21-241

IN THE
Supreme Court of the United States

MONSANTO COMPANY,
Petitioner,
v.

EDWIN HARDEMAN,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

SUPPLEMENTAL BRIEF FOR RESPONDENT

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The United States is correct. The court of appeals rightly held that FIFRA does not preempt Mr. Hardeman's claims, and there is no conflict in authority for this Court to resolve. The court's evidentiary ruling also created no conflict with other circuits considering the admissibility of expert testimony. None of Monsanto's supplemental arguments justifies review.

ARGUMENT

I. The Preemption Issue Does Not Warrant Review

A. Mr. Hardeman's Claims Are Not Expressly Preempted

1. FIFRA preempts common-law claims only when they impose (1) "a requirement '*for labeling or packaging*'" (2) "that is '*in addition to or different from*'" one of FIFRA's own requirements. *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 443-44 (2005) (quoting 7 U.S.C. § 136v(b)).[1] Claims that are "equivalent to," or narrower than, "FIFRA's misbranding provisions" are not preempted. *Id.* at 447 & n.23; *see id.* at 454 ("[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA.").

Mr. Hardeman's claims are narrower than FIFRA's misbranding provisions. That was the court of appeals' key conclusion. Pet. App. 13a. And Monsanto does not dispute the point in its briefs. The result is that Mr. Hardeman's claims are "fully consistent" with the statute and not preempted. *Bates*, 544 U.S. at 447. That should be the end of the matter.

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[1] Except where otherwise noted, citations to provisions of the U.S. Code are to Title 7.

2. Monsanto's central contention (Supp. Br. 3-5) is that EPA's decision to register a pesticide and approve its label imposes a "requirement" under FIFRA, so state-law claims that would require labeling changes are preempted. Not one appellate *judge* – let alone panel – has accepted this argument. Opp. 17.

FIFRA imposes no requirement to keep a registered pesticide's labeling the same. Monsanto suggests (Supp. Br. 3-4) that EPA dictates the language on a pesticide's labeling and that language cannot change after registration. Both suggestions are incorrect.

First, pesticide manufacturers – not EPA – propose labeling language. § 136a(c)(1)(C). EPA then reviews the proposed language to ensure it is "necessary" and "adequate to protect health" based on scientific material the manufacturer submits. § 136(q)(1)(G); *see* § 136j(a)(1)(E).

Second, EPA's decision to register a pesticide is not the last word on whether the pesticide's labeling is misbranded. Section 136a(f)(2) provides that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter," including the misbranding offense. If a pesticide is "registered but nevertheless misbranded," the manufacturer has a duty to update its label. *Bates*, 544 U.S. at 438. Failing to do so can lead to civil and even criminal liability. § 136*l*. Retaining a registered but misbranded label therefore is not a "requirement" of FIFRA – it is a violation.

Because registration by itself imposes no "requirement," "Monsanto's preemption argument turns not on registration alone" (Supp. Br. 7) but also on a hodgepodge of actions that purport to show EPA thinks glyphosate is not carcinogenic. Those actions add nothing to the preemption analysis. From filing

to verdict, Mr. Hardeman's case was about Monsanto's failure to warn of the cancer risks of formulated Roundup, not glyphosate in isolation. *See* Opp. 2, 6-7. Monsanto never has proposed any warning about the cancer risks of formulated Roundup, and EPA never has rejected one. Opp. 8. And EPA repeatedly has admonished that it has not determined whether glyphosate-based products like Roundup can cause cancer.[2]

3. Both the decision below and the United States' express-preemption position here track *Bates*. Monsanto's attempts (Supp. Br. 5-6) to recast and cabin that decision lack merit.

Monsanto focuses (Supp. Br. 5) on an example from *Bates* about a failure-to-warn claim requiring the word "DANGER" rather than "CAUTION." The example undercuts its arguments. By regulation, EPA "establishe[d] four Toxicity Categories for acute hazards of pesticide products," 40 C.F.R. § 156.62, and then mandated toxicity warnings for qualifying pesticides, *id.* § 156.64. So when a state-law failure-to-warn claim requires "DANGER" when EPA's regulation requires "CAUTION," of course there is preemption: That is a "requirement[] for labeling"

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[2] In 2017, as part of its re-registration review of glyphosate, EPA acknowledged a need for more research "to determine whether formulation components, such as surfactants, influence the toxicity of glyphosate formulations." EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 144 (Dec. 12, 2017), http://tinyurl.com/eparevdglyphosate. In its 2019 Interim Glyphosate Review, the agency again acknowledged that it had not determined whether glyphosate "formulations," like Roundup, pose any risks to human health. *See* EPA, *Glyphosate: Proposed Interim Registration Review Decision* 11 (Apr. 2019), http://tinyurl.com/y6h2u8w6.

that is "different from" what EPA's regulation would "require[]." § 136v(b).

