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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

PILLIOD, et al.

Plaintiffs,

vs.

MONSANTO COMPANY,

Defendant.

Case No. RG17862702

ASSIGNED FOR ALL PURPOSES TO
JUDGE WINIFRED SMITH
DEPARTMENT 21

MONSANTO COMPANY'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT

Hearing Date: July 19, 2019
Time: 11:00 a.m.
Department: 21
Reservation No. R-2087958

Trial Date: March 18, 2019

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I. INTRODUCTION

Monsanto has produced glyphosate-based herbicides (hereinafter "Roundup") in the United States and much of the world for more than 40 years. Roundup has a safety record supported by a body of studies more extensive than almost any other chemical in regular use anywhere. These studies include rigorous registration studies required by the U.S. EPA and European regulators to demonstrate the safety of Roundup, as well as many studies by independent scientists. Based on these studies, regulators across the world have concluded on multiple occasions, after multi-year evaluations and risk assessments, that glyphosate is *not* a human carcinogen. These facts highlight why the jury's verdict cannot be sustained. Monsanto seeks judgment notwithstanding the verdict ("JNOV") because the evidence was insufficient to support the verdict on any of Plaintiffs' claims and directed verdict should have been granted in Monsanto's favor. *See Magic Kitchen LLC v. Good Things Int'l, Ltd.*, 153 Cal. App. 4th 1144, 1154 (2007); *see also* Cal. Code Civ. Proc. § 629(a).[1]

II. PLAINTIFFS FAILED TO PRESENT SUFFICIENT EVIDENCE THAT ROUNDUP CAUSED THEIR NHL.

All of Plaintiffs' claims fail for lack of reliable causation testimony. *See Jones v. Ortho Pharm. Corp.*, 163 Cal. App. 3d 396 (1985) (affirming nonsuit where plaintiff failed to demonstrate medication caused cancer). Plaintiffs were required to show that "but for" their exposure to Roundup, they would not have developed their diseases. *See* CACI 430 ("Conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct."). But Plaintiffs' experts conceded that Plaintiffs could have developed their cancers even if they had never been exposed to Roundup. Declaration of Eugene Brown ("Brown Decl.") at Ex. A, Trial Transcript ("Tr.") 4166:22-4168:25. And those experts' unapologetically results-oriented differential diagnosis methodology was designed solely for this courtroom and did not comport with *Sargon*. *See, e.g.*, Tr. 4377:16-21; Tr. 5170:20-5171:9, 5172:5-6; *see also Sargon Enter., Inc. v. Univ. of S. Cal.*, 55 Cal. 4th 747, 771, 772 (2012).[2]

[1] Monsanto hereby incorporates by reference the arguments made in its concurrently filed Motion for New Trial.

[2] Dr. Sawyer's testimony alone is inadequate to submit causation to the jury because he "defer[red]" to Drs. Weisenburger's and Nabhan's differential diagnoses and "did not look at whatever other possible alternative causes [Plaintiffs] may have or not have." Tr. 3259:5-21. And although Dr. Sawyer testified as to Plaintiffs' exposure, he did not provide any dose of exposure.

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A. Drs. Weisenburger and Nabhan Failed to Reliably "Rule In" Roundup.

Drs. Nabhan and Weisenburger professed to rely on "three pillars" of science—epidemiology, animal studies, and mechanistic data—to "rule in" Roundup as the cause of Plaintiffs' NHL. But their testimony shows that they relied exclusively on just a few self-serving epidemiology studies and did not rely on animal toxicology studies or mechanistic studies. Tr. 2892:10-2893:24; Tr. 4055:19-23.

For epidemiology to be probative of specific causation, it must demonstrate a minimum risk ratio of 2.0. *See Cooper v. Takeda Pharm. Am., Inc.*, 239 Cal. App. 4th 555, 593 (2015) ("When . . . epidemiological studies are offered to prove specific causation . . . under California law those analyses must show a relative risk greater than 2.0 to be 'useful' to the jury." (quoting *Daubert v. Merrell Dow Pharm. Inc.*, 43 F.3d 1311, 1320 (9th Cir. 1995)). None of the data relied upon by Plaintiffs reliably satisfies the minimum 2.0 risk ratio. It is undisputed that adjusting for multiple pesticides makes data more reliable. Tr. 2906:10-23. Many of the studies did not find a statistically significant risk ratio of 2.0 or higher; and those that did were not adjusted for other pesticides. Tr. 2834:4-9; 2910:23-2911:5; 3915:22-3920:2, 3922:10-3924:16; 4099:8-4100:8. With respect to Plaintiffs' specific NHL subtypes, Drs. Nabhan and Weisenburger pointed to no data reporting a risk ratio of 2.0 or greater that is statistically significant when adjusted for other pesticides.

