No. 24-1097

In the
Supreme Court of the United States

MONSANTO COMPANY,

Petitioner,

v.

NANCY C. SALAS,

Respondent.

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

REPLY BRIEF FOR PETITIONER

DAVID M. ZIONTS
MICHAEL X. IMBROSCIO
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001

K. LEE MARSHALL
BRYAN CAVE LEIGHTON PAISNER
Three Embarcadero Ctr.
San Francisco, CA 94111

PAUL D. CLEMENT
Counsel of Record
MATTHEW D. ROWEN
JAMES Y. XI
NICCOLO A. BELTRAMO
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-8900
paul.clement@clementmurphy.com

Counsel for Petitioner

July 23, 2025

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes and Regulation

Other Authorities

REPLY BRIEF

There is an open and acknowledged split as to whether FIFRA preempts state-law failure-to-warn claims based on the content of pesticide product labels. The split has only deepened and increased in importance since the petition, as a Pennsylvania appellate court recently affirmed a $175 million damages award based on theories that are unavailable in the Third Circuit and elsewhere. Unable to deny that reality, respondent asserts that Monsanto's "cunning" strategy of seeking summary affirmance from the Eleventh Circuit to "fast track" the case to this Court somehow created an Article III problem. BIO.17, 23. That is baseless. Monsanto sought summary affirmance because the Eleventh Circuit had already rejected its preemption argument in *Carson v. Monsanto Co.*, 92 F.4th 980 (11th Cir. 2024), and denied its en banc petition to boot. Nothing in Article III required Monsanto to delay its inevitable Eleventh Circuit loss—or this Court's review—by inventing non-existent grounds for distinguishing *Carson* or requesting a slower affirmance. Nor was there anything unduly "cunning" about Monsanto's request, which simply respected both stare decisis in the Eleventh Circuit and this Court's position at the top of the federal judicial hierarchy.

Respondent's preservation arguments are equally meritless, as Monsanto pressed its express and implied preemption arguments at every stage of this case. And respondent's merits arguments are both unavailing and premature. Whether in *Monsanto Co. v. Durnell*, No. 24-1068 (docketed Apr. 9, 2025), which avoids even the supposed Article III and preservation

issues respondent imagines here, or in this case, which presents a clean alternative vehicle, this Court should grant review of a profoundly consequential question of federal law on which federal and state appeals courts are openly divided.

I. This Case Presents A Clean Vehicle To Resolve An Acknowledged Circuit Split On An Important Question.

A. As the petition in *Durnell* explained and numerous amici reinforced, courts are sharply divided on the question presented. *See Durnell*.Pet.17-23; Chamber.Br.11-12, 18-21; Croplife.Br.13-19.[1] At the federal level, the Ninth and Eleventh Circuits hold that FIFRA does not preempt state-law failure-to-warn claims based on health warnings that EPA has neither approved nor required, *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021); *Carson v. Monsanto Co.*, 92 F.4th 980 (11th Cir. 2024), whereas the Third Circuit holds the opposite, *Schaffner v. Monsanto Corp.*, 113 F.4th 364 (3d Cir. 2024). State courts are similarly divided. *See Durnell*.Pet.19 n.5, 22 n.6 (collecting cases).

The split has only deepened since the petition was filed. A Pennsylvania appellate court recently joined the no-preemption camp, *Caranci v. Monsanto Co.*, 2025 WL 1340970, at *9 (Pa. Super. Ct. May 8, 2025), which means there is now a split between state and federal appellate courts within the Third Circuit. Absent this Court's intervention, whether a Pennsylvania-law failure-to-warn claim is preempted or not will turn solely on whether the case proceeds in

[1] The amicus briefs were filed on the *Durnell* docket.

state or federal court. Needless to say, plaintiffs will have every incentive to add in-state defendants to prevent removal via diversity. That state-federal split within the Third Circuit is intolerable and illustrative of the broader split, which extends nationwide and demands this Court's review.

