CASE NOS. A155940 & A156706

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA
FIRST APPELLATE DISTRICT
DIVISION ONE

Dewayne Lee Johnson

Plaintiff and Respondent/Cross-Appellant,

v.

Monsanto Company

Defendant and Appellant/Cross-Respondent.

BRIEF OF *AMICUS CURIAE* GENENTECH, INC. IN SUPPORT OF DEFENDANT AND APPELLANT

On Appeal From the Superior Court for the State of California,
County of San Francisco, Case No. CGC-16-550128,
Hon. Suzanne R. Bolanos

KENDALL BRILL & KELLY LLP
Laura W. Brill (195889)
lbrill@kbkfirm.com
Nicholas F. Daum (236155)
ndaum@kbkfirm.com
Sharon S. Song (313535)
ssong@kbkfirm.com
10100 Santa Monica Blvd., Suite 1725
Los Angeles, California 90067
Telephone: 310.556.2700
Facsimile: 310.556.2705

Attorneys for Amicus Curiae Genentech, Inc.

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STATEMENT OF INTEREST AND INTRODUCTION

Genentech, Inc. ("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 and pioneered the use of revolutionary antibodies to treat various types of cancer, such as positive breast cancer, Chronic Lymphocytic Leukemia, Rheumatoid Arthritis, colorectal cancer, glioblastoma, and ovarian cancer. More recently, Genentech received approval for the first antibody treatment for Hemophilia A.

Genentech is also a science company dedicated to pursuing revolutionary medical breakthroughs for the 21st Century. As of July 2019, it has 67 new investigational medicines and 69 additional indications for existing medicines in clinical development. As of July 2019, Genentech has received 26 Breakthrough Therapy Designations from the FDA. And its scientists have been granted over 20,000 patents.

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, including cancer, heart disease, stroke and pulmonary disease. Further, it employs approximately 2,200 research employees, including approximately 1,800 scientists and 110 post-doctoral researchers. 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 the proper screening of scientific expert testimony for companies with scientifically innovative products and consumers who rely on their innovations. 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.

Without proper gatekeeping of expert evidence and reasonable restrictions on punitive damages, companies, like Genentech, 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.

LEGAL ARGUMENT

A. When Courts Fail To Impose Proper Gatekeeping Standards For Expert Testimony, Product Liability Suits Can And Do Produce Destructive Outcomes, Divorced From Science, That Hurt The Public

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." *Sargon Enterprises, Inc. v. Univ. of S. California*, 55 Cal. 4th 747, 771-72 (2012) ("[T]he trial court acts as a gatekeeper"); *see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Proper gatekeeping standards "give[] the [trial] court the discretion needed to ensure that the

courtroom door remains closed to junk science while admitting reliable expert testimony that will assist the trier of fact." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002). This gatekeeping function is especially important because jurors, "[w]hen presented with scientific arguments in complex litigation, … may be more likely to rely on a variety of cognitive heuristics, including 'hindsight bias,'" which hinders their ability to evaluate the validity and reliability of expert testimony. Worthington et al., *Hindsight Bias, Daubert, and the Silicone Breast Implant Litigation: Making the Case for*, 8 Psychol. Pub. Pol'y & L. 154 (2002).

The need for gatekeeping standards is not a trivial problem. A failure to observe proper standards for gatekeeping can have damaging consequences that can cause harm to litigants, the public, and confidence in the fair administration of justice. Without any basis in science, useful products can be pulled from the market. Businesses can be destroyed. Millions upon millions of dollars in litigation costs and litigation payments can be incurred—all without any basis in fact. When this happens, respect for the judiciary's ability to resolve complex disputes can deteriorate. As the following examples demonstrate, without proper gatekeeping standards that empower courts to exclude improper expert opinion testimony, lawsuits founded on questionable scientific theories have the potential to significantly damage the manufacturers of and drive from the market innovative products that have not caused any harm to the plaintiffs who filed suit. More generally, if companies cannot rely upon scientifically-sound gatekeeping standards for expert testimony, then useful, safe, and scientifically innovative products will not be brought to market. Courts must ensure the proper use of science in the courtroom in order for innovation to flourish in the marketplace—and if courts fail to properly perform their gatekeeper responsibility, the consequences are

very significant indeed.

