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Preemption: Third Circuit Upholds Dismissal of Strict-Liability Design-Defect Claims Against Generic Pharmaceutical Manufacturers

In *In re Fosamax (Alendronate Sodium) Products Liability Litigation (No. II)*, --- F.3d ---, No. 12-2250, 2014 WL 1687811 (3d Cir. Apr. 30, 2014), the United States Court of Appeals for the Third Circuit affirmed the dismissal of multiple plaintiffs' complaints against generic pharmaceutical manufacturers, holding that Plaintiffs' strict-liability design-defect claims were preempted by the Federal Food, Drug, and Cosmetic Act (FDCA).

Plaintiffs alleged that the defendants were liable for injuries Plaintiffs suffered after taking branded and/or generic Fosamax because the manufacturers had concealed the drug's risks, exaggerated the drug's benefits, and promoted the drug for off-label indications. *Id*. at *2. Plaintiffs' claims were brought under the theories of design defect, failure-to-warn, negligence, breach of express warranty, breach of implied warranty, fraudulent misrepresentation, and negligent misrepresentation. *Id*. The defendants that manufactured the generic drug (Generic Defendants) moved to dismiss, arguing that the claims against them were preempted because they related to duties under state tort law that directly conflict with duties under federal regulations. *Id*. The district court granted Generic Defendants' motion. *In re Fosamax (Alendronate Sodium) Products Liability Litigation (No. II)*, No. 11-3045, 2012 WL 1118780 (D.N.J. Apr. 3, 2012).

The Third Circuit affirmed. The Court first determined that the only claims on appeal were Plaintiffs' strict-liability design-defect claims. *In re Fosamax*, 2014 WL 1687811, at *4. Although the claims at issue were brought under the laws of 28 different states, the Court held that Plaintiffs' design-defect claims were preempted because the Generic Defendants could only avoid liability by changing the drug's labeling, altering the drug's design, or ceasing sales of the drug. *Id*. at *8. The Court explained that because Plaintiffs did not—and could not under *PLIVA, Inc. v. Mensing*, --- U.S. ---, 131 S. Ct. 2567 (2011) and *Mutual Pharmaceutical Co., Inc. v. Bartlett*, --- U.S. ---, 133 S. Ct. 2466 (2013)—seek a change in the labeling or a change in the drug's design, the only option under which Generic Defendants could avoid state-law liability would be by halting sales of the drug. *In re Fosamax*, 2014 WL 1687811, at *8. The Court noted, however, that the Supreme Court had "categorically rejected" exiting the market as a viable theory of liability in *Bartlett*. *Id*. (footnote omitted). Although the Court explicitly "decline[d] to consider whether there is any basis for distinguishing between negligence-based design-defect claims and strict-liability design-defect claims for pre-emption purposes," *id*. at *5, it implied that the result would likely be the same because it had "yet to hear how the Generic Defendants' duties under negligence-based design-defect claims would be any different from their duties . . . under strict-liability design-defect claims." *Id*. at *5 n.17.

Plaintiffs in product liability actions against generic pharmaceutical manufacturers often allege design-defect claims based on the drug's labeling and design, and imply that the manufacturer could simply avoid liability by halting sales of the drug at issue. The Third Circuit's decision in *In re Fosamax* clearly articulates that such arguments are preempted by the FDCA.

Punitive Damages: Pennsylvania Court Bars Claims for Punitive Damages in Risperdal Cases

In *In re: Risperdal Litigation*, No. 100300296 (Philadelphia County Ct. of Common Pleas, May 2, 2014), the Philadelphia Court of Common Pleas granted a motion for partial summary judgment brought by Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research and Development LLC (Defendants) as to Plaintiffs' claims for punitive damages for alleged injuries from the antipsychotic drug Risperdal.

Plaintiffs filed suit in Pennsylvania state court alleging that Janssen Pharmaceuticals, Inc., a Johnson & Johnson unit and the manufacturer of Risperdal, marketed the drug for off-label use while failing to provide adequate information about the associated risks. In its motion for summary judgment, Defendants argued that New Jersey law—which bars punitive damage claims related to a drug that was subject to premarket approval or licensure by the Food and Drug Administration—should apply because any potential punitive conduct over the marketing of Risperdal would have occurred at Janssen's two New Jersey facilities. In response, Plaintiffs argued that Pennsylvania law or the law of the individual plaintiffs' states where Risperdal was prescribed, ingested, and marketed should govern. Plaintiffs also alleged that significant wrongful conduct occurred in Pennsylvania because Janssen officials met repeatedly in Pennsylvania to discuss Risperdal marketing strategies and perform significant regulatory compliance, pre-approval submissions, labeling, and testing of the drug. The Court agreed with Defendants and held that New Jersey law applies to the issue of punitive damages, thus barring any recovery of punitive damages.

