Nos. 19-16636, 19-16708

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

EDWIN HARDEMAN
Plaintiff-Appellee/Cross-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellant/Cross-Appellee

On Appeal from the United States District Court
for the Northern District of California,
Nos. 16-cv-00525 & 16-md-02741 (Chhabria, J.)

EDWIN HARDEMAN'S REPLY BRIEF

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulations

Miscellaneous

INTRODUCTION[1]

The jury in this case awarded Plaintiff Edwin Hardeman $75 million in punitive damages based on overwhelming evidence that Monsanto has profited for *decades* from its underhanded and deceitful efforts to hide Roundup's carcinogenicity from the public. To this day, Monsanto continues to sell Roundup to millions of consumers worldwide and trumpet the product's safety—all the while continuing to refuse to test whether Roundup in fact causes non-Hodgkin's lymphoma ("NHL"), the cancer suffered by Hardeman and tens of thousands of other cancer victims. That is reprehensible in every sense of the word.

Monsanto's defense of the district's court's remittitur of the punitive damages award (from $75 million to $20 million, an amount less than 0.3 percent of Monsanto's net worth) fails as a matter of fact and law. On the facts, Monsanto's main argument is that it sold Roundup "in good faith" because it "had no special knowledge about [Roundup's] carcinogenicity." Third Step Brief for Monsanto, ECF 92 ("Monsanto Br."), at 1-2; *see also id*. at 58. This specious contention ignores that Hardeman established at trial what Monsanto has known

[1] Citations to "ER" are to Monsanto's Excerpts of Record. Citations to "PSER" are to Plaintiff's Supplementary Record Excerpts. Citations to "FER" are to Monsanto's Further Excerpts of Record. Citations to "PFER" are to Plaintiff's Further Excerpts of Record accompanying this brief.

for over three decades: that glyphosate—Roundup's active ingredient—poses a serious cancer risk. He also proved that Monsanto has refused to test the carcinogenicity of Roundup, which contains a mixture of glyphosate and other ingredients designed to make the herbicide even more toxic, despite *knowing* the risks of glyphosate and despite having been told by its own expert, world-renowned scientist Dr. James Parry, that Roundup could be *ten times* more genotoxic than glyphosate alone. *See* Plaintiff's Principal and Answer Brief, ECF 58 ("Hardeman Br.") at 28; PSER215.

Indeed, Monsanto's own internal emails showed that the company deliberately ignored Dr. Parry's findings, deliberately withheld them from EPA (in violation of FIFRA), and deliberately refused to test Roundup precisely *because* Monsanto knew that "the formulated product […] does the damage." Hardeman Br. at 26 (citing PSER283); *see also* PSER244 (email of Monsanto's chief glyphosate spokesperson Donna Farmer stating that "[we] cannot say that Roundup does not cause cancer [because] we have not done carcinogenicity studies with 'Roundup.'").

So Monsanto's supposed lack of "special knowledge" as to Roundup's carcinogenicity was a deliberate *choice* on the company's part. As a result, the notion that Monsanto sold Roundup in "good faith"—and thus the district court

was correct to reduce the punitive damage award by 75 percent—is absurd. It is also directly contrary to the record in this case.

Monsanto's legal arguments are no more convincing. Importantly, Monsanto concedes that due process does not impose any strict limit on the ratio of punitive to compensatory damages. Monsanto nonetheless seeks to defend the court's ruling by arguing that it "did not behave reprehensibly" with regard to its sales of Roundup—and thus any punitive/compensatory ratio in excess of 4:1 was necessarily unconstitutional. Monsanto Br. at 59. But that just brings Monsanto full circle back to its false claim of "good faith," which is contradicted by the record and was rejected by the jury.

Monsanto's other main legal argument is that the district court was right not to take the company's enormous wealth into account when reducing the punitive damages award because "tens of thousands of pending cases allege that Roundup causes non-Hodgkin's lymphoma" (Monsanto Br. at 60)—and thus Monsanto will eventually be punished enough.

Putting aside that this evidence was never presented to the jury (and thus it cannot justify the court's ruling), Monsanto ignores that the company *continues* to sell Roundup and *continues* to profit massively from those sales. This fact alone makes this case unique. Because Roundup is *still* on the market, and is *still* being aggressively marketed by Monsanto as perfectly safe, there is no end in sight to the

damage this product can and will inflict on unsuspecting consumers. The jury's punitive damages award reflects its understanding of that crucial reality. Its decision to award $75 million in punitive damages should not have been disturbed.[2]

ARGUMENT

I. MONSANTO'S ATTEMPT TO WHITEWASH ITS CONDUCT MISREPRESENTS THE FACTS.

A. Monsanto Buried Evidence, Deceived EPA, and Willfully Blinded Itself, the Public, and Regulators From Knowing the True Risks Of Roundup.

First and foremost, Monsanto did not sell Roundup in "good faith." Hardeman proved at trial that, as early as 1983, Monsanto knew that even glyphosate alone, without all the added ingredients that make Roundup particularly toxic, poses a serious cancer risk.

