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Can Design-Defect Claims Against Generic Pharma Survive?

Pre-emption under *Pliva v. Mensing*

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The United States Supreme Court's ruling in *Pliva v. Mensing*, 131 S. Ct. 2567 (2011), was a landmark decision for generic pharmaceutical manufacturers. In *Mensing*, the court held that failure-to-warn claims against generic pharmaceutical manufacturers were impliedly pre-empted by federal law. The court's decision was premised on its conclusion that under the Food, Drug and Cosmetic Act (FDCA), generic manufacturers "have an ongoing federal duty of sameness," which requires that the labeling and warnings for generic pharmaceuticals be identical to those of their brand-name counterparts. Because the FDCA and existing regulations under the Food and Drug Administration (FDA) make it impossible for generic manufacturers to unilaterally change their labels to strengthen or add new warnings, the court held that failure-to-warn claims were impliedly pre-empted.

Since *Mensing* was decided, numerous courts have tried to address the breadth and scope of the decision. Whereas plaintiffs have typically argued that *Mensing* only pre-empts a very narrow category of failure-to-warn claims, generic manufacturers have taken the position that *Mensing* should be broadly applied to pre-empt other types of claims.

Post-*Mensing*, courts have almost universally held that claims premised on allegations that the generic manufacturer failed to add new or additional warnings to its labeling are pre-empted. *See, e.g., In re Fosamax Products Liability Litigation*, MDL No. 2243, 2011 U.S. Dist. LEXIS 135006, at *34 (D.N.J. Nov. 21, 2011) (dismissing plaintiffs' failure-to-warn claim that defendant should have changed its label "to provide new, different, and stronger warnings"). In addition, most courts have not been receptive to plaintiffs' arguments that generic manufacturers should have used alternative modes of communication, such as "Dear Doctor" letters, to highlight warnings that were already contained in the product labeling. See, e.g., *Guarino v. Wyeth*, 823 F. Supp. 2d 1289, 1292 (M.D. Fla. 2011) (holding that the *Mensing* court "specifically rejected Plaintiff's failure-to-communicate argument"); *Del Valle v. Pliva*, No. 11-113, 2011 U.S. Dist. LEXIS 153473, at *17-18 (S.D. Tex. Dec. 21, 2011) (holding that plaintiff's Dear Doctor letter argument was precluded by *Mensing*). In light of the significant obstacles that *Mensing* has imposed on failure-to-warn claims, plaintiffs injured by generic pharmaceutical products are alleging different causes of action to try and get their cases to a jury.

One of the more interesting causes of action that plaintiffs are now asserting against generic pharmaceutical manufacturers is a design-defect claim. Traditionally, design-defect claims are not very common in pharmaceutical cases for two primary reasons. First, many jurisdictions require plaintiffs asserting a design-defect claim to prove that a safer alternative design existed. See, e.g., *Diluzio-Gulino v. Daimler Chrysler*, 385 N.J. Super 434, 440-41 (App. Div. 2006). Second, many jurisdictions have adopted Comment K to the *Restatement (Second) of Torts*, § 402A, which immunizes manufacturers of "unavoidably unsafe" products from design-defect claims where the product is accompanied by an adequate warning. See, e.g., *Grinage v. Mylan Pharm.*, 840 F. Supp. 2d 862, 869 (D. Md. 2011). In the vast majority of pharmaceutical cases, either plaintiffs cannot establish that the product can be designed in a safer alternative manner or the defendant can prove the affirmative defense that no alternative design would eliminate the

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product's side effects.

Despite these inherent flaws, post-*Mensing* plaintiffs have tried to assert design-defect claims against generic pharmaceutical manufacturers. Although *Mensing* only specifically addressed failure-to-warn claims, generic manufacturers have argued that the same principles that preclude failure-to-warn claims also pre-empt design-defect claims. See, e.g., *In re Fosamax*, 2011 U.S. Dist. LEXIS 135006, at *33-34. Generic manufacturers have argued that *Mensing*'s "duty of sameness" should be expanded to design-defect claims because the FDCA not only requires generic and brand-name pharmaceutical products to have identical labeling, but that they also share the same design. In order for a pharmaceutical manufacturer to obtain FDA approval to market a generic drug, the manufacturer must ensure that the generic drug is identical to the brand-name product not only in labeling but also in active ingredients, route of administration, dosage form, safety and efficacy. *Mensing*, 131 S. Ct. at 2574 n.2; 21 C.F.R. 355(j)(2)(A)(i)-(v). Essentially, if a manufacturer wants to manufacture and sell a generic medication, it must prove to the FDA that the designs of the generic and brand-name products are identical.

