



WARNING:
ALABAMA COURT'S BLAME-SHIFTING PHARMA DECISION
WILL HAVE SERIOUS SIDE EFFECTS

by
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Can a product manufacturer be subject to liability for a competitor's product? American tort law has always said, "No." It does not matter if the products are identical. Companies are not to be their competitors' keepers. Nor are they to be insurers of their competitor's products. Nevertheless, last month, the Supreme Court of Alabama overturned this fundamental of tort law. It held that a manufacturer of a brand-name prescription drug can be subject to liability even when a plaintiff alleges that he or she was harmed by a generic drug made by the brand-name manufacturer's competitor.

As discussed below, there were major shortcomings with this decision: (1) it appeared driven by a search for pockets for paying claims; (2) it came in the face of overwhelming case law to the contrary; (3) the court did not consider critical legal or health care consequences of its ruling; and (4) despite its rhetoric, the competitor liability theories approved could be easily applied to products in other industries.

The issue arose before the Alabama Supreme Court as a certified question from a U.S. District Court in *Wyeth, Inc. v. Weeks*. Mr. Weeks said he sustained injuries from long-term use of generic metoclopramide, but sued the manufacturer of the brand-name drug on which the generic was based. He alleged misrepresentation and fraud, claiming his physician was not adequately warned of potential consequences of long-term use when the drug was marketed and sold by the brand-name manufacturer.

In allowing the claims to go forward, the Alabama Court hinged its decision on the issue of "foreseeability." It held it was foreseeable to the brand-name manufacturer that statements it made about its products could result in a patient taking and being harmed by its generic counterpart. The Court said this was so for several reasons: generics must use the same labeling brand-name manufacturers develop for their drugs; physicians sometimes prescribe drugs based on safety and efficacy representations made by the branded drugs' manufacturers in the Physician's Desk Reference and other materials; and pharmacies often fill prescriptions with generic drugs because of state "generic drug substitution" laws.

The "foreseeability fallacy" in this ruling, though, is that the alleged harm is not a foreseeable result of the brand name manufacturers' conduct, but of laws over which they have no control. Congress made the public policy decisions to lower barriers of entry for generic drugs, as have state legislatures in enacting laws to require certain prescriptions be filled with

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available generics. These laws have led 90% of prescriptions for a drug to be filled with generics within months after a branded drug's patent expires. Most courts have said that using these laws as a basis for liability stretches foreseeability much too far.

To date, over seventy court decisions, including from four federal courts of appeal, have rejected this expansion of tort law. These courts recognized that a manufacturer cannot be subject to liability for a product it did not make. Brand-name drug manufacturers, in materials and labeling, are only referencing the safety and efficacy of their *own* drugs, no one else's. Also, artful pleading under misrepresentation and fraud does not nullify this requirement. A plaintiff must establish that the defendant owed her a duty, and manufacturers have no duty to users of another's product. Only two lower courts, a California appellate court and a federal trial court in Vermont, have allowed these claims.

The game changer, according to the Court, was the U.S. Supreme Court decision in *PLIVA v. Mensing*. *Mensing* held that duty to warn claims against manufacturers of generic drugs were preempted by the federal law requiring generic drugs to carry the same warning as their brand-name counterparts. The Alabama Court's decision to shift the generic's liability to the brand-name manufacturers is reminiscent of a comment by notorious plaintiffs' lawyer Dickie Scruggs about asbestos litigation. He called it "the endless search for a solvent bystander."

In point of fact, *Mensing* does not provide any new basis for competitor liability. It did not change tort law in Alabama or any other state. By contrast, before *Mensing* reached the Supreme Court, the U.S. Court of Appeals for the Eighth Circuit had dismissed the competitor liability claims in that suit. The Supreme Court made its ruling in light of this history, and on remand, the Eighth Circuit reiterated that the Supreme Court did not alter this determination. The availability of a competitor for litigation does not have any bearing on whether a claim can be brought against a company.

Since *Mensing*, about a dozen courts, including the U.S. Court of Appeals for the Fifth and Sixth Circuits, have rejected competitor liability for the same reasons. These courts have appreciated that establishing a tort duty also requires courts to consider the public policy implications of establishing the duty, as well as basic fairness. Saddling a company that has less than 10% of the market share with 100% of the liability exposure creates an unsustainable imbalance. The result will likely be brand-name manufacturers raising drug prices during periods of exclusivity to pay for this liability, and then departing the market once the drug's patent expires, taking their knowledgebase with them, rather than prolonging their liability exposure.

The underpinning of competitor liability, namely, that risks are the same for generic and brand-name drugs, is also not always true. FDA allows manufacturers of generic drugs, which can have different inert ingredients and release mechanisms, to have a rate and extent of absorption anywhere from 80 percent to 125 percent of that of the brand-name drug. In most circumstances, these differences might not have a therapeutic impact, but for certain types of drugs, the result can be different reactions in a patient's body, causing a potential impact on treatment and side effects.

Regardless of whether a court disagrees with *Mensing*, it should not be tempted to alter its state's tort law to find defendants for users of generic drugs to sue. The Alabama Supreme Court has now allowed the "genie" of blaming one company for products made by a competitor out of a tightly sealed tort bottle. Once out, as tort law history has shown, it will expand beyond its original shape and defined purposes. Other states' courts should not follow this ruling. As for defendants now subject to previously unforeseen liability in Alabama, they will have to consider turning to state elected officials for relief.