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Am I My Competitor's Keeper? Alabama's Highest Court Holds Brand-name Prescription Drug Manufacturer Liable for Claims on a Generic Drug Used by the Plaintiff.

The Supreme Court of Alabama recently held that "[u]nder Alabama law, a brand-name drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company." Wyeth, Inc. v. Weeks, No. 1101397, at 50-51 (Ala. Jan. 11, 2013). The Court reasoned that "it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce … when [the] alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated by the generic manufacturer." Id. at 52.

Weeks is contrary to numerous decisions refusing to impose liability on brand-name manufacturers for harm allegedly caused by a product that they did not manufacture, as even the Alabama Supreme Court acknowledged. However, Weeks was heavily influenced by the Alabama Supreme Court's interpretation of a recent decision of the United States Supreme Court that held that claims against manufacturers of generic drugs for failure to warn are preempted by federal law which requires the generic manufacturer's label to be identical to the brand-name labeling. PLIVA, Inc. v. Mensing, __ U.S. __, 131 S. Ct. 2567 (2011).

PLIVA, Inc. v. Mensing: Federal Law Preempts State Law Failure to Warn Claims Against Generic Drug Manufacturers

To understand the decision in Weeks, it is necessary to understand the Supreme Court's decision in Mensing, which held that state law claims against generic drug manufacturers based on a failure to warn theory are preempted by federal law. The plaintiffs in Mensing alleged that the generic drug manufacturers "knew or should have known of the high risk of tardive dyskinesia inherent in the long-term use of their product [metoclopramide]" and that they "knew or should have known that their labels did not adequately warn of that risk." Mensing, 131 S. Ct. at 2574. "The parties [did] not dispute that, if these allegations [were] true, *state law* required the [generic manufacturers] to use a different, safer label." Id. (emphasis added). The generic manufacturers, however, contended that *federal law* prevented them from using labels different from those used by the brand-name and thus

preempted the state law claims.

The Court noted that while a "brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label . . . , [a] manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's." Mensing, 131 S. Ct. at 2574. This "sameness" finding was critical to the Alabama Supreme Court's holding in Weeks.

With respect to whether, and to what extent, generic manufacturers could change their labels *after* initial FDA approval, the Supreme Court in Mensing deferred to FDA's determinations that (unlike brand-name manufacturers) generics cannot unilaterally strengthen the generic drug's warning label and that Dear Doctor letters qualify as "labeling" and, therefore, could not be used by generic manufacturers to send additional warnings to prescribing physicians and other healthcare professionals. Id. at 2575-76. The Court assumed, without deciding, that FDA was correct that generic manufacturers "could have proposed—indeed, were required to propose—stronger warning labels to the agency if they believed such warnings were needed." Id. at 2576-77.

As summarized by the Court, "State tort law places a duty directly on all drug manufacturers to adequately and safely label their products…. Federal drug regulations, as interpreted by the FDA, prevented the [generic manufacturers] from independently changing their generic drugs' safety labels. But, we assume, federal law also required the [generic manufacturers] to ask for FDA assistance in convincing the brand-name manufacturer to adopt a stronger label, so that all corresponding generic drug manufacturers could do so as well." Id. at 2577. The Court thus concluded that it was impossible for the generic manufacturers to do what state law required and that even if they had asked FDA for assistance in changing their labels, this would have fallen short of their state law obligations. Id. at 2577-78. Rejecting plaintiffs' argument that their claims should not be preempted to the extent that the generic manufacturers did not do all that they were permitted to do under federal law (*i.e.*, to ask FDA for assistance in changing the label) to comply with state law, the Court concluded "that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes." Id. at 2580-81.

The Court "acknowledge[d] the unfortunate hand that federal regulation has dealt" plaintiffs by preempting their claims merely because their prescription was filled with a generic drug, while the claims of individuals whose prescriptions were filled with the brand-name drug are not preempted. Id. at 2581. The dissent, likewise, warned that "the majority's preemption analysis strips generic-drug consumers of compensation when they are injured by inadequate warnings…. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings…. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue…. As a result, in many cases, consumers will have no ability to preserve their state law right to recover for injuries caused by inadequate warnings." Id. at 2592 (Sotomayor dissenting); see also id. at 2583 ("As a result of today's decision, whether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her

prescription with a brand-name or generic drug.").

