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.

APPLICATION OF GENENTECH, INC. TO FILE BRIEF AS *AMICUS CURIAE* 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

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Attorneys for Amicus Curiae Genentech, Inc.

Genentech, Inc. ("Genentech") respectfully requests permission to file the accompanying *amicus curiae* brief in support of Defendant and Appellant, pursuant to rule 8.520(f) of the California Rules of Court.

A. Background of *Amicus*

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 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*.

B. Interest of *Amicus*

This case raises important issues regarding the screening by courts of scientific expert testimony. 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 to be able to contest unsupported scientific theories in cases involving use of scientifically-developed products. Without proper gatekeeping of expert evidence, companies, like Genentech, whose entire business models are geared towards

creating innovative, scientific products face a prohibitive increase in their risk of liability.

This case also raises an important issue regarding the availability of punitive damages—specifically, whether punitive damages are available based merely on alleged "malice" in the sale of a product to the public, when the governing science-based regulatory agency has conducted a full and fair review of precisely the scientific theory raised by the plaintiff in a lawsuit, rejected that theory, and approved the product at issue as safe. This issue regarding punitive damages is also critically important to Genentech and other companies that use science and work with regulators and regulatory agencies to create innovative products.

C. Need For Further Briefing

Genentech is familiar with the issues before the court and the scope of their presentation. Genentech believes that further briefing is necessary to provide detailed discussion of certain issues that the parties did not have the opportunity to address fully.

Specifically, Genentech will explain (a) how, absent proper gatekeeping standards for expert opinions, product-liability lawsuits can and routinely do produce deeply harmful outcomes not based on science; (b) how, under the California Supreme Court's decision in *Sargon Enterprises, Inc. v. Univ. of S. California*, 55 Cal. 4th 747, 771-72 (2012), this Court both can and must

follow the lead of courts in other jurisdictions that have acted to exclude unscientific expert testimony; (c) how, under California law, punitive damages cannot be appropriate when (i) a company has obtained specific regulatory approval of a product's safety and (ii) there is no evidence of fraud on the agency or other misconduct which would make reliance on the agency's approval unreasonable.

D. CRC 8.200(c)(3) Statement

No party other than the proposed *amicus curiae* made a monetary contribution intended to fund the preparation or submission of this *amicus* brief.

Dated: August 30, 2019 KENDALL BRILL & KELLY LLP

By: /s/ Laura W. Brill
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