The experts also examined several studies that pooled data to increase their reliability and statistical power. Tr. 2733:23-2734:6; 4099:8-4100:3. Not one of those studies support a risk ratio of 2.0 or more. The NAPP data reported an "overall relative risk . . . [of] 1.13" and "no increased risk for NHL following glyphosate exposure." Tr. 2959:7-15.[3] Dr. Weisenburger also admitted that Leon (2019), the largest and most recent pooled-cohort study available, shows no increased risk of NHL and only a 1.36 risk ratio for the DLBCL subtype. Tr. 2960:1-4; 2982:6-11. Similarly, the most recent meta-analysis that Plaintiffs' experts relied on showed only a 1.4 risk ratio. Tr. 2732:15-2733:10.

[3] Drs. Nabhan and Weisenburger specifically relied on McDuffie (2001) and DeRoos (2003), which is data that has been subsumed by NAPP data to increase its power and reliability. Tr. 4100:17-4101:7. But even viewed in isolation, the McDuffie and DeRoos (2003) data does not reliably comport with *Cooper*. McDuffie was unadjusted for other pesticides. Tr. 2834:4-9, 4098:4-8. When another paper, Hohenadel, used the McDuffie data but controlled for maliathon, it showed no increased risk. Tr. 2908:4-2910:10. And DeRoos (2003) studied 47 pesticides but only captured 36 exposed Roundup cases, resulting in "sparse data bias." Tr. 4860:7-24.

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B. Drs. Weisenburger and Nabhan Failed to State a "Reasoned Explanation" Why They Ruled Out Plaintiffs' Alternative Risk Factors.

Drs. Weisenburger and Nabhan further failed to provide "a reasoned explanation illuminating why" they ruled out Plaintiffs' alternative risk factors that were supported by substantial evidence, including risk ratios equal to or in excess of those for glyphosate. *See Cooper*, 239 Cal. App. 4th at 578, 585-86 (requiring experts to exclude "alternative explanation[s] for the disease"). Both experts agreed, for example, that "there's something about aging which increases the chances or likelihood" of obtaining NHL five-or-six fold after the age of 65, which Mr. and Mrs. Pilliod are. Tr. 2866:11-14, 2867:8-12; 4134:7-11. Thus, Plaintiffs had to provide a reasoned explanation ruling out unknown or age-related causes, which they did not. Each Plaintiff also had numerous individual risk factors.

***Mrs. Pilliod*:** Dr. Weisenburger flatly admitted that people, like Mrs. Pilliod, who were "exposed to herbicides for more than 17 years" but were t(14;18) negative had "no increased risk of NHL" (Tr. 2803:1-6), and conversely that people, like Mrs. Pilliod, who were t(14;18) negative but smoked tobacco starting before age 20 had a statistically significant doubling of the risk of NHL (Tr. 2815:10-18). This means that Mrs. Pilliod's smoking history and not Roundup exposure was the most likely cause of her NHL according to Dr. Weisenburger's own research. Tr. 2806:12-17, 2808:1-25, 2810:1-2811:15. In addition, Mrs. Pilliod had several other significant risk factors for NHL that neither Dr. Nabhan nor Dr. Weisenburger adequately ruled out: a personal history of cancer (which more than doubles the risk of later having NHL); a family history of cancer; Hashimoto's disease (which triples the risk of NHL); and obesity. Tr. 2851:2-2855:18; 2867:21-2869:2; 4388:22-4389:13.