In 1985, based on a study showing that glyphosate caused rare tumors in mice, EPA found that glyphosate is a "category C oncogen." PSER270. Rather than accepting that conclusion and pulling its dangerous product from the market, or at least warning consumers that Roundup poses a cancer risk, Monsanto hired a

[2] Monsanto recently announced its intention to enter into a $10.9 billion settlement of tens of thousands of pending Roundup cases (*excluding* Hardeman's). *See* https://www.reuters.com/article/us-bayer-litigation-settlement-idUSKBN23V2NP. Monsanto's willingness to pay over $10 billion to settle these claims is difficult to square with its contention that Roundup is harmless.

purportedly independent pathologist to manipulate the science and present false information to EPA—information that was partially responsible for the agency changing its designation of glyphosate. *See* Hardeman Br. at 27.

This was just the first known incident in Monsanto's decades-long pattern of manipulating and undermining the science surrounding Roundup. In the 1990s, after numerous independent studies emerged showing an association between glyphosate and cancer (*id.* at 27-28), Monsanto once again hired its own expert, Dr. James Parry, to undermine this science. *Id*. at 28. As Hardeman has explained, the expert issued a damning report that not only confirmed the genotoxicity of glyphosate, it also showed that Roundup could be ten times more toxic than glyphosate alone. *Id.*

At that point, a reputable company would have at least conducted the tests Dr. Parry urged it to perform. But Monsanto instead sought to silence Dr. Parry, declined to do all the tests he recommended (*id.* at 29), and—as recounted in a serious of conscience-shocking internal emails that were presented to the jury in this case—flat-out refused to conduct any studies into whether the "formulated product" of Roundup—i.e., glyphosate plus surfactants—poses cancer risks above and beyond glyphosate alone. *Id*.; *see also id.* at 28 (Monsanto Director of Toxicology stating "We simply aren't going to do the studies Parry suggests.") Monsanto also paid ghostwriters to further white-wash the science on Roundup and

glyphosate, so that EPA and other regulators were left in the dark as to the true risks. *See id.* at 29-30.

Moreover, despite an annual R&D budget of over $1.5 *billion*, Monsanto never spent a penny on any epidemiological studies or any carcinogenicity studies of Roundup. PFER15. Instead, it spent its money covering up the potential dangers of its product and lying to the public that Roundup is perfectly safe, all the while privately acknowledging that "[we] cannot say that Roundup does not cause cancer [because] we have not done carcinogenicity studies with 'Roundup.'" PSER244; *see also* PSER210 (email discussing press release falsely stating that "studies have been performed on Roundup herbicide" and "none of these studies have shown any adverse findings.").[3]

B. Monsanto Has No Valid Response to Hardeman's Evidence of Obfuscation, Willful Blindness, and Failure to Testing.

In the face of this record, Monsanto attempts to whitewash its conduct by claiming Hardeman's allegations are "unfounded." Monsanto Br. at 54 n.23. But Monsanto misrepresents the facts at every turn.

[3] The only epidemiologist Monsanto ever employed actually recommended and designed a study to counteract the well documented methodological problems with the Agricultural Health Study ("AHS") that Monsanto relied on heavily at trial. *See* Hardeman Br. at 66 (describing same); PSER278-282. Monsanto never conducted that study or any epidemiological study on Roundup to this day. *See* PSER17.

1. The Mouse Study. With regard to the 1983 mouse study that formed the basis for EPA's initial conclusion that glyphosate is a category C oncogene and possible human carcinogen, Monsanto tries to recast its manipulation of the study as being the result of "issues with the methodology" (and specifically the control group) that "rendered its results inconclusive." Monsanto Br. at 54 n.23. But there is no evidence that anyone believed there were "issues with the methodology" prior to Monsanto's manipulation of the study and, unsurprisingly, Monsanto points to none.

In truth, Hardeman presented overwhelming evidence that Monsanto *did* manipulate the study results in order to garner favorable regulatory treatment of glyphosate. For example, after it became clear that EPA would classify glyphosate as possibly carcinogenic to humans, a February 22, 1985 internal Monsanto memo acknowledged its belief that "short of a new study or finding tumors in the control groups," EPA would not be persuaded to change glyphosate's classification. PSER296. And so, Monsanto set out to manufacture such a result, hiring its own pathologist to reach a pre-determined result and present it to EPA. Monsanto's expert found a tumor in the control group, just as Monsanto intended.

Additional evidence on this point is concrete and damning. A Monsanto memo from April 3, 1985 noted that "[the pathologist] will review kidney sections and present his evaluation of them to EPA in an effort to persuade the agency that

the observed tumors are not related to glyphosate." PSER298. This memo is remarkable because the pathologist did not even receive the pathology slides until April 14, 1985, over a week *after* the memo was written. PSER300. And prior to the review of the slides, there is no evidence that anyone observed or even suspected that there was an additional tumor in the control group.

Just as remarkable is the fact that EPA then re-sectioned the same set of kidney tissues in an attempt to validate Monsanto's finding, but that attempt *failed.* EPA concluded that "[t]he additional tumor in the control group, which has been diagnosed from the reevaluation of the original slides, was not present in the recut kidney sections." PSER478.

Accordingly, there was ample evidence for the jury to conclude that Monsanto manipulated the results of the crucial 1983 glyphosate study—a despicable act of deception and one that clearly affected EPA's classification of glyphosate—and Monsanto's ability to sell it.

