





Generic Preemption AFTER Levine

“THE EIGHTH CIRCUIT’S DECISION [AGAINST PREEMPTION] NOT ONLY THREATENS TO UNDERMINE THE PUBLIC’S CONFIDENCE IN GENERIC DRUGS; IT THREATENS THE LONG-TERM VIABILITY OF THE GENERIC PHARMACEUTICAL INDUSTRY IN THIS COUNTRY.”¹

INTRODUCTION

More than a year ago, the United States Supreme Court, in *Wyeth v. Levine*, held that state law failure-to-warn claims against brand-name drug manufacturers are not automatically preempted by the Food Drug and Cosmetic Act (FDCA). *Levine* applies only to branded pharmaceuticals, and the Court did not address the implications of its holding for generic drug manufacturers. Before *Levine*, a number of courts found that failure-to-warn claims against generic manufacturers were preempted by the Hatch-Waxman amendments to the FDCA.

The reasoning: because generic manufacturers were required to maintain the “same” label as the branded drug, generic manufacturers could not initiate label changes independent of the branded manufacturer. Generic manufacturers therefore argued that state law failure-to-warn claims could not succeed when the generic manufacturer complied with the FDCA and used the last approved label for the brand-name equivalent drug.

After *Levine*, the trend is for courts to find that failure-to-warn claims against generics manufacturers are *not* preempted by the FDCA. Both the Fifth and Eighth Circuits

have ruled against preemption.² A petition for certiorari was filed with the United States Supreme Court in *Mensing v. Wyeth*, and the Court has asked the Solicitor General to weigh in on the issue. The Court’s request for input from the Solicitor General suggests there may be enough interest from the Court to hear the appeal.

Appeals currently are pending before the Sixth and Ninth Circuits from decisions that found in favor of preemption.³ The Sixth Circuit has asked the FDA to submit a brief explaining its view of generic preemption. That brief will be filed 14 days after the

Solicitor General files its brief in *Mensing*.

Set forth below is an overview of the reasoning employed by the Eighth and Fifth Circuits in finding against preemption, as well as a summary of the generic manufacturers' arguments in favor of preemption. Finally, the article includes general thoughts on the potential implications of a Supreme Court decision that finds either for or against generic preemption.

NO GENERIC PREEMPTION — FIFTH AND EIGHTH CIRCUITS

The Eighth Circuit was the first federal court of appeals to consider generic preemption after *Levine*. The court premised its finding against preemption on its conclusion that a generic drug manufacturer should alert the FDA to any new hazard affecting a drug. The Eighth Circuit noted that generic manufacturers follow the same adverse event reporting requirements as brand manufacturers, and it emphasized 1992 comments by the FDA that generic manufacturers must submit periodic reports of adverse events even if they have not received any adverse reports or initiated any labeling changes.⁴ The court found “implicit” in this comment the FDA’s expectation that generic manufacturers will initiate label changes, and it concluded that such changes could be proposed to the FDA through the prior approval process. Because the court concluded that a generic manufacturer could at least propose a label change that the FDA could impose uniformly on all manufacturers, the Eighth Circuit declined to address whether generic manufacturers could change a label through the Changes Being Effectuated (CBE) procedure.

The Eighth Circuit concluded that in addition to initiating label changes through the prior approval process, a generic manufacturer could suggest that the FDA send out a warning letter to healthcare professionals. The court noted in a footnote that generic manufacturers could not unilaterally send out “Dear Doctor” letters, but offered no explanation for its conclusion that the authority regarding Dear Doctor

letters applicable to brand manufacturers applies equally to generics.

The Fifth Circuit in *Demaby* generally followed the Eighth Circuit’s reasoning, but it went further and concluded that a generic manufacturer could unilaterally make labeling changes through the CBE process.⁵ The Fifth Circuit held that the requirement that a generic drug label be the “same as” the brand label is imposed inflexibly only at the initial application stage. The Fifth Circuit’s reasoning indicates that, once a generic drug is approved and marketed, the CBE process is available to generic manufacturers just as



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it is to brand-name manufacturers. Presumably, the FDA then ensures uniformity by imposing label changes initiated by a generic manufacturer upon other manufacturers, including the branded manufacturer.

