ARNOLD & PORTER LLP

Product Liability Litigation Update

Recent Developments in the Law

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Preemption: Supreme Court Protects Generic Manufacturers From Design-Defect Claims

On June 24, 2013, the Supreme Court ruled 5-4 in *Mutual Pharmaceutical Co. v. Bartlett*, --- S.Ct. ---, 2013 WL 3155230, that, under *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), a plaintiff's state-law design-defect claim against generic drug manufacturers was preempted by federal law.

The case involved a US$21 million jury verdict for Karen Bartlett, who developed a rare skin condition after taking generic sulindac, a nonsteroidal anti-inflammatory drug (NSAID) manufactured by Mutual. Bartlett had sued Mutual in New Hampshire state court, and the case was tried solely on a design defect theory. The defendant had argued that the claim was preempted under *Mensing*, but the First Circuit disagreed and affirmed the trial court ruling.

The Supreme Court reversed. It explained that, under New Hampshire law, the duty to sell a product that is not unreasonably dangerous can be satisfied either by changing the product's design or by strengthening its warnings. But Mutual could not change its drug's design "as a matter of federal law and basic chemistry." Therefore its only recourse was to strengthen the warning. As the Court had held in *Mensing*, it was impossible for the generic company to comply with both its state-law duty to strengthen the warning label and its federal-law duty not to alter it. The claim was thus preempted.

The majority opinion also specifically rejected the First Circuit's reasoning that Mutual could comply with both its federal and state law duties if it simply stopped selling sulindac. The Court reasoned that such logic would apply in every instance where it has previously found impossibility preemption and would render the doctrine a dead letter.

At a minimum, *Bartlett* further shields generic drug manufacturers from state tort liability and puts an end to the "stop-selling" rationale as a potential loophole for avoiding preemption. *Bartlett*'s impact on state design-defect claims against branded pharmaceutical companies will be a significant issue for the courts to take up in the wake of the opinion.

An in-depth Advisory on *Bartlett* published by Arnold & Porter attorneys is available here.

CAFA: Supreme Court To Weigh In On Removal Of State Attorney General Suits

The Supreme Court granted certiorari on May 28, 2013 in *Mississippi ex rel. Hood v. AU Optronics Corp.*, 701 F.3d 796 (5th Cir. 2012) to settle a circuit split over how the "mass action" removal provision of the Class Action Fairness Act (CAFA) applies to state attorney general suits.

In *AU Optronics*, the Mississippi attorney general filed price-fixing claims against several electronics manufacturers alleging a conspiracy to fix prices on LCD displays. Defendants removed the case to federal court, arguing that the case was a "mass action" under CAFA, § 1332(d)(11)(B), because the "real parties in interest" in the suit included Mississippi consumers who numbered more than 100 and were completely diverse from defendants – thereby fulfilling CAFA's numerosity and minimal diversity requirements. The Fifth Circuit held that while the State was a real party in interest in the suit, so were the consumers and that was sufficient to fulfill CAFA's mass action removal requirements.

The Fifth Circuit's "claim-by-claim" approach contrasts with an opinion from the Fourth Circuit which reached the opposite conclusion when confronted with a nearly identical price-fixing suit against the same defendant. In that case, the Fourth Circuit had applied a different, "whole complaint" rule which held that the State's presence in the suit defeated removal. The Supreme Court's decision will be one to watch both in terms of the Court's general approach to CAFA and to the removability of state attorney general cases.

Preemption: Third Circuit Affirms Preemption Of False Labeling Claims

In *Young v. Johnson & Johnson*, No. 12-2475, 2013 WL 1911177 (3d Cir. May 9, 2013), the Third Circuit affirmed a New Jersey District Court's dismissal of false labeling claims against Johnson & Johnson, finding that the claims were preempted by the Food, Drug and Cosmetic Act (FDCA) as amended by the Nutrition Labeling and Education Act (NLEA).

Plaintiffs filed suit under the New Jersey Consumer Fraud Act and common law, alleging that Johnson & Johnson sold margarine that was packaged with false and misleading labels because, among other grounds, the manufacturer claimed the product contained "no trans fat" even though trace amounts of trans fat existed. The NLEA expressly preempts state requirements for nutrition labeling that are not "identical" to federal law. The defendant accordingly argued preemption on the basis that federal law required amounts of trans fat less than 0.5 grams per serving to "be expressed as zero." But plaintiffs countered that, despite this provision addressing "per serving" labeling, no federal regulation explicitly permitted manufacturers to make a factually inaccurate claim that the product as a whole is free of trans fats. Although the Third Circuit acknowledged that "FDA regulations do not specifically say a product can advertise itself as containing 'NO TRANS FAT' when it has an insignificant amount," it looked to other FDA regulations which permit "no fat" or "no saturated fat" labeling for products as a whole under similar circumstances. *Id*. at *2; 21 C.F.R. § 101.62(b)(1), (c)(1). Using this common-sense reasoning, the Court thus affirmed the district court's dismissal of the complaint.

This decision rejects the notion that express preemption narrowly depends on an exactly conflicting federal requirement, and makes New Jersey a less appealing place for plaintiffs to bring false nutrition labeling suits.

Preemption/Parallel Claims: Florida District Court Finds Pleading Too General To State A "Parallel" Claim

In *Kaiser v. Depuy Spine, Inc.*, --- F. Supp. 2d ---, 2013 WL 2006122 (M.D. Fla. May 14, 2013), the Court dismissed a complaint against a manufacturer of artificial spinal discs, finding the claims were preempted by federal law and not cognizable under the "parallel claims" exception to preemption.

Plaintiff brought negligence and strict liability claims after an artificial spinal disc allegedly failed and caused him bodily injury. Defendant argued that these claims were preempted under the Medical Device Amendments of 1976 (MDA), which generally preempt state law claims concerning medical devices subject to FDA's rigorous pre-market approval (PMA) process. In an attempt to avoid preemption, however, plaintiff alleged that the discs violated FDA's PMA requirements and argued that such allegations brought him within the "parallel claim" exception to preemption recognized in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

Applying Eleventh Circuit precedent, the Court explained that "[p]arallel claims must be specifically stated in the initial pleadings." *Kaiser*, 2013 WL 2006122, at *4. The Court then held that plaintiff failed to specify which federal regulations or requirements were violated, but instead had only pleaded in vague and general terms that defendant's product violated PMA requirements.

Kaiser stands as a nice example of the intersection of the parallel claim exception and the pleading requirements of *Twombly* and *Iqbal*: to avoid preemption, plaintiffs must do more than simply invoke the "parallel claim" exception in general terms but must adequately plead the facts necessary to show that their claim is truly parallel.

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