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Impossibility Preemption Possible For Brand-Name Drugs

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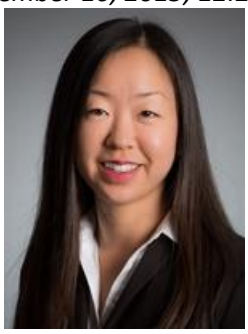
Erin M. Bosman


Julie Y. Park

Last week, the Sixth Circuit Court of Appeals issued a groundbreaking opinion in Yates v. Ortho-McNeil-Janssen Pharmaceuticals Inc. that could change the liability landscape for brand-name drug manufacturers. No. 15-3104 (6th Cir. Dec. 11, 2015). Yates is the first federal appellate authority to recognize "impossibility preemption" of design defect claims against brand-name drug manufacturers.

Background

The plaintiff in Yates was a teenager who used the brand-name Ortho Evra patch for birth control. She conceded that she was warned of the risk of stroke by her health care provider. She further admitted that she would have used the patch even if she had read the warnings regarding the increased risk of stroke and blood clots. One week after she started using the Ortho Evra patch, the plaintiff had a stroke.

Despite the label's clear disclosure of the risk of stroke and plaintiff's awareness of the increased risk from her health care provider, the plaintiff sued the defendants for failure to warn. She also brought claims for manufacturing defect, negligence and breach of implied and express warranties.

The Sixth Circuit affirmed the district court's grant of summary judgment on all claims. Most importantly, the court affirmed the district court's ruling regarding the state-law design defect claims and held that "Yates' state law design defect claims are preempted under Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013)."

Impossibility Preemption

The court held that the plaintiff's state-law design defect claims were preempted by federal regulation, regardless of whether the alleged defect occurred pre- or post-U.S. Food and Drug Administration

approval. In doing so, it became the first ever circuit court of appeals to find that federal law preempts design defect claims against brand-name drug manufacturers.

The court began its preemption analysis with a discussion of preemption principles: "State law claims can be preempted expressly in a federal statute or regulation, or impliedly, where congressional intent to preempt state law is inferred." The court explained that implied preemption exists where "(1) it is impossible for a private party to comply with both state and federal law and (2) the state law is an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." The court noted, however, that such impossibility preemption "is a demanding defense."

Relying on Wyeth v. Levine, 555 U.S. 555, 571 (2009), the court pointed out that "plaintiffs injured by brand-name prescription drugs retain state-law tort remedies against the manufacturer of those drugs, provided it is not impossible for the drug manufacturer to comply with both state and federal law."

Pre- and Post-Approval Design Defect Claims Preempted

Here, though, impossibility preemption occupied the forefront of the court's analysis. The court characterized the plaintiff's design defect claim as being of two types: (1) post-approval design defect, whereby the manufacturer should have lowered the dosage after FDA approval; and (2) preapproval design defect, whereby the manufacturer should have created a different form of the drug in the first place. Both imposed state-law duties that were impossible to comply with while still complying with federal law. Therefore, both were preempted under Bartlett.

Post-Approval Design Defect

The plaintiff argued that the manufacturer could have lowered the dosage of the drug to make it safer. Under applicable New York law, a product is defectively designed if it was unreasonably dangerous and a safer design was feasible. But under FDA regulations, once a drug is approved, "the manufacturer is prohibited from making any major changes to the qualitative or quantitative formulation of the drug product ... " 21 C.F.R. § 314.70(b)(2)(i). Changing the dosage level clearly constituted a "'major change' such that prior FDA approval is necessary."

The court held that, "[b]ased on the plain meaning of the regulation, ... defendants could not have altered the dosage ... without submission to the FDA and the agency's approval prior to distribution of the product made using the change." In short, the manufacturer could not have distributed an altered dosage of the drug without prior FDA approval. Therefore, it would have been impossible for the manufacturer to comply with FDA regulations and still distribute to the plaintiff a lower-dosage form of the drug.

Preapproval Design Defect

The plaintiff argued that the manufacturer should have created a different formulation of the drug in the first place. This argument, the court found, was too attenuated. The court invoked the Supreme Court's preemption opinion in PLIVA Inc. v. Mensing, 131 S. Ct. 2567, 2578 (2011), which rejected the notion that a manufacturer might be required to play a "mousetrap game" with the FDA. A preapproval duty would require the court to predict the outcome of too long a chain of events: that the manufacturer designed the drug differently, that the FDA would have approved the alternative design, that the plaintiff still would have selected that method of birth control and that she still would have suffered a stroke.

