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Innovator Liability Finds Sweet Home In Ala.

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Earlier this month, the Supreme Court of Alabama confirmed its January 2013 holding in Weeks v. Wyeth Inc. that manufacturers of brand drugs can be liable for injuries caused by generic drugs. Though the recent ruling puts Alabama in a very small minority of jurisdictions recognizing innovator liability, it still represents a state supreme court holding that exposes brand drug manufacturers to liability they had not previously known. The ruling will likely result in significant new filings by the plaintiffs' bar in Alabama and renewed arguments by them for other jurisdictions to follow Alabama's reasoning.

Reargument After January 2013 Opinion

The Weeks case was originally decided in January 2013.[1] In that opinion, the Alabama Supreme Court became the first state supreme court to hold that brand drug manufacturers could be liable for injuries caused by generic drugs because the warnings and labels relied on were those of the brand drug. That ruling was contrary to the overwhelming majority of other courts, both trial courts and appellate courts alike who ruled against liability unless the drug ingested was from the brand drug company. The state high court was excoriated by many for deciding such an important question without oral argument. When the court decided to rehear the case — this time with oral argument — many in the pharmaceutical industry viewed this as an omen that reversal was likely. As time passed, it was thought the court might be carefully crafting a new opinion.

That hope was misplaced. Weeks II is surprising and disappointing to the pharmaceutical industry; it essentially restates the original opinion despite the fact that it had been nearly one year since oral argument and many courts had weighed in on this issue in the intervening year and a half since the first opinion.

The Holding: Foreseeability Derives from Mensing Preemption

Essentially, the Alabama Supreme Court held that it was foreseeable that a generic drug user's doctor would rely on representations by a brand drug manufacturer. In reaching this conclusion, the court relied on PLIVA Inc. v. Mensing, which interpreted federal statutes and regulations as requiring generic

drug manufacturers to copy brand drug manufacturers' labels. Unlike most other courts that have examined this issue, the Weeks court found that the foreseeability deriving from the federal regulatory scheme was sufficient to establish that the brand drug manufacturer owed the generic drug user a duty of care.

In reaching this decision once again, the state high court highlighted Alabama law regarding misrepresentation and "the fact that two parties have had no contractual relationship or other dealings does not preclude the finding of a legal duty not to make a material misrepresentation or to suppress a material fact." The majority concluded its opinion by reiterating that the fraud or misrepresentation claim at issue here premises liability not on "a defect in the product itself but as a result of statements made by the brand name manufacturer that Congress, through the U.S. Food and Drug Administration, has mandated be the same on the generic version of the brand name drug."

Concurrence: Defending the Court's Dignity

Justice James Gregory Shaw of the Alabama Supreme Court specially concurred to clarify and defend the majority's opinion. He noted several points.

First, the court's holding in no way meant that a company could generally be held liable for products it did not manufacture. Second, the court did not create new law. Instead, it applied existing Alabama law dealing with fraudulent conduct. He found that Alabama case law "generally holds that a duty to disclose may be owed to a person with whom the defendant has had no prior dealings, specifically, where there is a 'duty' not to make a false representation." Third, the majority opinion is extremely narrow and would not apply outside the pharmaceutical context. This appears to be in direct response to critics who have "either shamefully misrepresented our holding or bordered on the hysterical" in response to the original Weeks opinion. Fourth, "No decision of any other jurisdiction addresses the precise question of Alabama law discussed in our answer." Finally, Justice Shaw rejected the notion that the decision might stifle business. Instead, the court's decision "epitomizes the kind of judicial restraint that should be expected of an appellate court."

Three Dissents

Three justices dissented. Chief Justice Roy Stewart Moore felt the court should not have accepted the certified question because the answer was not dispositive of the case in the trial court. Justice Tom Parker felt the court overstepped its authority, especially because he interpreted Mensing and Mutual Pharmaceutical Co. v. Bartlett as making "clear that [a generic drug] consumer is left without a remedy absent a legislative change by Congress."

