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Rejecting Brand-Liability Theory Post-Mensing

Law360, New York (December 19, 2011, 6:48 PM ET) -- On Sept. 22, 2011, the U.S. Court of Appeals for the Sixth Circuit ruled in Smith v. Wyeth Inc. that former brand manufacturers of Reglan — a prescription drug used to treat certain gastric disorders — could not be held liable for injuries caused by their competitors' generic versions of the drug. On Nov. 22, 2011, the court denied plaintiffs' petition for rehearing en banc.

In doing so, the Sixth Circuit became the first appellate court to address, and reject, the argument that the U.S. Supreme Court's recent preemption decision in Pliva v. Mensing (2011) either altered state law claims against brand manufacturers whose products were not ingested or undermined the prior weight of authority that a brand manufacturer owes no duty to a consumer of generic products.

Smith involved claims by three plaintiffs, each alleging that they had developed tardive dyskinesia following ingestion of generic metoclopramide. Plaintiffs asserted various tort claims, including traditional products liability theories of strict liability, negligence and breach of warranty against the generic manufacturers.

Against the former brand manufactures, plaintiffs asserted fraud and negligent misrepresentation claims arguing that the brand manufacturers had failed to warn plaintiffs (through their doctors) of the risks associated with the long term use of the generic drug. Each plaintiff alleged that his (or her) physician had relied on the brand manufacturers' labeling in the prescribing decision, though the pharmacies ultimately substituted generic versions, as was required by Kentucky law.

The U.S. District Court for the Western District of Kentucky granted judgment for the brand manufacturers under Kentucky law, and judgment for the generic manufacturers on the basis of federal preemption. Plaintiffs' appealed.

Following briefing and oral argument, the Sixth Circuit stayed its ruling pending the outcome of the U.S. Supreme Court's decision in Mensing. In its June 2011 decision, the Supreme Court determined that state-law failure-to-warn claims against generic drug manufacturers are preempted by the Supremacy Clause of the U.S. Constitution.

In subsequent briefing before the Sixth Circuit, plaintiffs argued that Mensing served to undermine the Fourth Circuit's 1994 decision in Foster v. American Home Prods. Corp. That decision found that there was no basis under Maryland law for holding brand manufacturers liable on a misrepresentation theory for injuries stemming from their generic counterparts' products.

Foster also reasoned, in dicta, that generic manufacturers could take advantage of the changes being effected regulations to alter their drug labeling, and that plaintiffs could, therefore, recover against those defendants. Plaintiffs' contended that because recovery against generics was held preempted in Mensing, the reasoning supporting Foster's central holding was no longer sound.

Relying on Mensing, the Sixth Circuit ruled the claims against the generic manufacturers were preempted. The court also affirmed dismissal for the brand manufacturers. The Smith court thereby declined plaintiffs' invitation to hold that Mensing undercut Foster, or that Mensing's holding regarding federal preemption altered Kentucky tort law as applied to claims against brand manufacturers in generic ingestion cases.

The Smith court held that plaintiffs' claims against the brand manufacturers were subject to the Kentucky Products Liability Act, regardless of the legal theory advanced. The court observed that a threshold to recovery under the act was a demonstration that the particular defendant's product caused the harm. The Smith plaintiffs, however, conceded that they had not ingested the brand manufacturers' products.

The court therefore concluded that plaintiffs could not meet this threshold, reasoning that a theory of liability requiring the court to attribute a deficiency in a brand manufacturer's labeling to products marketed by its generic competitors ran counter to the required showing that the defendant's product caused the injury. The Smith court commented that "[j]ust because a company is in the same business as a tortfeasor, the company is not automatically liable for the harm caused by the tortfeasor's product."

The Smith court also rejected the notion that the post-Mensing regulatory scheme governing brand and generic drugs rendered foreseeable the possibility that physicians would rely on brand manufacturers' warnings about their own products in prescribing generics. Endorsing the continued validity of Foster, the court cited favorably to that decision in concluding: "[a]s have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company."

The early returns suggest that the Sixth Circuit's opinion is in line with other post-Mensing jurisprudence, which likewise has declined to view Mensing as undermining Foster. Several additional courts are set to address this issue in the upcoming months.

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