Simply put, "[i]n contending that defendants' preapproval duty would have resulted in a birth control patch with a different formulation, [plaintiff] essentially argues that defendants should have never sold the FDA-approved formulation ... in the first place."

The court rejected the plaintiff's "never-start-selling" rationale just as the Supreme Court in Bartlett rejected the argument that a manufacturer must stop selling a drug if doing so is the only way to comply with state and federal regulation. If a drug manufacturer complies with federal law, it should not be compelled to stop selling or never to sell in the first place to comply with state law.

Adequacy of Warning

The court also found that the plaintiff failed to meet her burden on the failure-to-warn claim. She argued that (1) defendants' warnings were inadequate because they failed to convey the level of risk of stroke and (2) defendants had a duty to warn plaintiff directly pursuant to FDA regulations. Ultimately these claims failed, because the label clearly disclosed the risk of stroke and plaintiff conceded she was in turn warned by her health care provider.

On the adequacy of the warnings, the plaintiff argued that the warnings failed to convey the "degree of risk." She essentially claimed that the label "should have stated that the risk of stroke was higher than other methods of birth control, namely birth control pills." The court easily disposed of this argument, relying on DiBartolo v. Abbott Laboratories, 914 F Supp. 2d 601 (S.D.N.Y. 2012). As the DiBartolo court made clear, the requirement of identifying comparative risks "extends to patients with different underlying risk factors, not to different drugs treating the same ailment."

Notably, the court also rejected the plaintiff's argument that "a subsequent improvement to the label, even a change that is required by the FDA, is probative evidence of the label's previous failure to warn." Adopting the defendants' reasoning, the court noted that "[w]arnings can always be made 'better,' but 'better' is not the standard New York law requires — adequacy is." Here, the warnings in place at the time were adequate. As a result, the subsequent changes to the label were irrelevant.

The court also found that defendants had no duty to warn the plaintiff directly under the learned-intermediary doctrine. It is well established that, "[e]xcept where FDA regulations otherwise provide, the manufacturer's duty is to warn the doctor, not the patient." The record was clear that plaintiff's health care provider was well aware of the risk of stroke, "and the plaintiff admitted to being counseled about the risk of stroke associated with Ortho Evra." Accordingly, the court granted summary judgment on the failure-to-warn claim.

Manufacturing Defect, Negligence and Breach of Warranty

The court granted summary judgment on the remaining claims. Plaintiff could not sustain a claim for manufacturing defect, because there was no evidence that the patches she received differed from "either the manufacturing specifications or from other identical units." Her negligence claim was preempted because, under New York law, claims of negligence are preempted per se when the article in question is regulated by federal law. Here, FDA regulations govern. Finally, the plaintiff's warranty claims failed because defendants adequately warned her prescribing physician of the risks, those risks were communicated to her and there were no other representations to the plaintiff of the drug's safety or efficacy.

Conclusion

Yates marks a key development in the evolution of case law regarding a branded drug manufacturer's federal and state law liability. Bartlett made clear that certain design defect claims were preempted against generic manufacturers due to their inability to deviate from the brand manufacturer's design, including warnings. Here, the Sixth Circuit has made clear that federal regulation controls the safety and adequacy of the actual composition and design of the drug itself.

Brand-name drug manufacturers cannot be expected to comply with state law when doing so would require them to design a drug that is different from the one the FDA has approved for distribution and sale. Likewise, they cannot be required to alter the suggested dosage or administration of the drug subsequent to approval to comply with state law when doing so would violate the FDA regulation governing post-approval alterations to the drug's formulation.

After Levine, liability for brand-name drug manufacturers was fraught with "what-ifs," as manufacturers struggled to predict which FDA-approved labels might be deemed inadequate under state law. Even after Bartlett, the question of design defect remained open for brand-name drug manufacturers. The Yates decision finally offers some certainty that seeking and obtaining FDA approval can cut off certain avenues of liability.

—By James W. Huston, Erin M. Bosman, Julie Y. Park and Dean S. Atyia, Morrison & Foerster LLP

James Huston and Erin Bosman are partners in Morrison & Foerster's San Diego office. Bosman is chairwoman of the firm's product liability practice group.

Julie Park and Dean Atyia are associates in Morrison & Foerster's San Diego office.