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August 4, 2020

California Court's Preemption Ruling Clashes with EPA No-Cancer-Warning Determination for Roundup Labeling

by Lawrence S. Ebner

In the *WLF Legal Pulse* post EPA Finally Flexes Some Preemption Muscle, I explained that last year, the U.S. Environmental Protection Agency (EPA) repudiated California's attempt, under the State's Proposition 65 right-to-know law, to require manufacturers of glyphosate weed-control products (*e.g.*, Roundup®) to include a cancer-warning on their nationally uniform, EPA-regulated, pesticide product labeling. EPA announced, based on its "comprehensive evaluation of glyphosate," that it will not "approve product labels claiming glyphosate is known to cause cancer—*a false claim that does not meet the labeling requirements*" of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (emphasis added).

FIFRA, the nation's principal pesticide law, vests EPA with the sole and exclusive authority to regulate the content of pesticide labeling, and in § 24(b), expressly preempts a State from imposing "any requirements for labeling" that are "in addition to or different from" EPA's requirements. *See* 7 U.S.C. § 136v(b).

But on July 20, 2020 a three-judge California Court of Appeal panel issued an opinion in a Roundup personal-injury suit, *Johnson v. Monsanto Co.* The Court held in part that FIFRA does not preempt California state-court juries from awarding damages on the theory that Monsanto, Roundup's manufacturer, failed to provide a cancer warning. This unpublished preemption ruling not only is wrong as a matter of law, but also will encourage the national plaintiffs' contingency-fee bar to continue using misleading TV commercials and other media to troll for so-called "victims" of federally approved or highly regulated products.

Express Preemption

Like other courts, the California Court of Appeal misconstrued *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). In *Bates*, an agricultural crop-damage case, the Supreme Court held that FIFRA's preemption provision, § 24(b), "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." *Id.* at 443. The Court indicated that to fall within §24(b)'s express preemptive reach, a state-law, pesticide-related tort claim must satisfy two statutory conditions:

First, a claim must be premised on state common-law rules that qualify as "requirements for labeling." The Court held that failure-to-warn claims *meet this requirement* because they "set a standard" that a pesticide's labeling "is alleged to have violated by containing . . . inadequate warnings." *Id.* at 446.

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Second, such a requirement for labeling must be "in addition to or different from"—not "equivalent" or "parallel" to—EPA's labeling requirements. *Id.* at 447. In particular, the Court indicated that § 24(b) would not apply to "a state-law labeling requirement if it is equivalent to, and fully consistent with, FIFRA's misbranding provision," which defines a "misbranded" pesticide product to include labeling that does not contain adequate health or environmental warnings. *Id.* If a pesticide product is not misbranded under FIFRA, however, a state-law failure-to-warn claim necessarily would impose requirements for labeling that are in addition to or different from, and not equivalent to, EPA's labeling requirements, and thus, would be expressly preempted. *See id.* at 454.

The California Court of Appeal's cursory express preemption discussion in *Johnson v. Monsanto* is premised on the unsurprising generality that "California's requirement that products contain adequate warnings is wholly consistent with FIFRA's requirements that labels include necessary warnings and precautionary statements." Op. at 44. This superficial and facile "analysis," like other courts' post-*Bates* reflexive rejection of express preemption based on the supposed "equivalency" of state and federal warning requirements, fails to consider the way that EPA *actually* regulates pesticides and their labeling under FIFRA—comprehensive, product-by-product regulation based on continual, in-depth scientific reviews of each FIFRA-registered pesticide's potential human health and environmental risks. As Justice Breyer explained in his *Bates* concurrence, 544 U.S. at 554, state-law warning requirements must "be measured against" the way that EPA "give[s] content" to FIFRA's broad misbranding standards.

Contrary to the court's assertion, *Bates does* instruct that the type of a pesticide failure-to-warn claims at issue in *Johnson* are expressly preempted by FIFRA § 24(b). EPA has unequivocally determined, based on extensive review of scientific data, that Roundup's labeling would be false and misleading, *i.e.*, misbranded, *if it did* include a cancer warning. Under *Bates*, in the case of Roundup, a state-law failure-to-warn claim premised on the lack of a cancer warning would impose requirements for labeling that are not parallel to, or consistent with, FIFRA's *specific misbranding requirements for glyphosate*, but instead, are in addition to or different from those requirements. The Court of Appeal, therefore, should have held that FIFRA § 24(b) does have "the force of law," Op. at 45, and expressly preempts the plaintiff's Roundup-related failure-to-warn claims.