2. The Failure to Test. Monsanto next asserts that there is no "factual support" for Plaintiff's contention that it "intentionally failed to investigate a possible link between Roundup and non-Hodgkin's lymphoma…" Monsanto Br. at 54. This, too, is false.

In reality, Monsanto *admitted* it (1) "has never conducted an epidemiological study to study the association between glyphosate-containing formulations and

non-Hodgkin's lymphoma"; (2) "has not identified any 12-month or longer animal chronic toxicity studies that it has conducted on glyphosate since 1991"; (3) "has not conducted a long-term animal carcinogenicity study on any formulated pesticide product"; and (4) "admits that it never conducted a 12-month or longer animal carcinogenicity study on any surfactants used in glyphosate-based products." *See* PSER17-18.

Monsanto nonetheless defends its despicable conduct by claiming it conducted "all of the tests necessary for EPA repeatedly to approve Roundup for use." Monsanto Br. at 54. But Monsanto either ignores or fails to provide any meaningful response to the overwhelming evidence that, beginning in the mid-1980s, it intentionally avoided testing, *including tests ordered by EPA*, because it believed they would show Roundup was in fact dangerous and carcinogenic.

For example, Monsanto has no response to Hardeman's evidence showing Monsanto refused to repeat the same 1983 mouse study that led EPA to initially conclude that glyphosate is a "Category C oncogen," despite EPA's orders that Monsanto repeat the study. *See* PSER270, 448; *see also Johnson v. Monsanto Co.*, 52 Cal.App.5th 434, 2020 WL 4047332 at *31 (Cal. Ct. App. 2020) ("EPA

designed a new mouse study in consultation with Monsanto, but Monsanto did not conduct the study.").[4]

This failure was anything but harmless. The 1983 study and *every subsequent mouse study on glyphosate* reported increases in malignant lymphomas. *See* PSER315-16 (trial testimony of expert Dr. Christopher J. Portier). Had Monsanto conducted the study it was supposed to, the scientific community, regulators, and the public would have learned that Roundup is carcinogenic. But Monsanto stopped the truth from being exposed.

Monsanto also fails to rebut the overwhelming evidence of its despicable conduct surrounding Dr. James Parry, who Monsanto hired in an attempt to rebut multiple scientific articles concluding that Roundup and glyphosate are genotoxic. *See* Hardeman Br. at 27-28. This tactic backfired: not only did Dr. Parry find strong evidence that glyphosate may be genotoxic, he observed that Roundup may be up to *ten times* more genotoxic than glyphosate alone. *See* PSER215-220. But Monsanto has *admitted* that it never provided Dr. Parry's report to EPA, an act that violated FIFRA's crucially important reporting requirement. *See* Hardeman Br. at

[4] The *Johnson* decision, which affirmed a state-court jury's verdict against Monsanto in favor of a California man who is dying of cancer caused by Roundup, is also persuasive authority regarding Hardeman's preemption, failure-to-warn, design-defect, and evidentiary arguments.

29 (citing PSER405, testimony of former Monsanto scientist Mark Martins confirming that "Monsanto *never* shared the Parry report with *any* regulatory agencies") (emphases added); *see also* 7 U.S.C. § 136(a)(2), 40 C.F.R. §§ 159.152.[5]

All the while, internally, Monsanto knew as far back as at least 1999—13 years before Hardeman contracted NHL from his Roundup exposure—that Roundup is "currently very vulnerable in [genotox]." PSER239 (email from Monsanto Director of Toxicology and head of "product safety strategy" William Heydens). Monsanto did not dispute this finding at trial and does not even attempt to defend or explain its conduct on appeal.

[5] The importance of FIFRA's reporting requirement is discussed in the amici curiae brief of California Rural Legal Assistance Foundation *et al.*, ECF 72, at 13-15, 27-28; *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005) ("FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings."). Unlike pharmaceutical drugs, which typically undergo robust human testing prior to approval, pesticides rarely undergo any human testing prior to approval because it is "unethical to experiment on humans by exposing them to known doses of chemical agent." Federal Judicial Center, *Reference Manual on Scientific Evidence* (3d ed.), at 639, 658. Accordingly, FIFRA relies more heavily on reporting evidence of adverse events, as compared to statutes governing pharmaceutical drugs and medical devices, which involve more comprehensive safety data prior to approval. *See, e.g.*, Amici Curiae Brief for Public Law Scholars, ECF 64, at 7-9; 13-14 (describing differences between FIFRA and pharmaceutical and medical device statutory schemes).

Monsanto also has no answer to the incriminating emails of Monsanto scientist and chief glyphosate spokesperson Donna Farmer admitting that "[we] cannot say that Roundup does not cause cancer [because] we have not done carcinogenicity studies with 'Roundup.'" PSER244 (discussed in Hardeman Br. at 29); *see also* PSER257-58. Monsanto tries to dismiss these emails in a footnote, stating that Farmer was only "attempting to be extremely precise about the metes and bounds of Monsanto's testing at that point in time." Monsanto Br. at 13 n.6. But that's exactly the point: Farmer *was* being "precise" about the scope of Monsanto's testing, and she precisely *confirmed* that Monsanto has "*not* done any carcinogenicity studies with Roundup," despite *knowing*—in the words of Dr. Heydens—that "the formulated product […] *does the damage*." PSER283 (emphasis added).

