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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

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. LEGAL STANDARD 1

III. ARGUMENT 1

A. Monsanto Is Entitled to JNOV on All of Plaintiffs' Claims Because Plaintiffs Failed to Present Sufficient Evidence that Roundup Caused Their NHL. 1

1. Drs. Weisenburger and Nabhan Failed to Reliably "Rule In" Roundup 2

2. Drs. Weisenburger and Nabhan Failed to State a "Reasoned Explanation" Why They Ruled Out Plaintiffs' Alternative Risk Factors. 4

3. Drs. Weisenburger and Nabhan Failed to Rule Out Unknown Causes 5

B. Monsanto Is Entitled to JNOV On Plaintiffs' Warnings Claims. 6

C. Monsanto Is Entitled to JNOV On Plaintiffs' Design-Defect Claims. 9

D. Monsanto Is Entitled to JNOV on Plaintiffs' Negligence Claims. 12

E. Monsanto is Entitled to JNOV on Punitive Damages. 12

1. Plaintiffs Did Not Present Clear and Convincing Evidence Sufficient to Establish that Monsanto Acted with Malice, Oppression or Fraud. 13

2. The Punitive Damages Award Violates Due Process. 15

3. There Was No Evidence That Monsanto Employees Were Managing Agents. 16

F. Plaintiffs Failed to Present Admissible Evidence To Support Mrs. Pilliod's Future Economic Damages. 16

G. Monsanto is Entitled to JNOV on All of Plaintiffs' Claims Because They Are Preempted By Federal Law (FIFRA). 17

1. Express Preemption 17

2. Impossibility Preemption 18

IV. CONCLUSION 20

BRYAN CAVE LEIGHTON PAISNER LLP
THREE EMBARCADERO CENTER, 7TH FLOOR
SAN FRANCISCO, CA 94111-4070

TABLE OF AUTHORITIES

Page(s)

Cases

In re Agent Orange,
611 F. Supp. 1223 (E.D.N.Y. 1985) 8

Anderson v. Owens-Corning Fiberglas Corp.,
53 Cal. 3d 987 (1991) 7

In re Angelia P.,
28 Cal. 3d 908 (1981) 13

Beavers v. Allstate Ins. Co.,
225 Cal. App. 3d 310 (1990)....13

Brown v. Superior Court,
44 Cal. 3d 1049 (1988) 10

Browne v. McDonnell Douglas Corp.,
698 F.2d 370 (9th Cir. 1982)....11

Bunch v. Hoffinger Indus., Inc.,
123 Cal. App. 4th 1278 (2004)....18

Cooper v. Takeda Pharm. Am., Inc.,
239 Cal. App. 4th 555 (2015)....3, 4

Corenbaum v. Lampkin,
215 Cal. App. 4th 1308 (2013)....17

Daubert v. Merrell Dow Pharm. Inc.,
43 F.3d 1311 (9th Cir. 1995)....3

Delos v. Farmers Grp., Inc.,
93 Cal. App. 3d 642 (1979)....16

Dobbs v. Wyeth Pharm.,
797 F. Supp. 2d 1264 (W.D. Okla. 2011) 20

Dolin v. GlaxoSmithKline LLC,
901 F.3d 803 (7th Cir. 2018)....20

Dyna-Med, Inc. v. Fair Emp't & Hous. Comm'n.,
43 Cal. 3d 1379 (1987) 13

Egan v. Mutual of Omaha Ins. Co.,
24 Cal. 3d 809 (1979) 17

BRYAN CAVE LEIGHTON PAISNER LLP
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SAN FRANCISCO, CA 94111-4070

In re Fosamax (Alendronate Sodium) Products Liability Litigation,
852 F.3d 268 (3rd Cir. 2017) 19

