The Gift That Keeps On Giving (To Defendants)

Law360, New York (December 20, 2013, 6:04 PM ET) -- On Dec. 2, 2013, the Sixth Circuit joined a number of its sister courts and broadly applied PLIVA v. Mensing, further stifling the ability to maintain claims against generic drug manufacturers on a failure-to-warn theory. In so doing, the Sixth Circuit added another nugget to defendants’ ever-growing Mensing goldmine.

When the U.S. Supreme Court decided Mensing in 2011, and held that state law failure-to-warn claims against generic drug manufacturers were preempted by federal law, defendant drug manufacturers knew they had won a major victory. But the broad implication of this decision is only now becoming clear. Specifically, in the past two years, courts have cited Mensing to preempt straightforward state law failure-to-warn claims as well as design defect claims and other claims that they deem to be failure-to-warn claims in disguise.

This perceived expansion of Mensing has been, in part, attributed to plaintiffs’ ever-changing theories that attempt to hold generic drug manufacturers liable. Thus, while defendant drug manufacturers should continue to attack product defect claims under Mensing, their time would be well spent attempting to anticipate what creative arguments they may face in 2014.

PLIVA v. Mensing

In Mensing, plaintiffs claimed that generic drug manufacturers had failed to adequately warn of the alleged risk of developing tardive dyskinesia when taking the generic version of Reglan. The court held that plaintiffs’ state law failure-to-warn claims were preempted by the Federal Food, Drug, and Cosmetic Act’s federal labeling requirements because it would be impossible for the manufacturers to simultaneously comply with the FDCA’s requirement that generic drug manufacturers use the same label as the branded drug manufacturers and the state law requirement that such manufacturers change their labels to adequately warn of the risk of developing tardive dyskinesia.

In reaching this holding, the court specifically rejected the plaintiffs’ argument that generic drug manufacturers could meet a state law-based duty-to-warn by sending “dear doctor” letters, which would include additional warnings, as such letters qualify as “labeling” that must match brand-name drugs. Further, while the court “d[id] not resolve” whether generic drug manufacturers have a duty under federal law to request a strengthened label from the Food and Drug Administration when they know of potential risks associated with using their product, the court held that under the facts of Mensing, such a duty was irrelevant because merely requesting a stronger label from the FDA would not, in itself, comply with a state law duty-to-warn, which requires actually providing adequate labeling.

Plaintiffs’ first attempted to avoid preemption under Mensing by arguing that a defendant generic drug manufacturer was liable for injuries allegedly caused by its product under a
design defect theory, as opposed to a failure-to-warn theory. However, in June 2013, the Supreme Court held in Mutual Pharmaceutical Co Inc. v. Bartlett that design defect claims that turn on the adequacy of a drug warning are preempted under Mensing as well.

In Bartlett, to avoid liability under New Hampshire law, the defendant had two potential options: 1) redesign the drug to increase its usefulness or decrease its risk; or 2) strengthen the drug warning to avoid any risk of harm from hidden dangers or from foreseeable uses.

As generic drugs are required to have the same active ingredients, dosage form, route of administration and strength as the brand-name drug, the Bartlett defendant could not employ the first option. Similarly, because generic drug labels must be the same as brand-name drug labels, the defendant also could not take the second route. In light of this impossibility, the court held that plaintiff’s claims were preempted. Moreover, the court rejected the plaintiff’s argument that the generic drug manufacturer could simply stop selling its drug to avoid liability, finding that such a rationale would render impossibility preemption “all but meaningless.” With this holding, the Bartlett court expanded Mensing’s utility for generic drug manufacturers.[1]

**Circuit Courts’ Reliance on Mensing**

Plaintiffs have also attempted to elude Mensing preemption by bringing other non-design defect claims. However, these theories of liability largely have been rejected by the circuit courts. For example, in Strayhorn v. Wyeth Pharmaceuticals, the Sixth Circuit recently joined other courts and rejected a plaintiff’s proffered “narrow reading of Mensing.” In Strayhorn, plaintiffs in seven consolidated lawsuits alleged, like the Mensing plaintiffs, that generic Reglan caused them to develop tardive dyskinesia.

Here, plaintiffs tried to circumvent Mensing by arguing that it only preempted state laws that require generic drug manufacturers to change a label’s content, but not those that require manufacturers to merely provide additional warnings. Thus, plaintiffs argued that generic drug manufacturers could have sought FDA approval for a labeling change, or could have sent additional warnings to doctors and other healthcare professionals, thereby complying with both state and federal law. The Strayhorn court noted that “plaintiffs’ narrow reading of Mensing has been soundly rejected by all circuits to consider the argument,” so it did as well.

