No. 21-1272

IN THE

Supreme Court of the United States

MONSANTO COMPANY,
Petitioner,

v.

ALBERTA PILLIOD AND ALVA PILLIOD,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE COURT OF APPEAL OF CALIFORNIA

REPLY BRIEF FOR PETITIONER

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INTRODUCTION

Respondents provide no sound basis to deny certiorari. For decades, the Environmental Protection Agency (EPA)—like national regulators around the world—has concluded that glyphosate does not cause cancer in humans. Just last spring, in fact, EPA informed the Ninth Circuit that the agency's "robust … analysis and thorough review of the scientific literature" establishes that glyphosate "poses no human-health risks of concern." EPA Br. 1, *NRDC* v. *EPA*, Nos. 20-70787, 20-70801 (9th Cir. May 18, 2021). And two months ago, EPA again reiterated that it "continues to stand behind its robust scientific evaluation of the carcinogenic potential of glyphosate." Resp. App. 2a. Yet the court below held EPA's view legally irrele-

vant, both as to whether a glyphosate-based product requires a cancer warning and whether omitting such a warning was so reprehensible as to warrant a punitive-damages award four times the compensatory award. Those holdings—which marginalize the longstanding views of the expert agency charged by Congress with administering pesticide labeling nationwide—warrant review.

As to preemption, the decision below permits juries and legislatures in every State to rewrite a product's safety warning unilaterally, creating precisely the "50 different labeling regimes prescribing the … wording of warnings" that the preemption provision in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was intended to prevent, *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005). Nor can the decision be squared with the provision's plain language, which bars state-imposed labeling requirements that are "in addition to or different from" labeling requirements imposed "under" FIFRA, 7 U.S.C. §136v(b). FIFRA plainly does not require a cancer warning on glyphosate products, so the jury's mandate of such a warning here is unquestionably "in addition to or different from" the labeling FIFRA requires, *id.* And as *Bates* explained, a state-law mandate for a more aggressive warning than EPA's "more subdued" label—i.e., what respondents seek and the Court of Appeal allowed—is "pre-empted." 544 U.S. at 453; *see also Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 323, 330 (2008) (agency's safety assessment of a specific product preempts contrary state law).

As for punitive damages, respondents attempt to distract from the entrenched circuit conflict described in the petition by mischaracterizing Monsanto's position. Monsanto has never argued that a 1:1 punitive-to-

compensatory ratio is mandatory "no matter how egregious the defendant's misconduct," Opp. 34. Rather, courts disagree over whether that ratio is the constitutional ceiling when—as here, *see* Pet. App. 79a, 89a-90a—compensatory damages are high and the defendant's reprehensibility is not. That division warrants resolution by this Court.

ARGUMENT

I. PREEMPTION

A. Express Preemption

1. This case is a good vehicle

Respondents' lead argument regarding express preemption—and their only argument for why the petition should not at least be held pending the disposition of the petition in *Monsanto Co.* v. *Hardeman*, No. 21-241—is that this case is a poor vehicle to resolve the scope of FIFRA preemption. In particular, respondents contend (Opp. 15-18, 30-31) that the jury's verdict did not *necessarily* require Monsanto to change its labeling, making FIFRA preemption inapplicable here. The verdict did not necessarily require a label change, respondents say, either because it could rest on a design defect or because a cancer warning could be delivered without changing a label.

Respondents, however, pressed this same argument below, *see* Resps.' C.A. Principal-and-Resp. Br. 80-84, and the Court of Appeal did not endorse it (rightly so, *see* Monsanto C.A. Resp.-and-Reply Br. 21 & n.1, 27-28). Instead, the court "assumed" that respondents' claims *were* "entirely based on labeling and packaging requirements," Pet. App. 27a. Hence, "there is no doubt … that the [court] decided the crucial issue" of

whether the verdict imposed a requirement different from or in addition to what FIFRA requires. *United States* v. *Williams*, 504 U.S. 36, 42-43 (1992). That the court *could* have decided the case on another ground is no bar to certiorari.[1]

Respondents also note (Opp. 30) that this case arises from an intermediate state court. But this Court routinely grants review in such cases. *See, e.g.*, *Viking River Cruises, Inc.* v. *Moriana*, 142 S.Ct. 734 (2021); *Lange* v. *California*, 141 S.Ct. 2011 (2021).

