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Preemption: Sixth Circuit Declines to Resolve Questions Over Parallel Misbranding Theory of Liability and Rejects Innovator Liability Under Laws of 22 States

In *In re Darvocet, Darvon, and Propoxyphene Products Liability Litigation*, --- F.3d ---, No. 12-5368, 2014 WL 2959271, at *1 (6th Cir. June 27, 2014), the United States Court of Appeals for the Sixth Circuit issued a significant opinion affirming the dismissal of 67 of 68 Plaintiffs' claims against both generic and brand-name pharmaceutical manufacturers.

First, the Sixth Circuit affirmed the dismissal of claims against the generic companies. The district court, which supervised a multidistrict litigation involving claims relating to propoxyphene (branded as Darvocet or Darvon), had dismissed Plaintiffs' wrongful marketing, failure to warn and other related claims against generic manufacturers on both preemption and pleading grounds. *Id*. at *5. But on appeal, Plaintiffs' argued that their wrongful marketing claims were not preempted in light of Footnote 4 of the Supreme Court's decision in *Mutual Pharm. Co., Inc. v. Bartlett*, —— U.S. ——, 133 S. Ct. 2466 (2013). *Id*. at *6. In that Footnote, the Court commented that its preemption ruling does "not address state design-defect claims that parallel the federal misbranding statute." *Bartlett*, 133 S. Ct. 2477, n.4. Plaintiffs asserted that their wrongful marketing claims fell within that exception. *Id*. Under the federal misbranding statute, plaintiffs argued, a manufacturer must pull even an FDA-approved drug from the market when it is dangerous to health even if used in accordance with its labeling. *Id*. (*citing* 21 U.S.C. § 352(j)).

The Sixth Circuit acknowledged the uncertainty over whether Footnote 4 created an exception to preemption, and if so, what the scope of that exception should be. But it reasoned that, at a minimum, a plaintiff seeking to invoke a "parallel misbranding" theory must: (1) allege a cause of action for misbranding under state law, (2) identify new and scientifically significant information not already before the FDA, and (3) demonstrate that the FDA would have found the drug to be misbranded in light of the new information. *Id*. Here, the court held that "Plaintiffs cannot state such a claim because they do not point to 'new and scientifically significant information' that the Generic Manufacturers possessed that was not before the FDA." *Id*. at *9. Thus, the court dismissed the claims on pleading grounds without reaching the "thorny issues" concerning the existence and scope of any "parallel misbranding" theory. And, the Court of Appeals affirmed the dismissal of the remaining claims against the generic manufacturers on pleading and preemption grounds as well, adopting the reasoning of the lower court. *Id*. at *10-15.

Second, the Sixth Circuit also affirmed the dismissal of 67 of 68 misrepresentation claims against the brand-name Defendants, rejecting the innovator liability theory advanced by Plaintiffs under the laws of 22 states. *Id*. at *18. Plaintiffs argued that physicians had "reasonably and foreseeably" relied on representations of branded manufacturers when prescribing generic propoxyphene because physicians understood that generics are bioequivalent to and have the same labeling as branded drugs. *Id*. at *16. Yet, the court concluded that the misrepresentation claims failed under the 22 state laws at issue either because (1) they were, in fact, product liability claims subject to the "product identification requirement" rule (*i.e.* a plaintiff must assert that the defendant's product caused the plaintiff's injury) or (2) even if the misrepresentation claims were not product liability actions, branded manufacturers do not have a legal duty to plaintiffs. *Id*. at *17. The court reversed

dismissal of a lone claim where the Plaintiff had actually taken a branded drug and adequately pleaded a product liability claim. *Id*. at *20.

Darvocet is an important decision for defendants on both innovator liability and preemption. Although *Darvocet* did not directly rule on whether Footnote 4 creates an exception to preemption for state parallel misbranding claims, the court erected a pleadings bar and expressed skepticism that such an exception even exists. And, the Sixth Circuit's sweeping holding that 22 states would reject innovator liability solidifies the overwhelming weight of authority rejecting innovator liability. Notably, in analyzing Illinois law, the court also disagreed with a recent ruling by the Northern District of Illinois endorsing innovator liability. *See Dolin v. SmithKline Beecham Corp.*, 12–C–6403, 2014 WL 804458, at *9 (N.D. Ill. Feb. 28, 2014).

Alabama Supreme Court Upholds Decision Allowing Innovator Liability

On August 15, 2014, the Alabama Supreme Court issued a decision following rehearing in *Wyeth, Inc. v. Weeks*, 2014 WL 4055813 (Ala. Aug. 15, 2014) (" *Weeks II*"). The court held that a brand-name drug company may be liable for fraud or misrepresentation to a plaintiff claiming injury from ingestion of a generic version of the drug manufactured by a different company. The decision places Alabama in a very small minority of courts that have embraced the doctrine known as "innovator liability."

