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Preemption Torpedoes State Law Claims against Generics Makers in Zantac MDL

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A judge in the United States District Court for the Southern District of Florida presiding over the *In Re: Zantac (Ranitidine) Products Liability Litigation* multidistrict litigation, MDL No. 2924, has held that state labeling and design defect claims against the makers, re-packagers, retailers, and distributors of generic forms for the popular heartburn medication Zantac were preempted by federal law. The court subsequently dismissed these claims against 32 such Zantac generics makers and distributors.

The Zantac MDL was created by the United States Judicial Panel on Multidistrict Litigation on February 6, 2020. The plaintiffs allege that ranitidine, the active ingredient in Zantac and its generic forms, breaks down into N-nitrosodimethylamine ("NDMA"), which is part of a group of compounds that have been shown to increase the risk of cancer. The plaintiffs allege a variety of product liability and related claims against the makers and distributors of Zantac and its generic forms under federal and state laws.

The generic defendants filed a Motion to Dismiss arguing that the plaintiffs' state law claims, regardless of how they were labeled or pled, were actually claims for design defect and failure to warn, and were therefore preempted by federal law under the Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013). Those cases held that such claims against generic drug manufacturers are preempted because the manufacturers cannot remedy design defects or provide additional warnings while remaining in compliance with federal law. Plaintiffs countered that these claims were not preempted because they were based on the fact that ranitidine products were "misbranded when sold."

The court held that the design defect and failure to warn claims that the Supreme Court ruled preempted against generic drug manufacturers in *Mensing* and *Bartlett* were preempted against the generic defendants here, regardless of the plaintiffs' allegations that the ranitidine products were "misbranded." The court noted that, based on *Mensing* and *Bartlett*, federal courts have held numerous categories of claims against generic drug manufacturers to be preempted, even when plaintiffs do not specifically couch their claims as design defect or failure to warn. Courts have found preemption against generic drug manufacturers for claims of: failure to conduct testing; misrepresentation, fraud, and violation of consumer-protection statutes; and breaches of express and implied warranties.

Specifically addressing the plaintiffs' "misbranding" claims, the court noted that no court had adopted the plaintiffs' theory that impossibility preemption can be avoided by pleading that the drug is misbranded. It reasoned that "finding that Plaintiffs can avoid pre-emption by alleging that defects in ranitidine products made the products misbranded" under the U.S. Code "would render the vast body of pre-emption caselaw in the drug context, including binding Supreme Court decisions, meaningless." Accordingly, the court held that the plaintiffs' claims "based on alleged defects in ranitidine products, product labeling, or other communications that" the generics manufacturers "could not independently change while remaining in compliance with federal law [were] pre-empted."

But the plaintiffs argued there was at least one piece of information on the packaging of the products the defendants could have changed without FDA pre-approval: expiration dates. Under federal law, a generic drug's expiration date need not be the same as the expiration date for the listed brand-name drug. The plaintiffs argued that the defendants should have shortened the expiration dates for the products because the products did not remain "stable" through the expiration dates, resulting in higher levels of NDMA as time passed.

The court relied on *Wyeth v. Levine*, 555 U.S. 555 (2009), in addressing the expiration dates issue. *Wyeth* held that a failure to warn claim is not preempted if a drug manufacturer has the ability to change drug labeling through the CBE process without waiting for FDA approval, unless there is clear evidence that the FDA would reject the change. The court held that under *Wyeth v. Levine*, it might be possible for the plaintiffs to bring claims based on the expiration dates for these products that would not be preempted.

However, the plaintiffs' complaints simply did not contain such claims regarding expiration dates upon which relief could be granted, and plaintiffs did not identify state law duties in each of the relevant jurisdictions to support such claims. And, the court noted that these allegations – i.e., that expiration dates should have been shortened because the products became more dangerous over time – were inconsistent with plaintiffs' allegations that the products were dangerous upon being manufactured. While pleading in the alternative is permissible, a party may not plead internally inconsistent facts within a count.

The court ultimately gave the plaintiffs 30 days to re-plead against the generics makers.

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