Vaccines. The mere threat of lawsuits that rely on junk science deters scientific innovation—companies, even if they have scientific evidence demonstrating their products are safe and effective, may not want to risk being held liable for multi-million dollar verdicts because of some junk science theory resting on unsupported speculation. The country's experience with vaccines is illustrative. Lawsuits in the late 1970s alleging that the whooping-cough component of the DPT vaccine caused permanent brain damage led nearly all of its manufacturers to cease production, resulting in nationwide shortages. *See* Willett, *Litigation as an Alternative to Regulation: Problems Created by Follow-in Lawsuits with Multiple Outcomes*, 18 Geo. J. Legal Ethics 1477, 1488 n.60 (2005); *see also Brown v. Superior Court*, 44 Cal. 3d 1049, 1064 (1988) ("One producer of diphtheria-tetanus-pertussis vaccine withdrew from the market, giving as its reason 'extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance.' There are only two manufacturers of the vaccine remaining in the market, and the cost of each dose rose a hundredfold from 11 cents in 1982 to $11.40 in 1986, $8 of which was for an insurance reserve.") (internal citations omitted).

Although the allegation that the DPT vaccine causes neurological harm was subsequently "discredited" by 1986, there was only one American manufacturer of the polio vaccine; one manufacturer of the measles, mumps, and rubella vaccine; and two manufacturers of the DPT vaccine remaining at that time. *See* H.R. Rep. No. 99-908, 2d. Sess. p. 7 (1986), reprinted in 1986 U.S. Code Cong. & Admin. News, p. 6344; Sugarman, *Cases in Vaccine Court – Legal Battles Over Vaccines and Autism*, 357 N. Eng. J. Med. 1275, 1276 (2007).

In order to stem "further exit from the market" for listed vaccines,

Congress passed the National Childhood Vaccine Injury Act of 1986, which removed many personal-injury cases involving vaccines from the state-law tort system. Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. Rev. 741, 760-61 (2003). Only after such Congressional action was there success in "stabilizing prices" in the vaccine market. *Id.* at 761.

Even today, however, vaccines continue to be a source of public fear and controversy despite the lack of scientific evidence supporting these anxieties. For example, the country has been swept up with concerns that thimerosal, a mercury containing compound used as a preservative in vaccines, causes autism even when there is no research that shows any link between thimerosal in vaccines and autism. *See* Centers for Disease Control and Prevention, *Information about Thimerosal*, https://www.cdc.gov/vaccinesafety/Concerns/Thimerosal/Index.html, last accessed July 18, 2019 ("Many well conducted studies have concluded that thimerosal in vaccines does not contribute to the development of autism."). The public concerns about thimerosal, and the fear that these concerns would lead to baseless but costly lawsuits, have caused thimerosal to be removed from almost all childhood vaccines.

On a broader scale, the public's baseless fear of vaccines has fueled the anti-vaccination movement, which the World Health Organization has identified as a "top-10 international public health problem." World Health Organization, *Ten threats to global health in 2019*, https://www.who.int/emergencies/ten-threats-to-global-health-in-2019 last accessed August 20, 2019 ("Vaccine hesitancy – the reluctance or refusal to vaccinate despite the availability of vaccines – threatens to reverse progress made in tackling vaccine-preventable diseases."). Other public health experts have characterized the anti-vaccination movement as a "man-made, dangerous, and

wholly unnecessary crisis." Medical Press, *Anti-vaccine movement a 'man-made' health crisis scientists warn*, https://medicalxpress.com/news/2019-07-anti-vaccine-movement-man-made-health-crisis.html, published July 3, 2019, last accessed August 20, 2019.

Bendectin. In October 1979, the National Enquirer published a story linking Bendectin, a popular morning sickness drug, with birth defects. *See* Michael D. Green, *Benedictin and Birth Defects: The Challenges of Mass Toxic Substances Litigation* (U. Penn Press 1996). After similar media reports, "suddenly thousands of claims had been filed" alleging that Bendectin caused birth defects in plaintiffs' children when it was ingested by the plaintiffs during pregnancy. *Id.* The first Bendectin case was filed in June 1977 and went to trial in 1980; thereafter, almost 1700 suits were filed and twenty-seven of these cases went to trial in the United States, of which twenty-five were tried to a jury. *See* Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 Stan. L. Rev. 1, 5 (1993).