Implied Preemption

The Court of Appeal also erred by holding that the plaintiff's failure-to-warn claims are not *impliedly* preempted under the well-established doctrine of impossibility preemption. Under this doctrine, a state-law claim is impliedly preempted where it would be impossible for the defendant to comply with both federal and state law—for example, where, as in *Johnson*, a pesticide manufacturer would have to provide a cancer warning on its product labeling in order to avoid state-law liability for failure to warn even though EPA has determined that providing a cancer warning would be false and misleading, and thus, would violate FIFRA's prohibition against misbranded labeling. *See, e.g.*, *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013) (state-law claim impliedly preempted where "it was impossible for [manufacturer] to comply with both its state-law duty to strengthen the warnings on [a drug's] label and its federal-law duty not to alter [the drug's] label").

In other words, EPA's determination that a cancer warning on Roundup labeling would be false drives the implied preemption analysis as well as the express preemption analysis. Importantly, the Court of Appeal agreed in *Johnson* that under the Supreme Court's reasoning in *Wyeth v. Levine*, 555 U.S. 555 (2009), a prescription-drug implied preemption case, a pesticide-manufacturer defendant "may establish a preemption defense to a state failure-to-warn claim by providing clear evidence that the EPA would not have approved a label change." Op. at 48 (citing *Wyeth*, 555 U.S. at 571).

Further, the Court of Appeal acknowledged that under *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), "the question of whether a federal agency would not have approved a label change (thus preempting a state-law failure-to-warn claim) is for a judge, not a jury." Op. at 48-49.

According to the Court of Appeal: "Although Monsanto does not point to any federal regulation that a cancer warning would violate, it has pointed to evidence that arguably would support an impossibility defense." *Id.* at 49. But "Monsanto has not, on the record before us, established that FIFRA preempts Johnson's failure-to-warn claims. . . . despite the supplemental information provided by Monsanto, it has established no more than a *possibility* of impossibility." *Id.* at 49-50. The Court of Appeal further contended that EPA's "position that glyphosate is not harmful to humans and that a cancer warning on glyphosate is unnecessary . . . is not binding on this court." *Id.* at 51.

The Court of Appeal is wrong again. EPA's carefully considered scientific determination that glyphosate does not cause cancer, its repeated approval or Roundup and other glyphosate products' labels without cancer warnings, and its unequivocal determination that including a California Proposition 65 cancer warning on such labeling would be false and misleading, provide the clearest possible evidence that Monsanto could not have provided the cancer warning required by California tort law without violating FIFRA—specifically, FIFRA's statutory and regulatory prohibitions against distributing a pesticide with a warning that EPA has determined would be false and misleading, and thus, misbranded. *See* 7 U.S.C. §§ 136(q)(1)(a), 136j(a)(1)(E) & 136v(b); 40 C.F.R. § 156.10(a)(5).

A holding that "impossibility preemption," like express preemption, bars the plaintiff's failure-to-warn claims in *Johnson* neither conflicts with *Bates*, nor with the California Supreme Court's pre-*Bates* FIFRA preemption decision in *Etcheverry v. Tri-Ag Service*, 22 Cal.4th 316, 321 (Cal. 2000).

More specifically—

- Although FIFRA § 24(a), 7 U.S.C. § 136v(a), gives a State leeway to disagree with EPA's risk determinations and restrict or prohibit the use of an EPA-registered pesticide, FIFRA § 24(b) provides that *only EPA* can regulate the content of a pesticide's labeling, such as by determining what human health warnings to include, or not to include. *Bates* establishes that EPA's labeling determinations are just as binding on courts as they are on state regulatory agencies. At most, a court can impose liability on a pesticide manufacturer for failing to distribute a product with a label warning which, unlike a Roundup cancer warning, EPA has determined must be provided in order to avoid misbranding.

- The Court of Appeal's refusal to accept EPA's emphatic pronouncements—directed specifically to California—that a cancer warning on glyphosate labeling would be false and misleading, and in violation of FIFRA's misbranding provisions, as "clear evidence" that EPA would reject inclusion of such a label warning defies common sense. Indeed, the Court of Appeal's waffling on this point seems disingenuous. At the very least, the Court of Appeal should have remanded the case to the trial judge for an *Albrecht*-type hearing on whether there is clear evidence that EPA, having been fully informed by Monsanto, would have rejected a request to add a cancer warning on Roundup's labeling.

Conclusion

The California Court of Appeal's FIFRA preemption ruling in *Johnson v. Monsanto Co.* is fundamentally flawed as to both express and implied preemption. If Monsanto seeks further appellate review, there are compelling reasons as to why the plaintiff's failure-to-warn claims are both expressly and impliedly preempted by federal law.