In sum, the circuits that have considered non-traditional failure-to-warn theories “have interpreted Mensing to broadly preempt claims that are, at their core, claims that the generic manufacturer failed to provide additional warnings beyond that which was required by federal law of the brand-name manufacturers.”[2] Such holdings, coupled with the Supreme Court’s decision in Bartlett, signal that courts will likely continue to reject arguments that attempt to narrow Mensing’s holding or try to recategorize failure-to-warn claims under a different theory of liability.

This is not to say, though, that defendants relying on Mensing will no longer face challenges. Indeed, one circuit split seems to have emerged given that the Supreme Court has provided no guidance regarding whether generic drug manufacturers can be liable under state law for failing to update their labels to match those of brand-name drug manufacturers.[3] Notably, however, these “failure-to-update” cases have thus far been
infrequent as they primarily arise when a plaintiff is allegedly injured by a drug after the brand-name drug label is changed, but before the generic drug label is changed.[4]

What to Expect in 2014

Plaintiffs are likely to bring “failure-to-update” claims in 2014, given that at least one appellate court has held that these types of cases escape Mensing preemption. Such litigation has the potential to be extensive since determinations regarding how quickly generic drug manufacturers need to update their labels have not yet been made. However, as most courts have found that Mensing preempts claims against generic drug manufacturers which relate to the adequacy of the manufacturers’ warnings, it is likely that Fulgenzi and it progeny will not have far-reaching influence. Moreover, the Supreme Court may decide to resolve this failure-to-update issue in the coming months.[5]

Additionally, both Congress and the FDA may help clarify when claims against generic drug manufacturers will be preempted. Indeed, as noted in Bartlett, the Supreme Court “would welcome Congress’ ‘explicit’ resolution of the difficult pre-emption questions that arise in the prescription drug context.” Last year, Congress introduced a bill for the Patient Safety and Generic Labeling Improvement Act (2012 U.S. S.B. 2295 (NS)), which would have required generic drug manufacturers to follow the same labeling standards as brand-name drug manufacturers. While this bill died after being referred to committee, the bill suggests that Congress may take action in this area of law, and could ratify or overrule the Mensing holding. Still, the FDA may be more likely to provide guidance given the time it takes to pass a bill, and that the FDA, on Nov. 13, proposed a new rule that would allow generic drug manufacturers to use the same process as brand drug manufacturers to update safety information in product labeling. The proposed rule is listed in the Federal Register, and is open for public comment until Jan. 13, 2014.

Until action is taken by Congress or the FDA, courts will determine the depth of the Mensing goldmine. If the Sixth Circuit’s recent decision to align with the majority is any indication, Mensing likely will continue to provide generic drug manufacturers with a golden opportunity to have claims against them dismissed early.

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[1] But see Bell v. Pfizer, Inc., 716 F.3d 1087 (8th Cir. 2013) (holding that plaintiff's design defect claims were not preempted because plaintiff sufficiently argued that her claims were not failure-to-warn claims “at their core”).

1245, 1247–49 (11th Cir. 2013) (holding that claims against the generic manufacturer for not “adequately warn[ing] medical providers of the risks” were “premised upon an allegedly inadequate warning,” and therefore, preempted under Mensing); Bell v. Pfizer, Inc., 716 F.3d 1087, 1095–96 (8th Cir. 2013) (rejecting plaintiff’s argument that Mensing’s preemption analysis “applies only to allegations that a generic manufacturer should have unilaterally changed the content of its [] label”); Morris v. PLIVA, Inc., 713 F.3d 774, 777 (5th Cir. 2013) (per curiam) (finding that generic manufacturers are precluded from unilaterally changing their label under federal law); Gaeta v. Perrigo Pharm. Co., 469 Fed. Appx. 556 (9th Cir. 2012) (affirming grant of summary judgment based on federal preemption of plaintiff’s state law claims for negligence, breach of express warranty, and breach of implied warranty based on an inadequate warning).

[3] Compare Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 584 (6th Cir. 2013) (finding no preemption of plaintiff’s claim that the generic drug manufacturer’s warning was “inadequate to the extent that it did not include the language contained in the updated [brand-name drug]” ) with Strayhorn, 2013 WL 6224337 at *9 (rejecting plaintiff’s argument that the generic drug manufacturer should have sought FDA approval for a labeling change) and Morris v. PLIVA, Inc., 713 F.3d 774, 777 (5th Cir. 2013) (stating that a claim that a generic drug manufacturer is required to update its drug label to meet that of the brand-name drug manufacturer “sounds exclusively in federal (not state) law, and is [thus] preempted”).

[4] See e.g. Fulgenzi, 711 F.3d 578.

[5] Specifically, plaintiffs in Morris have revealed that they plan to file for a petition for certiorari with the Supreme Court.