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Client Alert **Product Liability Law**

In re Darvocet: Is There a "Parallel Misbranding" Exception to Generic Drug Preemption?

The Sixth Circuit recently reiterated the difficulty plaintiffs face in avoiding preemption of state-law claims against generic drug manufacturers in *In re Darvocet, Darvon, & Propoxyphene Products Liability Litigation*, Nos. 12-5368, et al. (6th Cir. June 27, 2014) (hereinafter "*Darvocet*"). Particularly of note in *Darvocet* is the court's analysis of the so-called "parallel misbranding" exception to preemption. Although it remains unclear whether such an exception actually exists, at the very least, *Darvocet* shows that it is exceedingly difficult to plead successfully.

It is now generally well accepted that generic drug manufacturers are usually shielded from state-law failure-to-warn and design defect claims. The U.S. Supreme Court shaped the contours of federal preemption pertaining to pharmaceutical drug labeling in a trilogy of landmark cases over the past five years. In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Court held that federal law generally does *not* preempt state-law failure-to-warn claims against manufacturers of brand-name prescription drugs because federal law allows brand-name manufacturers to alter labeling when they become aware of new risks associated with the drug. In *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), however, the Court distinguished generic prescription drugs from their brand-name counterparts. Because federal law prohibits generic drug manufacturers from unilaterally altering their drug labels and instead requires them to use the same label as the brand-name drug on which the generic is based (referred to as the "duty of sameness"), the Court concluded that federal law generally *does* preempt failure-to-warn claims against

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manufacturers of generic drugs. In *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), the Court rejected the "stop-selling" theory of avoiding preemption and extended the failure-to-warn rationale of *PLIVA* to design defect claims. In particular, the Court held 5-4 "that state-law design-defect claims that turn on the adequacy of a drug's warnings are preempted by federal law under *PLIVA*." *Id.* at 2470.

The "parallel misbranding" theory arose out of an amicus brief filed by the FDA in *Bartlett* in which the FDA argued that *Mensing*'s preemption analysis was limited to claims based on the adequacy of drug labeling. The FDA contended that "pure" design defect claims were distinguishable and they would not be preempted if they "parallel the FDCA's drug 'misbranding' prohibition." The FDA reasoned that because a manufacturer has a federal duty not to market a drug if it is "dangerous to health" even when used as provided in the labeling, a state-law duty similarly not to market the drug would not conflict with federal law if it appropriately accounted for the FDA's role under the FDCA. In its opinion, the *Bartlett* court included a footnote to state that its decision did not address "state design defect claims that parallel the federal misbranding statute." *Id.* at 2477 n.4. The Court stated:

> The misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is "dangerous to health" even if "used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof." The parties and the Government appear to agree that a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA.

Id. (internal citations omitted). Whether or not this footnote was meant to actually create an exception or to simply state that the issue was not addressed remains up for debate.

Indeed, the *Darvocet* court did not directly rule on the actual existence of the "parallel misbranding" preemption exception. Instead, the court sidestepped the "possibly thorny issue" of its actual existence by concluding that even if such an exception exists, it was not sufficiently pled by the plaintiffs. Most significantly, however, the *Darvocet* court provided a potential future framework when it construed the FDA Amicus Brief and Footnote 4 of *Bartlett* to identify "the minimum" that a plaintiff must show in order to avoid preemption of a design defect claim under the "parallel misbranding" exception: (1) allege a cause of action for misbranding under state law, (2) identify the

"new and scientifically significant information that was not before the FDA," and (3) demonstrate that the FDA would have found the drug to be misbranded in light of this new information in order to "appropriately account for the FDA's role under the FDCA."

Seizing on Footnote 4 in *Bartlett* despite its uncertain status, the plaintiffs in *Darvocet* claimed that the "parallel misbranding" preemption exception applied because the generic manufacturers "wrongfully marketed" an unreasonably dangerous product (the painkiller propoxyphene) by continuing to market the drug despite the fact that it was allegedly "dangerous to health" even when used as provided in the labeling, in violation of their federal duty. In particular, with respect to the first prong, plaintiffs asserted that the generic manufacturers' knew or should have known that the drug's risks outweighed its utility and that their decision to continue selling the drug were actionable under state-law theories of strict liability design defect, negligent design, negligent marketing, and breach of implied warranty. The *Darvocet* court, however, found prong one insufficiently pled because plaintiffs "fail[ed] to identify specific wrongful marketing claims from the states at issue that parallel, i.e., have elements identical to, a federal misbranding claim under 21 U.S.C. § 352(j)." *Darvocet*, slip op. at 13.

More importantly, the *Darvocet* court found that the plaintiffs failed to sufficiently plead the second prong because no "new information" sufficient to change the FDA's mind was alleged. Plaintiffs pointed to a multitude of sources to satisfy this prong: a 1978 complaint about potential risks associated with the propoxyphene by the Health Research Group via citizen petition; complaints arising out of various clinical and non-clinical studies in the ensuing decades; post-marketing adverse event data; the decision of the United Kingdom to withdraw propoxyphene from the market; and the recommendation of two FDA advisory committees to withdraw propoxyphene from the market in 2009. Significantly, the FDA declined to follow the committees' withdrawal recommendation. Instead, it ordered the NDA holder to update the drug's labeling to include certain warnings, and in 2009, ordered a clinical trial to re-assess risks associated with propoxyphene. In November 2010, based on data from the clinical trial, the FDA concluded that the risks of propoxyphene outweighed its benefits and asked all manufacturers to withdraw it from the market.

The *Darvocet* court concluded that the information pre-dating the 2009 clinical trial was not "new information" since all of it had been previously considered, reviewed, and rejected by the FDA as a basis for potential administrative action. "That the

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FDA approved continued marketing of propoxyphene in July 2009, notwithstanding the information Plaintiffs submit, is fatal to their misbranding claim before that time." *Darvocet*, slip op. at 14. With respect to the data from the 2009 clinical trial which ultimately led the FDA to conclude that the safety risks of propoxyphene outweighed its benefit and request market withdrawal, the *Darvocet* court found that the generic manufacturers "did not have access to, and thus had no ability to evaluate," the data. In other words, without access to the study data, the generic manufacturers had no way of knowing that the drug was misbranded (i.e., that it was "dangerous to health" even when used as provided in the labeling).

The Sixth Circuit affirmed the district court's dismissal of plaintiff's wrongful marketing claims finding that plaintiffs failed to sufficiently plead prongs one and two of the parallel "misbranding" framework. The third prong framework – that the FDA would have found the drug to be misbranded in light of new information – was not addressed by the *Darvocet* court.

Darvocet is significant because it is the first circuit court opinion to substantively analyze and apply the "parallel misbranding" preemption exception, even though the court declined to rule on its actual existence. *Darvocet*'s rigid interpretation of a perceived "parallel misbranding" exception severely limits plaintiffs in their quest to sidestep federal preemption of state law claims against generic manufacturers. The Sixth Circuit made clear that in order for a "parallel misbranding" exception to apply, plaintiffs must at the very least point to a specific state-law that parallels the federal misbranding statute and also present "new information" which had not previously been before the FDA and to which the generic manufacturer had access.

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