Gustavsen v. Alcon Labs., Inc.,
903 F.3d 1 (1st Cir. 2018) 19

Hall v. Conoco Inc.,
886 F.3d 1308 (10th Cir. 2018) 6

Hardeman v. Monsanto Co.,
Case No. 3:16-cv-0525-VC (N.D. Cal. May 3, 2019) 16

Henderson v. Sec. Nat'l. Bank,
72 Cal. App. 3d 764 (1977) 13

Howell v. Hamilton Meats & Provisions, Inc.,
52 Cal. 4th 541 (2011) 17

Johnson v. Monsanto Co.,
Case No. CGC-16-550128 (Cal. Super. Ct. August 18, 2018) 16

Jones v. Ortho Pharm. Corp.,
163 Cal. App. 3d 396 (1985) 1, 4

Kelly-Zurian v. Wohl Shoe Co.,
22 Cal. App. 4th 397 (1994) 17

Lambert v. General Motors,
67 Cal. App. 4th 1179 (1998) 10, 12

Ludwig v. Superior Court,
37 Cal. App. 4th 8 (1995) 15

Magic Kitchen LLC v. Good Things Int'l, Ltd.,
153 Cal. App. 4th 1144 (2007) 1

Medo v. Super. Ct.,
205 Cal. App. 3d 64 (1988) 16

Merck Sharp & Dohme Corp. v. Albrecht,
No. 17-290, 2019 WL 2166393, 587 U.S. ___ (May 20, 2019) 20

Mutual Pharm. Co. v. Bartlett,
570 U.S. 472 (2013) 19

Myers v. Trendwest Resorts, Inc.,
178 Cal. App. 4th 735 (2009) 7, 8

Nat'l Ass'n of Wheat Growers v. Zeise,
309 F. Supp. 3d 842 (E.D. Cal. 2018) 20

BRYAN CAVE LEIGHTON PAISNER LLP
THREE EMBARCADERO CENTER, 7TH FLOOR
SAN FRANCISCO, CA 94111-4070

O'Neil v. Crane Co.,
53 Cal. 4th 335 (2012) 11

Oaks v. E.I. Du Pont de Nemours & Co.,
272 Cal. App. 2d 645 (1969) 10

ONY, Inc. v. Cornershote Therapeutics, Inc.,
720 F.3d 490 (2d Cir. 2013) 14

PLIVA, Inc. v. Mensing,
564 U.S. 604 (2011) 19

Pooshs v. Philip Morris USA, Inc.,
904 F. Supp. 2d 1009 (N.D. Cal. 2012) 10, 11

Rosa v. City of Seaside,
675 F. Supp. 2d 1006 (N.D. Cal. 2009) 8

S.C. Anderson, Inc. v. Bank of Am.,
24 Cal. App. 4th 529 (1994) 17

Saller v. Crown Cork & Seal Co., Inc.,
187 Cal. App. 4th 1220 (2010) 12, 18

Sargon Enter., Inc. v. Univ. of S. Cal.,
55 Cal. 4th 747 (2012) 2

Seufert v. Merck Sharp & Dohme Corp.,
187 F. Supp. 3d 1163 (S.D. Cal. 2016) 20

Shade Foods, Inc. v. Innovative Prod. Sales & Mktg., Inc.,
78 Cal. App. 4th 847 (2000) 13

In re Silicone Gel Breast Implants,
318 F. Supp. 2d 879 (C.D. Cal. 2004) 8

State Farm Mut. Auto. Ins. Co. v. Campbell,
538 U.S. 408 (2003) 15

Stephen v. Ford Motor Co.,
134 Cal. App. 4th 1363 (2005) 12

Stevens v. Owens-Corning Fiberglas Corp.,
49 Cal. App. 4th 1645 (1996) 16

Trejo v. Johnson & Johnson,
13 Cal. App. 5th 110 (2017) ..... *passim*

Underwager v. Salter,
22 F.3d 730 (7th Cir. 1994) 15

BRYAN CAVE LEIGHTON PAISNER LLP
THREE EMBARCADERO CENTER, 7TH FLOOR
SAN FRANCISCO, CA 94111-4070

Valerio v. Andrew Youngquist Construction,
103 Cal. App. 4th 1264 (2002).....7

Whistler Invs., Inc. v. Depository Tr. & Clearing Corp.,
539 F.3d 1159 (9th Cir. 2008).....19