2. The Court of Appeal's decision conflicts with *Bates* and *Riegel*

The decision below is inconsistent with both *Bates* and *Riegel*, permitting juries to require cancer warnings for pesticides that EPA has deemed improper. Pet. 14-19. Respondents' contrary arguments fail.

a. Respondents begin by reiterating (Opp. 18-19) the Court of Appeal's conclusion that California's failure-to-warn standard parallels FIFRA's, Pet. App. 27a-28a. But a State's use of the same high-level legal

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[1] The same point forecloses respondents' contention that the petition should not be held for *Hardeman*: Because the decision below rested on the assumption that respondents' claims were based "entirely" on a labeling/packaging requirement, Pet. App. 27a, vacatur of that decision and a remand for the Court of Appeal to reconsider it would be required if this Court were to reverse the Ninth Circuit's preemption ruling in *Hardeman*. A hold is therefore warranted.

Alternatively, this petition should be held pending the Eleventh Circuit's decision in *Carson* v. *Monsanto Co.*, No. 21-10994 (argued Nov. 16, 2021), which raises the same issues. If the Eleventh Circuit affirms, its ruling will—as the United States' invitation brief in *Hardeman* stated (p.19)—present a direct conflict with the decision here.

standards as FIFRA is insufficient. Preemption turns on whether a state law requirement is "*genuinely* equivalent" to what FIFRA requires—i.e., whether the State requires specific warnings that EPA does not. *Bates*, 544 U.S. at 453-454. A contrary rule would mean that every California jury in cases like this could require a different warning label for Roundup, so long as each jury applied the same legal test as FIFRA. *Bates* forecloses such a regime, explaining that a State cannot, for example, require "a given pesticide's label … [to] state[] 'DANGER'" when EPA has already determined that the "more subdued 'CAUTION'" is appropriate. *Id.* at 453.

Respondents assert, however (Opp. 19), that *Bates* held a "'state cause of action that seeks to enforce' [FIFRA's] misbranding provisions" is not preempted. But what *Bates* was saying is that States may impose "different or additional *remedies*" from those available under FIFRA, because the law's express-preemption provision speaks only to "different or additional *requirements*." 544 U.S. at 448 (emphases added). That does not support respondents' arguments.

Next, respondents contend (Opp. 20) that EPA's decision to register a pesticide is not preemptive because EPA retains the authority to cancel a registration decision if later information comes to light. That is unavailing because Monsanto's preemption argument rests not just on registration but also on the fact that EPA has consistently found that no cancer warning is necessary and that Monsanto's label complies with that determination. Pet. 13-14. In any event, EPA's ability to revisit the appropriate label for a pesticide does nothing to support respondents' claim that any jury can depart from EPA's existing position. To the contrary, *Bates* explains that "a manufacturer should not be held

liable under a state labeling requirement subject to [FIFRA's express preemption provision] unless the manufacturer is also liable for misbranding as defined by FIFRA." 544 U.S. at 454.

Respondents also argue (Opp. 7-8, 20-21) that EPA has never evaluated the carcinogenicity of Roundup (as opposed to glyphosate). But EPA's registration process evaluates the safety of both glyphosate and the other ingredients in a glyphosate-based pesticide "with a battery of toxicity data from a multitude of studies." EPA, *Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision* 6 (Jan. 16, 2020), https://tinyurl.com/426uuejz. Regardless, respondents do not dispute that nothing in the Court of Appeal's preemption analysis turns on the distinction between glyphosate and Roundup. Pet. 6 n.1.[2]

Finally, respondents deny that their position is inconsistent with *Bates*, for one primary reason. In their view, because *Bates* cited an EPA regulation when giving the "CAUTION/DANGER" example of preemption, *see* 544 U.S. at 453, FIFRA preemption applies *only* when a regulation specifically mandates warning language for a particular pesticide's label. Opp. 28-29. That is incorrect.

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[2] Respondents' suggestion (Opp. 7-8) that EPA has not reached "a conclusion regarding the association between glyphosate exposure and risk of non-Hodgkin's lymphoma" is wrong. EPA explained to the Ninth Circuit last year that "the available studies did not demonstrate that glyphosate had *any* effect on non-Hodgkin lymphoma risk that could not be explained as the result of chance or bias," and that "substantial evidence supports EPA's expert judgment that the weight of the evidence most strongly supports the overall conclusion that glyphosate is not likely to be carcinogenic to humans." EPA Br. 38-39, *NRDC* v. *EPA*.