Monsanto contends that this example is about registration, not regulation. *See* Pet. 15-16. But a glance at *Bates* straightens out this topsy-turvy notion: The sentence before the DANGER/CAUTION example reads: "State-law requirements must also be measured against any relevant EPA *regulations* that give content to FIFRA's misbranding standards." *Bates*, 544 U.S. at 453 (emphasis added).

Monsanto next suggests (Supp. Br. 6) that *Bates*'s analysis and finding of no express preemption only applies to claims about pesticide efficacy. In its view, efficacy claims are not preempted because EPA does not review for efficacy, or require any specific efficacy labeling, as part of the registration process. But the DANGER/CAUTION example again undercuts this argument. These warnings – "DANGER" and "CAUTION" – are about safety, not efficacy. And *Bates*'s discussion about these safety warnings confirms that the FIFRA analysis is not just about efficacy. Monsanto has no response to this point, so it instead abruptly contradicts itself (Supp. Br. 6) to describe that DANGER/CAUTION passage from *Bates* as dicta.

4. Finally, Monsanto argues (Supp. Br. 6-8) that, because the preemption provisions here and in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), are similar, the preemption result should be the same. But the similarities between the statute in *Riegel* and FIFRA here end at the preemption provisions. Opp. 23-24.

Riegel involved claims under the Medical Device Amendments Act of 1976, which "swept back some state obligations and imposed a regime of detailed federal oversight." 552 U.S. at 316. In *Riegel*, this

Court held that FDA's premarket approval of a medical device imposes "requirements" under the statute's preemption clause, 21 U.S.C. § 360k(a), and preempts state-law failure-to-warn claims based on inconsistent duties. *See* 552 U.S. at 322-23, 327-30. This Court said FDA's premarket approval of the riskiest medical devices serves as conclusive evidence that "the approved form [of the devices] provides a reasonable assurance of safety and effectiveness." *Id.* at 323. So a plaintiff cannot argue that an approved device "violated state tort law notwithstanding compliance with the relevant federal requirements." *Id.* at 330. By contrast, FIFRA "authorizes a relatively decentralized scheme" that leaves States with broad power to regulate pesticide products – including the power to ban the sale of unsafe, but registered, pesticides. *Bates*, 544 U.S. at 450 (citing § 136v(a)). Under FIFRA, registration of a pesticide with EPA is only "prima facie evidence" of compliance, § 136a(f)(2), not proof the labeling is "adequate to protect health," § 136(q)(1)(F). And because a manufacturer with a registered product still could be liable for misbranding, it could be liable for state-law claims "that are fully consistent with federal requirements," like Mr. Hardeman's. *Bates*, 544 U.S. at 452.

The Medical Device Amendments have no analogue to section 136a(f)(2), which establishes that registration is not a defense to "any offense" under FIFRA, including the misbranding offense. Monsanto argues that section 136a(f)(2) "has 'no bearing on'" preemption because it "'stands for the unremarkable proposition that a registration is not a defense against an allegation that a product violates the terms of that registration.'" Pet. 17 (first quoting *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1026 n.4 (5th Cir. 1994); then quoting *Reckitt Benckiser, Inc. v. Jackson*, 762

F. Supp. 2d 34, 45 (D.D.C. 2011)). But that narrow reading of the section does not track its text, which establishes that registration is not a defense to "any offense" under FIFRA, not just violations of the terms of registration. § 136a(f)(2).

B. Mr. Hardeman's Claims Are Not Impliedly Preempted

1. The doctrine of implied preemption does not apply under FIFRA. Congress decided that FIFRA preempts state requirements only when they impose labeling or packaging requirements "in addition to or different from those required under [FIFRA]." § 136v(b). Congress also preserved a State's authority to *ban* federally approved pesticides. § 136v(a); *see also Bates*, 544 U.S. at 446 ("[A] state agency may ban the sale of a pesticide if it finds, for instance, that one of the pesticide's label-approved uses is unsafe."). Those decisions left no room for implied preemption.

