Two Post-Mensing Firsts

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In a post-Mensing world, plaintiffs -- faced with almost certain dismissal of any claim based on labeling, promotion or warnings -- are scrambling to re-define their claims against generic drug manufacturers. They are most certainly looking for their port in a storm. As our faithful readers know, we are keeping track of post-Mensing generic drug preemption decisions here -- an ever growing list of dismissals of failure to warn claims.

Today, however, our focus is on how Mensing is being applied to some of plaintiffs' "alternate" theories of liability. So we bring you two cases -- Gross v. Pfizer, Inc., ___ F. Supp.2d ___, 2011 WL 5865267 (D. Md. Nov. 22, 2011) (metoclopramide) and In re Fosamax Litigation, 2011 U.S. Dist. Lexis 135006 (D.N.J. Nov. 21, 2011) (alendronate sodium) (thanks to Anita Hotchkiss at Goldberg Segalla for forwarding this one). A quick note of interest for brand-defendants – in Gross, the court had dismissed plaintiff's claims against the brand defendants because she had not ingested the brand-name drug. Gross, 2011 WL 5865267, *1. Post-Mensing, the court denied plaintiff's motion to reconsider its judgment in favor of the brand defendants. Id.

Now back to generics. In both cases, generic defendants moved to dismiss all of plaintiffs' state law claims as preempted. First, both courts quickly and easily dismissed plaintiffs' failure to warn claims. Id. at *3 (plaintiff conceded her inadequate labeling claims were preempted); In re Fosamax, 2011 U.S. Dist. Lexis 135006, *34 ("Plaintiffs' claims of failure to warn are squarely preempted by Mensing). In In re Fosamax, the court also went on to find that nothing in the 2007 Food and Drug Administration Amendments Act ("FDAAA") changes the generic preemption analysis

> "Accordingly, the Mensing analysis is not affected by FDAAA because the Generic Manufacturers are still unable to unilaterally change drug labeling without special permission and assistance, which is dependent on the exercise of judgment by a federal agency."

Id. at *37-38 (citation and quotation marks omitted).

Next, the courts explained that plaintiffs' omission of the words "failure to warn" in certain claims, doesn't make them any less failure to warn claims. In Gross, for instance, plaintiff unsuccessfully argued that her negligence claim for concealing important safety information survived Mensing. Gross, 2011 WL 5865267 at *4. Really? Concealing safety information isn't a failure to warn claim? Likewise, the Fosamax court made short shrift of plaintiffs' breach of express warranty, fraud, misrepresentation, failure to conform to representation, negligent misrepresentation and violation of consumer protection statutes "because the gravamen of these allegations is the insufficiency of [the] labeling." In re Fosamax, 2011 U.S. Dist. Lexis 135006 at *43.

After doing away with all of the labeling-based claims, these courts examined two additional claims designed to circumvent Mensing – negligent continued selling and design defect. In Gross, plaintiff brought negligence claims alleging the generic manufacturer had a duty to cease selling metoclopramide. The court acknowledged that that very argument had been adopted by the Eighth Circuit and therefore rejected by the Supreme Court in Mensing. Gross, at *3. In holding the "stop selling" claims preempted, the court stated that it

> "is aware of no state law duty that would compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce. Nor could such a state law duty exist, as it would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce."

Id. The Fosamax court also didn't buy the "stop selling" argument. In re Fosamax, at *36, n.5 ("To accept Plaintiffs' argument that Generic Defendants could have simply stopped marketing alendronate sodium, this Court would have to directly contravene binding law;" "it is essentially a re-argument of Mensing.").

The Fosamax court also dismissed plaintiffs' design defect claims on the identical sameness rationale used in warning cases. In Mensing, the Supreme Court

> "found 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. As with the label, federal law requires that the "active ingredient of the [generic] drug is the same as that of the listed drug." Id. at *33 (citation omitted).

"Hence, the "duty of sameness" also applies in the context of generic drug design. Mensing stands for the principle that a federal duty of sameness arising out of FDA's regulatory requirements preempts any conflicting tort duty arising under state law."

Id. Because federal law requires generic Fosamax to have the same active ingredient as brand-name Fosamax, the generic defendants could not have changed the design of the drug and therefore, plaintiffs' design defect claims are preempted. Id. at *34.

So, at least in these two courts, plaintiffs have yet to find a safe harbor in which to dock and remain adrift in the swirling seas of Mensing.