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Alabama Supreme Court Adopts "Innovator Liability"

*by Jack Park**

In *Wyeth, Inc. v. Weeks*, the Supreme Court of Alabama, by an 8-1 margin, adopted the so-called "innovator liability" theory, holding brand-name drug manufacturer Wyeth liable for personal injuries suffered by an individual who bought and used only a generic drug product manufactured and sold by one of Wyeth's competitors.[1] Unless reversed on rehearing, this ruling—the first by a state's highest court—stands in contrast with the vast majority of decisions that have rejected the theory. Only a California court of appeals and a U.S. district court in Vermont have previously embraced the innovator liability theory.[2] Rulings from four federal courts of appeal and from Alabama's neighboring southeastern states are among those decisions to the contrary.[3]

The *Weeks* case came to the Alabama Supreme Court through a certified question from the U.S. District Court for the Middle District of Alabama.[4] In the underlying case, the plaintiff, Danny Weeks, sued five current and former drug manufacturers—both brand-name and generic—alleging that he was injured as a result of his long-term use of metoclopramide, the generic version of the anti-reflux prescription medication Reglan, which Wyeth formerly manufactured. The federal court asked the Alabama Supreme Court to answer the following question:

> Under Alabama law, may a drug company be held liable for fraud or misrepresentation (by misstatement or omission), based on statements made in connection with the manufacture or distributionof a brand-name drug, by a plaintiff claiming physical injury from a generic drug manufactured and distributed by a different company?

Weeks and cases like it arise from the fact that federal law and regulations treat brand-name and generic prescription drugs differently. After incurring the substantial research and development cost to produce a brand-name product (sometimes $1 billion or more for a drug), a brand-name manufacturer must show the Food and Drug Administration (FDA) that the new medicine is both safe and effective. The FDA approval process involves two major steps. First, a brand-name manufacturer must submit an "Investigational New Drug Application," which includes, among other things, information about the chemistry, manufacturing, pharmacology, and toxicology of the proposed medicine as well as information about animal tests and the human testing protocols.[5] Second, once human clinical trials are complete, the brand-name manufacturer must submit a "New Drug Application," which reports the results of the clinical trials and includes information about the drug's components and its composition as well as samples of the proposed labeling.[6]

When the patent protection for an FDA-approved brand-name product expires (as Reglan's did in the mid-1980s) competitors are free to enter the market by selling generic versions of the medicine. Generic manufacturers do not have to follow the rigorous pre-market approval process that the FDA imposes on brand-name manufacturers. Instead, they can submit an Abbreviated New-Drug Application, which must show that the generic version is bioequivalent[7] to its brand-name counterpart but which, otherwise relies on the FDA's approval of that brand-name counterpart.

By piggy-backing on the FDA's approval of the brand-name product, the generic manufacturers "avoid the costly and time-consuming process associated with a [New-Drug Application], which allows the dissemination of low-cost generic drugs."[8] The generic manufacturer also piggy-backs on the promotional and marketing efforts of the brand-name manufacturers.

The result, not surprisingly, is that low-cost generic drugs are frequently substituted for the brand-name version. Indeed, in 2011, generic drugs constituted more than 80% of the prescriptions filled in the United States.[9] Depending on a state's particular requirements, the prescribing physician or a pharmacist can substitute a generic drug for the brand-name medicine, a result frequently promoted by insurance plans.

Prescription drugs, of course, come with side effects, and the FDA mandates that approved drugs be accompanied by warning

labels that identify those risks. In fact, claims involving drug warning labels are the most common kind of lawsuits brought against pharmaceutical manufacturers. Frequently, when a plaintiff alleges that he has been injured by a drug product, he will sue the product's manufacturer alleging, among other things, that the product's warning label was inadequate.

As noted above, the question in *Weeks* was whether a plaintiff who consumed only the generic substitute for Reglan can hold Wyeth—which manufactured brand-name Reglan, not generic metoclopramide—liable for deficiencies in the warning label on the generic product's packaging. The courts have almost uniformly held that consumers of generic products cannot pursue claims against the brand-name manufacturers. The leading case is *Foster v. American Home Products Corp*., in which the Fourth Circuit held that "a name brand manufacturer cannot be held liable on a negligent misrepresentation theory for injuries resulting from the use of another manufacturer's product."[10] Since *Foster* was decided in 1994, more than 75 courts applying the law of 25 states have agreed with the Fourth Circuit.