Mr. Pilliod: Drs. Weisenburger and Nabhan failed to reliably rule out Mr. Pilliod's alternative risk factors of ulcerative colitis, genital warts, and recurrent skin cancers. Ulcerative colitis poses an "overall risk" for developing NHL that is "statistically significant [of] 1.5." Tr. 2857:13-15; 2864:10-12. Dr. Weisenburger, however, "didn't even know" Mr. Pilliod was diagnosed in 2006 with "inflammatory bowel most consistent with ulcerative colitis" until shown the pathology report during cross-examination. Tr. 2859:16-19. He thus could not have even considered this risk factor when he did his differential diagnosis and could not have formed an informed, reliable opinion. Drs. Weisenburger and Nabhan likewise failed to explain how they were able to exclude the statistically significant risk

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ratio of 3.0 to 3.1 in men, like Mr. Pilliod, who have experienced recurrent genital warts. Tr. 2884:5-8; 2885:13-16; 2887:22-2888:3. Finally, the experts' offhand dismissals of Mr. Pilliod's extensive history of prior skin cancers is not a reasoned explanation for excluding his many skin cancers as the risk factor that most contributed to his NHL. Tr. 2783:3-13; Tr. 2877:5-2879:3.

C. Drs. Weisenburger and Nabhan Failed to Rule Out Unknown Causes.

Finally, Drs. Nabhan and Weisenburger failed to offer any "reasoned explanation" for ruling out unknown causes. Approximately 70% of NHL cases result from unknown causes. Tr. 2791:15-20; 4163:15-21. Yet, neither expert ruled out idiopathic causes for any reason except that Plaintiffs had been exposed to Roundup, which is both results-driven and nonsensical given the epidemiology ratios. Tr. 2889:24-2890:14 (for a hypothetical person with Mr. Pilliod's same medical history "who hasn't been exposed to Roundup, [he] would say [he] has no idea why that person developed NHL" but for Mr. Pilliod "[he'd] say it's got to be the Roundup").

This type of litigation-oriented opinion is precisely why "differential etiologies are . . . only valid if . . . a substantial proportion of competing causes are known." Federal Jud. Center, Reference Manual on Scientific Evidence (3d ed. 2011) pp. 617-618, footnote omitted (Brown Decl. Ex. V). "Thus, for diseases [like NHL] for which the causes are largely unknown, . . . a differential etiology is of little benefit." *Id.* Plaintiffs' experts' differential etiology testimony on NHL is fundamentally unreliable, and as a result, the jury's verdict that Roundup caused Plaintiffs' NHLs is not supported by sufficient evidence. *See, e.g., Hall v. Conoco Inc.*, 886 F.3d 1308, 1314 (10th Cir. 2018).

III. MONSANTO IS ENTITLED TO JNOV ON PLAINTIFFS' WARNINGS CLAIMS.

To prove their warnings-based claims,[4] Plaintiffs were required to present competent evidence that Roundup's alleged risk of NHL was "known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge" at the time that Monsanto distributed the Roundup that allegedly caused their injuries. *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 1002

[4] A finding of no liability on the strict liability theory *necessarily* establishes no liability on a negligent failure-to-warn theory based on the same facts. *See, e.g., Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 132-33 (2017).

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(1991); *see also* CACI 1205. Here, the latest relevant time of distribution was 2011 for Mr. Pilliod and early 2015 for Mrs. Pilliod, and Plaintiffs failed to prove that the risk of NHL from exposure to Roundup was "known or knowable" at that time, or anytime thereafter.

Any exposure or distribution of the product after Plaintiffs were diagnosed with NHL is irrelevant because it could not have caused or contributed to the development of their NHL. Mr. Pilliod was diagnosed with DLBCL in 2011 and Mrs. Pilliod was diagnosed with PCNSL in the first half of 2015. Tr. 3772:6-10; 4157:23-4159:2. Thus, at the very latest, Monsanto's duty to warn cannot be judged later than 2011 for Mr. Pilliod or later than early 2015 for Mrs. Pilliod. Furthermore, Dr. Sawyer based his opinions on Mr. and Mrs. Pilliod's exposure to Roundup that allegedly caused their cancers from 1982 to 2012. Tr. 3246:11-3247:15; 3264:15-19; 3273:13-18. Plaintiffs did not quantify *any* alleged exposure after 2012 and thus did not present competent evidence that exposure after 2012 was sufficient to cause or contribute to their injuries.[5]

Plaintiffs argue that the risk of NHL was "knowable" as early as the 1980s because some animal studies showed an increase in tumors. But the existence of studies demonstrating a possible risk does *not* make the risk generally accepted.[6] *See Rosa v. City of Seaside*, 675 F. Supp. 2d 1006, 1014 (N.D. Cal. 2009) (rejecting argument that risk was "knowable," despite the existence of literature suggesting that risk could exist). CACI makes clear that a risk is not "knowable in light of 'the generally accepted' scientific knowledge" and does not give rise to a duty to warn if it is a *minority view* that is not "the 'prevailing' or 'best' scientific view." *See* CACI 1205, Directions for Use.

