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GENERICSWEB
THE SEARCH IS OVER

INNsight article by Lauren DeBruicker and James J. Halligan, January 2012

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How Plaintiffs are Playing their "Unfortunate Hand": the Impact of *PLIVA v. Mensing* on Personal Injury Claims against Generic Drug Manufacturers

Seven months ago, the U.S. Supreme Court issued a landmark decision finding that claims by injured plaintiffs alleging that generic drug manufacturers failed to warn adequately of the risks of their products are preempted, and thus forbidden, by federal law. In *PLIVA, Inc. v. Mensing*, the Court held that under the complex scheme of federal law governing brand and generic drugs, it was impossible for generics to change (much less strengthen) the safety warnings on their labels to comply with state law and still comply with the federal law's requirement that their labeling be and remain "the same as" brand drug labeling approved by the FDA. Under the U.S. Constitution's Supremacy Clause, America's highest court concluded, any conflicting state law must give way.

The effect of *Mensing* is that consumers of generic drugs are prohibited from bringing "failure to warn" claims that have been the crux of pharmaceutical litigation for over 30 years. Indeed, of all potential theories of liability against drug manufacturers, a claim for "failure to warn" is the lead and, in many cases, the **only** card played. Recognizing the import of its ruling – that because of differences in federal regulations for generic and brand drugs, brand drug patients can bring "failure to warn" claims that consumers of generic drugs cannot – the Supreme Court in its *Mensing* opinion "acknowledge[d] the unfortunate hand that federal drug regulation has dealt" consumers of generic drugs.

What follows is an analysis of how plaintiffs have played that hand since the Supreme Court's ground-breaking decision.

The Score to Date: Generics are Running the Tables

Courts have spent the seven months since *Mensing* trying to determine what, if any, claims remain against generics. The trend thus far is decidedly in favor of the manufacturers. Of the 30+ published cases decided since *Mensing*, courts have found plaintiffs' claims either preempted or otherwise insufficient under *Mensing* in all but a handful.

Even in cases where plaintiffs alleged claims in addition to the traditional "failure to warn," such as design or manufacturing defects, breaches of implied or express warranties, or fraud or negligence, most courts have dismissed not only the failure to warn claims, but the additional claims as well. Courts are finding these additional claims to be nothing more than a failure to warn claim under another name, and thus preempted under *Mensing*. The courts have also found plaintiffs' pleadings to be so dominated by factual allegations regarding the insufficiency of the generic drug's label warnings that the other causes of action, such as those for defective design (which require proof of a safer alternative design) or manufacturing defect (generally requiring proof of a deviation from the manufacturer's own production processes and standards) are utterly devoid of factual support and unable to survive a motion to dismiss the plaintiff's complaint.

A Plaintiff's Dilemma: to Hold or to Fold?

Recognizing the breadth of the *Mensing* decision, some plaintiffs' lawyers and their clients have decided simply to fold. Some have voluntarily withdrawn their cases against generics, and, of the published cases since *Mensing*, at least seven cases were dismissed on motions by generics that plaintiffs did not bother to oppose. They simply walked away.

Others have tried to at least shuffle the deck. In attempts to avoid *Mensing*, some plaintiffs (as we note in the next section) have repackaged traditional failure to warn claims as "alternate" claims, including claims that generics failed to *sufficiently or effectively communicate* their warnings, failed to make their federally-required warnings in a timely manner, and failed to simply stop manufacturing the drug altogether. These newly-crafted claims are strikingly similar to their traditional "failure to warn" counterparts, and have been largely rejected by the courts.

Indeed, only about six courts to date have allowed personal injury cases to proceed against generics post-*Mensing*, and even fewer have embraced these alternative claims. Those lucky plaintiffs who have survived such a motion have been favored by the very lenient standards of a motion to dismiss a plaintiff's complaint. There, plaintiffs are given the benefit of every doubt and are not required to prove their claims but merely state a legally plausible ground on which to proceed. Substantively, these claims fall short, and, as other courts have confirmed, are unlikely to survive through trial, much less on appeal.

What Cards Are Up Their Sleeves? Alternative Claims of Failure to Communicate Warnings, Failure to Timely Warn, and Failure to Discontinue Sales

Although in *Mensing* the Supreme Court largely adopted the FDA's position that communications from generics directly to medical providers about drug risks (or "Dear Doctor Letters") "would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading,'" the Court did not say that generics were precluded completely from sending Dear Doctor Letters. Rather, the Court observed that "any such letters must be

'consistent with and not contrary to [the drug's] approved . . . labeling.'" In doing so, the Court may have arguably, and perhaps inadvertently, left open a small window for claims based on the adequacy of a generic's warning after the FDA approves a labeling change to the reference listed drug ("RLD") labeling, but before the generic actually implements a revision of its labeling.

A handful of courts have recognized the potential for such "failure to communicate" claims after *Mensing*, but the validity of these decisions is questionable, and several courts have already rejected them as unfounded. Also, under legislation that took effect in 2008, the U.S. government is now solely responsible for sending communications to healthcare providers on behalf of ANDA holders. Given the inability of generics to unilaterally send Dear Doctor Letters without FDA approval, it is unlikely that a claim based on a failure to communicate warnings through Dear Doctor Letters would escape the reach of *Mensing*.

Another longshot bet is plaintiffs' new claim that generics should be liable for continuing to sell the products claimed to contain inadequate warnings. This theory has been explicitly or impliedly rejected by several courts already, noting the absence of any legal authority requiring a generic to withdraw its FDA-approved drugs from the market in the face of *allegations* of product defect.

A third alternative claim is based on a generic's delay in updating its labeling once the FDA has approved changes in the RLD's labeling. One court has already rejected this purported "delay in label change" argument as mere conjecture. Given the breadth of *Mensing* and ambiguity in FDA regulations on the timeliness of generic drug label changes to conform to RLD labeling, this claim, too, presents a long shot for plaintiffs

Who Holds the Winning Hand After *Mensing*?

As expected, *Mensing* stacked the decks dramatically in favor of generics, and a number of plaintiffs and their counsel, realizing this, have folded their cards. Some, however, will have the stomach and resources to continue to ante up until they see whether any of the new alternative claims hold up through trial and on appeal, or until Congress changes the federal law on which *Mensing's* federal preemption defense is based. As long as *Mensing* is the law of the land, generics can and should continue defending personal injury claims on preemption grounds and appeal any adverse decisions handed down at the trial court level.

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