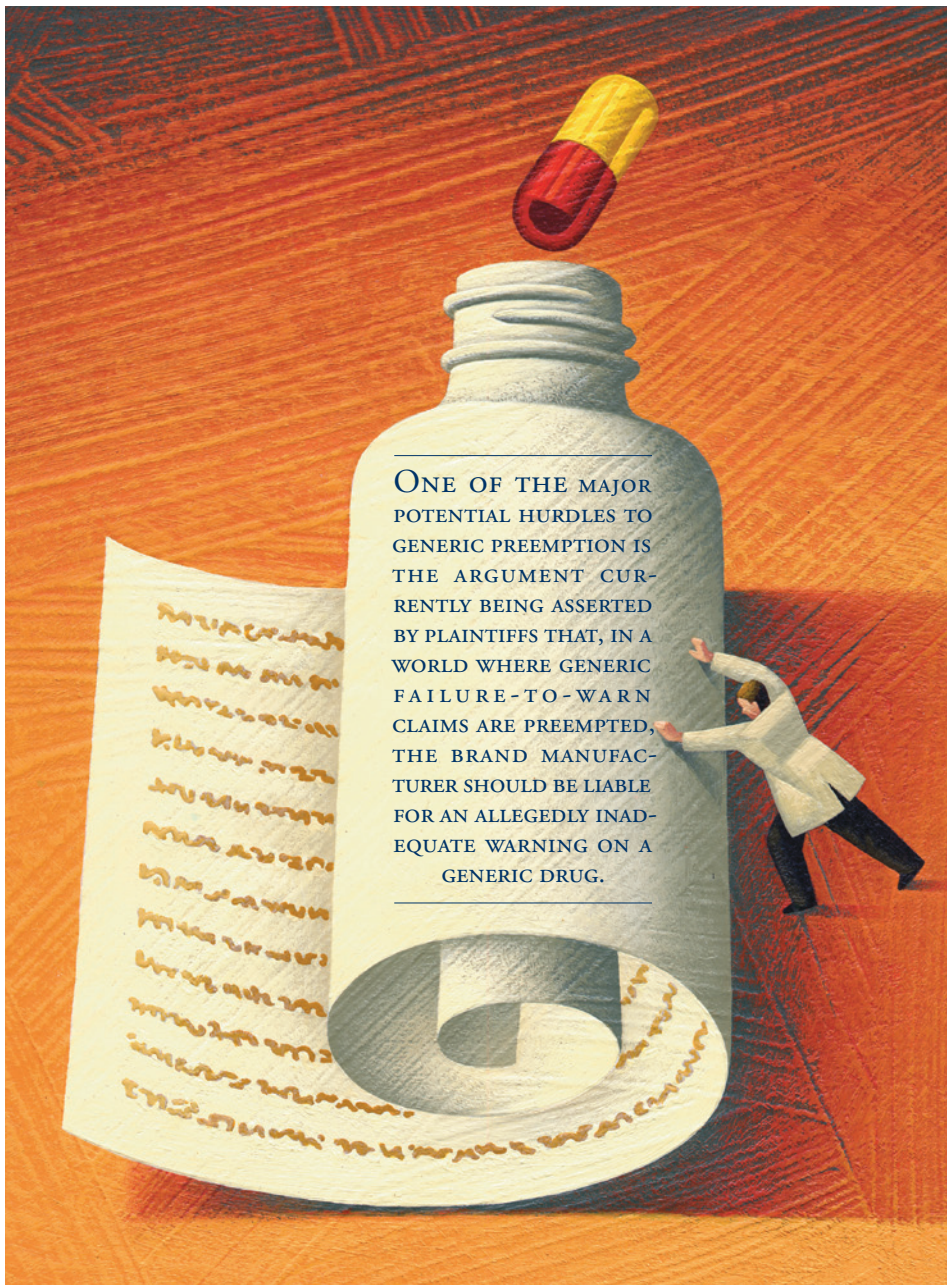
ARGUMENTS FOR GENERIC PREEMPTION

The arguments in favor of generic preemption — which are presently being made before the Sixth and Ninth Circuits and in support of the petition for certiorari in *Mensing* — generally focus on the Hatch-Waxman amendments’ intent to bring generic drugs quickly and cheaply to market. The mechanism for doing so was to require generic manufacturers to mimic the brand product in virtually all respects. Most importantly, the generic manufacturers rely on the requirement under 21 U.S.C. § 355(j)(2) that the labeling on a generic drug product be the “same as” the labeling the FDA previously approved for use on the brand-name equivalent. They argue that this

requirement makes it impossible to comply with the FDCA and any state law requiring that additional or different information should be in the label.