B. Respondent acknowledges that the Eleventh Circuit "diverged" from the Third Circuit on the question presented, BIO.25, but insists that this case does not present an occasion to resolve the split. According to respondent, this case "falls within the circumstances that [the Third Circuit] expressly declined to address" in a footnote—namely, whether "FIFRA required Monsanto to seek EPA approval for a modified Roundup label that included a cancer warning." BIO.24-25 (citing *Schaffner*, 113 F.4th at 386 n.13).

Respondent is doubly mistaken. That footnote just reserves judgment on the narrow question of whether FIFRA preempts a claim that seeks to hold a pesticide manufacturer liable under a theory that the plaintiffs suffered injuries because of the manufacturer's failure to bring to EPA's attention information that the manufacturer possesses but EPA lacks. *Cf. Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (en banc) (Watford, J., concurring) (discussing similar failure-to-warn-FDA theory in MDA context). And nothing in the decision below turns on a failure-to-warn-EPA theory. To the contrary, the Eleventh Circuit granted judgment to respondent after concluding that this case is "indistinguishable" from its previous decision in *Carson*, which squarely held that FIFRA does not

preempt a state-law failure-to-warn claim that "require[s] pesticide manufacturers to warn *users* of potential risks to health and safety." App.2-3 (brackets in original, emphasis added); *see also Carson*, 92 F.4th at 992 ("[B]oth FIFRA and Georgia common law require pesticide manufacturers to warn *users* of potential risks to health and safety." (emphasis added)). This case thus squarely implicates the circuit split.

C. This case is a clean vehicle to resolve the split. *Contra* BIO.24-26, the complaint alleges no failure-to-warn-EPA—as opposed to failure-to-warn-end-users—theory. While it alleges generally that Monsanto "faile[d] to give appropriate warnings about other risks of which Defendants knew or should have known are involved in the reasonably foreseeable use of and/or exposure to Roundup products," D.Ct.Dkt.73 ¶120(c), it focuses on the failure to warn end-users like respondent and never specifically alleges that Monsanto had a duty to warn EPA and violated that duty. *Compare* BIO.25 (citing D.Ct.Dkt.73 ¶¶18-20, 22, 118-19, 120(c)), *with* D.Ct.Dkt.73 ¶¶18-20, 22, 118-19, 120(c) (containing no allegations of the sort). *See also* D.Ct.Dkt.73 ¶120(a)-(b) (alleging that "Monsanto breached [its] duty … [b]y failing to provide adequate instructions, guidelines, and safety precautions to those … exposed to its Roundup products" and "[b]y failing to disclose to consumers … that the product's risk of harm was unreasonable and that there were safer and effective alternative herbicides available").

Regardless, even if the complaint alleged a failure-to-warn-EPA theory, it would have been unnecessary to prevail in the Eleventh Circuit under

Carson and would present no obstacle to this Court's review. This Court routinely grants review of important issues on which the courts of appeals are divided even when the respondent might have an argument available on remand. In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), for example, the Court granted review to consider whether FDA's approval of a medical device label preempted a state-law claim that sought to hold medical device manufacturers liable for failing to include additional warning labels required by state law, even though its resolution of that question arguably left open the possibility that plaintiffs could assert a failure-to-warn-FDA theory. *See id.* at 315-21; *see also Stengel*, 704 F.3d at 1234 (Watford, J., concurring). Thus, even if respondent had included a failure-to-warn-EPA claim in the complaint, that would not be a good reason to leave unresolved the specific preemption question on which the courts of appeals have concededly "diverged." BIO.25. That is particularly so because failure-to-warn-the-agency claims face distinct hurdles that failure-to-warn-the-user claims do not, *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001); *Stengel*, 704 F.3d at 1234 (Watford, J., concurring) (explaining that failure-to-warn-the-agency claims "face a causation hurdle that would not otherwise exist"), which is likely why claims against Monsanto nearly uniformly assert the latter but not the former. Moreover, in circuits like the Eleventh that expressly allow the latter, there is no incentive for plaintiffs to even try to plead and prove an alternative theory that would require clearing an unnecessary additional causation hurdle. *See, e.g.*, *Schaffner*, 113 F.4th at 386 n.13.

