American Council on Education
General Counsel

April 11, 2011

By United Parcel Service

Hon. Chief Justice Tani Cantil-Sakauye and Associate Justices
California Supreme Court
350 McAllister Street
Room 1295
San Francisco, California 94102-4797

Re: Sargon Enterprises, Inc. v. University of Southern California
(Case No. S191550)

Dear Chief Justice Cantil-Sakauye and Associate Justices:

On behalf of the American Council on Education ("ACE") and the other undersigned organizations, and in accordance with California Rule of Court 8.500(g), we respectfully urge the Court to grant the petition for review pending in *Sargon Enterprises v. University of Southern California* (Mar. 18, 2011, B202789 and B205034). The Court of Appeal's decision—curtailing trial court discretion to exclude highly speculative expert testimony on alleged profits lost when a university breached a non-commercial academic research agreement—is against the public interest. The ruling would jeopardize the integrity of academic research, deter the conduct of vital research, and substantially divert essential university resources. The Court should grant review to reaffirm that trial judges retain the discretion to exclude unreliable expert testimony and to clarify the applicable standard.

By requiring trial courts to admit speculative and unreliable expert testimony on supposed lost profits, the Court of Appeal's decision would facilitate exorbitant damages claims against non-profit research organizations by start-up companies claiming to be the next market leader in their industry. Hundreds of start-up companies enter into clinical trial agreements with universities, but only a tiny fraction of these go on to match the profits of industry leaders. Exaggerated lost profit damages claims would divert university resources from the institutions' core missions and discourage universities from conducting industry-sponsored research, to the detriment of society.

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Interest of amici curiae

ACE, a non-profit national educational association founded in 1918, represents all sectors of American higher education. Its membership of nearly 1800 institutions includes a substantial majority of the nation's colleges and universities. As a leading participant in higher education affairs, ACE's purpose is to further the goals of higher education including the interests of all members of the academic community—students, faculty, administration, and the institutions themselves. ACE's initiatives address issues of national importance, including the responsiveness of colleges and universities to the nation's needs. The Association of Public and Land-Grant Universities ("APLU") represents 189 public universities and land-grant institutions from all 50 states. APLU supports high-quality public higher education and serves its member institutions as they perform their traditional teaching, research, and public service roles. The Association of American Universities ("AAU"), which was founded in 1900, represents 63 public and private major research universities. AAU focuses on issues that are important to research-intensive universities, such as funding for research, research policy issues, and graduate and undergraduate education. The California Institute of Technology and the Board of Trustees of the Leland Stanford Junior University are two of the leading research universities of the world.

The *Sargon* case

Sargon Enterprises, Inc. ("Sargon"), a start-up company that has rights to a dental implant technology, sponsored for $200,000 a modest clinical trial of the implant at the University of Southern California ("USC"). Sargon soon become disenchanted with its relationship with USC. It sued USC for up to $1.1 billion in supposed lost profits.

In support of the lost profits claim, Sargon proffered the expert testimony of an attorney-accountant, who estimated that Sargon would have achieved commercial success comparable to the six largest dental implant companies in the world but for USC's alleged breach. The trial court properly excluded the testimony, reasoning that the expert's figures were "wildly beyond, by degrees of magnitude, anything Sargon has ever experienced in the past," and that the projections of future growth unrealistically assumed that Sargon "would have made the seamless transition from a three-person operation to sharing industry leadership with Nobel Biocare, a multi-million dollar international corporation." A divided panel of the Court of Appeal reversed, concluding that the trial court abused its discretion in excluding the testimony.

ACE and other associations submitted a letter to this Court in support of USC's petition for review of a prior Court of Appeal judgment in this case. (See American Council on Education et al., Letter in Support of Petition for Review in Case Nos. S132871 and S132872 (April 27, 2005).) Our letter noted profoundly negative policy implications of the Court of Appeal's unprecedented decision to permit a lost-profit damages claim to go forward in the context of an academic research agreement. This Court denied the petition for review. The

Court of Appeal's instant decision compounds the earlier error by stripping the trial court of its gatekeeper authority with respect to unreliable evidence about lost profits.