False scientific theories drove the Bendectin litigation. *Id.* at 9 ("The FDA has been joined by its Canadian counterpart in concluding that there is no demonstrated association between Bendectin and birth defects."); Dennis P. Hays, *Bendectin: A Case of Mourning Sickness*, 17 Drug Intelligence Pharmacy 826, 927 (1983) ("The drug regulatory agencies of the U.S., the United Kingdom, Australia, Switzerland, and Germany have evaluated the data independently and found no evidence that Bendectin is teratogenic.") Indeed, even in 1980, the Food and Drug Administration ("FDA") had concluded that "available data do not demonstrate an association between birth defects and Bendectin." Sanders, *supra* at 7.

But the flurry of lawsuits caused Bendectin to be withdrawn from the market in 1983, *id.*, and ultimately prompted the U.S. Supreme Court's

landmark decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 (1993) (holding that trial courts must determine via "a preliminary assessment [] whether the reasoning or methodology underlying the [expert] testimony is scientifically valid and [] whether that reasoning or methodology properly can be applied to the facts in issue). After the litigation was over, it became clear in the scientific community that Benedictin did not cause the birth defects claimed. Sanders, *supra* at 9; Hays, *supra* at 927. Nonetheless, at that point it was too late—hhad been withdrawn from the market, and it did not return until 30 years later under a different trademark name.

Norplant. Norplant was an innovative contraceptive device that was introduced to female consumers in the United States "in January 1991 after FDA approval in 1990." Anna Birenbaum, *Shielding the Masses: How Litigation Changed the Face of Birth Control*, 10 S. Cal. Rev. L. & Women's Stud. 411, 418 (2001). Before being released onto the market, Norplant had undergone twenty years of testing, *id.* at 411, and it provided a comprehensive list of warnings and "potential side effects in its marketing campaign." Eric Lindenfeld, *The Unintended Pregnancy Crisis: A No-Fault Fix*, 17 Marq. Benefits & Soc. Welfare L. Rev. 285, 298 (2016). And soon after its release, Norplant became one of the most popular contraceptives in the world. *Id.* at 297.

But soon thereafter, "thousands of lawsuits were filed on behalf of plaintiffs alleging injury" resulting from the use of Norplant. Birenbaum, *supra* at 412. The claimants complained of "the now-discredited shifting constellation of symptoms … [of] an ill-defined array of autoimmune disorders." Lindenfeld, *supra* at 298. By 1995, "as many as 50,000 women [had] alleged serious personal injury lawsuits against the manufacturer." *Id.* As a result of the overwhelming litigation, which caused sales of the Norplant

device to plummet, the manufacturer of Norplant decided to permanently withdraw the product from the U.S. market in 2002. *Id.* at 298-99; *see also* Shari Roan, *Maker of Norplant Decides to Take Product Off Market*, Los Angeles Times, published Aug. 5, 2002, https://www.latimes.com/archives/la-xpm-2002-aug-05-he-norplant5-story.html, last accessed August 12, 2019.

The lawsuits against Norplant were founded on completely meritless scientific theories. Even while the number of lawsuits against the Norplant manufacturers were growing, "the FDA, the World Health Organization and the American Society for Reproductive Medicine [had] continued to support the product as a safe and effective method of birth control." Birenbaum, *supra* at 430-31. But the "Norplant device was simply unable to recover from the negative publicity" and the "tumultuous decade of litigation." Lindenfeld, *supra* at 299. Tragically, since its permanent withdrawal from the U.S. market, "Norplant has since been shown to be one of the most highly efficacious contraceptives ever marketed, with failure rates just under one-percent." *Id.*

B. Under *Sargon,* This Court Can And Must Adopt The Same Gatekeeping Standards That Other Courts Have Used To Exclude Non-Scientific Expert Testimony

a. Sargon *Requires California Courts To Act As Gatekeepers To Exclude Unscientific Expert Testimony*

In *Sargon*, the California Supreme Court required California's trial courts to scrutinize proffered expert testimony:

> [U]nder Evidence Code sections 801, subdivision (b), and 802, **the trial court acts as a gatekeeper** to exclude expert opinion testimony that is (1) based on matter of a type on which an expert may not reasonably rely, (2) based on reasons unsupported by the material on which the expert relies, or 3) speculative. Other provisions of law, including decisional law, may also provide reasons for excluding expert opinion testimony.

Sargon, 55 Cal. 4th at 771–72 (emphasis added).

