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News Release

Bayer announces filing of petition to U.S. Supreme Court for review of *Hardeman* decision

- Company argues errors on federal preemption and expert evidence standards necessitate review of rulings
- Decision could affect thousands of *Roundup*™ cases and other litigation

Leverkusen, August 16, 2021 – Today Bayer – through its subsidiary Monsanto – filed its Petition for a Writ of Certiorari with the U.S. Supreme Court in Hardeman, the only Roundup™ federal product liability case to have gone to trial. The Petition urges the Court to review the Ninth Circuit Court of Appeals' decision on two grounds. First, the state-law failure-to-warn claims at the center of the case are preempted by federal law, as the U.S. Government argued in its amicus filing in the Ninth Circuit. Second, the admission of expert testimony departed from federal standards, enabling plaintiff's causation witnesses to provide unsupported testimony on the principal issue in the case, Roundup™'s safety profile.

The Petition addresses the significance of these errors and importance of Supreme Court review, arguing: "The Ninth Circuit's errors mean that a company can be severely punished for marketing a product without a cancer warning when the near-universal scientific and regulatory consensus is that the product does not cause cancer, and the responsible federal agency has forbidden such a warning." Because, the Petition explains, this case was the first trial for the Roundup™ cases consolidated in the multidistrict litigation in Northern California, "the decision below will control thousands of other federal suits, and undoubtedly influence still others pending across the country."

The Petition underscores that consistent regulatory assessments in the U.S. and worldwide, and the overwhelming weight of scientific evidence, support the conclusion

that glyphosate-based herbicides are safe and not carcinogenic. In light of the EPA's approval of the Roundup™ label without a cancer warning, any state-law failure-to-warn claims premised on such warning would plainly conflict with federal law and thus are preempted. Courts across the U.S. have divided on this basic question of when federal law preempts state law, which makes review by the U.S. Supreme Court both important and necessary. Indeed, it has been 16 years since the Supreme Court ruled on FIFRA preemption, and the prior case did not involve a warning that EPA had rejected.

Earlier this year Bayer announced a five-point plan to manage and resolve future litigation risk arising from the Roundup™ litigation. Supreme Court review and reversal of the Ninth Circuit's flawed ruling is a major factor in this plan and likely will determine whether the litigation will largely end (if the court issues a favorable decision on a cross-cutting issue like federal preemption) or the company implements a claims process to resolve claims over the next 15 years (in the event of an adverse outcome). Bayer took an additional provision in Q2 2021 to reasonably account for future litigation exposure in the event of an adverse outcome. Bayer expects the Supreme Court to decide in the next six months whether it will grant review of the Hardeman case.

Key Arguments

On federal preemption, Bayer argues that state-law failure-to-warn claims should be preempted on the grounds of both express preemption (because they are preempted by a specific statutory provision) and conflict preemption (because the state-law claims necessarily conflict with federal requirements).

On express preemption, the Petition argues the Ninth Circuit erred by holding that the state-law claims were not "in addition to or different" from FIFRA's requirements, even though they conflicted with the EPA's consistent finding that glyphosate does not cause cancer in humans. This result is compelled by Supreme Court precedent, which the Petition explains, holds that "where EPA determines that a pesticide should be accompanied by one warning (such as 'CAUTION') but a jury concludes under state law that the label should include a more aggressive one (such as 'DANGER'), state law is preempted." The Ninth Circuit's reading of the "in addition to or different" language also splits with how other courts have understood similar preemption provisions in other federal statutes.

On conflict preemption, the Ninth Circuit wrongly held that there was no conflict between the state-law claims and FIFRA's requirements, even though EPA would not approve the kind of label required by the state-law jury verdict and even though Monsanto cannot unilaterally change its label without agency approval. This ruling too conflicts with Supreme Court precedent, which holds that either scenario establishes implied preemption. Moreover, if left in place, the Ninth Circuit's ruling would lead to a highly undesirable result: States could require pesticide manufacturers to include warnings on their labels even when EPA has expressly informed manufacturers that doing so would be unlawful.

With regard to expert evidence, the Petition explains that the Ninth Circuit wrongly blessed the admission of expert testimony on the issue of whether glyphosate caused Mr. Hardeman's cancer even though that testimony "rested on little more than subjective intuitions." This result conflicts with Federal Rule of Evidence 702 and Supreme Court precedent, which require "trial courts to play 'a gatekeeping role' to ensure that expert opinions are reliable … [and] the product of 'reliable principles and methods,' 'reliably applied … to the facts of the case.'"

The Petition states that the Ninth Circuit's lenient standard "has distorted [existing law] beyond recognition," and "blurs the boundaries between science and speculation with a third category called 'art,'" or unsupported intuitions purportedly rooted in clinical experience. The brief argues that "no matter how much clinical experience an expert has, intuition without scientific validation is not 'the product of reliable principles and methods.'" The argument concludes: "By requiring trial courts to admit expert conclusions that are based on clinical experience – even when sound scientific evidence refutes those conclusions – the Ninth Circuit has codified the fallacy that when scientists speak, their views are necessarily rooted in reliable scientific principles."

Note:
Link to the Petition.

About Bayer
Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and planet thrive by

supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability, and quality throughout the world. In fiscal 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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