***Wyeth, Inc. v. Weeks*: Alabama Elects to "Remedy" the "Unfairness" of *Mensing* by Shifting the Generic Manufacturer's Preempted State Tort Liability to the Brand-Name Manufacturer**

In Weeks, the Alabama Supreme Court answered a question certified to it by the United States District Court for the Middle District of Alabama:

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

Weeks, No. 1101397, at 2.[1]

In Weeks, Mr. Weeks claimed injuries from long-term use of metoclopramide, the generic form of the brand-name drug Reglan®. Mr. Weeks conceded that he "did not ingest any Reglan® manufactured by the three brand-name defendants." Id. Mr. Weeks contended, however, "that the brand-name defendants are liable for Mr. Weeks's harm on fraud, misrepresentation, and/or suppression theories because they at different times manufactured or sold brand-name Reglan® and purportedly either misrepresented or failed adequately to warn Mr. Weeks or his physician about the risks of using Reglan® long-term." Id. at 2-3.

In analyzing the plaintiffs' misrepresentation claims, the Alabama Supreme Court noted that state law permits a pharmacist to fill a prescription for a brand-name drug with a less-expensive generic version unless the prescribing physician indicates otherwise on the prescription and that many insurance plans promote the use of generics. Id. at 8-9. The court further noted the differences between the federal approval processes for brand-name drugs and generics and the differences in the ability of manufacturers of these drugs to alter their labeling to strengthen warnings. Id. at 9-23. The court noted that, under federal law, "a brand-name manufacturer, upon discovering a clinically significant hazard, may modify its label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' without FDA approval." Id. at 15

1 The district court that certified the question to the Alabama Supreme Court noted that four federal district court decisions and two Alabama trial courts had concluded that brand-name manufacturers could not be held liable for harm caused by their competitors' generic products under Alabama law. Id. at 3-5 (citing Simpson v. Wyeth, Inc., No. 7:10-CV-01771-HGD (N.D. Ala. Dec. 9, 2010), report and recommendation adopted (N.D. Ala. Jan. 4, 2011) (holding that a brand-name manufacturer has no duty under Alabama law to warn of the risks associated with a competitor's generic product); Mosley v. Wyeth, Inc., 719 F. Supp. 2d 1340 (S.D. Ala. 2010 (same); Barnhill v. Teva Pharm. USA. Inc., No. Civ. 06-0282-CB-M (S.D. Ala. Apr. 24, 2007 (holding that a brand-name manufacturer of the drug Keflex® has no duty under Alabama law to warn of the risks associated with a competitor's generic product); Overton v. Wyeth, Inc., No. CA 10-0491-KD-C (S.D. Ala. Mar. 15, 2011), report and recommendation adopted (S.D. Ala. Apr. 7, 2011); Buchanan v. Wyeth Pharm., Inc., No. CV-2007-900065, Order at 1 (Ala. Cir. Ct. Oct. 20, 2008); Green v. Wyeth Pharm., Inc., No. CV-06-3917 ER (Ala. Cir. Ct. May 14, 2007)). The district court noted that its decision in Weeks v. Wyeth, Inc., No. 1:10-cv-602 (M.D. Ala. Mar. 31, 2011) (denying brand-name manufacturers' motion to dismiss on the ground that the plaintiffs there had pleaded a claim that defendants perpetrated a fraud on the physician) created an intrastate split. Weeks, No. 1101397 at 3-4.

(quoting 21 C.F.R. § 314.70(c)(7)). However, "[t]he FDA has determined that a generic manufacturer cannot unilaterally strengthen a warning label for a generic drug or send a 'Dear Doctor' letter … because doing so would violate the [federal] statutes and regulations requiring the label of a generic drug to match the brand-name manufacturer's label." Id. at 16 (citing Mensing, 131 S. Ct. at 2575). The court noted that this difference—the ability of brand-name manufacturers to unilaterally strengthen their labels under federal law and the inability of generic manufacturers to do so under federal law—meant that state law failure to warn claims against brand-name manufacturers are not preempted by federal law, while similar claims against generic manufacturers are preempted. Id. at 17-23 (discussing Wyeth v. Levine, 555 U.S. 555 (2009) (state law failure to warn claims against brand-name manufacturers not preempted by federal law) and Mensing, 131 S. Ct. 2567 (state law failure to warn claims against generic manufacturers preempted by federal law)).