Plaintiffs failed to meet their burden of presenting evidence that, in 2011 or before, it was the

[5] Plaintiffs have argued that "Monsanto's liability should be judged at least up to when the Pilliods ceased using the product." *See* Pls.' Opp. to Nonsuit at 2. By Plaintiffs' own admission, the latest possible relevant time of distribution is 2011. *See* First Am. Compl. ¶ 14. It is black-letter law that "a pleader is bound by well pleaded material allegations." *Valerio v. Andrew Youngquist Construction*, 103 Cal. App. 4th 1264, 1271 (2002); *Myers v. Trendwest Resorts, Inc.*, 178 Cal. App. 4th 735, 746 (2009). "Facts established by pleadings . . . *may not be contradicted by the party whose pleadings are used against him or her*." *Id.*; *see also See Womack v. Lovell*, 237 Cal. App. 4th 772 (2015).

[6] Numerous courts have acknowledged that it is problematic to rely on animal studies alone in determining carcinogenicity. *See, e.g., In re Agent Orange*, 611 F. Supp. 1223, 1241 (E.D.N.Y. 1985) (animal studies are "generally viewed with more suspicion than epidemiological studies . . . ."); *In re Silicone Gel Breast Implants*, 318 F. Supp. 2d 879, 912 (C.D. Cal. 2004) ("The animal studies . . . do not support any conclusion about specific causation.").

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"prevailing" or "generally accepted" view in the scientific community that exposure to Roundup carried a risk of NHL. The uncontroverted evidence established that until the IARC monograph was published in 2015—*after the exposure they claim caused their harm and after the onset of their cancers*—every single regulatory agency that had examined the prevailing science had determined there was insufficient evidence that glyphosate could cause cancer in herbicide users. *See, e.g.*, Tr. 1926:13-25. Plaintiffs' own general causation expert, Dr. Christopher Portier, testified that even he did not come to the opinion that glyphosate was a carcinogen at any time prior to 2015. Tr. 1902:6-9.

Even if the Court were to consider what was known or knowable after the relevant time period, it would not alter the analysis because Plaintiffs did not offer competent evidence that the 2015 IARC hazard assessment determination was or is the prevailing or generally accepted view in the scientific community. To the contrary, after IARC published its Monograph, numerous scientific and regulatory agencies worldwide re-assessed their views, rejected IARC's classification, and re-affirmed their prior conclusions that glyphosate is not likely to be a carcinogen.[7] Moreover, IARC conducts only a hazard assessment, meaning that it "does not establish the exposure conditions that would pose cancer risks to individuals in their daily lives." Tr. 2225:19-24.[8]

IV. MONSANTO IS ENTITLED TO JNOV ON PLAINTIFFS' DESIGN-DEFECT CLAIMS.

For both their strict liability and negligent design claims, Plaintiffs must prove that there was a defect in the design of Roundup and that the defect caused their harm. *See Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 142 (2017).[9]

[7] *See, e.g.*, Tr. 1899:23-1900:1 (ECHA); 1900:3-10; 4082:22-4083:4 (Australian Pesticides and Veterinary Medicines Authority); 1900:11-23; 4075:14-20 (Health Canada); 1929:22-1930:2 (EFSA); 1953:7-15 (EFSA & ECHA); 1970:14-16 (EPA); 4081:11-4082:6 (New Zealand).

[8] *See, e.g.*, Tr. 2247:15-19 (Plaintiffs' causation expert Dr. Jameson testifying that scientists at ECHA, EFSA, EPA, Health Canada, and Australia disagree with him); Tr. 1900:11-1901:1 (As of 2017, no pesticide regulatory authority considered glyphosate to be a carcinogenic risk of concern to humans). Plaintiffs argue that IARC was a prevailing view because 94 scientists agreed with it. The fact that 94 of the world's millions of scientists expressed agreement with IARC does not make it the "prevailing" view in the scientific community in light of the overwhelming disagreement with IARC by the world's regulators; rather, that is the epitome of a minority view.