The regulation *Bates* cited (40 C.F.R. §156.64) merely identifies the general characteristics of pesticides that would warrant a "DANGER," "CAUTION," or "WARNING" label. The regulation does not require EPA to apply particular wording to a particular pesticide and thus creates no conflict with state law. Rather, the regulation applies to "*[a]ny* pesticide product" that fits the criteria—a finding that, logically, EPA would have to make. Moreover, the regulation leaves the ultimate choice of wording to "the Agency['s] determin[ation]" in some instances (i.e., if EPA found it necessary to assign a more severe warning than the regulatory criteria required). *Id.* §156.64(a), (b)(1) (emphasis added). A conflict with state law would thus arise only where EPA decided that a specific pesticide label should say "CAUTION."[3]

Lastly, respondents contend (Opp. 22, 29) that to preempt state law, EPA must promulgate pesticide-specific regulations. But as just discussed, nothing in *Bates* requires that impractical approach. Furthermore, EPA does not make product-specific wording decisions via regulation; it does so through a process *prescribed* by regulation. *See* 7 U.S.C. §136a(c)(5)(B); 40 C.F.R. §§156.62, 156.64. And as EPA's own registration manual says, once approved and registered, a "pesticide's label is a legal document[:] The label is the law!" EPA, *Pesticide Registration Manual*, https://tinyurl.com/47cysjr5 (updated May 17, 2022). Because the label is "the law," it—together with EPA's consistent findings of no carcinogenicity—is preemptive.

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[3] Respondents also cite (Opp. 29) a regulation not discussed in *Bates*: 40 C.F.R. §156.62. But that regulation does not classify specific pesticides either, instead laying out metrics for EPA to determine pesticides' toxicity levels.

b. Respondents attempt to distinguish *Riegel* (and various circuit decisions) on the ground that each interpreted the Medical Device Amendments (MDA) rather than FIFRA. Opp. 22-23, 27-28. But respondents do not dispute that the two statutes' express-preemption provisions are materially identical—and hence this Court has relied on MDA case law to interpret FIFRA and vice versa. Pet. 16. Indeed, respondents themselves cite an MDA case to support their preemption arguments. Opp. 19, 23.

Respondents instead contend (Opp. 22, 28) that FIFRA is different from the MDA because of 7 U.S.C. §136a(f)(2). But that provision "has no bearing" on preemption. *MacDonald* v. *Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994). It says only that registration is not a "defense for the commission of any offense *under [FIFRA]*." 7 U.S.C. §136a(f)(2) (emphasis added). Respondents' claims arise not under FIFRA, but under California tort law. Pet. 18. Respondents counter (Opp. 22) that their state-law claims are "fully consistent with" FIFRA's requirements and thus are parallel to a FIFRA misbranding claim, meaning they fall under §136a(f)(2). But their claims are *not* "fully consistent" with FIFRA since the jury's verdict requires a warning that EPA does not. *Supra* pp.5-6.

Respondents also argue (Opp. 22-23) that the MDA is "meaningfully different" from FIFRA because FIFRA gives "States … broad[er] power to regulate pesticide products" than the MDA confers regarding the regulation of medical devices. It is true that FIFRA gives states broader authority than the MDA to regulate in-state *use*, but that is irrelevant because FIFRA expressly withholds the power to "impose … any requirements for labeling" that are in addition to or different from FIFRA's requirements, 7 U.S.C.

§136v(b), just as the MDA does. As *Bates* explained, this provision plays an "important[] role" in the statutory scheme, preventing "50 different labeling regimes prescribing the … wording of warnings." 544 U.S. at 452.

Respondents relatedly posit (Opp. 23) that there is less risk under FIFRA than under the MDA that unduly aggressive warnings will foreclose appropriate use of products. To the contrary, the business and consumer confusion that would result from one State requiring a cancer warning on a pesticide like Roundup while EPA does not is substantial. Pet. 24-26. And while individual "weeds are not life-threatening" (Opp. 23), a coalition of over 50 different agricultural groups has recently explained that allowing each State to impose its own pesticide-labeling requirements threatens extremely severe consequences, including not only "undermining the ability of U.S. agricultural producers to help meet global food needs," but also "reduc[ing] crop yields at a time when lives depend on us producing every bushel possible." Letter to Hon. Joseph R. Biden (May 23, 2022), https://tinyurl.com/3tsnewmc; *see also* WLF Amicus Br. 13.

c. Respondents resort finally to policy arguments. They argue, for example (Opp. 32), that Monsanto's interpretation of FIFRA would "bar all failure-to-warn claims based on a pesticide's 'labeling' other than claims about the pesticide's efficacy." Even putting aside that policy arguments are misplaced because the statutory text provides "the best evidence for" "congressional purposes" regarding preemption, *Riegel*, 552 U.S. at 326 n.5, this argument fails. A plaintiff could certainly bring a non-efficacy failure-to-warn claim if a manufacturer failed to comply with the label approved by EPA (e.g., by omitting a required cancer warning). This

"threat of a damages remedy" serves the important function of "giv[ing] manufacturers an additional cause to comply" with EPA's requirements. *Bates*, 544 U.S. at 447-448.

