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Door Closes, Window Opens For Generic-Drug Injury Claims

By **Greg Ryan**

Law360, New York (June 24, 2013, 7:58 PM ET) -- Though its ruling on Monday stamped out one remaining glimmer of hope for plaintiffs looking to hold generic-drug makers liable for their injuries, the U.S. Supreme Court appears to have created another by maintaining that the decision does not address allegations that parallel federal misbranding law.

Five of the court's nine justices ruled that a design defect claim against Mutual Pharmaceutical Co. Inc. was preempted, because its generic anti-inflammatory drug sulindac must be designed the same way as its brand-name counterpart under federal law.

*The decision erased not only a \$21 million award to sulindac user Karen Bartlett, but the most significant victory for a consumer suing a generic-drug maker since the Supreme Court issued its **landmark Mensing decision** almost two years ago to the day. The court held in Mensing that federal law preempts failure-to-warn claims against generics makers, and following the ruling, few plaintiffs besides Bartlett have been able to prevail against the companies in personal injury litigation.*

The majority opinion, authored by Justice Samuel Alito, left plaintiffs with a surprise opening, however. Justice Alito included a footnote that specified that the decision does not address design defect claims "that parallel the federal misbranding statute," which requires manufacturers to pull a drug from the market if it proves dangerous to users' health when used as recommended.

Misbranding allegations are "one of the most promising avenues left" for injured generic-drug users after the Mensing and Bartlett rulings, Lou Bograd, senior litigation counsel at the Center for Constitutional Litigation, told Law360 on a conference call Monday.

"The footnote potentially makes this ruling extremely narrow," Bograd said.

According to the footnote, Mutual, Bartlett and the federal government — which participated in oral argument in the case on the side of Mutual — seemed to agree that a drug can only be considered misbranded based on "new and scientifically significant information" not presented to the U.S. Food and Drug Administration.

The misbranding statute is not applicable to the Bartlett case because the jury was not asked to determine whether sulindac was misbranded based on new information, according to the footnote. But, "in any worthwhile design defect case, there should be new scientific evidence that would render the drug misbranded," Bograd said.

Plaintiffs attorney Bill Curtis said that though it was difficult to determine the form a parallel generic-drug claim would take, the footnote had already caught the attention of the plaintiffs bar.

The parallel claims could include allegations that a generics maker failed to update its drug's labeling when the FDA said it should have, according to Reed Smith LLP counsel James Beck.

*Such claims have found success since the Mensing decision. A California appeals court **ruled earlier in June**, for instance, that a lawsuit against Teva Pharmaceuticals USA Inc. and other makers of a generic form of the osteoporosis drug Fosamax was not preempted by Mensing*

because the companies had failed to update the product's labeling.

"Of all of the claims I've seen — and I've read every post-Mensing generic preemption case — I'd have to say that's the only one I see that could survive the one-two punch of Mensing and Bartlett," Beck said.

Though there have been few actual rulings on the failure-to-update theory, Curtis said "there are a surprising number of generic-drug companies that don't copy the brand-name label." He pointed to a 2012 report that found 68 percent of the drugs studied by researchers had discrepancies in the brand-name and generic labeling.

Many of the same attorneys who litigate generic-drug injury cases are familiar with parallel claims in the context of medical device injury litigation. There, plaintiffs have had some success avoiding preemption by asserting state-law claims that parallel federal requirements under the Medical Device Amendments to the Food, Drug and Cosmetic Act.

Blackwell Burke PA partner Peter Goss suggested that the parallel claims envisioned by the court could include allegations related to a manufacturing issue in which the drug is not as potent as its label claims. The FDA seems to have started paying more attention to manufacturing issues with generics makers, he said.

However, "a parallel claim of that nature has got to be much narrower than a parallel claim for a [premarket-approved] medical device," Goss said.

Attorneys cautioned that the footnote was just that — a footnote. The majority did not rule that federal law allows for state-law claims based on federal misbranding law. It ruled only that it was not addressing the question.

Still, it represents at least a possible path to finding a generic-drug maker liable for an injury, a precious nugget in the post-Mensing — and now post-Bartlett — world, they said.

Other than a few victories based on a generics maker's failure to update a label, plaintiffs have largely had to put their faith in the theory of innovator liability, which holds that a brand-name maker can be found liable for an injury allegedly caused by a generic version of its drug.

*Only a California appeals court, a Vermont federal court and the Alabama Supreme Court have endorsed the theory, and the Alabama Supreme Court recently said it was **going to reconsider that decision**.*

--Editing by John Quinn and Chris Yates.

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