Plaintiffs around the country, though, now assert that the U.S. Supreme Court's June 2011 decision in *PLIVA, Inc. v. Mensing* changed the legal landscape. In *PLIVA*, the Court held that federal law preempts state court lawsuits alleging that generic drug makers failed to provide adequate warnings about the risks associated with the use of their products. The *Mensing* plaintiffs contended that generic drug manufacturers have a duty to change the labels on their products to reflect developments in the knowledge related to risk of use that occurred after the Food and Drug Administration first approved the label.

The Supreme Court rejected that contention. Because federal regulations require the makers of generic drugs to use the same warning label as the one on the brand-name version, the Court held that generic manufacturers cannot "unilaterally" change their labels. Instead, agreeing with the FDA, it said that the generic manufacturers had to work through the brand-name manufacturers to change the labels. But, because federal law and regulations prohibit the generic manufacturers from independently strengthening their warning labels as state law might compel them to do, the state-law claims against the generic drug-makers are preempted.

The Court recognized that federal preemption dealt the consumers of generic drugs an "unfortunate hand." The Eighth Circuit had already followed *Foster* to hold that the plaintiff, Gladys Mensing, who consumed only generic drug products, had no claim against the brand-name manufacturer.[11] Accordingly, the Supreme Court's holding that Mensing's claims against the generic manufacturers are preempted left her with, as Justice Sotomayor lamented in dissent, "no right to sue."[12] The Court explained, though, that given the dictates of federal statutory and regulatory law, the problems attributable to the warning labels on generic drugs were for Congress, the FDA, or both, to solve.

By foreclosing certain claims against generic drug manufacturers, *PLIVA* leaves a remedial "gap." Even though the U.S. Supreme Court put the burden on Congress and the FDA to plug the hole, that gap seemed to loom large in the Alabama Supreme Court's thinking.

In *Weeks*, the majority concluded that the brand-name manufacturer Wyeth could be held liable for deficiencies in the generic product's label because it should have "foreseen" that the generic manufacturer would use Wyeth's warning label. The majority explained, "[A]n omission or defect in the labeling for the brand-name drug would necessarily be repeated in the generic labeling, foreseeably causing harm to a patient who ingested the generic product."[13] It also surmised that a prescribing physician would rely on the brand-name manufacturer's label "even if the patient ultimately consumed the generic version of the drug."[14] Finally, the majority deemed the possibility of physical injury to be within the brand-name manufacturer's "reasonabl[e] contemplat[ion]."[15]

Accordingly, the majority held that a brand-name drug manufacturer can be held liable for defective warnings even "by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company."[16] The majority asserted that state-law tort lawsuits fill a gap in the enforcement and regulatory structure because they "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly and serve a distinct compensatory function that may motivate injured persons to come forward with information."[17] In short, the majority said that it was "not fundamentally unfair" to the brand-name manufacturer to make it answer for "the warnings on a product it did not produce" because the brand-name manufacturer drafted those warnings and the generic manufacturer "merely repeated" them.[18]

Justice Glenn Murdock dissented from the Alabama Supreme Court's decision to embrace the innovator liability theory. He recognized that "[t]here is no good outcome to this case," because *PLIVA* forecloses Mr. Weeks' claims against the manufacturers of the generic medicine he took. Justice Murdock then explained that the majority strayed from "certain bedrock principles of tort law and . . . [the] economic realities underlying those principles."[19] In his view, the majority's focus on foreseeability overlooked the core tort principle of duty, which requires that there be a preexisting "relationship" between the parties. A brand-name manufacturer that neither made nor sold that allegedly injurious generic metoclopramide to Mr. Weeks had no such relationship—and, thus, owed no duty to—him.

Justice Murdock also disagreed with the majority's treatment of the case law. As noted above, the *Weeks* decision departs from most other court rulings in the country rejecting innovator liability, and *PLIVA* did not upset that consensus.

Justice Murdock explained, *PLIVA* "did nothing to undermine the essential rationale in the plethora of pre- and post-*PLIVA* decisions holding that *brand-name* manufacturers are not liable for injuries caused by deficient labeling of generic drugs they neither manufactured nor sold."[20] He noted that, even when the pre-*PLIVA* courts seemed to assume that the plaintiffs could pursue their defective warning claims against the generic manufacturer, their conclusion that the brand-name manufacturers were not liable for the generic manufacturer's warning labels was independent of that assumption.[21] Indeed, it's not only the courts that ruled before *PLIVA* that reject attempts to hold brand-name drug manufacturers responsible for the labels on generic products, but each of the 18 post-*PLIVA* decisions as well. Justice Murdock pointed out, "Every one of the post-PLIVA decisions has held that the

manufacturers of brand-name drugs have no duty or liability to the consumer of a generic drug manufactured and sold by another company."[22]

Unless reversed on rehearing, *Weeks* is likely to spawn more litigation in Alabama about the adequacy of drug warnings.[23] Notably, that litigation will take place just as the FDA considers amending its regulations to overrule *PLIVA* and eliminate federal preemption of claims against generic drug manufacturers.[24] A change in the FDA's regulations to allow suits against generic manufacturers would make the Alabama Supreme Court's embrace of the "innovator liability" theory unnecessary.