Sargon focused on ensuring not only that an expert has relied on (in general) a "methodology" that might sometimes be appropriate, but whether the methodology was applied appropriately to produce reliable conclusions in any particular case. As the Court held, a court must inquire into not only the type of material on which an expert relies, but also whether that material actually supports the expert's reasoning. *Id.* at 772. "A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id.* at 771. If, the Supreme Court emphasized, the "reasons" for an expert opinion are unsound or "speculative," it must be excluded. *Id.* at 770-71. Put simply, the trial court can – and must – determine whether the "matter relied on can provide a reasonable basis for the opinion or whether that opinion is based on a leap of logic or conjecture." *Id.*

Moreover, the Court in *Sargon* 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*, 509 U.S. at 595). 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)).

b. Because Of Sargon*, California Courts Can Follow The Lead Of Courts In Other Jurisdictions That Have Acted To Exclude Unscientific Expert Testimony*

Because it focuses squarely on the trial court's gatekeeping function and excluding unsound and speculative expert testimony, *Sargon* brings 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.

Cases from other jurisdictions provide useful exemplars of how courts should uphold scientific standards in admitting expert testimony. The approach of these courts should now, under *Sargon*, be adopted in California. Indeed, courts from other jurisdictions recognize—like the California Supreme Court did in *Sargon*—that, "[i]n deciding whether a step in an expert's analysis is unreliable," trial courts must "undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002). Accordingly, trial courts acting as gatekeepers "may, indeed must, look beyond the conclusions of the experts to determine whether the expert testimony rests on a reliable foundation." *Kalamazoo River Study Group v. Rockwell Int'l Corp.*, 171 F.3d 1065, 1072 (6th Cir. 1999) (alterations omitted).

Federal courts applying standards similar to *Sargon* recognize that "when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached," the opinion must be excluded. *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 255 (2d Cir. 2005). Thus, litigants are assured that "expert testimony based on assumptions lacking factual foundation in the record [will be] properly excluded." *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 790 (3d Cir. 2009); *see also Davison ex rel. Davison v. Cole Sewell Corp.*, 231 F. App'x 444, 450 (6th Cir. 2007) (affirming exclusion of expert testimony because it "was not supported by an adequate factual foundation, but rather was based solely upon conjecture and speculation"); *Elcock v. Kmart*, 233 F.3d 734, 754 (3d Cir. 2000) ("expert's testimony … must be accompanied by a sufficient factual foundation

before it can be submitted to the jury").

Courts from other jurisdictions have recognized that this rigorous gatekeeping function is particularly appropriate in cases—like this one—in which experts 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.

"A differential diagnosis seeks to identify the disease causing a patient's symptoms by ruling in all possible diseases and ruling out alternative diseases until (if all goes well) one arrives at the most likely cause." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010). Like other scientific tests, a proper differential diagnosis involves careful scientific judgment, and 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 as part of their analysis. 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). Thus, this methodology provides expert witnesses ample means to mask the precise sort of speculative, results-oriented causation opinions that *Sargon* is intended to exclude.

In *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010), the Sixth Circuit carefully examined a doctor's "differential diagnosis" that claimed to establish that manganese caused Parkinson's disease in a patient. The *Tamraz* court noted that the plaintiff's expert's speculation was based on a general belief that some toxins, combined with genetics, may cause Parkinson's disease. The Sixth Circuit correctly concluded that the causation

analysis was no more than a "hypothesis" about what caused the disease, and thus not admissible expert testimony. Even though the expert at issue in that case (a respected medical doctor) claimed to be providing a "differential diagnosis," the Sixth Circuit carefully examined that differential diagnosis and concluded that, on the facts there, the diagnosis rested on speculation. *Tamraz*, 620 F.3d at 674 (noting that differential diagnosis is not an "'incantation that opens the *Daubert* gate.'") (citations omitted); *see also*, e.*g., 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.").

Beyond "differential diagnosis," many courts have rejected misuse of other flexible, easily-manipulated methods of showing epidemiological causation. In *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 795 (3d Cir. 2017), the Third Circuit emphasized that "[f]lexible methodologies" used to prove causation can be implemented in multiple ways, even when they are "generally reliable" techniques in the abstract. 858 F.3d at 795. As a result, a district court's gate-keeping responsibility requires the court to ensure that a method employed by an expert "is truly a methodology, rather than a mere conclusion-oriented selection process" by scrutinizing the expert's "specific techniques" and requiring experts applying these methodologies to "explain 1) how conclusions are drawn for each … criterion [identified] and 2) how the criteria are weighed relative to one another." *Id.* at 796 (citation omitted). The *Zoloft* court ultimately affirmed the exclusion of an expert whose analysis relied on, *inter alia*, a "conclusion-driven" re-analysis of past studies, unreliable "ad hoc adjustments" to epidemiological data, and an inconsistent consideration of statistically insignificant study results. *Id.* at

798-800. *See also Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 514 (W.D. Pa. 2003) (excluding expert witnesses whose "efforts to apply the … principles to the available evidence" were "not scientifically reliable" and granting summary judgment for defendant); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 604 (D.N.J. 2002) (excluding causation opinion where the expert "did not adequately explain his methods for assessing the[ir] internal validity").

