

Showdown in Alabama: Litigators vs. Innovators



BY PHIL GOLDBERG

SEPTEMBER 2015

Every once in a while, personal injury lawyers come up with new ways to sue that can be real head scratchers. Courts usually weed out these theories, but they get through on occasion. This happened last year in Alabama, where the Alabama Supreme Court held that a company can be subject to liability, not for its own products, but for products entirely made and sold by its competitors. This theory for liability has been dubbed “innovator liability” because it is used primarily against companies that invent new products even though the plaintiffs in the cases are alleging that they have been harmed only by similar or “knock-off” products of other companies.

Alabama’s policy-makers appreciated that it makes no legal or economic sense for innovators to own the liability for an entire product line.

In May, the Alabama Legislature and Governor, in a swift bipartisan manner, overturned their state Supreme Court’s innovator liability ruling. Alabama’s policymakers appreciated that it makes no legal or economic sense for innovators to own the liability for an entire product line. In addition to being legally unprincipled, this liability theory punishes innovation, which could have devastating long-term impacts on consumers and businesses alike. The downsides of such liability are too great.

Alabama’s Rejection of “Innovator Liability”

The Alabama case, *Wyeth, Inc. v. Weeks*, involved prescription medicines, but it could have easily been over other products. The plaintiff, Mr. Weeks, fully acknowledged that he had taken only generic versions of the drug metoclopramide, alleging injury from its long-term use. Yet, he sued Wyeth, which did not make any of these generic drugs but had sold the brand-name version of the drug many years earlier. He alleged that Wyeth had not adequately warned doctors of the potential consequences of long-term use when it marketed the brand-name drug.

The Supreme Court of Alabama ruled on this case twice. In January 2013, it voted 6-3 to allow the lawsuit against Wyeth to proceed under this novel innovator liability theory, but soon thereafter granted Wyeth’s motion for reconsideration. Many observers believed the court might change its mind. While the case was under reconsideration, two federal courts of appeal and the Supreme Court of Iowa issued broad rejections of “innovator liability” theories, including as accepted in *Weeks*. The Iowa

high court referred to *Weeks* as an “outlier.” Nevertheless, in August 2014, the Alabama court affirmed its ruling by the same 6-3 margin.

During this year’s legislative session, the Alabama legislature stepped in, voting overwhelmingly to override this ruling. Legislatures hardly ever overturn judicial rulings, so it was important that this one was done with broad bipartisan support. The Alabama Senate voted 32 to 0, and the Alabama House voted 86 to 14. The legislation (S.B. 80) made it clear that a manufacturer can be subject to liability only for its own products, and not those of its competitors, even when its “design is copied or otherwise used by [another] manufacturer.” Alabama Governor Robert Bentley signed the bill, which will take effect in the next few weeks.

The decisiveness of this rebuke is important, both legally and for American health care. In today’s day and age, some 90% of all drug prescriptions are filled by generics within months of a drug patent’s expiration. Any trend exposing brand-name drug manufacturers for the liability costs of the entire drug market could irreparably harm the American health care system.

The Innovator Liability Landscape

Alabama’s legislative override of *Weeks* has national importance. Innovator liability theories, which first surfaced in the 1990s, have been rejected by more than 100 courts, including U.S. Courts of Appeals for six different federal circuits. However, in 2008 a California mid-level appellate court hearing a prescription drug case became the first court in the country to break with traditional tort law and approve an innovator liability theory. A federal district court in Vermont followed in 2010, making the Alabama Supreme Court the third, and highest, court to grant these theories.

Personal injury attorneys bringing these cases expected innovator liability to gain significant traction after the 2011 U.S. Supreme Court ruling in *PLIVA v. Mensing*. In *Mensing*, the Court held that warning-based claims against manufacturers of generic drugs are preempted by federal law, which requires a generic drug to carry the same warning as its brand-name counterpart. Their hope was that judges would allow innovator liability theories so that an aggrieved user of generic drugs could sue the brand-name manufacturer when preemption blocked potential recovery from the generic drugs’ manufacturers.