The generic manufacturers also distinguish the Supreme Court’s holding in *Levine* by emphasizing that *Levine* turned on the Court’s finding that the brand manufacturers were charged with “primary responsibility for their drug labeling” and for “crafting an adequate label and ensuring that its warnings remain adequate.” Generics, to the contrary, are charged with the entirely different task of insuring that their labels remain “the same as” the latest FDA-approved label for the brand-name equivalent product. The generic manufacturers argue that this distinction renders the analysis in *Levine* inapplicable in determining whether state law failure-to-warn claims against generic manufacturers are preempted.

Finally the generic manufacturers argue that, from a practical perspective, a finding against preemption will negate the entire purpose of the Hatch-Waxman amendments and undermine the affordability of generic drugs. The generic manufacturers highlight the laborious and expensive approval process for a new drug and note that, post-approval, the FDA makes decisions about labeling changes based on the original applicant’s clinical data, all the scientific literature about the drug, and all adverse events reported to the FDA since approval. Generic manufacturers are not required to compile and analyze this data, and they assert that the imposition of the requirement that they maintain the label could be achieved only through the cost of the generic drug rising to that of the brand-name drug’s price. One of the fundamental assumptions of the Hatch-Waxman amendments is that by streamlining the generic approval process, generic drugs will be brought to market quickly and at a lower price than the brand product. If the generic manufacturers are required to undertake the same steps required of the brand manufacturer to compile and analyze pre- and post-market data, the costs of generic drugs will undoubtedly increase.



CONTE AND GENERIC PREEMPTION

One of the major potential hurdles to generic preemption is the argument currently being asserted by plaintiffs that, in a world where generic failure-to-warn claims are preempted, the brand manufacturer should be liable for an allegedly inadequate warning on a generic drug. This argument gained notoriety in *Conte v. Wyeth*, 168 Cal. App. 4th 89 (Ca. Ct. App. 2008), where a California court held that a name-brand drug manufacturer owed a duty-of-care to an individual injured by a generic drug even when the plaintiff never ingested the brand manufacturer's product. Although *Conte* has received much attention, it has gained little traction and has generally

been rejected by courts. Most courts have refused to follow *Conte* on the grounds that liability for injury caused by a product can be imposed only where the product causing the alleged injury was manufactured and/or supplied by the defendant.

One can posit that the resounding rejection of *Conte* by most courts is related to the seemingly growing conclusion that failure-to-warn claims against generic manufacturers are not preempted. It may be easier for courts to find against generic preemption than to leave the impression that a plaintiff is without a remedy. This is, of course, not to suggest that a ruling in favor of generic preemption will result in the widespread

adoption of the holding in *Conte*. Indeed, a holding from the Supreme Court in favor of generic preemption may do nothing to "resurrect" *Conte*. However, in the event the Court finds in favor of generic preemption, it seems likely that at least some judges will be tempted to follow *Conte* rather than give the appearance that they have left a plaintiff without a remedy. If that happens, then the progeny one can expect from *Conte* will soon be marching up the appellate ladder behind *Mensing*.

CONCLUSION

Although the post-*Levine* weight of authority appears to be against it, there are strong legal and practical arguments in favor of generic preemption. Those arguments are presently before the Supreme Court on a petition for certiorari, and the Court has at least expressed an interest in hearing what the government's position is with respect to generic preemption. The Solicitor General will be weighing in on the issue soon, but it will likely be several months before the Court determines whether it will accept the appeal of *Mensing*. Acceptance of the appeal should resolve the issue. A refusal by the Court to hear it at this time will leave manufacturers waiting for decisions from the Sixth and Ninth Circuits and for the law to develop in other jurisdictions.

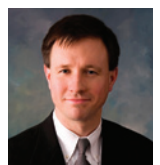
¹ Brief of the Generic Pharmaceutical Association as Amicus Curiae in Support of Petitioners *Pliva, Inc. et al.*, On Petition for Writ of Certiorari to the U.S. Court of Appeals for the Eighth Circuit, Nos. 09-993, 09-1039 (April 21, 2010) (supporting writ petition filed by defendant generic manufacturers from the Eighth Circuit's decision in *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009)).

² See *Demahy v. Actavis*, 593 F.3d 428 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

³ See *Smith v. Wyeth, Inc.*, No. 09-5460 (6th Cir.); *Gaeta v. Perrigo Pharms. Co.*, No. 09-15001 (9th Cir.).

⁴ See *Mensing*, 588 F.3d at 609 (citing 57 Fed. Rep. 17950, 15965 cmt 53 (April 28, 1992)).

⁵ See *Demahy*, 593 F.3d at 439-441.



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