Respondent's other vehicle arguments are no more persuasive. Respondent asserts a preservation objection on the theory that the question presented involves issues that were "not raised or litigated" below. BIO.18. That contention is baseless. Respondent does not dispute that Monsanto raised its express and implied preemption arguments at every stage of the proceedings—first before the MDL court in the Northern District of California, then again before the trial court in the Southern District of Florida, then again before the Eleventh Circuit. Respondent just insists that Monsanto failed to "feature" 40 C.F.R. §152.44(a) as prominently below as respondent predicts Monsanto "intends to … before this Court." BIO.20-22. But Monsanto's express preemption argument is not limited to 40 C.F.R. §152.44(a), *see Durnell*.Pet.23-32, and Monsanto cited 40 C.F.R. §152.44(a) below, *see, e.g.*, CA11.Dkt.5 at 10-11 (citing 40 C.F.R. §152.44(a) and *Schaffner*, 113 F.4th at 379-93); Mot.9-10, *In re Roundup Prods. Liab. Litig.*, No. 3:16-md-2741 (N.D. Cal. filed Jan. 3, 2019), Dkt.2419; *see also* Mot.2, *Salas v. Monsanto Co.*, No. 3:21-cv-6173 (N.D. Cal. filed June 15, 2023), Dkt.38 (incorporating by reference earlier briefing before the MDL Court). To the extent respondent's real complaint is that Monsanto primarily cited 40 C.F.R. §152.44(a) in support of its implied preemption arguments rather than its express preemption ones, that is beside the point. Having raised both implied and express preemption defenses below, Monsanto is perfectly free to make new arguments and cite new authorities in support of those defenses in this Court. *Yee v. City of Escondido*, 503 U.S. 519, 534-35 (1992). It is, *a fortiori*, entitled to feature authorities cited

below more prominently or as support for additional arguments.

Last and least, respondent suggests that Monsanto "may have … created an Article III" issue by seeking summary affirmance of the district court's decision. BIO.23. That objection is frivolous. While an appellant's request for summary affirmance by a court of last resort would be a true head-scratcher, asking an intermediate appellate court to summarily affirm to pave the way for this Court's review makes perfect sense and raises no Article III issue. Indeed, given *Carson*, Monsanto had no other realistic option to preserve its right to seek review in this Court. It was certainly under no Article III obligation to raise frivolous grounds for distinguishing *Carson* or to ask the Eleventh Circuit to rule against it slowly. Not surprisingly, this Court has routinely granted review in comparable circumstances. *See, e.g.*, *Jack Daniel's Props., Inc. v. VIP Prods. LLC*, 599 U.S. 140 (2023); *VIP Prods. LLC v. Jack Daniel's Props., Inc.*, 2022 WL 1654040, at *1 (9th Cir. Mar. 18, 2022) (granting motion for summary affirmance). Contrary to respondent's suggestion, Monsanto's decision to seek summary affirmance did not "destroy[]" "adversity." BIO.i.[2] In light of *Carson*, there was nothing more to legitimately dispute in the Eleventh Circuit. But

[2] Respondent's only authority for its position is a divided Fifth Circuit decision that has since been vacated. *See United States v. Aguilar-Torres*, 116 F.4th 341 (5th Cir. 2024), *en banc pet'n granted*, 130 F.4th 450. But even the panel majority in that case acknowledged that Article III poses no obstacle when a defendant "notices an appeal and offers his argument for reversal while acknowledging existing precedent." 116 F.4th at 342 n.1. That is precisely what Monsanto did here. CA11.Dkt.5 at 10-12.

given our three-tiered federal judiciary, agreeing to summary affirmance at the court of appeals so that the parties could carry their adversarial dispute to this Court without unnecessary delay is fully consistent with the letter and spirit of Article III.