[9] Plaintiffs' negligent failure-to-warn and negligent design claims also fail for the independent reason that they have presented no evidence whatsoever about the appropriate standard of care. *See* CACI 1220-1222; *Stephen v. Ford Motor Co.*, 134 Cal. App. 4th 1363, 1367 (2005).

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This is fundamentally not a design-defect case. Rather, Plaintiffs presented evidence about Monsanto's failure to warn about an alleged health risk. Nevertheless, if Plaintiffs' design-defect claim is that glyphosate is unavoidably unsafe because it causes cancer, it is invalid under California law. *See Brown v. Superior Court*, 44 Cal. 3d 1049, 1059-60 (1988). Second, imposing liability on Monsanto based on Roundup's use of glyphosate, a raw ingredient, would be the same as imposing categorical liability, which is not allowed under California law. *See Pooshs v. Philip Morris USA, Inc.*, 904 F. Supp. 2d 1009, 1025-26 (N.D. Cal. 2012).

To get around these legal deficiencies, Plaintiffs have tried to articulate a design-defect claim based on the combination of glyphosate and the surfactants used in Roundup. But any claim based on that theory fails because Plaintiffs have put forth *no* evidence that the specific *design* of Roundup caused their harm; in other words, they failed to demonstrate that they would not have contracted NHL if they had used a different glyphosate-based formulation or if Roundup used an alternative surfactant. *See, e.g., O'Neil v. Crane Co.*, 53 Cal. 4th 335, 347 (2012) (plaintiff must prove design caused harm).

Neither of Plaintiffs' specific causation experts, Dr. Nabhan nor Dr. Weisenburger, testified that Roundup, as opposed to glyphosate on its own, caused Plaintiffs' NHL. Tr. 2891:12-15. The only expert who gave any meaningful testimony about the formulation was Dr. Sawyer. And although Dr. Sawyer testified that certain surfactants are safer than the POEA used in Roundup, his testimony was far from sufficient to establish that Plaintiffs' cancer was caused by Monsanto's use of POEA as opposed to a different surfactant. He did not testify that Plaintiffs' cancer would have been avoided had Monsanto used a different formulation. His testimony focused on his opinion that Roundup is more genotoxic than glyphosate, meaning that it can cause damage to DNA. Tr. 1700:13-15. But just because something is genotoxic does not mean that it will lead to cancer. Tr. 1983:1-24. Moreover, he could not reliably opine as to whether the formulation caused Plaintiffs' NHL because he is not an oncologist or medical doctor of any sort, and he admittedly did not consider Plaintiffs' other risk factors. Tr. 3259:5-9. In short, Plaintiffs have not demonstrated that Roundup's *design* caused their NHL. And in any event, the evidence was not sufficient to prove that glyphosate or Roundup causes NHL generally.

Plaintiffs' design-defect claims fail for the additional reason that this case does not qualify for

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the consumer expectations test, which was the only strict liability theory Plaintiffs pursued. The consumer expectations test is "reserved for cases in which the everyday experience of the product's users permits a conclusion that the product's design violated minimum safety assumptions." *Trejo,* 13 Cal. App. 5th at 156. This is not such a case, and JNOV must be granted on the design-defect claims.[10]

V. MONSANTO IS ENTITLED TO JNOV ON PUNITIVE DAMAGES.

To recover punitive damages, Plaintiffs had to prove by clear and convincing evidence that Monsanto committed malice, oppression, or fraud. Civ. Code § 3294. California law "does not favor punitive damages and they should only be granted with the greatest of caution," *Dyna-Med, Inc. v. Fair Emp't & Hous. Comm'n.*, 43 Cal. 3d 1379, 1392 (1987), and in the "clearest of cases," *Henderson v. Sec. Nat'l. Bank*, 72 Cal. App. 3d 764, 771 (1977). Plaintiffs must prove punitive damages by clear and convincing evidence, which requires proof that "leave[s] no substantial doubt [and is] sufficiently strong to command the unhesitating assent of every reasonable mind." *In re Angelia P.*, 28 Cal. 3d 908 (1981). Plaintiffs failed to meet this burden.

A. Plaintiffs Did Not Present Clear and Convincing Evidence Sufficient to Establish that Monsanto Acted with Malice, Oppression or Fraud.