Given that generic manufacturers are legally bound to use the brand-name product's design, many courts have held that state law claims challenging the design of the product are also pre-empted under *Mensing* because the same "duty of sameness" that precludes generic manufacturers from unilaterally and voluntarily changing the warnings for the product also preclude generic manufacturers from voluntarily and unilaterally changing the design of the product. See, e.g., *In re Fosamax*, 2011 U.S. Dist. LEXIS 135006, at *32-34, 41-42; *In re Pamidronate Prod. Liab. Litig.*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012); *Metz v. Wyeth*, No. 8:10-cv-2658, 2012 U.S. Dist. LEXIS 42432, at *10-13 (M.D. Fla. Mar. 28, 2012); *Johnson v. Teva Pharm. USA*, No. 2:10-cv-404, 2012 U.S. Dist. LEXIS 71384, at *11-13 (W.D. La. May 21, 2012); *Eckhardt v. Qualitest Pharm.*, 858 F. Supp. 2d 792, 801-2 (S.D. Tex. 2012); *Aucoin v. Amneal Pharm.*, No. 11-1275, 2012 U.S. Dist. LEXIS 100889, at *30-31 (E.D. La. July 20, 2012); and *In re Darvocet Prod. Liab. Litig.*, MDL No. 226, 2012 U.S. Dist. LEXIS 30593, at *106-7 (E.D. Ky. Mar. 5, 2012).

Earlier this year, however, the United States Court of Appeals for the First Circuit rejected arguments that design-defect claims against generic pharmaceutical manufacturers were impliedly pre-empted under *Mensing*. See *Bartlett v. Mutual Pharm. Co.,* 678 F.3d 30 (1st Cir. 2012). *Bartlett*, which was filed in the United States District Court for the District of New Hampshire, involved claims that the plaintiff developed Stevens Johnson Syndrome as a result of her use of the defendant Mutual Pharmaceutical Company's generic form of sulindac, a nonsteroidal anti-inflammatory drug. In light of *Mensing*, the plaintiff dismissed her failure-to-warn claim and proceeded solely with a design-defect theory of liability. At trial, the plaintiff argued that the risks of Stevens Johnson Syndrome associated with sulindac outweighed its benefits, and won a jury verdict against Mutual for $21.06 million.

On appeal, Mutual argued that the plaintiff's design-defect claim was pre-empted by *Mensing*. The First Circuit acknowledged that there was no evidence that sulindac, a one-molecule drug, could have been designed in a different or safer form. But, the First Circuit noted that the *Bartlett* case was unique in two ways. First, the court ruled that under New Hampshire law, the plaintiff could establish a design defect without proof of a safer alternative design. The First Circuit held that to establish a design defect, the plaintiff only had to prove that sulindac was unreasonably dangerous. Second, the court noted that prior to trial Mutual abandoned its "unavoidably unsafe" affirmative defense under Comment K to the *Restatement (Second) of Torts*, § 402A. In light of these factual circumstances, the court held that the plaintiff's design-defect claim was not pre-empted under *Mensing* because Mutual had the option to not make sulindac at all. Although the First Circuit acknowledged that in *Mensing*, the Supreme Court rejected this "market withdrawal" argument as it related to failure to warn claims, the court held that there was no indication that the Supreme Court would extend *Mensing* to design-defect claims. Mutual filed a petition for certiorari with the Supreme Court, arguing that the First Circuit's decision directly conflicts with the court's decision in *Mensing*. The court granted Mutual's petition on Nov. 30.

In the post-*Mensing* era, it is clear that plaintiffs are trying to assert different causes of action and theories of liability such as design-defect claims in order to maintain claims against generic pharmaceutical manufacturers. Whether plaintiffs will succeed in maintaining these new theories and causes of action still remains to be seen. The Supreme Court's decision in *Bartlett* is likely to establish further precedent on these issues. ■