arguments, particularly in cases where the FDA had considered and not approved the increased warnings that product liability plaintiffs allege necessary through their state tort law claims. This potential openness is noteworthy as well because Justices Sotomayor and Kagan were not on the Court when *Levine* was decided, and are thus setting forth their positions for the first time.

In rejecting the *Mensing* majority's distinction between generic and brand-name prescription drug manufacturers, Justice Sotomayor argued that before finding state tort law claims against generic manufacturers preempted she would "as in *Levine* … require the Manufacturer to show that the FDA would not have approved a proposed label change." *Mensing*, 131 S. Ct. at 2588. Building considerably on the potential preemption exception in *Levine*, however, Justice Sotomayor then went on to discuss specific scenarios in which state tort law claims would be preempted. First, Justice Sotomayor opined that "[i]f a generic manufacturer defendant proposed a label change to the FDA but the FDA rejected the proposal, it would be impossible for the defendant to comply with a state-law duty to warn." This scenario is similar to that suggested in *Levine*, and perhaps does not add much to any future brand-name prescription drug preemption debates (although Justice Sotomayor's reiteration of the point does bolster the point that *Levine* does not foreclose all implied preemption arguments in such cases).

Justice Sotomayor's next two examples, however, provided considerably more meat to the *Levine* exception. Justice Sotomayor next stated that "[l]ikewise, impossibility would be established if the FDA had not yet responded to a generic manufacturer's request for a label change at the time a plaintiff's injuries arose." *Id*. at 2588-89. This is a significantly broader exception than suggested in the first example, because it would find preemption even prior to (and potentially without) any FDA rejection of increased warnings. Although it might be argued that this exception was intended to apply only to generic manufacturers (who do not have CBE authority), Justice Sotomayor's repeated arguments in her opinion that it would be "absurd" to treat generic and brand name manufacturers differently for preemption purposes undermines that argument. *See Id*. at 2592-93. As her third example, Justice Sotomayor allowed that "[a] generic manufacturer might also show that the FDA had itself considered whether to request enhanced warnings in light of the evidence on which a plaintiff's claim rests but had decided to leave the warnings as is." *Id*. at 2589. Here, there does not appear to be any potential distinction between generic and brand-name prescription drug manufacturers. And given that this last example is exactly the situation posed in cases involving SSRI prescription drugs and suicidality, it provides strong evidence that the post-*Levine* cases rejecting preemption in that context were wrongly decided. *See, e.g.*, *Mason*, 596 F.3d 387.

Although more ambiguous, Justice Sotomayor's opinion also suggests that even the liberal wing of the Court is not convinced by arguments that prescription drug manufacturers can be held liable for negligent marketing. In the Eighth Circuit opinion reversed by *Mensing*, the court had suggested as an alternative argument around preemption that it was not impossible for generic manufacturers to comply with both federal labeling requirements and state tort law because "[t]he generic defendants were not compelled to market metoclopramide. If they realized that their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product." *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (2009). This issue was not advanced before the Supreme Court by the respondents, but Justice Sotomayor could have seized upon this argument in support of her dissent, if she considered it persuasive. She elected not to do so. *See Id*. at 2587 n.8.

Conclusion

Extrapolations forward from Supreme Court preemption opinions can be risky business. Over the past 25 years, the Court's language has often swung dramatically from pro- to anti- preemption positions, as the majority in each given case has sought to build a precedential foundation for their preferred position. However, the opinions in *Mensing*, coming from Justices who, up until now had been viewed as skeptical of implied preemption (and in Justice Sotomayor's case, who likely will continue to be so viewed), should provide firmer ground for seeking to advance select preemption arguments in future cases. Indeed, if these Justices continue to hold the views they expressed in *Mensing*, there would be a clear majority in favor of implied preemption of certain types of claims in brand-name prescription drug product liability litigation, and the implied preemption defense will play a significant role in this litigation going forward.