The Alabama Supreme Court followed this rationale, citing *Mensing* many times. The dissenting opinion called *Mensing* the “impetus” for the court’s decision. Indeed, a federal district court in Illinois followed suit in February 2014. However, dozens of other courts have continued to reject innovator liability. As these other courts explained, *Mensing* had nothing to do with innovator liability. *Mensing* dealt exclusively with federal law, whereas innovator liability is solely a question of each state’s tort law. In *Mensing*, the U.S. Supreme Court did not open the door for innovator liability or suggest changes to state tort law in any way.

As indicated, the Iowa Supreme Court was one of the courts to recently reject innovator liability, properly characterizing it as “deep-pocket jurisprudence [which] is law without principle.” The notion that a court should find someone else to blame rather than allow a plaintiff to go without recovery is not a viable theory for liability. Legendary plaintiffs’ attorney Dickie Scruggs called this tactic, which he popularized in asbestos litigation, “the endless search for the solvent bystander.” Alabama’s override of *Weeks* sends a powerful message by reversing any momentum that *Weeks* may have provided to innovator liability versions of deep-pocket jurisprudence.

The “Foreseeability Fallacy” of Innovator Liability

Innovator liability violates a basic tenet of American tort law: there must be a legal relationship between a plaintiff and a defendant. In other words, the defendant must have owed (and breached) a legal duty of care to that plaintiff in order to be subject to liability for that plaintiff’s alleged harms. A product manufacturer may have a legal duty to its own customers to manufacture a lawful, non-defective product. However, that manufacturer does not owe any such duty to its competitors’ customers to assure that its competitors make lawful, non-defective products.

In an effort to bridge this gap, which should be insurmountable, the Alabama Supreme Court hinged its ruling entirely on the concept of “foreseeability.” The court held that when a brand-name drug manufacturer markets and sells its own drugs, often during the drugs’ period of patent exclusivity, it is “foreseeable” that, even years later, a patient could take and be harmed by generic versions of those drugs.

Even the courts allowing innovator liability acknowledge that a manufacturer cannot owe a duty to customers of its competitors to assure that the competitors make lawful, non-defective products.

The court based its conclusion on the fact that a physician sometimes prescribes a generic drug based on what he or she learned about the brand-name drug in the Physician’s Desk Reference and other materials, and that a pharmacy often fills a prescription, even for a brand-name drug, with an available generic pursuant to its state’s “generic substitution” law. Also, a manufacturer of a generic drug cannot separately warn about potential risks of a drug because federal drug law requires generics to have the same labeling as their brand-name counterparts.

The fallacy with this ruling, the U.S. Court of Appeals for the Sixth Circuit explained, is that “generic consumers’ injuries are not the foreseeable result of the brand manufacturer’s conduct, but of laws over which the brand manufacturers have no control.” Congress made the public policy decision to lower barriers of entry for generic drugs, as have state legislatures in enacting laws that require certain prescriptions to be filled with available generics.

In his famous 1928 opinion in *Palsgraf v. Long Island Railroad Co.*, Judge Cardozo warned against over-reliance on foreseeability. Indeed, the California Supreme Court cautioned in another well-known case, *Thing v. La Chusa*, that on clear days “a court can foresee forever.” This is why foreseeability often is only one factor in creating a legal duty in tort law. Other considerations include the relationship of the parties, the remoteness of the conduct to the harm and public policy concerns.

Here, using federal drug laws as a basis for state tort liability stretches foreseeability too far. Brand-name drugs companies do not make representations or omissions about generic versions of their drugs. They inform physicians solely about their own products, often years before generic drugs enter the marketplace.