This series of events provided the jury with powerful evidence of Monsanto's "willful and conscious disregard of the rights or safety of others," Cal. Civ. Code § 3294(c)(1), especially because Monsanto *knew* it was "very vulnerable in [the area of genotoxicity studies]." PSER239; Monsanto Br. at 51. In other words, Monsanto *had* "special knowledge" of Roundup's dangers (Monsanto Br. at 51), but it knowingly withheld that knowledge from EPA and the public.

Against this backdrop, EPA's approval of glyphosate—which Monsanto points to as a mitigating factor for purposes of punitive damages—is meaningless.

See Monsanto Br. at 56. FIFRA makes clear that Congress intended EPA to be, at all times, *fully* informed and review *all* available evidence of a pesticides risk, regardless of materiality or the registrant's view of the weight of the evidence. 7 U.S.C. § 136(a)(2) ("[i]f at any time *after the registration* of a pesticide the registrant has *additional* factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant *shall* submit such information to the Administrator.") (emphases added). Yet Monsanto willfully and consciously failed to provide EPA with the damning Perry report—an act that not only violated FIFRA, but shows Monsanto's despicable disregard of human life.

Monsanto misrepresents the facts when it says "all the scientific investigation Dr. Parry wanted done was ultimately done—in some cases by Monsanto, in others by a third party." *Id*. at 55 (citing testimony of expert Dr. Christopher Portier at FER30). Monsanto deceptively omits a key portion of Dr. Portier's testimony on this point. He actually stated: "*with the exception of point I* [of Dr. Parry's final report, listing recommended tests], I think somebody has done *most* of the rest of [the recommended tests]." FER30 (emphases added). [6]

[6] This was confirmed by the testimony of former Monsanto employee, Dr. Larry Kier, who described his role at Monsanto as "the expert that was most familiar with genetic toxicology testing for glyphosate," and later served as a genotoxicology consultant for Monsanto. PSER371. Dr. Kier corroborated that Monsanto did not conduct all of the tests Dr. Parry recommended. PSER373-74.

Monsanto also ignores Dr. Portier's testimony that the evidence of Roundup's genotoxicity "has strengthened" since Dr. Parry presented his findings and recommendations. FER30. Dr. Portier's testimony confirmed that Monsanto's willful refusal to conduct the necessary testing did just what Monsanto hoped: it buried the truth, leaving scientists and the public unaware of the true extent of Roundup's genotoxicity and carcinogenic risk for decades.

Monsanto simply has no answer to the fact that it refused to test *because* it believed the tests would reveal that Roundup is genotoxic. This is perhaps best encapsulated by an internal email stating: "I don't know for sure how suppliers would react—but if somebody came to me and said they wanted to test Roundup I known how I would react—*with serious concern*." PSER272 (emphasis added). Monsanto ignores this statement and the equally damning email from Dr. Heydens stating that "Glyphosate is OK *but the formulated product (and thus the surfactant) does the damage*." PSER283 (emphasis added).

This evidence resolves any doubt that Monsanto was not merely negligent. Rather, it *knew* its product was likely carcinogenic, or genotoxic at an absolute minimum, yet—despite a whopping $1.5 billion annual R&D budget, PFER15—refused to test for whether Roundup causes cancer, in willful and conscious disregard for the safety of its consumers.

3. The Ghostwriting. As to Monsanto's notorious ghostwriting campaign, which was designed to combat all the emerging science on Roundup and glyphosate, Monsanto contends that "the only article" discussed by Hardeman "disclosed Monsanto's involvement" and that there is "no evidence that article was used improperly to influence regulatory treatment of glyphosate." Monsanto Br. at 55-56. Both contentions are flatly contradicted by the record.

First, the notion that the ghostwritten Williams article "disclosed Monsanto's involvement" (*id*. at 55) is blatantly deceptive. As the district court observed (PFER5), the Williams article was "portrayed as independent" but, in reality, the article was authored by Monsanto employees and was not independent at all—rather it was controlled entirely by Monsanto. Hardeman Br. at 30.[7]

Second, the ghostwritten Williams article *was* used to deceive regulators. Monsanto ignores the evidence Hardeman introduced at trial that Monsanto itself described the ghostwritten Williams article as an "invaluable asset" for "responses to agencies" and "regulator[y] reviews." Hardeman Br. at 30; *see also* PSER252. Moreover, there is clear evidence that EPA *did* rely on the Williams article, which

[7] Although the article disclosed that Monsanto had *some* involvement, it failed to disclose two critical facts: that Monsanto wrote the entire article; and that the listed authors, who were merely used in order to create the veneer of independence and objectivity, did not. PSER540.

was cited in support of a host of EPA decisions and position papers, including the EPA's 2017 *Revised Glyphosate Issue Paper*,[8] which repeatedly cited the Williams article and listed it as relevant to its carcinogenicity assessment of glyphosate. Just as Monsanto withheld the Parry report from EPA and all other "regulatory agencies," Monsanto never came clean and disclosed its role in ghostwriting the article to the EPA.[9]

Making matters even worse, Monsanto admitted that, by the late 1990s, the accumulating scientific studies raised "valid concerns" as to Roundup's genotoxicity. PSER404. But Monsanto hid these concerns from the public, instead proclaiming that "none of these studies have shown any adverse findings." PSER210. And it proceeded to publish the ghostwritten Williams article, which falsely concluded that "[t]he balance of credible data…confirms the safety of glyphosate and Roundup and conforms to the fact that glyphosate is non-carcinogenic." PFER36.