More generally, courts in other jurisdictions have applied *Sargon*-like standards to exclude unreliable evidence. In *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 265-270 (2d Cir. 2002), for example, the Second Circuit affirmed a trial court order excluding expert testimony offered to show a causal link between the plaintiff's exposure to workplace toxins and his injuries. In that case, one expert "fail[ed] to apply his stated methodology reliably to the facts of the case" by omitting significant variables from his analysis. *Id.* at 268-269 (internal quotation marks omitted). Another expert's testimony was unreliable and inadmissible because "the analytical gap between the studies on which she relied and her conclusions was simply too great." *Id.* at 270. In *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194 (11th Cir. 2002), the court excluded general causation expert testimony that improperly relied on animal studies, case reports, chemical analogies and regulatory findings. Likewise, in *Glastetter v. Novartis Pharmaceuticals Corp.*, 252 F.3d 986, 989 (8th Cir. 2001), the court rejected general causation experts' "reli[ance] on various types of scientific data - published case reports; medical treatises; human rechallenge/ dechallenge data; animal studies; internal [company] documents; and the FDA's [regulatory findings regarding the drug]" explaining that "this data does not demonstrate to an acceptable degree of medical certainty" that the drug at issue caused strokes.

Sargon permits—indeed, requires—this Court to apply similar standards in reviewing the expert evidence admitted in this case. *See Sargon*, 55 Cal. 4th at 772 ("In short, 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 which characterizes the practices of an expert in the relevant field.'") (quoting *Kumho*, 526 U.S. at 152). By doing so, this Court can help alleviate the potential of the litigation system to cause disastrous consequences based on misunderstanding of scientific evidence.

C. Under California Law, Punitive Damages Cannot Be Appropriate When (a) A Company Has Relied On Specific Regulatory Approval Of A Product's Safety and (b) There Is No Evidence Of Fraud On The Agency Or Any Other Misconduct Which Would Make Reliance On The Agency's Approval Unreasonable

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. More specifically, under Civil Code section 3294, punitive damages may be awarded in a products liability case only if the defendant is guilty of "oppression, fraud, or malice." *See Siva v. Gen. Tire & Rubber Co.*, 146 Cal. App. 3d 152, 158 (1983). The statute defines "malice" as "conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others"; "oppression" as "despicable conduct that subjects a person to cruel and unjust hardship in conscious disregard of that person's rights,"; and "fraud" as "an intentional misrepresentation, deceit, or concealment of a material fact

known to the defendant with the intention on the part of the defendant of thereby depriving a person of property or legal rights or otherwise causing injury." Cal. Civ. Code § 3294. Further, "[t]he imposition of 'grossly excessive or arbitrary' awards is constitutionally prohibited," and "due process entitles a tortfeasor to 'fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose.'" *Simon v. San Paolo U.S. Holding Co.*, 35 Cal. 4th 1159, 1171 (2005) (quoting *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416-17 (2003)).

Under these standards, companies that work closely with scientifically-based regulators who analyze products, data, and labels with a scientific lens 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, at least when, as here, there is no evidence that the companies have engaged in intentionally wrongful conduct directed at that regulatory review (i.e., misrepresentations, bribes, or other intentional misconduct aimed at subverting the regulatory process.) Actions taken with the express, reasonable, and valid approval of a scientifically-based regulator cannot reasonably constitute "despicable conduct" or "conscious disregard of the rights or safety of others." *See* W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 Stan. L. Rev. 547, 581 (2000) ("[R]egulatory compliance defense[s] against punitive damages should be adopted more generally."). 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.