Again, the Iowa Supreme Court got to the heart of the issue. It recognized that drug companies are no differently situated than other innovators: “Where would such liability stop? If a car seat manufacturer recognized as an industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor’s seat that copied the design?” “[T]o expand tort liability to those who did not make, or supply, the injury-causing product used by plaintiffs involves policy choices and social engineering more appropriately within the legislative domain.”

Innovator Liability Is Bad Health Care Policy

Progressives who care about the quality of American health care should consider the potential health care impact of saddling 10 percent of the prescription drug market with 100% of the liability. In short, what would innovator liability mean for the ability of patients to have access to affordable prescription medicines? When courts have considered these important public policy concerns, they have come to the conclusion that creating broad, new financial pressures on brand-name drug manufacturers would end up harming American health care consumers.

The most obvious concern is that people would have to pay higher prices for their brand-name prescription medicines during the period of innovator exclusivity. Given the low percentage of brand-name prescriptions after a patent expires, brand-name drug manufacturers would likely have to amass additional resources during their window of exclusivity to pay for the anticipated competitor liability claims.

Another important concern is that fear of innovator liability will drive brand-name manufacturers to leave a drug’s market once generics become available and proceeds from the brand-name drug diminishes greatly. If this were to happen, consumers will have lost the company most familiar with a medicine and one that likely has the greatest infrastructure and resources to facilitate post-market research and analysis into any late developing safety issues with a drug. Further, while generic drugs are bioequivalent to brand-name drugs, they are not identical, and some people will lose the version of the drug that most benefits them.

It also will be riskier for brand-name drug manufacturers to innovate important medicines in the first place, particularly when a drug may come with major side effects or are for small classes of patients and will not drive large revenues. Researchers at Tufts University’s Center for the Study of Drug Development recently estimated that it now takes, on average, \$2.6 billion to bring a new drug to market, which is double the figure from a decade ago. The whole process can take more than ten years, with FDA approving only 8-12 percent of the new drug applications it receives. Drugs with high litigation risk profiles will be avoided in favor of safer blockbusters that can overcome these high costs.

Liability may very well be appropriate when a manufacturer has wrongfully caused someone injury, but it is not a vehicle for simply finding available pockets for paying claims.

Finally, there are no corresponding therapeutic benefits to innovator liability. As one federal judge sitting in Oregon explained, “I cannot find that a decision to hold a manufacturer liable for injury caused by its competitor’s product is rooted in common sense.” One often hears that liability can provide a deterrent effect, but disproportionate liability is not an accurate measure of deterrence. If labeling or marketing practices overstate benefits or downplay risks of a drug, its brand-name manufacturer can be subject to significant liability already, as well as substantial civil fines from the U.S. Department of Justice and state attorneys general.

Conclusion

With rare exception, tort and product liability laws are made in state courts. Judges make decisions about who can be subject to liability for what and to whom under each state’s common law. On occasion, a court goes too far and recognizes a theory for liability that has no basis in the law and establishes the wrong public policy. The Alabama legislature should be applauded for overturning with broad bipartisan support its state Supreme Court’s ruling to allow innovator liability.

The civil justice system should remain principled. Liability may very well be appropriate when a manufacturer has wrongfully caused someone injury, but it is not a vehicle for simply finding available pockets for paying claims. There must be a relationship, or legal duty, between the parties in each and every individual case. Further, the U.S. Court of Appeals for the Fourth Circuit stated, liability is “especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer’s statements by copying its labels and riding on the coattails of its advertising.” Brand-name and generic drugs may be bioequivalent, and federal and state law may encourage the availability of generic drugs, but that does not make companies their competitors’ keepers.

About the Author

Phil Goldberg is the director of the Progressive Policy Institute’s Center for Civil Justice and a partner in the Washington, D.C.-based Public Policy Group of Shook Hardy & Bacon L.L.P. Before joining the firm, he worked for three Democratic Members of the House of Representatives, including one who served on the House Judiciary Committee.

About PPI

The Progressive Policy Institute (PPI) is an independent research institution that seeks to define and promote a new progressive politics in the 21st century.