White v. Ultramar, Inc.,
21 Cal. 4th 563 (1999).....17

Wilgus v. Hartz Mountain Corp.,
No. 3:12-CV-86, 2013 WL 653707 (N.D. Ind. Feb. 19, 2013).....18

Womack v. Lovell,
237 Cal. App. 4th 772 (2015).....8

Wyeth v. Levine,
555 U.S. 555 (2009).....19

Statutes

7 U.S.C. § 136(G).....18

7 U.S.C. § 136(q).....20

7 U.S.C. § 136(q)(1)(F).....18

7 U.S.C. § 136a(c).....18

7 U.S.C. § 136a(c)(5)(D).....18

7 U.S.C. § 136j.....20

7 U.S.C. § 136v(b).....18

Cal. Civ. Code § 3294(b).....17

Cal. Code Civ. Proc. § 629(a).....1

Civ. Code § 3294.....13

Other Authorities

CACI 430.....2

CACI 1205.....7, 8, 10, 18

CACI 1220-1222.....12

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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 a jury verdict proclaiming that Roundup caused Plaintiffs' cancer and that Monsanto's behavior in relying on the science and the regulators was so egregious to warrant a $2 billion punitive damages award requires exceptional scrutiny. That verdict cannot be sustained for the multiple reasons discussed below. Monsanto therefore 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.

II. LEGAL STANDARD

A party is entitled to JNOV when "there is no evidence of sufficient substantiality to support" the jury's verdict. *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). The plaintiff must "produce evidence which supports a logical inference in his favor and which does more than merely permit speculation or conjecture." *Jones v. Ortho Pharm. Corp.*, 163 Cal. App. 3d 396, 402 (1985) (affirming nonsuit where plaintiff failed to demonstrate medication caused cancer).

III. ARGUMENT

A. Monsanto Is Entitled to JNOV on All of Plaintiffs' Claims Because Plaintiffs Failed to Present Sufficient Evidence that Roundup Caused Their NHL.

All of Plaintiffs' claims fail for lack of reliable causation testimony. *See Jones*, 163 Cal. App. 3d at 403. 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

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the same harm would have occurred without that conduct.").

Plaintiffs' specific causation experts (Drs. Weisenburger, Nabhan, and Sawyer) failed to reliably opine that Roundup was a substantial factor in causing Plaintiffs' NHL. *See Sargon Enter., Inc. v. Univ. of S. Cal.*, 55 Cal. 4th 747, 771, 772 (2012) (testimony that is "speculative," "unreliable," and fails "to employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert" cannot support a verdict). Instead, they admitted 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. Drs. Weisenburger and Nabhan both relied on an unapologetically results-oriented differential diagnosis methodology designed solely for this courtroom. *See, e.g.*, Tr. 4377:16-21 (Dr. Nabhan and Dr. Weisenburger's differential diagnoses were inconsistent with World Health Organization guidelines for identifying the cause of lymphomas); Tr. 5170:20-5171:9, 5172:5-6 (Levine explaining that Plaintiffs' experts' methodology is "not a valid methodology," and not used in practice).[1]

1. 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 (Dr. Weisenburger admitted he did not independently review animal data or mechanistic data); Tr. 4055:19-23 (Dr. Nabhan admitted he is not an expert in animal studies). As for epidemiology, both experts relied primarily on Eriksson (2008) and data subsumed in the North American Pooled Project ("NAPP") for "ruling in" Roundup as the cause of Plaintiffs' NHL. Tr. 2833:1-25.

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 . . .

[1] 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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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)). Because "[a] relative risk of 2.0 implies a 50% probability that the agent at issue was responsible for a particular individual's disease," *Cooper*, 239 Cal. App. 4th at 593-94, "[a] relative risk of less than two . . . actually tends to disprove legal causation," *Daubert*, 43 F.3d at 1321.