In light of the scientific and regulatory evidence discussed above, Plaintiffs cannot meet their punitive-damages burden. Monsanto's reliance on a worldwide regulatory safety consensus was reasonable corporate conduct and nothing close to the "despicable" conduct required to support punitive damages. Indeed, Plaintiffs' expert Dr. Nabhan acknowledged that, even today, reasonable people can disagree about whether glyphosate should be classified as a carcinogen. Tr. 4072:20-4073:2. This concession should preclude an award of punitive damages. Even if the jury disagrees with the experts at EPA, EFSA, ECHA, Health Canada, the Australian Pesticides and Veterinary Medicines Authority, and other respected agencies, the record cannot possibly support a finding of *clear and convincing* evidence that Monsanto acted with *malice or oppression* simply for selling a product that expert regulators believed, and still believe, is safe for human use. Such evidence precludes any possible finding that

[10] Plaintiffs' negligent design claims fail for the same reasons as their strict liability design defect claims. *See Lambert v. General Motors*, 67 Cal. App. 4th 1179, 1185 (1998) (where liability is based on design, strict liability and negligence claims merge).

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Monsanto "intended" to cause harm or acted despicably.

On top of these facts, the specific evidence Plaintiffs highlighted in this case does not come close to clear and convincing evidence of "despicable" conduct in which Monsanto consciously disregarded probable danger. Plaintiffs highlight the following acts or omissions:

- Monsanto's supposed failure to perform follow-up genotoxicity studies recommended by Dr. Parry in 1999. Tr. at 1365:1-1374:6, 3586:6-3594:2.
- Monsanto's alleged "ghostwriting" of toxicology papers for Dr. Williams in 2000 and the Intertek papers in 2016. Tr. 1374:7-1376:21; Reeves Dep. at 458:15-466:13 (Brown Decl. Ex. B); Heydens Dep. at 29:24-36:20 (Brown Decl. Ex. F); Koch Dep. at 295:13-297:18 (Brown Decl. Ex. G).
- Monsanto's supposed efforts to play "whack-a-mole" in response to scientific findings on glyphosate (Goldstein Dep. at 73:14-75:7 (Brown Decl. Ex. E)), to "orchestrate an outcry" against IARC, (Tr. 1398:7-1400:20; Goldstein Dep. at 135:20-136:11), and to otherwise "discomfort" its opposition (Murphey Dep. 204:21-210:7 (Brown Decl. Ex. I)).
- Monsanto's allegedly improper communications with Jess Rowland and others at EPA and other regulatory agencies. Reeves Dep. at 715:22-725:13 (Brown Decl. Ex. B).
- Monsanto failed to do carcinogenicity studies on Roundup. Reeves Dep. at 183:1-185:21 (Brown Decl. Ex. B).

Many of these assertions are untrue and are contradicted by the evidence, and the remaining allegations, even if true, do not amount to clear and convincing evidence of "despicable" conduct.

For instance, the evidence showed that Monsanto *did* complete many of the studies recommended by Dr. Parry. Martens Dep. at 212:4-230:2 (Brown Decl. Ex. H) The evidence further showed that in every case of alleged "ghostwriting," Monsanto's contributions were either publicly identified or did not rise to the level warranting authorship or recognition. Heydens Dep. at 376:3-409:17. The evidence also showed that Monsanto did not engage in any wrongdoing in its responses to the scientific findings on glyphosate from IARC and other sources or in its communications with Jess Rowland, EPA, or any other regulatory agency. Goldstein Dep. at 129:14-133:15, 135:20-136:11; Reeves Dep. 715:27-721:20. Instead, the company's conduct in anticipating the IARC decision was consistent with a company that truly believes its product to be safe. Furthermore, Monsanto's actions and communications in response to these scientific findings amount to protected speech under the First Amendment. *See, e.g.*, *ONY, Inc. v. Cornershote Therapeutics, Inc.*, 720 F.3d 490, 497 (2d Cir. 2013); *Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994); *Ludwig v. Superior Court*, 37 Cal. App. 4th 8,

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21 (1995).[11] The evidence also demonstrated that Monsanto would, and did, warn of risks associated with Roundup when those risks were known. *See* Tr. 3146:17-18. Finally, the evidence showed that Monsanto has not done a long-term carcinogenicity study on Roundup because such a study is impossible. Martens Dep. at 205:9-207:15.

