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# Sixth Circuit Affirms Impossibility Preemption of Branded-Drug Design-Defect Claims

by James M. Beck

In *Mutual Pharmaceutical Co. v. Bartlett*, the U.S. Supreme Court recognized preemption of design and related warning-defect claims asserted against manufacturers of generic prescription drugs. Because simultaneous compliance was impossible with both an immediate state-law duty to produce safe products and federal law requiring prior Food and Drug Administration (FDA) approval of the same changes, the Court held, "[S]tate-law design-defect claims ... that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." 133 S. Ct. 2466, 2497 (2013).

Although solely involving a generic drug, *Bartlett* took pains to point out, when discussing the governing federal scheme, that prior FDA review of significant design changes is mandated for *all* drugs: "Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the [drug's] qualitative or quantitative formulation." *Id*. at 2172 (citations omitted). *Bartlett* thus stands for design-defect preemption extending to state-law "major change" allegations against all drugs, not just generics. Since *Bartlett*, a number of federal district courts have so held, preempting design-defect claims against branded drugs for this reason.[1]

Recently, *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, ___ F.3d ___, 2015 WL 8538119 (6th Cir. Dec. 11, 2015), became the first post-*Bartlett* appellate decision recognizing impossibility preemption of design-defect claims involving branded drugs. The product in *Yates* was a hormone-based contraceptive patch. Stroke risks posed by hormonal contraceptives have been well known for decades, and the product at issue carried specific and detailed warnings about this risk. These product warnings were adequate as a matter of law. However, plaintiffs' counsel in this multi-district litigation anticipated problems with warning claims. Thus, the claim primarily at issue in *Yates* attacked the drug's FDA-approved design, contending that the hormonal content of each patch should have been "reduc[ed]" by one quarter. *Id*. at *12. Because this design change would require prior FDA approval, *Yates* held these allegations preempted.

While declining to impose complete preemption of "all design defect claims," *id*. at *10, the reasoning in *Yates* only omits "minor" changes for which the FDA requires no advance notice. *Id*. at *12. Because "minor" changes will rarely, if ever, be asserted in product-liability litigation, in practice *Yates* should approach blanket preemption. That manufacturers are "prohibited from making any unilateral changes to the drug's composition" was "[i]mportant to the preemption findings in *Bartlett*." *Id*. at *10. The design-defect claim in *Bartlett* "was barred by impossibility preemption because [federal law] prohibited the manufacturer from unilaterally changing the composition or labeling of the drug, as state law required." *Ibid*. Whether considered "post-approval" or "pre-approval," state-law design-defect claims were preempted. *Id*. at *11.

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[1] *Rheinfrank v. Abbott Laboratories, Inc.*, ___ F. Supp. 3d ___, 2015 WL 5836973, at *5-6 (S.D. Ohio Oct. 2, 2015); *Shah v. Forest Laboratories, Inc.*, 2015 WL 3396813, at *5 (N.D. Ill. May 26, 2015); *Booker v. Johnson & Johnson*, 54 F. Supp. 3d 868, 874-75 (N.D. Ohio 2014); *Amos v. Biogen Idec, Inc.*, 28 F. Supp. 3d 164, 168-69 (W.D.N.Y. 2014).

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"[P]ost-approval" design defects were "clearly preempted" because both "major" and "moderate" design changes require FDA preapproval. *Id*. at *12. A drug "manufacturer is prohibited from making any major changes to the qualitative or quantitative formulation of the drug product." *Ibid*. Likewise, "[m]oderate changes must be reported to the FDA at least 30 days *prior* to distribution of the drug product made using the change." *Ibid* (regulatory quotations omitted) (emphasis original). "Minor" changes could be unilateral, but dosage changes impacting product safety were not "minor." "Therefore, to the extent [plaintiff] argues that defendants should have altered the formulation of [the patch] after the FDA had approved the patch, we find this claim clearly preempted." *Ibid*. Product-liability litigation presupposes alternative designs that correct "unreasonably dangerous" products. *Id*. at *9. Thus, correction of actionable design defects cannot be "minor" and cannot be done unilaterally.[2]

Plaintiffs' "pre-approval" design-defect theory asserted that "no federal law ... would have prohibited defendants from designing a different drug in the first instance." *Yates*, 2015 WL 8538119, at *12. Plaintiffs therefore argued that a state-law duty to design only "reasonably safe product[s] prior to FDA approval" would not be preempted. *Ibid*. The Sixth Circuit disagreed. First, such allegations were "too attenuated," and lacked "any coherent pre-approval duty that defendants would have owed to [plaintiff]" during product development. *Id*. at *13. In any event plaintiffs' alternative design would also require prior FDA approval. *Ibid*.

Second, any "pre-approval claim" demanded that the manufacturer "never start selling" its FDA-approved product. *Id*. at *14. This requirement was merely another iteration of the "stop selling" argument held preempted in *Bartlett*:

> In contending that defendants' pre-approval duty would have resulted in a birth control patch with a different formulation, [plaintiff] essentially argues that defendants should never have sold the FDA-approved formulation of [the drug] in the first place. We reject this never-start[-]selling rationale for the same reasons the Supreme Court in *Bartlett* rejected the stop-selling rationale of the First Circuit.

*Ibid*.

The *Yates* court refused to apply its prior precedent, decided shortly after *Wyeth v. Levine*, 555 U.S. 555 (2009),[3] allowing a design-defect claim to escape preemption. *See Wimbush v. Wyeth*, 619 F.3d 632, 643 (6th Cir. 2010) ("no physical impossibility between complying with a state law duty to exercise reasonable care in the process leading up to placing a drug on the market and complying with the federal government's process for approving drugs"). That prior precedent "predates the Supreme Court's analyses in *Mensing* and *Bartlett*," *Yates*, 2015 WL 8538119, at *13, and was limited to its facts—a drug "taken off the market" before any litigation—while preemption protects drugs that "medical providers continue to prescribe." *Ibid* (discussing and distinguishing *Wimbush*).

*Yates* is a potential game-changer for branded prescription drugs and perhaps "substantially equivalent" medical devices. *Cf. In re Celexa & Lexapro Marketing & Sales Practices Litigation*, 779 F.3d 34 (1st Cir. 2015) (labeling claim requiring prior FDA approval is preempted). While labeling claims like those at issue in *Celexa* are uncommon, FDA regulations governing design changes for "premarket notification" devices (*i.e.* § 510k) impose submission requirements quite similar to those at issue in *Yates*. *See* 21 C.F.R § 807.81(a)(3)(i) (requiring prior submission of any "change or modification in the device that could significantly affect the safety or effectiveness of the device").

Since virtually all design changes important enough to matter in product-liability litigation require prior FDA review, they too should be preempted under *Yates*. While *Levine*'s holding that pharmaceutical manufacturers can independently strengthen label warnings shields many failure-to-warn claims from being preempted, outside the warning context that same reasoning creates a powerful preemption sword.

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[2] A "minor" modification not requiring prior FDA review must "have a minimal potential to have an adverse effect on ... the safety or effectiveness of the drug product." 21 C.F.R. § 314.70(d)(2)(i). Conversely, a "major" change has "substantial potential," and a "moderate" change has "moderate potential," for an "adverse effect" on "factors" that "relate to the safety or effectiveness of the drug product." *Id*. at §§ 314.70(b)(1), (c)(1).

[3] Only warning claims were at issue in *Wyeth v. Levine*, 555 U.S. at 560-61.

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