None of the data relied upon by Plaintiffs reliably satisfies the minimum 2.0 risk ratio. It is undisputed that adjusting for multiple pesticides improves the accuracy of the data, because unadjusted studies can introduce confounders into the analysis. 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. For example, Eriksson (2008) did not adjust for other confounding pesticides and showed no statistically significant result at or above 2.0 when adjusted. Tr. 2834:4-9; 2910:23-2911:5. The same is true for Hardell (2002), which incorporated the data from Hardell (1999). Tr. 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.[2] Dr. Weisenburger also admitted that Leon (2019), the largest and most recent pooled-cohort study available, shows no increased risk of NHL generally and only a 1.36 risk ratio for the DLBCL subtype. Tr. 2960:1-4; 2982:6-11. Similarly, the

[2] 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. When compared with the vast epidemiological data available, which in totality includes thousands of exposed cases, one small and flawed study alone cannot support causation as a matter of law.

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most recent meta-analysis that Plaintiffs' experts relied on, Zhang, showed only a 1.4 risk ratio. Tr. 2732:15-2733:10. Even ignoring the much better studies relied upon by Monsanto's experts, which show *no* increased risk of NHL, Plaintiffs' *best* evidence does not support a risk ratio of 2.0 or higher.

2. 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's Negative t(14;18) Translocation*:** Plaintiffs cannot justify Dr. Weisenburger's and Dr. Nabhan's disregard of testing showing that Mrs. Pilliod's t(14;18) chromosome translocation was negative, which 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. Because Plaintiffs cannot patch this methodological hole, Plaintiffs have implored that "it is not for the Court to resolve such fact-intensive questions." Nonsuit Opp. at 9. But, it is this Court's responsibility to ensure that any jury verdict is supported by admissible evidence that comports with *Sargon*. *See Jones*, 163 Cal. App. 3d at 403 ("The fact that a determination of causation is difficult to establish cannot, however, provide a plaintiff with an excuse to dispense with the introduction of some reasonably reliable evidence proving this essential element of his case."). The decision of Drs. Weisenburger and Nabhan to bury this genetic testing guts any reliable basis for their causation opinion for Mrs. Pilliod. Tr. 2807:1-4 (Q. And you knew sitting there all morning that Mrs. Pilliod had a negative t(14;18) translocation; right? A. Yes). Dr. Weisenburger flatly admitted that people, like Mrs. Pilliod, who were "exposed to herbicides for

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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). Given these admissions, the evidence was not sufficient to support the jury's finding that Mrs. Pilliod's NHL was caused by exposure to Roundup.

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's Alternative Risk Factors: 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 is an incurable disease that "for men" 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 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. The epidemiology is replete with data that "confirm an increased risk of NHL in patients with recurrent skin cancer" by showing risk ratios between 2.0 and 3.0 that Mr. Pilliod's experts failed to deal with in any meaningful manner. Tr. 2877:5-2879:3.

3. 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. Dr. Weisenburger testified that 70% of NHL cases result from unknown

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causes, and Dr. Nabhan agreed with that assessment. Tr. 2791:15-20; 4163:15-21. Yet, neither expert ruled out idiopathic causes for any reason other than 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) (finding that "because the evidence had pointed to idiopathic causes in most cases of acute myeloid leukemia," "the district court could reasonably view the failure to rule out idiopathic causes as fatal error tainting the differential diagnosis."). Because of Plaintiffs' many risk factors, and the fact that at least 70% of NHL cases are idiopathic, the most likely cause of Plaintiffs' NHL must be unknown.

