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Perdue v. Wyeth Pharmaceuticals, Inc.: A Triple Knockout on Pre-Emption and Innovator Liability Grounds

Article By:

Beth S. Rose

Vincent R. Lodato

Pharmaceutical companies recently achieved a significant legal victory in a product liability suit involving amiodarone (brand name Cordarone®) that plaintiff filed in the United States District Court for the Eastern District of North Carolina. See Sara Perdue, as Executor of the Estate of *Marjorie Newton v. Wyeth Pharmaceuticals, Inc., et al.*, Civil Action No. 4:15-cv-00208-FL, 2016 U.S. Dist. LEXIS 94636 (E.D.N.C. Jul. 20, 2016). Amiodarone/Cordarone® is a prescription medication approved by the FDA as a treatment of last resort for life-threatening recurrent ventricular arrhythmias. The FDA approved Cordarone® in December 1985 when it granted Wyeth Pharmaceuticals, Inc.'s ("Wyeth") New Drug Application. Amiodarone has been cleared for marketing in generic form since the late 1990s. In December 2004, the FDA mandated that amiodarone be accompanied by a medication guide pursuant to 21 C.F.R. § 208.1.

In Perdue, plaintiff alleged that the decedent's physician prescribed her amiodarone for an off-label use - the treatment of non-life threatening atrial fibrillation. According to the Complaint, the decedent was provided with amiodarone manufactured by Zydus Pharmaceuticals USA, Inc., Teva Pharmaceuticals USA, Inc. and Barr Laboratories, Inc. (hereinafter "generic manufacturers"). The Complaint also alleged that the prescribing physician's decision to prescribe amiodarone was influenced by off-label promotion conducted by Wyeth and the generic manufacturers. The Complaint further alleged that when the decedent went to her pharmacy to pick-up her prescription, the pharmacy failed to provide her with the FDA-required medication

guide for amiodarone because the generic manufacturers failed to supply them to the decedent's pharmacy. Plaintiff alleged that the decedent developed severe and increasing pulmonary disease as a result of her use of amiodarone which ultimately led to her death. Plaintiff brought suit against the generic manufacturers alleging the following causes of action: (1) failure to warn; (2) failure to provide the FDA-required medication guide; and (3) off-label promotion in violation of FDA regulations. Although the decedent did not take brand-name Cordarone®, the Complaint also named Wyeth as a defendant asserting that its off-label promotional efforts contributed to the decedent's death.

All of the defendants moved to dismiss plaintiff's Complaint for failure to state a claim. The generic manufacturers primarily attacked plaintiff's Complaint on federal pre- emption and inadequate

pleading grounds. Specifically, the generic manufacturers argued that all of plaintiff's claims were essentially failure to warn claims and therefore, pre-empted by the U.S. Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). They also argued that plaintiff's off-label promotion and medication guide claims were pre-empted by federal law under the U.S. Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) because plaintiff's claims were entirely premised on alleged violations of the Food, Drug and Cosmetic Act ("FDCA") and FDA requirements. Finally, the generic manufacturers argued that plaintiff's claims were not pled with sufficient facts to satisfy the federal pleading standards. Wyeth's motion argued that because there was no allegation that the decedent ever took Wyeth's brand-name Cordarone®, plaintiff could not assert a cause of action against the company.

On July 20, 2016, the Eastern District of North Carolina granted the defendants' motions in their entirety. First, relying on *Mensing*, the Court held that because the FDCA limited generic manufacturers' ability to include additional warnings on their products, plaintiff's failure to warn claims were pre-empted by federal law. Although plaintiff had argued that her Complaint did not assert a failure to warn claim, the Court pointed out that the Complaint contained numerous allegations that the amiodarone labeling failed to include adequate warnings.

Next, the Court turned to plaintiff's off-label promotion claim. The Court explained that under *Buckman*, to survive a motion to dismiss, plaintiff's claim must fall within a narrow set of claims that are "premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." In evaluating plaintiff's off-label promotion claim, the Court looked to the allegations

of plaintiff's Complaint and determined that plaintiff's allegations were "entirely dependent" on alleged violations of the FDCA rather than any North Carolina law that addressed off-label drug promotion. In reaching this decision, the Court rejected plaintiff's argument that her negligence per se claim survived *Buckman* because it is a traditional state law cause of action. The Court explained that:

Buckman requires more, however, than the existence of a general state law principle providing a cause of action for violation of a health and safety statute. *Buckman* requires pre-existing state law causes of actions that parallel federal safety requirements.

Because plaintiff's claims existed "solely by virtue of the FDCA regulations regarding off-label promotion," and plaintiff could not identify any specific North Carolina law that "parallel[ed] and predat[ed]" the FDCA's requirements, the Court held that plaintiff's off-label promotion claim was impliedly pre-empted under *Buckman*.

Lastly, the Court reached the same result with respect to plaintiff's medication guide claim. The Court again turned to the allegations of plaintiff's Complaint and noted that the manufacturers' obligations to provide medication guides were "grounded solely in the FDCA and related regulations." Since plaintiff's medication guide claim was not premised on any specific state law that required the distribution of medication guides, the Court held that plaintiff's medication guide claim was also pre-empted under *Buckman*. Accordingly, the Court dismissed plaintiff's claim against the generic manufacturers in their entirety with prejudice.

With respect to Wyeth's motion, the Court agreed with the overwhelming line of cases in which courts have refused to extend liability to brand-name manufacturers where plaintiffs claim they only

ingested generic drugs. The Court simply explained that “[u]nder North Carolina law, a defendant may not be held liable for injuries allegedly caused by the use of another’s product.” As a result, the Court dismissed plaintiff’s claims against Wyeth without prejudice giving plaintiff the opportunity to present additional facts to support her claim against Wyeth.

The Court’s decision in *Perdue* represents a significant victory not only for Wyeth and the generic manufacturers, but for the pharmaceutical industry as a whole. Most significantly, the Court correctly adopted a broad interpretation of the U.S. Supreme Court’s implied pre-emption decision in *Buckman* and used it to preclude the assertion of off-label promotion and medication guide claims that have not been frequently addressed by prior courts. The Court held that when a plaintiff’s claim relies on requirements or obligations imposed on the manufacturer by the FDCA or FDA regulations, such claims are pre-empted unless plaintiff can point to a specific state law statute of common law claim that parallels those federal requirements. Reliance on general state common law claims, like negligence per se, is insufficient to withstand implied pre-emption under Buckman. The Court also re-affirmed the Mensing decision’s preclusion of failure to warn claims and agreed with the vast majority of nationwide decisions that have rejected innovator liability claims.

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