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[8] Available at https://tinyurl.com/eparevdglyphosate.

[9] Monsanto's ghostwriting campaign did not end with the 2000 Williams article. In 2010, Monsanto responded to pressure from "regulatory reviews" with an "increased focus on claims in the peer reviewed literature" by again turning to ghostwriting. PSER255. For example, Monsanto toxicologist Donna Farmer ghostwrote portions of a "safety" review, stating in an email "[a]ttached is the first 46 pages. I added a section in gentox…Also we cut and pasted in summaries of the POEA surfactant studies." PSER292.

So at the same time Monsanto was *privately* acknowledging "valid concerns" as to Roundup's potential dangers, Monsanto was *publicly* pushing a ghostwritten article "confirm[ing]" the absence of any such concerns—a textbook example of bad faith, and one with deadly consequences.

4. The Active Suppression. Monsanto also actively sought to squelch emerging evidence of Roundup's true risk. For example, in response to a 2008 epidemiological article reporting that Roundup exposure more than doubled the risk of NHL, Monsanto's principle glyphosate spokesperson Donna Farmer remarked "We have been aware of this paper for a while and knew it would only be a matter of time before the activists pick[ed] it up." PFER12. But rather than warning consumers or even investigating further, Farmer asked "Here is their bottom line…how do we combat this?" PFER12; *see also* PFER336-39 (Monsanto employees discussed suppressing glyphosate from an epidemiological abstract so that it would not appear on public search results.)

Of course, one way Monsanto could have "combat[ted]" this evidence would have been to sponsor an epidemiological study of its own. But—to this day—Monsanto has refused to conduct any such study, just as it has refused to test the dangers of Roundup. *See supra* at 6 n.3, 8-9. That's not "good faith"; that's beyond reprehensible.

C. There is No "Regulatory Consensus" that Roundup is Safe.

Monsanto also argues the district court was right to remit the punitive award "given the consensus at the time of Hardeman's exposure supporting the view that glyphosate was *not* carcinogenic." Monsanto Br. at 52. Here too, Monsanto is misstating the facts.

1. The Lack of Findings Regarding Roundup. First, of course, this case is about the carcinogenicity of Roundup, not glyphosate alone, and—as Hardeman and his amici have explained—EPA has not made *any* findings regarding the carcinogenicity of Roundup, which contains a mixture of glyphosate and "[s]urfactants and other coformulants" that "can be toxic in their own right, or increase the risk posed by glyphosate." Amici Curiae Brief of Center for Food Safety, et al., ECF 65 ("CFS Br.") at 11; *see also* Amici Curiae Brief of Environmental Working Group, ECF 73 ("EWG Brief") at 18-20; Hardeman Br. at 12-13 (explaining that EPA has never evaluated glyphosate-based formulations yet repeatedly acknowledged a need to do so and intent to do so in the future).[10]

[10] As CFS writes (Br. at 9-10), although "EPA understands [glyphosate] formulations are more toxic than glyphosate alone,…*[it] nevertheless focused its cancer evaluation on pure glyphosate…*" *Id*. (emphasis added; footnote omitted). *See also* EWG Br. at 19-20 (explaining that EPA has "failed to consider [glyphosate-based formulations (GBFs)]" in its risk assessments")).

EPA made this clear in its April 2019 *Proposed Glyphosate Interim Registration Review Decision 0178* ("*2019 Interim Decision*"), which described EPA's efforts to conduct a "human health risk assessment" for glyphosate.[11] There, EPA bluntly stated that "there are few research projects that have attempted to directly compare technical grade glyphosate to the formulations under the same experimental design." *Id*. at 47. "Furthermore," said EPA, "there are even fewer instances of studies comparing toxicity across formulations." *Id*. Making matters worse, "*none* of the *in vivo* studies with commercial formulations were found to be of adequate quality for use in *human risk assessment*." *Id*. (emphasis added).

Given this lack of data, EPA expressly *declined* to make any "human risk assessment" for Roundup. Instead, it stated that "EPA has been collaborating with the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences to develop research intended to evaluate the role of glyphosate in product formulations and the differences in formulation toxicity. *The results of this research will be considered when available*." *Id*. (emphasis added).

Monsanto has no good answer to these statements, which establish beyond any doubt that EPA has not made any determination as to the carcinogenicity of glyphosate-based formulations like Roundup. Instead, Monsanto tries to fudge the

[11] This document is difficult to locate on EPA's website, so Plaintiff is providing a copy in supplemental record excerpts submitted along with this brief. *See* PFER37-90.

issue by citing EPA's January 2020 *Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision* 6 (Jan. 16, 2020), https://bit.ly/2AwRLrm, which states that EPA has "evaluated the hazard potential (i.e., toxicity) of glyphosate and any inert ingredients with a battery of toxicity data from a multitude of studies throughout the risk assessment process." Monsanto Br. at 12. But this statement merely shows that EPA has evaluated the hazard potential of certain "inert ingredients" used in Roundup. It does *not* show that EPA has made any findings about those ingredients *when used in combination with glyphosate* in a formulated product like Roundup.