B. Monsanto Is Entitled to JNOV On Plaintiffs' Warnings Claims.

To prove their warnings-based claims[3] under California law, 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 (1991); *see also* CACI 1205 (plaintiff must prove that the product had risks "that were known or knowable in light of the scientific knowledge that was generally accepted in the scientific community at the time of [manufacture/distribution/sale]"). Here,

[3] 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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SAN FRANCISCO, CA 94111

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. And Mrs. Pilliod testified that she sprayed only "a little" Roundup from 2012-2015. Tr. 3740:6-14; 3794:22-3795:1. 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. Although Mrs. Pilliod testified that she sprayed "a little" Roundup after 2012, 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.[4]

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.[5] *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

[4] 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, that date was 2011. Plaintiffs admitted in their Complaint that they sprayed Roundup "between 1975 and 2011." 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). When "complaints. . . contain allegations of fact in support of a claim or defense, the opposing party may rely on the factual statements as judicial admissions." *Myers v. Trendwest Resorts, Inc.*, 178 Cal. App. 4th 735, 746 (2009). And "[f]acts established by pleadings as judicial admissions are conclusive concessions of the truth of those matters, are effectively removed as issues from the litigation, and *may not be contradicted by the party whose pleadings are used against him or her*." *Id.* Such an admission will bind a party throughout litigation, including at trial. *See Womack v. Lovell*, 237 Cal. App. 4th 772 (2015). Mr. and Mrs. Pilliod are thus bound by their admission in the operative Complaint that they each used roundup "between 1975 and 2011." First Am. Comp. ¶ 14. Therefore, the latest possible relevant time of distribution for purposes of Plaintiffs' claims is 2011.

[5] 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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literature suggesting that risk could exist, because risk was not "generally recognized" or "prevailing" in the scientific and medical community, and a duty to warn required that it be both). 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. Rather, a duty to warn arises only when a risk is "(1) generally recognized (2) as prevailing in the relevant scientific community, and (3) represents the best scholarship available." *Id.* (emphasis added)).

Plaintiffs failed to meet their burden of presenting evidence that, in 2011 or before, it was the "prevailing" or "generally accepted" view in the scientific community that exposure to Roundup carried a risk of NHL. In fact, they did not present evidence of a single scientific or regulatory body that had concluded that glyphosate was a likely human carcinogen at that time. To the contrary, 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, and no scientific organization had ever classified glyphosate as a probable human carcinogen. *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.

Plaintiffs' failure to provide proof that, in 2011 or earlier, it was the prevailing, generally accepted view in the scientific community that exposure to glyphosate carries a risk of NHL necessitates entry of JNOV on their failure-to-warn claims. The evidence is undisputed that no scholarship, much less the "best scholarship available," at the time Plaintiffs were exposed to Roundup established that there was a causal link between NHL and exposure to glyphosate or Roundup. The conclusion that the prevailing science did not require a warning about NHL was thus not just a majority view; it was the only view.

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

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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.[6] 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. At most, Plaintiffs presented evidence of a new, minority view in the scientific community that emerged in 2015 and has since been repeatedly rejected by regulators looking at the actual risk from real world exposure.[7] Indeed, it is now four years after the IARC Monograph on glyphosate was published, and IARC's views still have not been adopted by worldwide regulators. As CACI makes clear, a minority view does *not* make a risk immediately "known or knowable" in order to require a duty to warn. *See* CACI 1205, Directions for Use.

C. 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) ("A design defect exists when the product is built in accordance with its intended specifications, but the design itself is inherently defective."); *Lambert v. General Motors*, 67 Cal. App. 4th 1179, 1186 (1998).

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 causes cancer, it is invalid under California law for two reasons. First,

[6] *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).

[7] *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.

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California has adopted comments j and k of the Restatement (Second) of Torts 402A. Comment k provides that a manufacturer of an "unavoidably unsafe product" is liable only if it failed to warn of a defect that it either knew or should have known. *See Brown v. Superior Court*, 44 Cal. 3d 1049, 1059 (1988). If Plaintiffs are arguing that Roundup is unavoidably unsafe, then their design-defect claim is precluded by California law. *See id.* at 1060; *Oaks v. E.I. Du Pont de Nemours & Co.*, 272 Cal. App. 2d 645 (1969). 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) (applying California law and rejecting that cigarette company could be liable for defective design of cigarettes because "[t]aken to its logical conclusion, the argument . . . would mean that the only remedy for this alleged design defect would be a ban on the manufacture and sale of any cigarettes.").