B. Conflict Preemption

Respondents fare no better in addressing implied preemption. As Monsanto explained, the decision below is inconsistent with this Court's cases holding that state law is implicitly preempted if (1) there is "clear evidence" that the relevant agency would not approve a warning required under state law, *or* (2) the warning could only be added with prior approval. Pet. 21-23 (citing *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 617-619 (2011), and *Wyeth* v. *Levine*, 555 U.S. 555, 571 (2009)).

Respondents first repeat (Opp. 24-25) the Court of Appeal's view that conflict preemption is categorically inapplicable in FIFRA cases, Pet. App. 30a. *But see* Pet. 23-24. Respondents' lone authority for this argument is a separate opinion in *Bates* for two Justices—and even that opinion stated only that *Bates* "decline[d] to address" *whether* implied preemption applied. 544 U.S. at 458 (Thomas, J., concurring in the judgment and dissenting in part). Because that question "merely lurk[ed] in the record" in *Bates*, the Court's decision did nothing to resolve it. *Cooper Industries, Inc.* v. *Aviall Services, Inc.*, 543 U.S. 157, 170 (2004).

Respondents' effort to distinguish *PLIVA* also fails. As respondents recognize (Opp. 25-26), *PLIVA* held that "when a state-law claim imposes a duty to change the label, it is impliedly preempted" because "[t]he manufacturer has no right to update the label on its own." The same is true under FIFRA: EPA must approve substantive changes to a label before a manu-

facturer can use it. Pet. 22. Even the April 2022 EPA letter that respondents cite underscores that the agency must "approve" a cancer warning before one can be added. Resp. App. 1a.

Lastly, respondents argue (Opp. 26-27) that there is not "clear evidence" under *Wyeth* to establish conflict preemption. Respondents, however, do not dispute that as of when this suit was filed (June 2017), all available evidence indicated that EPA would not approve a cancer warning on glyphosate. Pet. 7-9, 22-23. While respondents again rely on EPA's April 2022 letter, the warning that letter mentions is *California's* determination that glyphosate is carcinogenic—a finding made *after* this suit was filed and after the end of respondents' exposure.

II. PUNITIVE DAMAGES

The Court of Appeal affirmed a punitive-damages award four times respondents' substantial compensatory damages, even though there was no disagreement that Monsanto's conduct was (at most) "at the lower end" of reprehensibility. Pet. 26-31. Under those circumstances, five circuits and the South Dakota Supreme Court hold that punitive damages cannot constitutionally exceed compensatory damages. Pet. 27-28. Two other circuits and the Montana Supreme Court, meanwhile, reject such a limit. Pet. 28.

Respondents do not contest the existence of (or need to resolve) this conflict. Instead, they wrongly assert (Opp. 34) that Monsanto argues for a 1:1 limit on punitive damages so long as compensatory damages are substantial. Not so. *See, e.g.*, Pet. 27.

Respondents also argue (Opp. 30-32) that Monsanto's conduct was "highly reprehensible." But again, re-

spondents are fighting the Court of Appeal's own decision. The court merely noted that Monsanto's conduct sufficed to support *some* punitive damages—and did not dispute the dissent's conclusion that Monsanto's conduct was "at the lower end" of the reprehensibility spectrum. Pet. App. 77a, 89a. Indeed, although respondents contend (Opp. i, 1) that Monsanto "knew" and "has known" that Roundup causes cancer, no member of the court below disputed that (1) "there was consensus among regulatory agencies that Roundup did *not* cause a risk to humans at real world exposure levels"; (2) "[t]here was *no* evidence that Monsanto believed, let alone knew, that Roundup or glyphosate were carcinogenic"; and (3) there was "*no* evidence that Monsanto hid any scientific study from regulators or the scientific community." Pet. App. 88a (emphases added).

In sum, this case is an excellent vehicle to resolve the longstanding conflict regarding the constitutional limit for punitive-damages awards in cases like this—and, in the process, provide its first clarification in 15 years of the constitutional limitations on such awards.[4]

[4] Alternatively, the Court may wish to invite the views of the United States on this question, which was not presented in *Hardeman*. *Cf. Epic Systems Corp.* v. *Tata Consultancy*, No. 20-1426 (U.S. Oct. 12, 2021). Those views would be particularly salient here given the tension between the jury verdict and Monsanto's compliance with EPA's repeated determinations about glyphosate's safety.

CONCLUSION

The petition should be granted or else held pending this Court's disposition of *Hardeman*.

Respectfully submitted.

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