B. The Punitive Damages Award Violates Due Process.

Plaintiffs' punitive damages arguments, which are premised almost entirely on alleged conduct that occurred before or after the time period of distribution that allegedly caused Plaintiffs' harm, cannot support an award of punitive damages without violating Monsanto's federal due process rights. A punitive damage award cannot be premised on "conduct that bore no relation to the [Plaintiffs'] harm." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003) ("A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages. A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business."); *accord Medo v. Super. Ct.*, 205 Cal. App. 3d 64, 68 (1988) ("Punitive damages are not simply recoverable in the abstract. They must be tied to oppression, fraud or malice in the conduct which gave rise to liability in the case.").

There is no evidence providing a causal nexus between Plaintiffs' diagnosis of NHL in 2011 and 2015 and any of Monsanto's actions that occurred after the onset of Plaintiffs' NHL or before Roundup was distributed to Plaintiffs. Monsanto's alleged efforts to "ghostwrite" the 2016 Intertek papers, "orchestrate an outcry" to the IARC Monograph, communicate with EPA employee Jess Rowland, and numerous other pieces of evidence introduced by Plaintiffs in this case cannot serve as the basis for punitive damages.

The excessive punitive damages award in this case violates due process for the additional reason that Monsanto has already been punished *twice* for the same alleged conduct. In considering the propriety of punitive damages, the court should consider whether "there is the likelihood of several jury-imposed punitive damage awards, each of which is sufficient to punish in the entirety for the misconduct involved." *Delos v. Farmers Grp., Inc.*, 93 Cal. App. 3d 642, 667 (1979). Both past and likelihood of

[11] Plaintiffs admit that the evidence surrounding Jess Rowland is largely irrelevant to punitive damages. Tr. 4298:20-24.

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future punitive damages are relevant in calculating the adequate amount of punitive damages. *Stevens v. Owens-Corning Fiberglas Corp.*, 49 Cal. App. 4th 1645, 1661 (1996).

Here, no punitive damages are necessary to punish or deter, as Monsanto has already been ordered to pay over $100 million in punitive damages in the *Johnson* and *Hardeman* cases. *See Johnson v. Monsanto Co.*, Case No. CGC-16-550128 (Cal. Super. Ct. August 18, 2018); *Hardeman v. Monsanto Co.*, Case No. 3:16-cv-0525-VC (N.D. Cal. May 3, 2019).

C. There Was No Evidence That Monsanto Employees Were Managing Agents.

Plaintiffs' claims for punitive damages also fail because they have not identified any wrongdoing by Monsanto's officers, directors, or managing agents. *See* Cal. Civ. Code § 3294(b). A "managing agent" under section 3294(b) is limited to employees with "broad discretion" that "determine[] corporate policy." *Egan v. Mutual of Omaha Ins. Co.*, 24 Cal. 3d 809, 822-23 (1979). Plaintiffs provided no evidence that any of Monsanto's witnesses in this case were "managing agents" or that any company policy was malicious. There was no evidence whatsoever that any Monsanto employee at any time thought Roundup causes cancer. To the contrary, numerous company witnesses testified that the company has time and time again found the product to be safe.

VI. PLAINTIFFS FAILED TO PRESENT ADMISSIBLE EVIDENCE TO SUPPORT MRS. PILLIOD'S FUTURE ECONOMIC DAMAGES.

Mrs. Pilliod's entire future economic damage case was based on her purported need for a lifetime supply of Revlimid. But Mrs. Pilliod failed to prove the amount of her future damages with reasonable certainty and with admissible, competent evidence. *See S.C. Anderson, Inc. v. Bank of Am.*, 24 Cal. App. 4th 529, 537-38 (1994); *Howell v. Hamilton Meats & Provisions, Inc.*, 52 Cal. 4th 541 (2011); *Corenbaum v. Lampkin*, 215 Cal. App. 4th 1308 (2013). Instead, she only introduced evidence of a price of Revlimid that bore no relationship to what she or her insurance company might actually pay for the drug. Tr. 3981:1-4, 4201:14-17, 4202:12-14, 4201:21-24. The judgment awarding Mrs. Pilliod $2,957,710 in future economic damages must be vacated.