In *Weeks II*, plaintiff alleged he was injured by his use of the generic drug metoclopramide. Despite never ingesting the branded product, Plaintiff brought fraud and misrepresentation claims against both generic and brand-name manufacturers. The brand-name manufacturers moved to dismiss. In January 2013, the Alabama Supreme Court issued an 8-1 decision holding that a brand-name manufacturer may be held liable for injuries suffered by a plaintiff who only ingested a generic version of the drug. *Wyeth, Inc. v. Weeks*, 2013 WL 135753 (Ala. Jan. 11, 2013) (" *Weeks I*"). In *Weeks I*, the court relied on a foreseeability analysis that had only been embraced by a few courts: finding that because of the generic labeling regulations on sameness, a defective warning in the brand-name labeling "would necessarily be repeated in the generic labeling, foreseeably causing harm to a patient who ingested the generic product." 2013 WL 135753, at *15.

In a 6-3 decision, the Alabama Supreme Court confirmed this result in *Weeks II*. Responding to Wyeth's argument that it owed no tort "duty" to generic-ingesting plaintiffs because there is no "relationship" between an innovator seller and a generic purchaser, the court attempted to distinguish prescription drugs from other consumer products such as "lawnmowers, automobiles, and other products," pointing to their heavy regulation by FDA. 2014 WL 4055813, at *22. The court stated that under the regulatory scheme, Wyeth "authored the label with its warnings, and the generic manufacturers, as required by FDA regulations, copied that label verbatim." *Id*. at *21. Thus, the court found plaintiff's fraud claim was not the same as "a products-liability claim where privity is needed." *Id*.

The *Weeks II* decision places Alabama in a very small minority of courts that have adopted "innovator liability." Most courts have held that holding an innovator company liable for injuries allegedly caused by a product manufactured by a different company violates the longstanding "product-identification" requirement and stretches the concept of foreseeability beyond its outer limits.

FDA Issues Guidance on the Use of Nanotechnology in Regulated Products

On June 24, 2014, the Food and Drug Administration (FDA) issued four guidance documents—three final and one draft—related to the use of nanotechnology in regulated products. These documents, though non-binding, provide useful insight into the FDA's views on the relationship between nanotechnology and the existing regulatory structure.

The three final guidance documents are: (1) *Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*; (2) *Safety of Nanomaterials in Cosmetic Products*; and (3) *Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives*. The first guidance provides an overview of the FDA's approach to the regulation of nanotechnology products. The other two address specific areas: cosmetics and manufacturing changes in the production of food and food contact substances. FDA also issued a draft guidance entitled *Use of Nanomaterials in Food for Animals*.

These guidance documents are significant because they represent a final policy clarifying the FDA's general approach to nanotechnology. Prior to the finalization of these documents, organizations relied on their own understandings of the interaction between nanotechnology and existing regulations. The new guidance documents provide a common jumping-off point for all designers, developers, and manufacturers in the field. In the coming years, the agency will likely issue additional product- or process-specific guidance documents, in

the vein of the final guidance concerning the use of nanotechnology in cosmetics and the manufacturing process for food and food contact substances. There are currently no guidance documents specific to drugs or medical devices, and there is not yet final guidance on the use of nanotechnology in food for animals. As the trend toward nanotechnology continues, product-specific guidance will become increasingly important. Both companies and regulators will need to determine whether an application of nanotechnology is truly novel or whether it can be addressed by traditional regulatory mechanisms. Industry members should consider their own products, regulatory history, and design and development processes—along with FDA guidance—in determining how their use of nanotechnology fits into the larger regulatory framework.

Supreme Court Declines to Resolve Circuit Split on Preemption

On June 23, 2014, the Supreme Court denied *certiorari* in *Medtronic, Inc. v. Stengel*, No. 12-1351, 2014 WL 2807193 (June 23, 2013). In doing so, it declined to resolve a deepening circuit split and let stand an *en banc* decision by the U.S. Court of Appeals for the Ninth Circuit holding that the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetics Act (FDCA) do not preempt for state-law claims based on a failure to report adverse information to FDA.

In *Stengel v. Medtronic, Inc.*, Plaintiffs alleged that Medtronic had failed to report to the FDA information about known risks associated with one of its devices, even though it was required to do so under the MDA. 704 F.3d 1224, 1226 (9th Cir. 2013) (*en banc*). The district court found that the proposed amendment was preempted under *Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001), which held that the MDA impliedly preempted state law claims alleging misrepresentations to the FDA. *Id*. A divided Ninth Circuit panel affirmed. *Stengel*, 704 F.3d at 1226. But, the Ninth Circuit granted rehearing *en banc* and reversed. The Ninth Circuit held that Plaintiffs' "failure to report" theory could state a "parallel" claim because it "specifically alleges, as a violation of Arizona law, a failure to warn the FDA [and that] Arizona law contemplates a warning to a third party such as the FDA." *Id.* at 1233. The court summarily distinguished *Buckman* stating that Plaintiffs' state-law claim did not concern the FDA's pre-market approval process at issue in *Buckman*. *Id*. A more in-depth analysis of the Ninth Circuit's *en banc* decision is available here.

By denying *certiorari*, the Supreme Court rejected an invitation to resolve a significant circuit split. The Fifth and Ninth Circuits have held that *Buckman* does not preempt claims premised on a failure-to-report adverse events to FDA, but the Sixth and Eighth Circuits have reached the opposite conclusion. *Compare id. and Hughes v. Bos. Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), *with In re Medtronic, Inc.*, *Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010) and *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005). Until the Supreme Court weighs in on this issue, medical device manufacturers will face varying law in different parts of the country on this important issue.

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