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September 21, 2020

VIA TRUEFILING

The Honorable Tani Cantil-Sakauye,
Chief Justice of California
The Honorable Associate Justices
California Supreme Court
350 McAllister Street
San Francisco, California 94102-4783

Re: ***Johnson v. Monsanto Company***
Supreme Court Case No. S264158

Letter Supporting Petition for Review in *Johnson v. Monsanto Company* (1st Dist., Div. 1, July 20, 2020) Case Nos. A155940 & A156706

Dear Honorable Justices:

We represent Genentech, Inc. ("Genentech"). Under California Rules of Court, rule 8.500(g), Genentech submits this letter of support and respectfully requests that the Court grant review in the above-referenced matter.

This case provides the Court with the opportunity to ensure that verdicts in California are based on sound science. The Court should act on that opportunity. Following the Court's prior opinion in *Sargon Enterprises, Inc. v. Univ. of S. California*, 55 Cal. 4th 747 (2012), it should apply standards already developed by other courts to exclude unscientific expert testimony. And it should hold that punitive damages are inappropriate when, with no evidence of misconduct in the regulatory process, a competent regulatory agency has examined the same scientific theory at issue in a lawsuit, rejected it, and expressly approved a product as appropriate for sale.

I. Interest of Genentech

Genentech, a member of the Roche Group, is one of California's leading biotechnology companies. Founded in 1976, and based in South San Francisco, California, Genentech was the first "biotechnology" company. It developed the first recombinant therapeutic human proteins approved by the U.S. Food and Drug Administration (FDA) starting in the 1980s. Genentech is also a science company dedicated to pursuing revolutionary medical breakthroughs for the 21st Century.

In order to develop safe, innovative and effective products, Genentech must necessarily undertake significant commercial risks, involving substantial investments of time, resources, energy and scientific expertise. Genentech has invested literally tens of billions of dollars over

the past 43 years in the research and development of innovative products, and has discovered and introduced more than forty significant therapies for serious and life-threatening diseases. Further, it employs approximately 2,200 research employees. Last year alone, Genentech's scientists published more than 350 papers in leading peer-reviewed scientific journals, including *Nature*, *Science*, and *Cell*.

Genentech writes to highlight the importance of proper gatekeeping of scientific expert testimony for companies with scientifically innovative products. It is critically important for Genentech and other California-based companies to be able to contest unsupported scientific theories in cases involving use of scientifically developed products. It is also critically important to Genentech and other companies that use science to create innovative products that punitive damages not be permissible when a governing regulatory agency has expressly considered and rejected a scientific theory raised by a plaintiff in litigation. Otherwise, companies whose entire business models are geared towards creating innovative, scientific products face a prohibitive increase in their risk of liability. Many of these companies may be driven out of the market, or compelled to move their businesses away from California. That negatively impacts not only the progress of science, but also a significant portion of California's economy.

II. Following *Sargon*, The Court Can Adopt The Same Gatekeeping Standards That Other Courts Have Used To Exclude Non-Scientific Expert Testimony

In *Sargon*, the Court required California's trial courts to scrutinize proffered expert testimony. 55 Cal. 4th at 771-72 (holding that trial courts are "gatekeep[ers]," responsible for "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"). The Court specified that the trial court's focus as gatekeeper "must be solely on principles and methodology, not on the conclusions that they generate," quoting the Supreme Court's decision in *Daubert*. *Id.* at 772 (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 595 (1993)). The Court further clarified that "the gatekeeper's role 'is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field,'" referencing another Supreme Court decision. *Id.* (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

The Court should grant review of this case to affirm that *Sargon* brought California jurisprudence in line with that of many other courts, especially federal circuit courts, that have acted to uphold reasonable scientific standards for expert testimony. Indeed, cases from other jurisdictions provide useful exemplars of how the rigorous gatekeeping function can be used in cases—like this one—in which an expert can easily appear to use the "differential diagnosis" scientific method to make an unscientific showing of specific causation of harm to an individual plaintiff. While differential diagnosis is a recognized method, because it is a multi-factor test, its application can easily mask conclusions that are profoundly speculative, unscientific, and unreliable. *See* Victor E. Schwartz & Cary Silverman, *The Draining of Daubert and the Recidivism of Junk Science in Federal and State Courts*, 35 Hofstra L. Rev. 217, 250 (2006)

(providing that unless rigorously scrutinized, "expert witnesses can cross what is sometimes a fine line between differential diagnosis and pure guesswork" when ruling in or out potential causes); *see also Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010) (noting that differential diagnosis is not an "incantation that opens the *Daubert* gate"); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005) ("[A]n expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient.").

By granting review, the Court can help alleviate the potential of the litigation system to cause disastrous consequences based on misunderstanding of scientific evidence.