The view of amici curiae

California and the nation benefit tremendously from academic research. University-industry relationships foster scientific innovation and enhance public access to pathbreaking medical and other research advances. USC scientists collaborating with industry have made breakthroughs, for example, in measurement and control of chemical processes that aid pharmaceutical and other product testing and in the development of an innovative moldable bone material used in craniofacial reconstructive surgery. (See Office of Intellectual Property, University of Southern California, Success Stories, http://ip.research.sc.edu/success_stories.shtml.) The fruits of such academic-industry partnerships spur economic growth. "Approximately $30 billion of economic activity each year, supporting 250,000 jobs, can be attributed to the commercialization of new technologies from academic institutions." (Council on Governmental Relations, The Bayh-Dole Act: A Guide to the Law and Implementing Regulations (Oct. 1999) p. 9.) These relationships are crucial to the vitality of California's economy. (See ICF Consulting, California's Future: It Starts Here: UC's Contributions to Economic Growth, Health, and Culture (Mar. 2003) p. 4-9 ["Productivity gains derived through UC research will contribute an estimated $5.2 billion to the growth in Gross State Product and create more than 104,000 new jobs between 2002 and 2011."].) The Court of Appeal's decision threatens to jeopardize the benefits of university-industry collaboration.

Under the Evidence Code, an expert's opinion must be "[b]ased on matter . . . that is of a type that reasonably may be relied upon by an expert in forming an opinion upon the subject to which his testimony relates." (Evid. Code, § 801, subd. (b).) The rule confides to the trial judge a crucial gatekeeping function. He or she must screen unreliable expert testimony from the jury's consideration, determining whether the underlying methodology is based in science and logic. The trial court has "wide discretion to exclude expert testimony . . . that is unreliable." (*People v. McWhorter* (2009) 47 Cal.4th 318, 362.)

The expert testimony at issue in *Sargon* vividly illustrates the dangers of curtailing this judicial gatekeeping function. The expert would have invited the jury to predict Sargon's future lost profits by comparing Sargon—a company with fewer than twenty employees and around $100,000 in annual profits—to the six most successful dental implant companies in the world. The Court of Appeal summarized the expert's methodology as follows:

> [The expert] would have opined that had USC not breached its contract, Sargon would have obtained a market share comparable to a handful of the world's leading dental implant companies. Using this analysis, the jury would have compared Sargon with companies having a market share of 4.8 percent, 7 percent, 17 percent, and 22–23 percent, with profits from $220 million on the low end to $1.1 billion on the high end. The jury would have been asked to select the

> company most comparable to Sargon and award the corresponding amount for lost profits.

(Typed Opn. 28–29.)

That flawed approach reflects the inherent unreliability and speculative nature of any attempt to predict lost profits supposedly resulting from the breach of an academic research agreement. Of the hundreds of companies that enter into clinical research agreements with universities, the number that go on to replicate the commercial successes of industry leaders is small. Among the new drugs and medical devices that are approved each year by the Food and Drug Administration only a tiny fraction become "blockbuster" products. To ask a jury to predict, based on comparison to industry success stories, the future profitability of a technology start-up company is to invite a grossly inflated probability judgment.

If trial judges are not permitted to screen out baseless expert theories of that sort, clinical research agreements will become "ticket[s] in a litigation lottery." (*Moore v. Regents of the Univ. of Cal.* (1990) 51 Cal.3d 120, 146.) Start-up companies would be encouraged to circumvent the long and uncertain process of developing and marketing a product, resting instead on bare claims that they would have been the next Google or Amgen if the sponsored research had turned out as they had hoped. Trial judges must have the freedom to separate speculation from scientifically rooted expert opinion.

Disregard for the trial court's gatekeeper function is especially harmful in the context of research agreements, where predictions about profits a company supposedly would have made are inherently unreliable. Clinical trial agreements and other research sponsorship arrangements are unlike commercial contracts in which a particular result is promised. Until a clinical trial has been conducted, its results are uncertain. Whether a study will turn out favorably or unfavorably for a corporate sponsor, much less whether the findings will lead to a measurable increase in profits, is unknown. As a Nobel laureate observed, "research is risky: if you knew the outcome, it would not really be research. There is an inherent uncertainty about research." (Joseph P. Stiglitz, *Economic Foundations of Intellectual Property Rights* (2008) 57 Duke L. J. 1693, 1712.) Indeed, it is precisely because the results are not foreordained, and a favorable outcome is thus perceived as credible, that companies sponsor clinical trials conducted by unbiased academic researchers. Translating those uncertainties into reasonable predictions of a company's future success is a delicate task that calls for careful consideration of the underlying probabilities.