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Endnotes

1 ___So. 2d ___, 2013 WL 13573 (Ala. Jan. 11, 2013), *available at* http://alabamaappellatewatch.com/wp-content/uploads/2013/01/Wyeth-v.-Weeks.pdf. On February 4, 2013, the dissent of Associate Justice Glenn Murdock was released. *See id.* (Murdock, J., dissenting), *available at* http://wlflegalpulse.files.wordpress.com/2013/02/weeks-dissent.pdf.

2 *See* Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299 (2008); Kellogg v. Wyeth, 762 F. Supp. 2d 694 (D. Vt. 2010).

3 To date, more than 75 published decisions applying the law of 25 states have rejected the notion that the brand-name manufacturer is responsible to the consumer of generics. Those decisions include Demahy v. Schwarz Pharma, Inc., 702 F.3d 177 (5th Cir. 2012); Smith v. Wyeth, Inc., 657 F. 3d 420 (6th Cir. 2011); Mensing v. Wyeth, Inc., 658 F.3d 867 (8th Cir. 2011); Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1004).

4 The U.S. District Courts for the Northern and Southern Districts of Alabama are among the courts that have gone the other way. *See, e.g.*, Simpson v. Wyeth, Inc., No. 7:10-cv-01771-HGD (N. D. Ala. Dec. 9, 2010) (not reported); Overton v. Wyeth, Inc., No. CA-10-1491-KD-C (S.D. Ala. Mar. 15, 2011) (not published); Mosley v. Wyeth, 719 F. Supp. 2d 1340 (S.D. Ala. 2010); Barnhill v. Teva Pharm. USA, No 06-282-CB-M (S.D. Ala. 2007).

5 *See* 21 U.S.C. § 355(b); 21 C.F.R. § 312.21.

6 *See* 21 U.S.C. §§ 355(b)(1), 355(d)(5).

7 *See* 21 U.S.C. § 355(j)(2)(A)(iv)(2006); 21 C.F.R. pt. 320 (2009).

8 Wyeth, Inc. v. Weeks, 2013 WL 13573 at * ___ (Ala. Jan. 11, 2013); No. 1:10-cv-602, slip op. at 13, *available at* http://www.reedsmith.com/files/uploads/DrugDeviceLawBlog/Weeks.pdf.

9 *See* IMS Institute for Healthcare Informatics, The Use of Medicines in the United States: Review of 2011 26 (April 2012), *available at* http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

10 29 F.3d 165. 167 (4th Cir. 1994).

11 *See* Mensing v. Wyeth, Inc., 588 F. 3d 603, 612–14 (8th Cir. 2009).

12 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2592 (2011) (Sotomayor, J., dissenting).

13 *Weeks*, No. 1:10-cv-602, slip op. at 41.

14 *Id.* at 42.

15 *Id.* at 45.

16 *Id.* at 51.

17 *Id.*

18 *Id.* at 52.

19 Wyeth, Inc. v. Weeks, No. 1:10-cv-602, slip op. at 1(Ala. Jan. 11, 2013) (Murdock, J., dissenting), *available at* http://wlflegalpulse.files.wordpress.com/2013/02/weeks-dissent.pdf.

20 *Id.* at 4 (emphasis in original)

21 *Id.* at 11–12

22 *Id.* at 28–29.

23 One scholar notes that the innovator liability theory is not, necessarily, limited to prescription drugs. He explains:

> [T]he same sorts of questions may arise with other types of consumer goods, ranging from nonprescription drugs and foods to household chemicals and appliances; in other words, crossover tort litigation could occur in any market served by brand-name companies that actively promote their wares but face competition from largely identical but lower-priced store brands.

Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copcat Product*, 45 Tort Trial & Insurance Prac. L.J. (2010), *available at* http://www.americanbar.org/content/dam/aba/publications/tort_insurance_law_journal/tips_vol45_no3_4_Noah.authcheckdam.pdf.

24 *See* Brief for the United States of America as Amicus Curiae Supporting Petitioner at 15 n.2, Mutual Pharm. Co. v. Bartlett, ___ S. C.t ___ (2013) (No. 12-142), *available at* http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v2/12-142_pet_amcu_usa.authcheckdam.pdf.