III. The Court Should Grant Review To Set The Relevant Standards Governing Punitive Damages In Highly Regulated Industries

In California, the standard for awarding punitive damages is very high: Plaintiffs must present clear and convincing evidence that the defendant has intentionally misrepresented or concealed information, engaged in despicable conduct, or consciously disregarded the safety of others. *See* Judicial Council of California Civil Jury Instructions ("CACI") 3945. Under these standards, companies that work closely with scientifically-based regulators who analyze products, data, and labels with a scientific lens generally should not be subject to punitive damages where the governing regulatory agencies have reviewed a company's product and concluded that the product does not pose a risk to human health after an extensive review. *See Johnson & Johnson Talcum Powder Cases*, 37 Cal. App. 5th 292, 335 (2019), *review denied* (Oct. 23, 2019) (holding that punitive damages are not warranted where the FDA has not found any conclusive causal link between the accused product and the human harm the product alleged caused and the statistical causal association "remains under scientific investigation").

As relevant to this case, the Environmental Protection Agency ("EPA"), a federal regulatory agency like the FDA, enforces requirements for pesticide products under the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"), which governs the distribution, sale, and use of pesticides. Regarding the herbicide glyphosate, the EPA reaffirmed on August 7, 2019 that its scientists have "concluded that glyphosate is 'not likely to be carcinogenic to humans,'" specifically noting that the agency "considered a more extensive dataset than [the International Agency for Research on Cancer ("IARC")], including studies submitted to support registration of glyphosate and studies identified by EPA in the open literature as part of a systematic review." EPA, Letter to Glyphosate Registrants (Aug. 7, 2019), https://www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf (last visited Nov. 15, 2019). Based on its finding that glyphosate is not likely to be carcinogenic, the EPA further mandated that Proposition 65 warning statements, which "inform Californians about significant exposures to chemicals that, under the terms of Proposition 65, are believed to cause cancer, birth defects or other reproductive harm," must "be removed from all product labels where the only basis for the warning is glyphosate" in order for such products to be in compliance with the requirements of FIFRA. *Id.* Further, since August

2019, the EPA "has thoroughly evaluated potential human health risk associated with exposure to glyphosate and [again] determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." EPA, Glyphosate Interim Registration Review Decision, Case No. 0178 (Jan. 22, 2020); *see also* EPA, Glyphosate Proposed Interim Registration Review Decision (April 23, 2019) (same). Under these factual circumstances, the punitive damages standard under applicable California law would not be met, at least absent a finding that a manufacturer selling products using glyphosate, such as Monsanto, had materially mislead the agency by intentionally providing it with false information or engaged in other seriously wrongful conduct, such as bribery or threats aimed subverting the integrity of the regulatory process. *See* Cal. Civ. Code § 3294.

It is difficult for science-based companies like Genentech to operate—much less innovate—if civil juries, on the basis of dubious expert testimony, can award not only damages, but *punitive* damages based on "malice," against a company whose scientific process has been fully vetted, analyzed, and approved by an appropriate government agency. Punitive damages are meant to deter against and punish intentionally wrongful conduct in exceptional cases—not to allow civil juries to second-guess an existing science-based and valid system for regulation of innovative enterprises. Accordingly, manufacturers that comply with regulatory standards without any misrepresentation to or concealment of material fact from the agency, after subjecting themselves to the detailed scrutiny of a regulatory agency, should not be liable for punitive damages.

Therefore, for all the reasons stated above, Genentech respectfully asks the Court to grant the Petition for Review in this case.

Respectfully submitted,

By: _____
Laura W. Brill
Attorney for Genentech, Inc.

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

At the time of service, I was over 18 years of age and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is 10100 Santa Monica Blvd., Suite 1725, Los Angeles, CA 90067.

On September 21, 2020, I served true copies of the following document(s) described as **GENENTECH, INC.'S AMICUS LETTER SUPPORTING PETITION FOR REVIEW IN JOHNSON V. MONSANTO COMPANY (1ST DIST., DIV. 1, JULY 20, 2020) CASE NOS. A155940 & A156706** on the interested parties in this action as follows:

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Case No. A155940 & A156706
Via TrueFiling

ELECTRONIC SERVICE: I electronically filed the document(s) with the Clerk of the Court by using the TrueFiling system. Participants in the case who are registered TrueFiling users will be served by the TrueFiling system. Participants in the case who are not registered TrueFiling users will be served by mail or by other means permitted by the court rules.

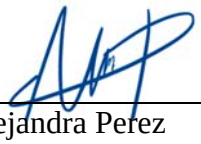
Honorable Suzanne Bolanos
San Francisco County Superior Court
400 McAllister Street
San Francisco, CA 94102

Trial Judge
Case No. CGC16550128
Via U.S. Mail

BY MAIL: I enclosed the document(s) in a sealed envelope addressed to each interested party at the address indicated above or on the attached service list. I placed each such envelope for collection and mailing, following our ordinary business practices. I am readily familiar with Kendall Brill & Kelly LLP's practice for collecting and processing correspondence for mailing. On the same day that the correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on September 21, 2020, at Los Angeles, California.



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