To the extent respondent suggests that the parties' settlement creates some other "jurisdictional obstacle," BIO.23-24, that contention lacks merit too. While Monsanto consented to judgment against it, it expressly retained the right to appeal the judgment on "federal preemption" grounds and made clear that the "amount" that "Monsanto will pay Plaintiff … depends upon the outcome of the appeal." D.Ct.Dkt.74 at 1-2. Both parties thus retain an interest in the outcome. That is no different from the settlement agreement in *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), which similarly specified that the amount of the plaintiffs' ultimate recovery would depend on the result of the appeal. *Id.* at 371. Yet the Court squarely held that the agreement did not moot the appeal. *Id.*; *see also, e.g.*, *Linde v. Arab Bank, PLC*, 882 F.3d 314, 324-25 (2d Cir. 2018); *Keefe v. Prudential Prop. & Cas. Ins. Co.*, 203 F.3d 218, 223-24 (3d Cir. 2000). Respondent tries to distinguish *Havens Realty* on the theory that the appellant there did not "seek relief against its own interests in the Court of Appeals." BIO.24. But as just explained, Monsanto's request for summary affirmance to seek Supreme Court review presents no Article III problems, and combining two features that present zero Article III problems in a single case does not create a problem or meaningfully distinguish *Havens Realty*. *Cf. FCC v. Consumers' Rsch.*, 145 S.Ct. 2482, 2511 (2025) ("[A] meritless public nondelegation challenge plus a meritless

private nondelegation challenge cannot equal a meritorious 'combination' claim.").

II. The Decision Below Is Wrong.

On the merits, respondent largely rehashes the Eleventh Circuit's flawed reasoning from *Carson*. In respondent's telling, her failure-to-warn claim "is fully consistent with" FIFRA's statutory misbranding prohibition because both require "necessary warning[s] to protect health and the environment." BIO.27. But assessing express preemption at such a high level of generality just resurrects the "nominal[] equivalen[ce]" standard that *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), laid to rest. *See Durnell*.Pet.26-27. Indeed, under respondent's (il)logic, virtually all failure-to-warn claims are "consistent" with FIFRA's misbranding provision—which would leave juries free to impose all manner of labeling requirements for the same pesticide, no matter how different from what EPA requires or from what other juries have imposed. *See Schaffner*, 113 F.4th at 392-93. Congress plainly did not envision a reading of FIFRA that authorizes "50 different labeling regimes" prescribing the "wording of warnings." *Bates*, 544 U.S. at 452. Yet that is exactly what respondent's position requires.

Respondent points out that "'requirements for labeling' are most naturally read as mandatory rules for the *informational content* that must go on or with the pesticide." BIO.29. But EPA's process for approving pesticide labels *does* impose "informational content that must go on or with the pesticide." As the Third Circuit explained in *Schaffner*, EPA's approvals necessarily "identify the contents required to be

included on a pesticide label." 113 F.4th at 390. Once approved, a "pesticide product's label is a legal document. The label is the law!" EPA, *Pesticide Registration Manual* 3 (Apr. 2017), https://perma.cc/N322-6Q8P; *see* Pet.5. EPA regulations forbid manufacturers from adding new "precautionary statements" without prior EPA approval. Pet.5. A jury verdict holding Monsanto liable for failing to add a new cancer warning that EPA has repeatedly determined is not required—and in fact is affirmatively forbidden—would demand that manufacturers do just that.