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 O'Neil v. Crane Co.*, 53 Cal. 4th 335, 347 (2012) ("A bedrock principle in strict liability law requires that 'the plaintiff's injury must have been caused by a 'defect' in the [defendant's] product."); *see also Browne v. McDonnell Douglas Corp.*, 698 F.2d 370, 371 (9th Cir. 1982); *Pooshs*, 904 F. Supp. 2d at 102.

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

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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 genotoxicity is different than carcinogenicity, and 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. Dr. Sawyer did not conduct a differential diagnosis, determine that Roundup should be ruled in, or rule out alternative causes. 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 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. "[W]hen the ultimate issue of design defect calls for a careful assessment of feasibility, practicality, risk, and benefit, the case should not be resolved simply on the basis of ordinary consumer expectations [because] '. . . in many instances it is simply impossible to eliminate the balancing or weighing of competing considerations in determining whether a product is defectively designed or not . . . .'" *Id.* In a jury case, "the trial court must initially determine as a question of foundation, within the context of the facts and circumstances of the particular case, whether the product is one about which the ordinary consumer can form reasonable minimum safety expectations." *Saller v. Crown Cork & Seal Co., Inc.*, 187 Cal. App. 4th 1220, 1233 (2010).

The consumer expectations test cannot be applied to the facts here because this case involves complex scientific details about how Roundup works *and* expert testimony about the "effect of the product upon [Plaintiffs'] health." *See Trejo*, 13 Cal. App. 5th at 156. In short, the ultimate issue of design defect in this case "calls for a careful assessment of feasibility, practicality, risk, and benefit"; accordingly, the consumer expectations test does not apply, and JNOV must be granted on Plaintiffs'

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design-defect claims.[8]

D. Monsanto Is Entitled to JNOV on Plaintiffs' Negligence Claims.

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). Plaintiffs did not present *any* evidence—expert or otherwise—of the standard of care allegedly applicable to Monsanto or that a reasonable manufacturer under the same or similar circumstances would have designed the product differently or warned of the alleged risk. Accordingly, Plaintiffs have not established that Monsanto acted unreasonably or contrary to the applicable standard of care.

E. 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); *Shade Foods, Inc. v. Innovative Prod. Sales & Mktg., Inc.*, 78 Cal. App. 4th 847, 891 (2000). Plaintiffs failed to meet this burden. Thus, if the Court does not grant JNOV with respect to liability, it should at the very least grant partial JNOV in Monsanto's favor on the issue of punitive damages. *See Beavers v. Allstate Ins. Co.*, 225 Cal. App. 3d 310, 323 (1990) (holding that court has authority to grant partial JNOV on punitive damages if there is no substantial evidence to support punitive award).

[8] 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 depends on the proof of a design defect, no practical difference exists between negligence and strict liability; the claims merge. Even if [defendant] did not test the [product] and did not warn customers . . . in the absence of a defect, those omissions would not be important. Testing, for example, would not disclose the existence of a defect where there is none." (citations omitted)).

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1. 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 in connection with Monsanto's decision to develop, market, and sell Roundup, or its failure to warn consumers of alleged carcinogenicity. 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 Monsanto "intended" to cause harm to anyone 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).