If trial judges were improperly stripped of their discretion to scrutinize and screen out unreliable predictions of future success, the fruitful partnership between industry and academia would be destabilized. The prospect of enormous lost profit claims, driven by baseless expert testimony, would tend to undermine the integrity and independence that are vital to the academic research enterprise. It would impose on institutions and researchers an unseemly and hazardous incentive—or at least the appearance of such an incentive—to ensure sponsor satisfaction, even

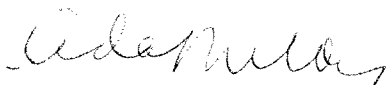
when doing so entails unsound or improper research conduct. Researchers would be seen as more likely to take steps to ensure favorable results or to marginalize adverse research events, for fear that a sponsor dissatisfied with research outcomes will sue and claim lost profits. Such influences inevitably would compromise public trust in the research enterprise.

The threat of seeing speculative lost-profits evidence submitted to a jury would also deter institutions from engaging in clinical research that is vital to the nation's scientific needs. Faced with "the whip of a giant 'lost future profits' award," (*Postal Instant Press, Inc. v. Sealy* (1996) 43 Cal.App.4th 1704, 1718), research institutions may conclude that they must reduce significantly, or even eliminate altogether, research activity sponsored by industry. Such an outcome would impede research and its benefits to public health and well-being and would weaken California's economy.

Finally, wildly exaggerated damages based on speculative profitability projections would drain limited institutional resources. As federal and state budgets have tightened, academic institutions, which generally charge sponsors modest amounts to conduct clinical research, have had to perform research with ever more carefully husbanded resources. Fueled by unreliable testimony, lost-profit liability under research agreements would divert resources from core academic missions—teaching, research, and public service—to for-profit business ventures.

For these reasons, we submit that the Court of Appeal's ruling should not stand. We urge this Court to grant review to reaffirm that trial judges retain "wide discretion" to exclude unreliable expert testimony and to clarify the applicable standard.

Sincerely,



Ada Meloy
General Counsel
American Council on Education

Association of American Universities
Association of Public and Land-Grant Universities
Board of Trustees of the Leland Stanford Junior University
California Institute of Technology

PROOF OF SERVICE

Re: Case Number S191550
Sargon Enterprises, Inc. v. University of Southern California

I hereby declare that I am a citizen of the United States, am over 18 years of age, and am not a party in the above-entitled action. I am employed in Washington, D.C., and my business address is Hogan Lovells US LLP, 555 Thirteenth Street, NW, Washington, D.C. 20004.

On **April 11, 2011**, I served the attached document described as **AMICI CURIAE LETTER** on the interested parties in this action as follows:

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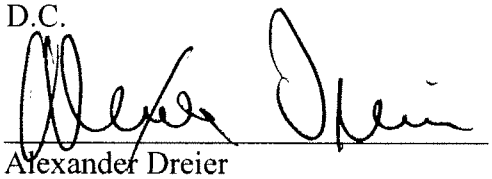
BY MAIL. I am readily familiar with the practices of Hogan Lovells US LLP for collecting and processing correspondence for mailing with the United States Postal Service. Under that practice, it would be deposited with the United States Postal Service on that same day at Washington, D.C., in the ordinary course of business. I enclosed the foregoing in sealed envelopes addressed as shown above, and such envelopes were placed for collection and mailing

with postage thereon fully prepaid at Washington, D.C., on that same day following the ordinary course of business.

BY E-MAIL. I caused said documents to be transmitted by electronic mail to the following e-mail address(es): abrowne@bwgfirm.com; egeorge@bwgfirm.com; johnquinn@quinnemanuel.com; michaelwilliams@quinnemanuel.com; michaellifrak@quinnemanuel.com; kathleensullivan@quinnemanuel.com; danbromberg@quinnemanuel.com; kbendell@usc.edu.

I, Alexander Dreier, declare under penalty of perjury that the foregoing is true and correct.

Executed on **April 11, 2011**, at Washington, D.C.



Alexander Dreier