Unsurprisingly, this Court did not conduct an implied-preemption analysis in *Bates*. The defendant had made the argument, *see* Resp. Br. at 36-37, *Bates v. Dow AgroSciences LLC*, No. 03-388 (U.S. Nov. 24, 2004), and if the Court had found implied preemption it would have affirmed rather than remanded.

2. Monsanto draws its implied-preemption arguments from prescription drug cases under the Federal Food, Drug, and Cosmetic Act ("FDCA"). This Court conducts an implied-preemption analysis in such cases because, unlike here, Congress has "declined to enact [an express-preemption] provision for prescription drugs." *Wyeth v. Levine*, 555 U.S. 555, 567 (2009).

Monsanto first argues (Supp. Br. 8-9) that it could not add a warning to Roundup's labels without EPA's approval. That contention derives not from FIFRA but from the FDCA, under which FDA imposes a "duty

of sameness" on generic-drug labels, which always must match the label of the brand-name equivalent drug. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 616 (2011). But unlike generic-drug manufacturers, which have a "federal-law duty to keep the label the same," *id.* at 618, pesticide manufacturers "have a continuing obligation to adhere to FIFRA's labeling requirements," *Bates*, 544 U.S. at 438. *PLIVA*'s rule does not apply.

Monsanto next argues (Supp. Br. 9-10; Pet. 21) that it cannot add a cancer warning to Roundup labels because EPA would not accept it. Again under the FDCA, state-law failure-to-warn claims are preempted when there is "clear evidence" that FDA would not have approved the warning that state law requires. *Wyeth*, 555 U.S. at 571. The only sources of "clear evidence" of what an agency would do in that kind of hypothetical situation "are agency actions taken pursuant to the FDA's congressionally delegated authority": "notice-and-comment rulemaking," an order "formally rejecting a warning label," or "other agency action carrying the force of law." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019). But here, EPA has promulgated no regulation requiring certain warnings on glyphosate-based product labels and barring others. Nor has the agency taken other action rejecting a warning about Roundup's cancer risks.

3. Here, EPA has made clear it would approve a label warning of Roundup's cancer risks because such a label would not be misbranded. *See* SG Br. 14. When a manufacturer's proposed label is not misbranded, FIFRA provides that EPA "shall" approve it. § 136a(f)(1). As a result, federal law imposes no competing "duty to keep the label the same," *PLIVA*,

564 U.S. at 618, and there is no "clear evidence" showing Mr. Hardeman's claims are preempted, *Wyeth*, 555 U.S. at 571. This alone forecloses Monsanto's implied-preemption arguments.

II. The Expert-Testimony Issue Does Not Warrant Review

Monsanto's second question presented involves only fact-bound application of settled law. Monsanto's unhappiness with the result is not a basis for review.

The company focuses (Supp. Br. 11-12) on *Tamraz v. Lincoln Electric Co.*, 620 F.3d 665 (6th Cir. 2010), *cert. denied*, 563 U.S. 988 (2011). There, the Sixth Circuit held that physicians may "testify to etiology," *id.* at 673, but the problem was that the expert there had "failed to cite *any* non-speculative evidence for his conclusion," *id.* at 674. Here, Mr. Hardeman's experts relied on "epidemiological, animal, and cellular" studies, and they used "clinical experience" only to supplement the studies on which they relied. Pet. App. 28a (footnote omitted). The law is the same; only the facts differ. Opp. 32-33.

Also in *Tamraz*, the court held that experts must rule out "unknown (idiopathic) causation" as an alternative explanation for a plaintiff's illness. 620 F.3d at 675. Mr. Hardeman's experts did just that. Opp. 33-34. And the court of appeals articulated the same rule as the one that governed this case. Pet. App. 33a. No split therefore exists.

Finally, Monsanto points (Supp. Br. 12) to "a sweeping statement" about admissibility from an older Ninth Circuit case. But the statement refers only to a district court's discretion to permit an expert "to rely on clinical experience" when "conducting differential diagnosis to render specific causation opinions." Pet. App. 27a. Monsanto identifies no

circuit decision holding that such reliance is impermissible, particularly when invoked merely to "supplement the epidemiological studies on which [the experts] relied." *Id.* at 28a.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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