The court acknowledged that "other federal courts applying Alabama law have held that Alabama law does not allow a person who consumed a generic version of a brand-name drug to sue the brand-name manufacturer based on fraudulent misrepresentation." Weeks, No. 1101397 at 23. The court rejected these decisions, along with decisions involving other state law, largely on the grounds that the decisions preceded Mensing and incorrectly assumed that the generic manufacturers were responsible for their own warning labels. Weeks at 25-26 ("Reliance upon the reasoning in Mosley that a generic manufacturer is responsible for its own warning labels and revisions of those labels is unsound."); Id. at 27 ("Accordingly, the federal court's conclusion in Overton that a generic manufacturer becomes responsible for its own warning label after the ANDA process is incorrect."); Id. at 30 ("Like Mosley and Overton, Simpson was issued before [Mensing] was decided, and the federal court's conclusion in Simpson—that generic manufacturers have their own duty to correctly advise a physician of risks associated with the generic drug regardless of the fact that a generic label is required to be the same as the brand-name label—is questionable."); Id. at 40 ("The Foster court's finding that manufacturers of generic drugs are responsible for the representations they make in their labeling regarding their products is flawed based on the 'sameness' requirement discussed in [Mensing]."[2] The court noted that a few courts have allowed claims to proceed against brand-name drug manufacturers for harm allegedly caused by ingestion of a generic drug. Weeks, at 35-39 (discussing

2 For years prior to Mensing, consumers of generic drugs have attempted to assert theories of liability against brand-name drug manufacturers whose products they never ingested. For the most part, courts have rejected these claims, with only a few courts allowing such claims. The leading case is Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994). In that case, the Fourth Circuit, applying Maryland law, rejected the plaintiffs' claims against the brand-name drug manufacturer for negligent misrepresentation, where the product allegedly causing injury was the generic version of the drug. The court concluded that the claim for negligent misrepresentation was an attempt to recover for product liability without meeting strict requirements for product liability, including the requirement that the defendant manufactured the product at issue. Id. at 168. The court also determined that the generic manufacturer could not escape liability by merely relying on the brand-name manufacturer's product labels. "When a generic manufacturer adopts a name brand manufacturer's warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed…. [A]s an expert, a manufacturer of generic products is responsible for the accuracy of labels placed on its products." Id. at 169-70.[2] The court noted that "[t]here is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control. This would be 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." Id. at 170. Finally, the court noted that under Maryland law, the brand-name manufacturer had no duty to users of other manufacturers' products. Id. at 171.

Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299 (2008) (manufacturer of brand-name drug may be held liable for injuries to consumer of generic equivalent if injuries were foreseeably caused by negligence or intentional misrepresentation by the brand-name manufacturer) and Kellogg v. Wyeth, 762 F. Supp. 2d 694 (D. Vt. 2010) (brand-name manufacturer has duty to use reasonable care to avoid causing injury to consumers of generic equivalent)).

The court noted that, following Mensing's holding that generic labeling must be identical to name-brand labeling, "an 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." Weeks, at 41. The court concluded that because brand-name drug manufacturers are aware that the patents on their drugs will eventually expire and that a generic equivalent will eventually be made available, the "name-brand manufacturer could reasonably foresee that a physician prescribing a brand-name drug (or a generic drug) to a patient would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version of the drug." Weeks, at 41-42. By so holding, the Alabama Supreme Court expanded a brand-name drug manufacturer's duty of care well beyond traditional principles of foreseeability in tort and product liability law.

In explaining why a name-brand manufacturer owes a duty to consumers of generic drugs, the court noted that it had previously recognized claims for third-party fraud. Id. at 42-45. The court held that "physical harm suffered by a consumer of prescription medication would have been reasonably contemplated by a manufacturer who made fraudulent statements on the warning label related to that medication." Id. at 45. In response to the brand-name defendants' argument that Alabama had "never extended third-party-fraud liability to a defendant who did not manufacture the product about which the plaintiff is complaining," the court declared that "prescription medication is unlike other consumer products" in that the latter are "used to make life easier or to provide pleasure" while the former "may be necessary to alleviate pain and suffering or to sustain life." Id. at 45-46. Armed with this distinction, the court added that "the brand-name manufacturer is under a continuing duty to supply the FDA with postmarketing reports of serious injury and can strengthen its warnings on its own accord," while "a generic manufacturer's label must be the same as the brand-name manufacturer's label, and the generic manufacturer cannot unilaterally change its label." Id. at 46-47.