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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 in an accredited laboratory and either submitted them to the EPA or, in some instances, published the results. 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. Monsanto cannot be punished for the exercise of these constitutionally-protected rights. *See, e.g.*, *ONY, Inc. v. Cornershote Therapeutics, Inc.*, 720 F.3d 490, 497 (2d Cir. 2013) ("statement[s] . . . made as part of an ongoing scientific discourse about which there is considerable disagreement" are not actionable); *Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994) ("Scientific controversies must be settled by the methods of science rather than by the methods of litigation."); *Ludwig v. Superior Court*, 37 Cal. App. 4th 8, 21 (1995) ("Those who petition the government are generally immune from . . . liability.").[9] Furthermore, the evidence demonstrated that Monsanto would, and did, warn of risks associated with Roundup when those risks were known. Indeed, the Roundup label *does* warn about certain risks that are generally accepted in the scientific community. For example, Dr. Sawyer testified that "[g]lyphosate is well-known as an irritant *and even labeled as such*." 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.

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

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2. 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. In their Opposition to Monsanto's Motion for Nonsuit, Plaintiffs contend that "post-2012 evidence is on its face relevant to the continuing conscious disregard of GBHs' NHL risk." *See* Pls.' Opp. to Nonsuit at 2. However, this argument ignores well-established law on punitive damages. 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."). Indeed, "[p]unitive 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." *Medo v. Super. Ct.*, 205 Cal. App. 3d 64, 68 (1988).

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 (Reeves Dep. 458:15-18, 460:3-466:13), "orchestrate an outcry" to the IARC Monograph (Goldstein Dep. 129:14-133:15, 135:20-136:11), communicate with EPA employee Jess Rowland (Reeves Dep. 715:22-722:17), 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 future punitive damages are relevant in calculating the adequate amount of punitive

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damages. *Stevens v. Owens-Corning Fiberglas Corp.*, 49 Cal. App. 4th 1645, 1661 (1996) ("Punitive damages previously imposed for the same conduct are relevant in determining the amount of punitive damages required to sufficiently punish and deter. The likelihood of future punitive damage awards may also be considered, although it is entitled to considerably less weight." (citations omitted)).

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).

3. 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), and who "exercise[] substantial discretionary authority over significant aspects of a corporation's business." *White v. Ultramar, Inc.*, 21 Cal. 4th 563, 572, 577 (1999); *see also Kelly-Zurian v. Wohl Shoe Co.*, 22 Cal. App. 4th 397, 422 (1994) (supervisory employee is not a "managing agent" unless he or she also has authority to establish or change the company's business policies).

Plaintiffs provided no evidence that any of Monsanto's witnesses in this case were "managing agents." Nor did Plaintiffs prove that there was a specific company policy that 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 as to the safety protocols that Monsanto follows, and that the company has time and time again found the product to be safe.

F. 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 she or her insurer are likely to pay for that drug with admissible, competent evidence. *See S.C. Anderson, Inc. v. Bank of Am.*, 24

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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 the general 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. Based on her failure to make this showing, if JNOV is not granted on Plaintiffs' causes of action, then the judgment awarding Mrs. Pilliod $2,957,710 in future economic damages must be vacated.

G. Monsanto is Entitled to JNOV on All of Plaintiffs' Claims Because They Are Preempted By Federal Law (FIFRA).

1. Express Preemption

The Federal Insecticide, Fungicide, and Rodenticide Act ("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.

First, *Bates* makes clear that common law failure-to-warn claims "qualify as 'requirements for labeling or packaging'" as defined in § 136v(b). *Bates*, 544 U.S. at 446. Here, Plaintiffs' claims for negligence and strict liability failure to warn were based on purported deficiencies in Roundup's labeling. Thus, the first prong of the *Bates* test is satisfied. *Id.*; *see also Wilgus v. Hartz Mountain Corp.*, No. 3:12-CV-86, 2013 WL 653707, at *6 (N.D. Ind. Feb. 19, 2013) (expressly preempting claims of breach of implied warranty, strict product liability, and negligence based on an alleged failure to warn).

