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Product Liability Law Alert

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Sixth Circuit delivers big win for drug manufacturers

Introduction

In the case *In re: Darvocet, Darvon, and Propoxyphene Products Liability Litigation*, 2014 U.S. App. LEXIS 12111 (6th Cir. June 27, 2014), the United States Court of Appeals for the Sixth Circuit delivered a major victory for drug manufacturers, holding that: (1) even if a wrongful marketing/parallel misbranding claim exists against generic manufacturers and is not preempted by federal law, plaintiffs must plead three demanding elements to survive a motion to dismiss; and (2) 22 states would not recognize a cause of action in which a plaintiff generic consumer sought to hold a brand-name manufacturer responsible, on a misrepresentation theory, for the plaintiff's use of a drug that the brand manufacturer did not produce.

The Facts

The case consolidated 68 claims against both generic and brand-name manufacturers for personal injuries related to the use of the drug propoxyphene (brand-name Darvocet or Darvon). 2014 U.S. App. LEXIS 12111, at 2. The drug is a painkiller first patented and manufactured by Eli Lilly and Company in 1957. *Id*. at 7. After Congress passed the Hatch-Waxman Act in 1984, other pharmaceutical companies began to market generic versions of the drug. *Id*. The drug has a checkered regulatory history. *Id*. at 7-9. Indeed, the United Kingdom began a phased withdrawal of propoxyphene from the market in 2005. *Id*. at 8. The FDA held out for several years, eventually directing Xanodyne Pharmaceuticals, Inc. to undertake a clinical trial to assess the risks of a particular cardiac complication in 2009. *Id*. The study linked propoxyphene use to risk of heart rhythm abnormalities. *Id*. After reviewing the results of the study, the FDA asked all manufacturers to withdraw propoxyphene from the market in 2010. *Id*. at 8-9. The manufacturers complied. *Id*. at 9.

Each plaintiff in the appeal alleged that they ingested propoxyphene products after the FDA directed Xanodyne to conduct the study in 2009 but prior to the FDA's requested withdrawal of the drug in 2010. *Id*. The plaintiffs alleged that the generic manufacturers continued marketing propoxyphene products after they knew or should have known, based on the initial data from the 2009 study, that the risks of the drugs exceeded their benefits. Id. at 2-3. Most of the plaintiffs also sought to hold one or more of the brand manufacturers liable for their injuries, alleging that they made misrepresentations about propoxyphene, which led the plaintiffs' physicians to prescribe the generic equivalent of propoxyphene to the plaintiffs. *Id*. at 3. The district court granted the defendants' motions to dismiss or for judgment

on the pleadings. *Id*.

Thereafter, the Supreme Court decided *Mutual Pharmacy Co. v. Bartlett*, 133 S. Ct. 2466 (2013), which held that state "design defect" claims that turn on the adequacy of a drug's warnings are preempted by federal law. The Court, however, wrote in a footnote ("Footnote 4"), that it did not address "state design-defect claims that parallel the federal misbranding statute." *Id*. at 2477 n.4. Seizing on Footnote 4 in *Bartlett*, the plaintiffs here brought wrongful marketing claims against the generic manufacturers based on the parallel misbranding theory. 2014 U.S. App. LEXIS 12111, at 12.

This appeal ensued, and the Sixth Circuit became only the second federal appellate court to consider this cause of action.[1]

The Court's Analysis

Notably, the court sidestepped the issue of whether to recognize parallel misbranding claims in light of Footnote 4, instead affirming that the plaintiffs had not pleaded such claims plausibly pursuant to *Iqbal. Id*. at 24-28. The court wrote that, were such a claim to exist, a plaintiff would have to do, at a minimum, the following three things:

> (1) allege a cause of action for misbranding under state law,[2] (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 [Federal Food, Drug, and Cosmetic Act]."

Id. at 25. Even assuming that the other elements of the three-part cause of action were met, the court held that the plaintiffs failed to plead the second element. *Id*. at 25-28. Because the generic manufacturers could not access and evaluate the 2009 study prior to the FDA's own review, the plaintiffs did not plead sufficient "new and scientifically significant information that was not before the FDA."[3] *Id*.

The principal claim against the brand manufacturers was misrepresentation. The court summarized the plaintiffs' argument as follows:

> [P]hysicians reasonably and foreseeably relied on representations by Brand Manufacturers in writing prescriptions for generic propoxyphene because they understand that generic drugs are required by federal law to be bioequivalent to, and labeled the same as, RLDs [reference-listed drugs]. State laws permit, and sometimes require, pharmacists to fill prescriptions with generic medications. Thus, they argue, it was reasonably foreseeable to Brand Manufacturers that physicians would rely on their representations in prescribing generic propoxyphene.

Id. at 46. Because the lawsuits on appeal arose under the substantive laws of 22 different states, the court conducted a state-by-state *Erie* analysis, contained in Appendix A to the opinion, finding that the highest courts in each of the 22 states would not recognize the plaintiffs' misrepresentation claims under their respective state laws. In examining Ohio law, for example, the court was guided by *Hogue v. Pfizer, Inc.*, 893 F. Supp. 2d (S.D. Ohio 2012), in which the United States District Court for the Southern District of Ohio rejected misrepresentation claims by generic consumers against brand name manufacturers. *Id*. at 86-88. The court held that the Ohio Supreme Court would construe the plaintiffs' misrepresentation claims as product liability claims under the Ohio Product Liability Act ("OPLA"). *Id*. at 87-88. OPLA requires proof that the defendant manufactured "the actual defective product in the product liability claim." *Id*. at 87 (internal citation omitted). Therefore, the court held that the plaintiffs' claims would fail because the plaintiffs did not allege that they were injured by the brand manufacturers' product, but rather by the generic manufacturers' product. *Id*. at 88.

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[1]The Fifth Circuit recently held that these types of claims are impliedly preempted. *Lashley v. Pfizer, Inc.*, 750 F.3d 470 (5th Cir. 2014).

[2]The court suggested that such state law claims would have to "parallel, i.e., have elements identical to, a federal misbranding claim under *21 U.S.C. § 352(j)*." 2014 U.S. App. LEXIS 12111, at 25.

[3]In addition to the wrongful marketing claims brought against the generic manufacturers, the plaintiffs also asserted failure-to-warn claims and various state law claims against those manufacturers. Id. at 28-45. A summary of the court's analysis of these claims, in which the court applied *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) to preempt these claims, is beyond the scope of this Law Alert. *Id*.

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All told, the Sixth Circuit affirmed dismissal of 67 of the 68 claims, reversing and remanding only one case, a case that involved the use of a brand-name drug. *Id*. at 59-60.

Significance for Generic Manufacturers

A second federal appellate court has now considered the novel wrongful marketing/parallel misbranding cause of action. While the Sixth Circuit did not find such claims to be preempted by federal law as did the Fifth Circuit in *Lashley*, it did erect a high pleading threshold, requiring plaintiffs to plead three difficult elements in order to allege a claim that will survive a motion to dismiss. Further, the opinion does leave open the possibility that the Sixth Circuit or the Supreme Court will consider the preemption issue in the future and put such claims to bed for good.

Significance for Brand-Name Manufacturers

Brand-name manufacturers can take comfort in yet another court, this time a federal appellate court, joining the overwhelming majority of courts that have rejected "the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug." *Id*. at 51 (quoting *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994)). Such misrepresentation claims appear to have survived the dismissal stage in only a few jurisdictions.

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