Any such conclusion, moreover, would run directly contrary to what EPA said just nine months earlier in the *2019 Interim Decision*, which—as recounted above—repeatedly stated that EPA has not made any findings as to glyphosate-containing formulations like Roundup.

Nor can Monsanto plausibly contend that EPA's conclusions as to the disaggregated components of Roundup are sufficient to show that Roundup itself is noncarcinogenic, in light of Donna Farmer's emails *admitting* that "[we] cannot say that Roundup does not cause cancer [because] we have not done carcinogenicity studies with 'Roundup.'" PSER244 (discussed in Hardeman Br. at 29); *see also* PSER257-58. These emails show that Monsanto knows full well that

glyphosate is not the same as Roundup. And EPA has never made *any* conclusions regarding the latter.

2. The Lack of Regulatory Consensus on Glyphosate.

As to glyphosate, there is no scientific or regulatory consensus that glyphosate is safe, nor has there ever been. *See* Hardeman Br. at 9-13. In fact, like the jury in *Johnson v. Monsanto*, the jury in this case "rejected the notion that there is 'consensus'" on the question of whether glyphosate poses a carcinogenic risk to humans. 2020 WL 4047332 at *31.

Monsanto's reliance on the supposed "regulatory consensus" ignores the company's long history of failing to test and the fact that it withheld key evidence (such as the Parry report) from *all* regulatory agencies, not just EPA. PSER405 (admitting same at trial).

That aside, this argument is dramatically at odds with the 2015 conclusion of the World Health Organization's International Agency for Research on Cancer ("IARC")—an independent body made up of 17 volunteer experts from 11 countries—that glyphosate *is* a probable carcinogen. *See* Hardeman Br. at 10-11; PSER 509-10.

And unlike EPA, which relies heavily on industry-generated studies and data from Monsanto that focused predominantly on glyphosate in isolation, IARC relied mostly on peer-reviewed scientific studies, including those that focused more on

glyphosate formulations, like Roundup. *See* Hardeman Br. at 11 (citing PSER 506); CFS Br. at 38; EWG Br. at 7-18.

3. EPA's Mixed Findings About Glyphosate.

But even as to glyphosate, EPA's conclusions have been mixed and riddled with error. *See* CFS Br. at 20-36; EWG Br. at 31-34. Monsanto tries to portray the EPA as solidly supporting its contention that glyphosate alone is non-carcinogenic. The truth is far different.

First, of course, EPA unanimously classified glyphosate as a category C oncogen in 1985. Hardeman Br. at 9. When EPA changed its classification of glyphosate in 1991 based on Monsanto's rigged mouse study (and its subsequent refusal to conduct the EPA's requested re-do of same), EPA's FIFRA Scientific Advisory Panel ("SAP") was deeply and acrimoniously split on whether glyphosate causes cancer. *Id.* at 10.

Even more recently, prior to the publication of *EPA's 2017 Revised Glyphosate Issue Paper*, an employee within EPA's Office of Research and Development noted that its scientists would be split on whether glyphosate is carcinogenic with some classifying the herbicide as "likely to be carcinogenic." PSER501-02.

Likewise, EPA's FIFRA SAP, which was convened to review the EPA's methodology and report, was split with respect to whether glyphosate was a

carcinogen, with some members concluding that "the weight-of-evidence conclusion based on EPA's 2005 Guidelines naturally leads to suggestive evidence of potential carcinogenic effects." PSER573; *see also* Hardeman Br. at 10. The SAP further concluded that "the EPA evaluation does not appear to follow the EPA (2005) Cancer Guidelines." PSER572.[12]

Thus, the notion that there is some kind of rock-solid regulatory conclusion as to the safety of glyphosate is not even true as to EPA, an agency riddled with internal debate on that very issue. Regardless, the record clearly establishes that EPA has never evaluated the carcinogenicity of Roundup—the product at issue.

II. MONSANTO'S DEFENSE OF THE DISTRICT COURT'S REMITTITUR IGNORES OR MISSTATES THE LAW.

Monsanto fares no better with its legal arguments relating to punitive damages.

A. The Jury's Punitive Damages Award Did Not Offend Due Process.

First, there is no constitutional barrier to a punitive damages award in excess of a single-digit ratio. *See* Hardeman Br. at 97-98. Monsanto *concedes* this is true as a general matter, stating "that the Supreme Court has indicated [some cases] may constitutionally exceed a single-digit ratio between compensatory and punitive damages." Monsanto Br. at 68 (citations omitted). Given the breadth,

[12] Hardeman also presented expert testimony at trial that EPA failed to follow its own guidelines in reaching its conclusions on glyphosate. PSER316-21. The amici briefs of the Center for Food Safety and the Environmental Working Group discuss this fact as well.

scope, and sheer duration of Monsanto's misconduct, this is one of those cases. *Boeken v. Philip Morris, Inc.*, 26 Cal.Rptr.3d 638, 685 (Cal. Ct. App. 2005).

Monsanto also ignores a key fact that makes this case different from all the others it cites in its own defense: this case involves a deadly product that is *still* on the market and is *still* being touted by the company as safe. Even if the jury's full verdict is restored in this case, it pales in comparison to Monsanto's *future* profits from the sale of Roundup and associated products. *See* PSER277 (showing compound annual growth rate of Monsanto's Roundup was projected to be approximately $215 million a year as far back as 2000).