Respondent insists that a "regulation directly mandating labeling content carries preemptive force, whereas one merely governing procedures that may indirectly affect labeling content does not." BIO.30. But EPA does not make product-specific wording decisions via regulation; it does so through a process *prescribed* by regulation. Pet.4-5. To the extent respondent is suggesting that labeling requirements imposed via EPA's pesticide registration and approval process cannot constitute "requirements" under FIFRA, BIO.30, that squarely contradicts *Riegel*. *Riegel* interpreted the MDA's materially identical preemption provision, and it squarely held that the FDA's "[p]remarket approval" of a device "imposes 'requirements'" for purposes of the MDA's preemption provision. 552 U.S. at 322-23. The Court reasoned that "a device that has received premarket approval" must "be made with almost no deviations from the specifications in its approval application," since "the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323. That analysis "carries over to FIFRA."

Schaffner, 113 F.4th at 388. "If the prohibition on modifying medical devices following their approval for safety establishes 'requirements' for medical devices, then FIFRA's regulatory approach, which employs the same two elements, should likewise establish 'requirements' under [FIFRA's] similar preemption provision." *Id.* at 388-89.

Respondent claims that FIFRA is different from the MDA because the MDA preempts any requirement which is "different from, or in addition to," any "requirement *applicable* under [the MDA] *to* the device," BIO.34 (citing 21 U.S.C. §360k(a)), whereas FIFRA preempts "*requirements for labeling* or packaging in addition to or different from those required under this subchapter," 7 U.S.C. §136v(b) (emphasis added). But while the MDA certainly preempts a broader universe of "requirements" (i.e., not just "requirements for labeling or packaging"), nothing in the text suggests that the term "requirement" means one thing in the MDA and something different in FIFRA. *See Riegel*, 552 U.S. at 323-24. More specifically, there is no textual basis for limiting the word "requirements" to requirements imposed via statute or regulation—as opposed to requirements imposed via *procedures established by regulation*—in FIFRA but not in the MDA.

Finally, respondent notes that a "miscellaneous" provision elsewhere in FIFRA says that "registration" is not "a defense for the commission of any offense under this subchapter." 7 U.S.C. §136a(f)(2). But as the Third Circuit explained, §136a(f)(2) does not address preemption of state law. *See Schaffner*, 113 F.4th at 397; *Durnell*.Pet.28. And while EPA's

registration decisions of course are "not 'dispositive'" of FIFRA compliance, BIO.33, that misses the point. Far from supporting the conclusion that EPA's registration decisions similarly are not conclusive for purposes of preemption, *see* BIO.33, the fact that §136a(f)(2) expressly imposes a limit on the effect of registration "'cautions against inferring' the same limitation in another provision," i.e., the preemption provision. *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 26, 34 (2016).

Regardless, Monsanto's preemption argument is not that registration alone is dispositive; it turns also on EPA's consistent statutory determination that no cancer warning is necessary. There is a material difference between treating "registration" as a defense and treating EPA's labeling determinations as one. If a manufacturer misbrands its pesticide by deviating from the EPA-approved label, then registration would obviously not prove compliance with FIFRA. But once EPA has made a conclusive determination that no cancer warning is required (and, in fact, would render the pesticide affirmatively misbranded), it would be nonsensical to preclude the pesticide manufacturer from asserting that labeling determination as a defense. Indeed, nothing in §136a(f)(2) addresses labeling determinations at all, let alone suggests that they cannot support a preemption defense.

CONCLUSION

For the foregoing reasons, this Court should hold the petition for certiorari pending the Court's resolution of *Durnell* or, in the alternative, grant it.

Respectfully submitted,

DAVID M. ZIONTS
MICHAEL X. IMBROSCIO
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001

K. LEE MARSHALL
BRYAN CAVE LEIGHTON PAISNER
Three Embarcadero Ctr.
San Francisco, CA 94111

PAUL D. CLEMENT
Counsel of Record
MATTHEW D. ROWEN
JAMES Y. XI
NICCOLO A. BELTRAMO
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-8900
paul.clement@clementmurphy.com

Counsel for Petitioner

July 23, 2025