Justice Glenn Murdock passionately dissented, penning an opinion equal in length to that of the majority's. He opened by quoting Alexander Hamilton and invoking the great American "spirit of enterprise" to highlight the injustice that would no doubt result from the court's holding. The dissent's reasoning was twofold. First, every other court (with the exception of Conte v. Wyeth Inc. and Kellogg v. Wyeth Inc.) that had evaluated this issue disagreed with the Alabama Supreme Court. Second (not content with the herd mentality argument), Justice Murdock fell back on the tried-and-true premise that this would "stretch the concept of foreseeability too far." (See Foster v. American Home Products.) Justice Murdock's variation on this theme was that foreseeability alone is insufficient to create a duty; in addition to foreseeability there must be a relationship between the two parties.

After conducting an extensive survey of decisions on the issue, Justice Murdock came full circle, predicting the negative impact that the court's holding would have on free enterprise. He worried that brand drug manufacturers would be unable to predict their liability and this would create an insurability issue. Meanwhile, the court's reasoning could spill over into areas beyond pharmaceuticals and compound the problem.

Impact Limited to Alabama

Justice Murdock's concerns about the court's decision reaching beyond drugs are unnecessarily alarmist given the unique federal regulatory scheme governing drugs and the stringent requirements that generic drug manufacturers maintain labels identical to those of the brand drug manufacturers'. However, innovator liability is now the law of the land in Alabama, and brand drug manufacturers should be concerned that filings there will increase. The good news for pharmaceutical manufacturers is that out-of-state plaintiffs face two significant hurdles in taking advantage of the holding in Weeks II: (1) jurisdiction and (2) choice of law.

First, Alabama trial courts must decide whether they have jurisdiction over out-of-state plaintiffs who sue manufacturers headquartered outside of Alabama. A California appellate court recently faced this issue and held that that state's courts have jurisdiction over claims brought by non-California plaintiffs against non-California defendants alleging injury from the drug Plavix.[2] The California appellate court based this holding on concepts of specific jurisdiction, finding that defendant's nearly $1 billion in sales of Plavix in California during a six-year time frame satisfied "the minimum contacts requirement for specific jurisdiction."[3] Furthermore, these commercial activities were sufficiently "related" to out-of-state plaintiffs' claims because Plavix drug "sales in California have led to injuries to California residents that are the same as those suffered by" the plaintiffs.[4]

Even if an Alabama court reached the same conclusion that it had jurisdiction over out-of-state claims, Alabama follows the principle of lex loci delicti, which means that the substantive rights of an injured party will be determined by applying the law of the state where the injury occurred. Alabama trial courts are unlikely to deviate from this rule after the Alabama Supreme Court's in-depth discussion and unequivocal holding in Fitts v. Minnesota Mining & Manufacturing Co. In Fitts, the court considered the appellant's argument that it should adopt the "most significant relationship" approach, conducted a multistate survey and concluded: "The newer approaches to choice-of-law problems are neither less confusing nor more certain than the traditional approach. Until it becomes clear that a better rule exists, we will adhere to our traditional approach."[5]

In light of this controlling precedent, it's unlikely any trial court in Alabama would decide that Alabama law governs claims brought by out-of-state plaintiffs for injuries that occurred outside Alabama. Therefore, it appears that Weeks II may have limited, if any, impact beyond Alabama's borders as long as other jurisdictions continue to find arguments for innovator liability unpersuasive. Brand drug manufacturers may also be able to curb the impact of Weeks II in Alabama by encouraging legislation that would overcome the ruling, rather than face unlimited liability for another company's drugs.

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[1] See "Weeks Defies Years of Jurisprudence," Morrison and Foerster client alert.

[2] Bristol-Myers Squibb Co. v. Super. Ct., 228 Cal. App. 4th 605, 175 Cal. Rptr. 3d 412 (2014)

[3] Id., 175 Cal. Rptr. 3d at 434.

[4] Id.

[5] Fitts v. Minn. Mining & Mfg. Co., 581 So.2d 819, 823 (Ala.1991) (quotation omitted)