Monsanto does not address that fact at all. Instead, it argues that large punitive damages are limited to cases where the jury has imposed a relatively small compensatory damages award. This is wrong. The size of the compensatory award is, of course, one factor to be considered, but it does not supplant the other guideposts, the most important of which is the reprehensibility of the defendant's conduct. *See State Farm Mut. Auto. Ins. Co.*, 538 U.S. at 425; *see also Bigler-Engler v. Breg, Inc.*, 213 Cal.Rptr.3d 82, 109 (Cal. Ct. App. 2017) ("Although a reduction in compensatory damages may make a punitive damages award more vulnerable to attack (e.g., because the resulting ratio between punitive and compensatory damages is too high), the jury's punitive damages award must be assessed separately according to applicable standards.").

Monsanto is therefore left with arguing that its conduct was insufficiently reprehensible to sustain the jury's award here. But, in so arguing, Monsanto has no answer to the fact that its conduct led to the very real possibility of Plaintiff's death, and could *still* be fatal. Nor can Monsanto deny that its conduct has put—*and continues to put*—thousands of other individuals at risk of death. Thus the "very conduct that injured [Hardeman] was directed at all [consumers] in the United States, repeated over many years with knowledge of the risk to human life and health, and is probative of intentional deceit." *Boeken*, 26 Cal.Rptr.3d at 680 (citing *State Farm*, 538 U.S. at 423-24). These facts alone warrant a punitive damages award in excessive of a single-digit ratio.

But, of course, there's more. Monsanto is one of the wealthiest companies in America—in 2018, it was purchased by Bayer for $63 *billion*, PFER3—and it continues to reap immense wealth from the sale of Roundup. *See* CFS Amici Br. at 5 & n.5. Fundamental to "punitive damages[']s broader function [of] deterrence and retribution" is consideration of the defendant's financial condition. *State Farm*, 538 U.S. at 416, 428; *see also Bullock v. Philip Morris USA, Inc.*, 113 Cal.Rptr.3d 382, 403–04 (Cal. Ct. App. 2011) ("The defendant's financial condition remains an essential consideration under California law and a permissible consideration under the due process clause in determining the amount of punitive damages necessary to further the state's legitimate interests in

punishment and deterrence.") (citations omitted). But "the function of deterrence...will not be served if the wealth of the defendant allows him to absorb the award with little or no discomfort." *Neal v. Farmers Ins. Exch.*, 582 P.2d 980, 991 (Cal. 1978).

Given Monsanto's enormous wealth during the relevant time period (and still today), any punitive award less than the $75 million awarded by the jury risks being absorbed as simply "a routine cost of doing business." *Lane v. Hughes Aircraft Co.*, 993 P.2d 388, 402 (Cal. 2000), *as modified* (May 10, 2000) (Mosk, J., concurring); *see also Century Surety Co. v. Polisso*, 43 Cal.Rptr.3d 468, 501 (Cal. Ct. App. 2006), *as modified on denial of reh'g* (June 16, 2006) (upholding punitive award of over $56 million because it was "only 3.2 percent of [defendant's] net worth" and anything less would have been mere "slap on the wrist"); *Boeken*, 129 Cal.App.4th at 1696 (noting that, for the "very wealthy wrongdoer," "a multiplier of 5 to 10 percent of net worth may be necessary to deter" future wrongdoing.)[13]

[13] Monsanto ignores *Lane*, no doubt because *Lane*'s discussion of punitive damages provides strong support for the propriety of the jury's award here. There, the California Supreme Court observed, "[t]he purpose of punitive damages is to *prevent* oppression, fraud and malice, not merely to force defendants to internalize the social costs of that conduct…[T]he law of punitive damages does not punish a large corporation simply for being large; it takes wealth into consideration so as to ensure the award creates an adequate deterrent, even though the award may still be small in relation to the corporation's net worth." 993 P.2d at 402 (Mosk, J., concurring) (citing *Neal*, 582 P.2d 980, and cases cited therein) (emphasis in original).

Monsanto tries to distinguish Hardeman's cited cases on the ground that they involved low compensatory damages. *See* Monsanto Br. at 57-58. But Monsanto ignores the *other* factors that justified the punitive damages in those cases: namely the degree of the defendants' reprehensibility and their enormous wealth. *See Neal*, 582 P.2d at 991; *Weeks v. Baker & McKenzie*, 74 Cal.Rptr.2d 510, 534 (Cal. Ct. App. 1998), *as modified on denial of reh'g* (June 2, 1998); *Mathias v. Accor Economy Lodge*, 347 F.3d 672, 676, 687 (7th Cir. 2003); *see also Bullock*, 131 Cal.Rptr.3d at 398–99 ("To be sure, *State Farm* requires reasonable proportionality between punitive damages and actual or potential harm to the plaintiff. But what ratio is reasonable necessarily depends on the reprehensibility of the conduct, '"the most important indicium of the reasonableness of the award"') (citations omitted).