Plaintiffs regularly bring pharmaceutical products liability suits in states where punitive damages are available. The *In re: Risperdal Litigation* demonstrates that courts will limit the effects of such forum shopping and, where appropriate, apply the law of the state where manufacturers are headquartered and where drug development and relevant marketing strategies occur.

Preemption: Mensing/Bartlett Preemption Rationale Extended to Drug Distributors

In *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Products Liability Litigation*, 2014 WL 1632149 (S.D. Ill. Apr. 24, 2014), the U.S. District Court for the Southern District of Illinois granted in part and denied in part defendant's motion for judgment on the pleadings.

Plaintiff alleged that the generic version of the oral contraceptive Yaz caused her to suffer an acute pulmonary embolism. She filed a lawsuit against the branded-manufacturer (which also manufactured the generic drug) and the drug distributor, bringing claims including strict liability, failure to warn, negligence, and fraud. 2014 WL 1632149, at *1. The distributor defendant moved for judgment on the pleadings, arguing that Plaintiff's state law tort claims are preempted by federal law. The district court first addressed a threshold question—whether the Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, --- U.S. ---, 131 S. Ct. 2567 (2011) and *Mutual Pharmaceutical Co., Inc. v. Bartlett*, --- U.S. ---, 133 S. Ct. 2466 (2013), which held state law warnings-based tort claims against generic manufacturers preempted, applied equally to drug distributors. *Id*. at *6. The court found that "the principles announced in *Mensing* and *Bartlett* are equally applicable to generic distributors" because "[u]nder applicable federal regulations, generic distributors have no more authority than generic manufacturers to alter a drug's composition, label, or design." *Id*.

Having found *Mensing* and *Bartlett* applicable, the court next rejected Plaintiff's attempts to distinguish her design defect claim from the claim preempted in *Bartlett*. First, the court did not accept Plaintiff's argument that unlike the state law at issue in *Bartlett*, Illinois design defect law "imposes no affirmative duty [on manufacturers], and instead serves to spread risk." *Id*. at *7. "Just as in New Hampshire, Illinois' strict liability does not mean that manufacturers have no affirmative duties." *Id*. at *8. Second, the court rejected Plaintiff's contention that *Bartlett* was distinguishable because New Hampshire applied a risk-utility approach while Illinois uses a consumer-expectations test, finding "this is a distinction without a difference" because the tests are simply "two different ways whereby a plaintiff can prove the same ground of liability." *Id*. The court did, however, recognize what it called an "exception" under *Bartlett* for state law claims that parallel the federal misbranding statute (requiring a manufacturer to pull a drug from the market—even if FDA-approved—if it is "dangerous to health"). Based on a footnote in *Bartlett*, in which the Court expressly stated it was "not address[ing] state design-defect claims that parallel the federal misbranding statute," *Bartlett* 133 S.Ct. 2477 n.4, the district court found that "to the extent the plaintiff's design defect claim parallels the federal misbranding statute, it is not foreclosed by *Bartlett*." *Id*. at 10. The court accordingly denied the distributor defendant's motion for judgment on the pleadings with respect to the parallel misbranding claim, but granted

the motion as to the failure to warn claim.

The *In re Yasmin and Yaz* decision extends the *Mensing/Bartlett* preemption rationale to generic drug distributors and demonstrates one court's unwillingness to distinguish *Bartlett* based on state law differences. The decision, however, also seizes upon dicta in *Bartlett*, which plaintiffs are likely to continue to argue creates an "exception" for state law claims that parallel the federal misbranding statute. The Sixth Circuit is currently addressing this issue in *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig. (Miller v. Eli Lilly)*, No. 12-5929, and will likely render its decision later this year.

For questions or comments on this newsletter, please contact the Product Liability group at product@aporter.com.

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