Some states have already taken action to codify defenses against punitive damages for manufacturers who have obtained federal regulatory approval of their products. For example, many states, including Arizona, New Jersey, Ohio, Oregon, and Utah, have enacted statutes creating a defense to punitive damages if a drug manufacturer complies with the requirements imposed by the Food and Drug Administration ("FDA"), a federal regulatory agency. *See, e.g.*, Ariz. Rev. Stat. Ann. § 12-701 (West 1992) (providing that drug manufacturers are not liable for punitive damages if they complied with FDA regulations, so long as the defendant did not defraud FDA); N.J. Stat. Ann. § 2A:58C-5c (West 1987) (same); Ohio Rev. Code Ann. § 2307.801(c)(1)(a) (Anderson 1998) (same); OR. Rev. Stat. § 30.927 (1993) (same); Utah Code Ann. § 78-18-2(1) (1992) (same).

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. *See Chemical Enforcement*, https://www.epa.gov/enforcement/waste-chemical-and-cleanup-enforcement#chemical, assessed July 16, 2019. Under FIFRA, all pesticides sold in the United States must be registered with the EPA, and in the registration application, "manufacturers must submit draft label language addressing a number of different topics, including ingredients, directions for use, and any information of which they are aware regarding 'unreasonable adverse effects of the pesticide on man or the environment.'" *Etcheverry v. Tri-Ag Serv., Inc.*, 22 Cal. 4th 316, 321, 993 P.2d 366, 368 (2000) (citing 40 C.F.R.

§ 152.50 (1999)). Moreover, in order for a pesticide to be registered with the EPA, the EPA "must find that the pesticide, when used in accordance with its labeling, 'will perform its intended functions without unreasonable adverse effects on the environment.'" *Id.* (quoting § 136a(c)(5)(C)). "Unreasonable adverse effects on the environment" are defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* (quoting § 136(bb)). The EPA further verifies FIFRA compliance through a comprehensive FIFRA compliance monitoring program "which includes inspecting facilities, reviewing records and taking enforcement action where necessary." *See* Chemical Enforcement, https://www.epa.gov/enforcement/waste-chemical-and-cleanup-enforcement#chemical, assessed July 16, 2019.

Regarding the herbicide glyphosate, the EPA reaffirmed on April 30, 2019 that "EPA continues to find that there are no risks to public health when glyphosate is used in accordance with its current label and that glyphosate is not a carcinogen." EPA, *EPA Takes Next Steps in Review Process for Herbicide Glyphosate, Reaffirms No Risk to Public Health* (Apr. 30, 2019), https://www.epa.gov/newsreleases/epa-takes-next-step-review-process-herbicide-glyphosate-reaffirms-no-risk-public-health (last visited July 16, 2019). The EPA's "scientific findings on human health risk [of glyphosate] are consistent with the conclusions of science reviews by many other countries and other federal agencies." *Id.*; *see also* Andreotti et al., *Glyphosate Use and Cancer Incidence in the Agricultural Health Study*, JNCI: J. of Nat'l Cancer Institute, 110(5): 509-516 (May 2018) (finding that the Agricultural Health Study shows no non-Hodgkin's lymphoma risk from glyphosate use). Under these circumstances, the punitive damages standard under California law would not be met absent a finding by the EPA that a manufacturer selling

products using glyphosate, such as Monsanto, had engaged in misrepresentation or intentionally wrongful interference with the regulatory process described above. *See* Cal. Civ. Code § 3294.

Allowing juries to award punitive damages for products that have been specifically examined and approved by regulatory agencies creates a large risk of confusion for life-science-based companies and may deter the progress of science. If such punitive damages awards are allowed, companies face the risk of massive punitive damages awards unless they routinely second guess the safety decisions of regulators. Accordingly, manufacturers who comply with regulatory standards without any misrepresentation or concealment of material fact, after subjecting themselves to the detailed scrutiny of a regulatory agency, should not be liable for punitive damages.

CONCLUSION

This case provides the Court with an opportunity to ensure that verdicts in California are based on sound science. The Court should act on that opportunity. Under *Sargon*, it should apply standards already developed by other courts to exclude speculative and 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.

Respectfully submitted,

DATED: August 30, 2019

KENDALL BRILL & KELLY LLP

By: */s/ Laura W. Brill*
Laura W. Brill
Attorneys for Amicus Curiae
Genentech, Inc.

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 8.204(c) of the California Rules of Court, I hereby certify that this brief contains 5,162 words, including footnotes. In making this certification, I have relied on the word count of the Microsoft Word computer program used to prepare the brief.

Respectfully submitted,

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KENDALL BRILL & KELLY LLP

By: */s/ Laura W. Brill*
Laura W. Brill
Attorneys for Amicus Curiae
Genentech, Inc.