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VII. MONSANTO IS ENTITLED TO JNOV ON ALL OF PLAINTIFFS' CLAIMS BECAUSE THEY ARE PREEMPTED BY FEDERAL LAW (FIFRA).

A. Express Preemption

FIFRA has an express preemption clause that prohibits States from imposing "any requirements for labeling or packaging" that are "in addition to or different from" FIFRA's requirements. 7 U.S.C. §§ 136a(c), 136v(b). In *Bates v. Dow Agrosciences LLC*, the Supreme Court established a two-part "parallel-requirements" test to determine whether a state-law claim is pre-empted by FIFRA: (1) the state requirement must be *for labeling or packaging*, and (2) it must impose a labeling or packaging requirement that is *in addition to or different from* FIFRA's requirements. 544 U.S. 431 (2005). Plaintiffs' claims satisfy both parts of the *Bates* test and are expressly preempted.

The first prong of the *Bates* test is satisfied because Plaintiffs' claims for negligence and strict liability failure to warn were based on purported deficiencies in Roundup's labeling. *See id.* The second prong of the *Bates* test is satisfied because failure-to-warn claims under California law impose different and additional requirements than FIFRA. Whereas FIFRA requires warnings only about risks associated with "widespread and commonly recognized" uses, 7 U.S.C. § 136(q)(1)(F) & (G), 136a(c)(5)(D), California law requires warnings about all potential risks that are "reasonably foreseeable," CACI No. 1205.

B. Impossibility Preemption

Plaintiffs' claims are also preempted by FIFRA under the doctrine of impossibility preemption because Monsanto cannot make the label or design changes Plaintiffs seek without prior EPA approval. Federal law preempts state law "where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). A state tort claim is preempted if it seeks product changes that cannot be made without first obtaining the approval of a federal regulatory agency. *Wyeth v. Levine*, 555 U.S. 555, 568-73 (2009); *Mensing*, 564 U.S. at 617-24; *Bartlett*, 570 U.S. at 480. Thus, "[i]f a private party . . . cannot comply with state law without first obtaining the approval of a

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federal regulatory agency, then the application of that law to that private party is preempted." *Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 9 (1st Cir. 2018).

Monsanto moved for summary judgment on this ground. In its order denying summary judgment, the Court found that there were triable issues of fact. After the trial in this matter concluded, the United States Supreme Court issued an opinion holding that the issue of impossibility preemption is one for the court to decide—not a jury. *See Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290, 2019 WL 2166393, 587 U.S. ___ (May 20, 2019). The Supreme Court clarified that the relevant inquiry is whether the relevant federal and state laws "irreconcilably conflict." *Id.* at *8. Because it is now clear under *Albrecht* that courts must decide the issue of impossibility preemption, the Court here should find that Plaintiffs' claims are preempted as a matter of law. *See id.*

The evidence amply demonstrated that the warnings proposed by Plaintiffs irreconcilably conflict with federal law because Monsanto must obtain approval from the EPA for any label change, and the EPA has considered and rejected the risk that Roundup is carcinogenic on multiple occasions. *See* Monsanto's 3/19/2019 RJN, Exhibits 1 and 2; Monsanto's 4/4/2019 Supp. RJN, Exhibit 1 and 5 through 9. *See Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1169 (S.D. Cal. 2016). Indeed, on April 23, 2019, EPA issued its Proposed Interim Registration Review Decision on Glyphosate concluding that "EPA did not identify any human health risks from exposure to any use of glyphosate." Monsanto's 5/1/2019 RJN, Exhibit A.[12] EPA expressly repudiated IARC's glyphosate classification and public comments criticizing its 2016 and 2017 Draft Glyphosate Assessments. Furthermore, in light of EPA's findings, Monsanto would be in violation of FIFRA's misbranding provisions if it added the warning that Plaintiffs claim California law requires. *See* 7 U.S.C. §§ 136(q), 136j; *see also Nat'l Ass'n of Wheat Growers v. Zeise*, 309 F. Supp. 3d 842 (E.D. Cal. 2018).

VIII. CONCLUSION

For all the reasons stated herein, the Court should grant Monsanto's motion for judgment notwithstanding the verdict and enter judgment in favor of Monsanto and against Plaintiffs.

[12] Although the jury did not hear this evidence, the Court can consider it in determining whether Plaintiffs' claims were preempted as a matter of law since the question of preemption is one for the Court, not the jury.

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