Two aspects of the Weeks decision are favorable to brand name manufacturers: an endorsement of the learned intermediary doctrine and the affirmation that a lack of causation can cut off a plaintiff's claim against a brand-name manufacturer (i.e., once the duty to warn is met, the manufacturer has no further duty to warn the patient directly). In addressing the requirement of detrimental reliance on the alleged fraudulent statement, the court noted that the plaintiffs "have alleged that [the patient's] physician reasonably relied on the representations made by the [name-brand manufacturer] regarding the long-term use of Reglan in prescribing Reglan to [the patient]." Id. at 47. "In other words, the [plaintiffs] are arguing that if a defendant's misrepresentation to a third party causes the third party to take actions resulting in

the plaintiff's injuries, then the factual causation link is satisfied and that, here a misrepresentation to [the patient's] physician would directly impact the medical care received." Id. at 47-48. The court concluded that under the learned-intermediary doctrine, a drug "manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug," and that "[o]nce that duty is fulfilled, the manufacturer has no further duty to warn the patient directly." Id. at 50. "However, if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient." Id.

In conclusion, the court answered the certified question as follows: "Under Alabama law, a brand-name drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company." Id. at 50-51. Failure to warn claims against brand-name manufacturers are not preempted by federal law, but such claims against generic manufacturers are preempted. Id. at 51-52. "In the context of inadequate warnings by the brand-name manufacturer placed on a prescription drug manufactured by a generic-drug manufacturer, it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not product because the manufacturing process is irrelevant to misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated by the generic manufacturer." Id. at 52.

What will be the Legacy of *Weeks*?

Will Weeks usher in a new wave of post-Mensing decisions where brand-name manufacturers will bear responsibility for harms allegedly caused by their competitors' generic products, or will it remain an outlier like Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299 (2008) and Kellogg v. Wyeth, 762 F. Supp. 2d 694 (D. Vt. 2010)?

Numerous courts-- both federal and state-- that have addressed this issue post-Mensing have continued to follow Foster and its progeny in holding that a brand-name manufacturer cannot be held liable for harm caused by a product that it did not manufacture or distribute. Although the Weeks court cited two of these decisions, it did not discuss any of them. These cases recognize that the Supreme Court's holding in Mensing dealt only with a generic manufacturer's preemption defense. Mensing did not purport to alter the state law tort liability of brand-name manufacturers or to make brand-name manufacturers responsible for harm allegedly cause by its generic competitors' products.[3]

In fact, Mensing does not even alter generic manufacturers' state tort duties; rather, it assumes that generics owe duties under state law to warn about known dangers of its product, but concludes that, because

3 To the contrary, both the majority and the dissent in Mensing assumed that the preemption defense for the generic manufacturer would leave plaintiffs injured by generic drugs without any remedy, not that the generic's state tort law duty would be shifted to brand-name manufacturers.

generic manufacturers cannot unilaterally comply with such duties as a matter of *federal* law, these state law duties cannot be enforced by plaintiffs. That generic manufacturers cannot be held liable for their alleged failure to comply with their state tort law obligations does not logically explain an expansion of brand-name manufacturers' state tort law obligations to fill this gap and does not justify the Alabama Supreme Court's creation of a special rule in tort law for prescription drug products.

It is certainly possible that some courts will follow Weeks to expand the state tort law duties of brand-name manufacturers to fill the gap left by Mensing. However, we remain encouraged by the numerous decisions that have recognized that the "unfairness" of Mensing does not justify a re-writing of state tort law to expand brand-name manufacturers' liability to cover harm caused by drugs that they neither manufactured nor distributed. As such, there is hope that the notoriety of Weeks will remain as an outlier in product liability law.

Please click **here** for a copy of Wyeth, Inc. v. Weeks, No. 1101397 (Ala. Jan. 11, 2013). Please click **here** for a copy of PLIVA, Inc. v. Mensing, __ U.S. __, 131 S. Ct. 2567 (2011).