Monsanto also argues that that *Neal* and *Weeks* "predate the Supreme Court's articulation of due process principles governing punitive damages." Monsanto Br. at 59. Not only is this factually inaccurate—*Weeks* was decided two years ***after*** *BMW v. Gore* laid out the "guideposts" relevant to the constitutional limits on punitive damages—but both *Neal* and *Weeks* apply effectively the same standard as articulated in *BMW* and *State Farm*. *See Neal*, 582 P.2d at 990 ("we are afforded guidance by certain established principles…"); *Weeks*, 63 Cal.App.4th

at 1166 ("In determining whether an award is excessive the courts apply three criteria…").

Perhaps most importantly, in those cases, the punitive-to-compensatory ratio dwarfed that at issue here: *Neal* approved punitive damages *74 times* greater than the amount of compensatory damages awarded, *Weeks* approved punitive damages *70 times* greater than the compensatory damages award, and *Mathias* upheld a ratio of 37.2:1 (more than *double* the ratio of the jury's punitive award here). Here, by comparison, the jury's punitive award barely exceeds a single-digit ratio and is less than 1 percent of Monsanto's net worth. PFER3 (explaining that Monsanto's net worth was $7.8 billion prior to Bayer's acquisition of the company).

B. The District Court's Reasons for Reducing the Punitive Damages Award Do Not Withstand Scrutiny.

The district court nonetheless reasoned that the award should be slashed from $75 million to $20 million based on certain "mitigating" factors: namely, the "scientific debate" regarding "whether glyphosate causes NHL" and the absence of any evidence that Monsanto has hidden actual knowledge "that glyphosate cause[s] cancer." ER7-8. But the jury had already considered the "mitigating evidence," and weighed it against the degree of Monsanto's culpability, as it was instructed. ER1703.

The district court's decision that the jury had not given *enough* consideration to Monsanto's so-called "mitigating evidence" should not stand. Particularly

where it relies on the testimony of witnesses, the jury's assessment of the weight of that testimony should not have been disturbed. *See Johnson*, 2020 WL 4047332 at *27 (citing *Buell-Wilson v. Ford Motor Co.*, 46 Cal.Rptr.3d 147, 175 (Cal. Ct. App. 2006), *vacated on other grounds*, 550 U.S. 931 (2007)). And where, as here, that testimony has already been found reliable and admissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the weight given to that testimony (versus any contradicting evidence from the defendant) should be a matter for the jury. *See Bankhead v. ArvinMeritor, Inc.*, 139 Cal.Rptr.3d 849, 860 (Cal. Ct. App. 2012), *as modified* (Apr. 25, 2012) (upholding jury's award of punitive damages—"amount[ing] to 37.5 percent of ArvinMeritor's net profit for 2010"—based on the jury's weighing of expert testimony); *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1015 (9th Cir. 2004) (upholding punitive damages awarded by jury in insurance bad-faith case where there was competing expert testimony regarding the reasonableness of defendants' conduct); *Buell-Wilson*, 46 Cal.Rptr.3d at 175 (a jury is "entitled to" "reject[] the testimony of [the defendant's] experts").

Monsanto's main answer is that "judges have a constitutional responsibility to scrutinize whether a punitive damages award is consistent with due process." Monsanto Br. at 60 (citations omitted). Of course that is true. But the case cited by Monsanto for this proposition—*Cooper Industries, Inc. v. Leatherman Tool*

Group, Inc., 532 U.S. 424, 435 (2001)— confirms that a "court of appeals must review the proportionality determination '*de novo*,'" rather than under the more-lenient abuse-of-discretion standard. *Id.*

While judges certainly have a constitutional duty to scrutinize awards, a determination to reduce an award should not turn on a view of the evidence that was rejected by jury and is in conflict with the verdict. *See id.* Here the district court's evaluation of reprehensibility turned on just that: a view that "the scientific debate" mitigated Monsanto's conduct. *See* Hardeman Br. at 100. But any "scientific debate" was a consequence of Monsanto's own conscious refusal to test Roundup and its own undermining and manipulation of the science. *See supra* at 8-14; Hardeman Br. at 26-30.

Monsanto also argues that the district court's drastic reduction of the punitive damages award was appropriate because of the "tens of thousands of pending cases alleg[ing] that Roundup causes non-Hodgkin's lymphoma," and the resulting risk that "thousands of litigants [could] *each* [] recover $75 million in punitive damages based on the same conduct." Monsanto Br. at 60-61. But that was not one of the district court's stated reasons for reducing the punitive damages, nor could it have been: "evidence of punitive damages imposed in other cases must be presented to the jury in the first instance." *Stevens v. Owens-Corning Fiberglas Corp*., 57 Cal.Rptr.2d 525, 537 (1996) (citations omitted). Thus, while prior

punitive awards for the same conduct, or "[t]he likelihood of future punitive damage awards may also be considered, *although it is entitled to considerably less weight*," such evidence must be presented to the jury if it is to influence the punitive damages award. *Id*. (emphasis supplied).

Here, Monsanto never presented such evidence to the jury. In fact, Monsanto moved to *exclude* evidence of other verdicts and the number of pending lawsuits. PFER24-28. Thus, Monsanto's reliance on the potential for punitive damages in *other* cases cannot justify the district court's erroneous decision to reduce the award. The decision should be reversed and the jury verdict upheld.

CONCLUSION

The district court should not have disturbed the jury's award of punitive damages, which comports with due process and was supported by overwhelming evidence of despicable conduct.

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