Sills Cummis & Gross P.C.

Client Alert **Product Liability Law**

Product Liability Claims Against Generics After Pliva v. Mensing: Do Any Claims Survive?

Following the U.S. Supreme Court's seminal decision in *Pliva v. Mensing*, 131 S. Ct. 2567 (2011), do any product liability claims against generic manufacturers survive? While the issue has yet to be fully litigated, one U.S. District Court Judge in New Jersey recently answered that question with a resounding "no." On November 21, 2011, the Honorable Garrett E. Brown, the former Chief Judge for the U.S. District Court in New Jersey who presided over the MDL, *In re Fosamax (Alendronate Sodium) Products Liability Litigation (No. II)*, granted the generic manufacturers' motion to dismiss virtually *all* of the theories of plaintiffs' Complaint.[1] Judge Brown found that the "duty of sameness" underlying the *Mensing* decision applied not only to failure to warn claims, but also to other legal theories advanced by plaintiffs. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, No. 08-008, 2011 U.S. Dist. LEXIS 135006 (D.N.J. Nov. 21, 2011) ("*Fosamax*"). On December 29, 2011, Judge Brown's successor, the Honorable Joel A. Pisano, issued *sua sponte* an Order to Show Cause to plaintiffs' counsel as to why Judge Brown's Memorandum Opinion and Order ("Order") should not be the law of the case. If Judge Pisano determines that Judge Brown's Order is the law of the case, virtually all claims against generic manufacturers in the *Fosamax* litigation will fall. Clearly, Judge Brown's opinion has implications in the *Fosamax* case and beyond.

[1] The only exceptions were the manufacturing defect, loss of consortium and restitution claims. Judge Brown dismissed the manufacturing defect claim without reaching the pre-emption issue because plaintiffs' pleadings did not contain sufficient supporting factual allegations as required by *Twombly* and *Iqbal*. The loss of consortium and restitution claims were also dismissed because their viability was dependent on the survival of plaintiffs' state tort claims, which were dismissed on pre-emption grounds.

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By way of background, Fosamax and its generic equivalent, alendronate sodium, are oral medications for the treatment of osteoporosis and Paget's disease. Plaintiffs were prescribed Fosamax and claim that the drug caused osteonecrosis of the jaw and of the femur. Numerous complaints relating to femur fractures were filed in federal courts throughout the country against brand and generic manufacturers, and were eventually centralized in the District of New Jersey for pre-trial proceedings. Plaintiffs' Complaints contain numerous causes of action including defective manufacturing, defective design, failure to warn, negligence, fraud, misrepresentation, failure to conform to representation, negligent misrepresentation, breach of express and implied warranties, violation of consumer protection laws, restitution and loss of consortium.

The generic manufacturers' motion to dismiss required Judge Brown to evaluate the nature and extent to which the *Mensing* decision impacted various claims against them. In *Mensing*, the U.S. Supreme Court found that failure to warn claims against generic manufacturers were impliedly pre-empted by the Food Drug and Cosmetic Act ("FDCA") because the FDCA and FDA regulations precluded a generic manufacturer from unilaterally making changes to a product's labeling and warnings. Plaintiffs' failure to warn claim in *Fosamax* fell squarely within the *Mensing* ruling, and not surprisingly, Judge Brown found that this claim was pre-empted. *Id.* at *34.

Mensing, however, specifically addressed only failure to warn claims. The availability of other tort claims against generic manufacturers was not before the U.S. Supreme Court. In Judge Brown's evaluation of the generic manufacturers' motion, he found that the crux of the Supreme Court's decision was its conclusion that "generic manufacturers have a federal duty of 'sameness' to, at all times, insure that the label for the generic drug is identical to the label adorning the corresponding reference-listed drug." *Id.* at *28 (citing *Mensing*, 131 S.Ct. at 2575). Judge Brown determined that the *Mensing* "duty of sameness" rationale extended to virtually all of plaintiffs' claims. *Id.* at *33.

With respect to plaintiffs' design defect claim, Judge Brown explained that a generic drug is "designed to be a copy of the reference listed drug" and must be "identical in active ingredients, safety and efficacy." *Id.* at *32-33. To obtain approval of an Abbreviated New Drug Application, the generic manufacturer must establish pharmaceutical equivalence and bioequivalence. In other words, a generic manufacturer that refused to use the same active ingredient as the brand manufacturer could not receive FDA approval to market the drug. Under these circumstances, Judge Brown held that the "duty of sameness" applied to generic drug design and that plaintiffs' design defect claims were also pre-empted. *Id.* at *32-34.

Judge Brown applied the same analysis to plaintiffs' negligence, warranty and fraud related claims. He looked beyond the formulaic elements of each legal theory to identify the true basis of the cause of action. For example, plaintiffs' negligence claim maintained that the generic manufacturers failed to exercise ordinary care regarding a variety of activities including labeling, marketing, promotion, testing and design. Judge Brown found that the labeling, marketing and promotion claims were pre-empted because plaintiffs were alleging that defendants should have changed their product labeling. Since *Mensing* required the generic manufacturers to use the same product label as the brand manufacturer, it would be impossible for the generics to comply with the alleged state law tort duty and still be in compliance with federal law. *Id.* at *40. To the extent that plaintiffs' negligence claim alleged a failure to exercise ordinary care in the product's design and testing, Judge Brown again found that it ran afoul of the *Mensing* "duty of sameness". He determined that plaintiffs were essentially alleging that the generic manufacturers should have changed the active ingredient of the drug. *Id.* at *41. As discussed above, such a change was prohibited by FDA requirements.

Similarly, the Court held that plaintiffs' breach of implied warranty claim was pre-empted because it was based on the argument that the product should be designed differently. *Id.* at *41-42. The express warranty, misrepresentation and fraud claims were pre-empted because the gravamen of each allegation was based on alleged defects in the product labeling. *Id.* at *42-44.

If Judge Brown's Order becomes the law of the case in the *Fosamax* litigation, all of plaintiffs' claims against generic manufacturers will be dismissed with prejudice. This result seems likely as Judge Pisano's Order to Show Cause states that "it appear[s] to the Court that all claims asserted against generic manufacturers emanate from a general theory of failure to warn" and are therefore pre-empted by *Mensing.* Whether other federal and state courts will adopt Judge Brown's reasoning remains to be seen. *See Stevens v. Pliva, Inc.*, No. 6:10-0886, 2011 U.S. Dist. LEXIS 147684, at *5 (W.D. La. Nov. 15, 2011) (failure to warn and design defect claims pre-empted by *Mensing*); *but see Fisher v. PLIVA USA, Inc.*, No. 4:09-cv-00252-TLW, at pp. 4-11 (D.S.C. January 11, 2012) (implied warranty, negligence, fraudulent concealment and unfair trade practice claims still viable after *Mensing*). For the time being, Judge Brown's ruling is a welcome result for defendants in that litigation and a potential blueprint for generic manufacturers to obtain early dismissal in other cases.

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