As for the second prong of the *Bates* test, 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),

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136a(c)(5)(D), California law requires warnings about all potential risks that are "reasonably foreseeable," CACI No. 1205; s*ee also Saller v. Crown Cork & Seal Co.*, 187 Cal. App. 4th 1220, 1230 n.7 (2010). Reasonably foreseeable uses encompass a much broader category of uses than just those that are "widespread and common[]." *See, e.g.*, *Bunch v. Hoffinger Indus., Inc.*, 123 Cal. App. 4th 1278, 1303 (2004) (applying California's reasonable foreseeability test, which requires a manufacturer to "anticipate" potential and hypothetical uses of its product when deciding on appropriate label). Accordingly, the second prong of the *Bates* test is also satisfied, and Plaintiffs' warnings-based claims are expressly preempted by FIFRA.

2. 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); s*ee also Whistler Invs., Inc. v. Depository Tr. & Clearing Corp.*, 539 F.3d 1159, 1166 (9th Cir. 2008). "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). Of particular relevance for this case, 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); *Pliva, Inc. v. Mensing*, 564 U.S. 604, 617-24 (2011); *Bartlett*, 570 U.S. at 480. Thus, "[i]f a private party . . . cannot comply with state law without first obtaining the approval of a 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); *see also Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 152-53, n.22 (2017).

Monsanto moved for summary judgment on this ground, arguing that Monsanto needed prior approval from EPA to make any label or design changes to Roundup, and that there is clear evidence that EPA would reject any design or label changes. In its order denying summary judgment, the Court found "that there are triable issues of material fact whether Monsanto is entitled to judgment on

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[its] impossibility defense" that there is "clear evidence" EPA would have rejected a label change adding a cancer warning to Roundup. Brown Decl. Ex. P, 3/18/2019 Order (citing *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 852 F.3d 268, 299 (3rd Cir. 2017)). Yet, the Court refused Monsanto's proposed jury instruction that would permit the jury to make that factual finding. Tr. 4767:25-4770:23 (rejecting Monsanto's proposed special instructions concerning EPA).

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.*; *see also Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 816 (7th Cir. 2018) ("As a matter of law, this is what [*Wyeth*] called 'clear evidence' that the FDA would have rejected the warning that plaintiff seeks under Illinois law.").

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 (EPA's 2016 Glyphosate Issue Paper and 2017 Revised Glyphosate Issue Paper), Monsanto's 4/4/2019 Supp. RJN, Exhibit 1 (EPA's 1993 Registration Eligibility Decision (RED) Glyphosate), Exhibit 5 (EPA's 2015 Cancer Assessment Review Committee), Exhibits 6-9 (federal register statements concerning glyphosate from 1999, 2002, 2008, and 2013). *See Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1169 (S.D. Cal. 2016) ("The FDA's repeated conclusion that scientific data did not support warning of pancreatic cancer risk coupled with the FDA's statement that product labeling was adequate amounts to clear evidence that the FDA would have rejected a pancreatic cancer labeling change."); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1276-77 (W.D. Okla. 2011) (the FDA's "repeated conclusions . . . that there was no scientific evidence to support a causal connection between [selective serotonin

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reuptake inhibitors] and suicidality in adult patients" constituted "clear evidence that the FDA would have rejected" an expanded warning for suicide). 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) (enjoining Proposition 65's warning requirement as to glyphosate on First Amendment grounds because such warning would be "misleading to the ordinary consumer"). It cannot comply with both federal and state law.

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 at pg. 35. EPA, however, identified ecological risk due to off-target spray that it is remedying by "proposing that herbicide resistance language be added to all glyphosate labels" and other "certain labeling clean-up/consistency efforts to bring all glyphosate labels up to modern standards." *Id.* EPA acted on its own to propose label changes to remedy ecological risks it identified during its registration review process, yet declared it "did not identify any human health risks from exposure to any use of glyphosate" and expressly repudiated IARC's glyphosate classification and public comments criticizing its 2016 and 2017 Draft Glyphosate Assessments. This is clear evidence that EPA has not, and would not, approve a label amendment to include a cancer warning; thus, Plaintiffs' warnings claims are preempted.[10]

IV. 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.

[10] 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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