

No. 10-290

IN THE
Supreme Court of the United States

MICROSOFT CORPORATION

Petitioner,

v.

141 LIMITED PARTNERSHIP AND
INFRASTRUCTURES FOR INFORMATION INC.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE FEDERAL CIRCUIT

**UNIVERSITY PATENT OWNERS AND LICENSEES
AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS**

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**STATEMENT OF INTEREST
OF THE *AMICI CURIAE*¹**

This brief is submitted by a collection of diverse university patent owners and licensees, which includes:

- Arizona State University's Arizona Science and Technology Enterprises LLC
- Emory University
- The Regents of the University of California
- Rensselaer Polytechnic Institute
- Temple University
- The University of New Mexico
- The University of Utah
- The University of Utah Research Foundation
- Wisconsin Alumni Research Foundation
- Research Corporation Technologies

1. Pursuant to this Court's Rule 37.6, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Additionally, counsel for both parties have consented to the filing of this brief, and their consents have been filed with the Clerk of this Court.

as *amicus curiae* in support of the Respondent to urge the Court to uphold the “clear and convincing” evidentiary standard for proving the facts underlying an invalidity defense, as firmly established by the common law of the United States and this Court for well over a century, and to respectfully request that the Federal Circuit be affirmed.

Arizona State University’s Arizona Science and Technology Enterprises LLC (“AzTE”) was established in 2003 as an Arizona Limited Liability company with the Arizona State University Foundation as its sole member. Under agreements with Arizona State University (“ASU”), AzTE operates as the exclusive intellectual property management and technology transfer organization for ASU. Among U.S. institutions with at least \$200 million in research expenditures, AzTE ranks in the top ten in invention disclosures, licenses and options, and startups, per \$10 million in research. AzTE has no financial interest in any of the parties to the current action.

Emory University (“Emory”), a top twenty research university, is an inquiry-driven, ethically engaged and diverse community whose members work collaboratively for positive transformation in the world through leadership in teaching, research, scholarship, health care and social action. Emory generates substantial research funding that contributes directly to the public good. For example, Emory is a leader in HIV research. More than nine in ten HIV patients in the United States who are on lifesaving therapy take Emtriva (emtricitabine) or 3TC (lamivudine), both of which were created at Emory. The Emory Vaccine Center and the Yerkes National Primate Research Center One developed one of the leading vaccine candidates against HIV. Emory has no financial interest in any of the parties to the current action.

The University of California (“UC”) is a public university that educates students from undergraduate levels to the most advanced graduate levels, with a stated commitment to education, research and public service. The Regents of the University of California (“Regents”) is a board that governs the UC system, which includes ten university campuses, three national laboratories that UC participates in managing, and five teaching medical centers. Several of the UC campuses as well as the Office of the President have technology transfer offices, which license UC-developed inventions and implement UC’s policy and obligation to develop and ensure broad utilization of federally-funded and other UC technology so that the benefits can be enjoyed by the citizens of California and the national general public. Regents has no financial interest in any of the parties to the current action.

Rensselaer Polytechnic Institute (“Rensselaer”) is the nation’s oldest technological university. The university offers degrees from five schools: Engineering; Science; Architecture; Humanities, Arts, and Social Sciences; and the Lally School of Management & Technology; as well as an interdisciplinary degree in Information Technology. For almost two centuries, Rensselaer has maintained its reputation for providing an undergraduate education of undisputed intellectual rigor based on educational innovation in the laboratory, classroom, and studio. Driven by talented, dedicated, and forward-thinking faculty, Rensselaer has dramatically expanded the research enterprise by leveraging their existing strengths and focusing on five signature research areas: biotechnology; computation and information technology; experimental media and the arts; energy and the environment; and

nanotechnology. Rensselaer is especially well-known for its success in the transfer of technology from the laboratory to the marketplace so that new discoveries and inventions benefit human life, protect the environment, and strengthen economic development.

Temple University (“Temple”) is a comprehensive public research university with 17 schools and colleges and 39,000 students. Temple is the 28th largest university in the United States and the nation’s fifth largest provider of professional education, including law, dentistry, medicine, pharmacy, and podiatric medicine. With more than \$90 million in external funding to support advanced research by its scholars, scientists and students, Temple actively seeks patent protection to attract the investment necessary to commercialize new discoveries. Temple discoveries in the marketplace include sustained drug delivery technology for nutraceuticals and pharmaceuticals, diagnostic tests for chronic fatigue syndrome, instruments for the diagnosis and treatment of tooth decay, and pheromone attractant technology for pest control. Products in the pipeline include treatments for ocular disorders, diagnostics and therapeutics for cancer, devices to increase fuel economy and reduce emissions, and technology to treat severe lung disorders. Through continued advancement of the university’s research enterprise, Temple is ensuring its place as a nexus of discovery, education, translational research and service, dedicated to improving quality of life and expanding our understanding of the world for the benefit of society. Temple has no financial interest in any of the parties to the current action.

The University of New Mexico (“UNM”) is a public research institution founded in 1889. It ranks in the top five

in rate of growth of National Institute of Health funding, spends over \$200 million in annual research funding, and has a wealth of laboratory facilities, high performance computing and information systems capabilities, as well as collaborative ties to researchers at Los Alamos National Laboratory and Sandia National Laboratories. Through its wholly-owned nonprofit licensing arm, UNM licenses innovative technology developed at UNM, including optics, microfluidics, and high performance materials as well as therapeutics, diagnostics, medical devices, and drug discovery tools. UNM has no financial interest in any of the parties to the current action.

The University of Utah (“UU”) is the state’s oldest and largest institution of higher education, and one of the state’s largest employers. It ranks among the top public research institutions in the country, with a particular distinction in medicine, genetics, pharmacy, and engineering. UU is first in efficiency in starting companies, second in overall companies started, ninth in revenue per research dollar, and second in inventions generated per research dollar. UU has no financial interest in any of the parties to the current action.

The University of Utah Research Foundation (“UURF”) has managed intellectual property developed by faculty, staff, and students of UU since 1967. Through the establishment of commercial partnerships with industry and the development of products from these technologies, UURF benefits the public and promotes economic growth. In 2010, UU spun off the highest number of startups based on licensed university technology in the nation. UURF has no financial interest in any of the parties to the current action.

Wisconsin Alumni Research Foundation (“WARF”) was founded in 1925 as a nonprofit entity to promote, encourage, and aid scientific investigation at the University of Wisconsin-Madison (UW-Madison). One of WARF’s first accomplishments was to patent a vitamin D discovery that eventually eliminated the childhood disease rickets worldwide. Since its founding, WARF has processed approximately 6,000 inventions created by UW-Madison faculty and staff, obtained 1,900 U.S. patents on these inventions, entered into over 1,600 license agreements with companies around the globe, and returned over \$1 billion in licensing-fee income to UW-Madison to fund research programs and initiatives.

The Bayh-Dole Act has made it possible for WARF to make the contributions to the public good that it does today. In the middle to late 1960s, government agencies kept title to inventions that had been funded with federal money. As a consequence, invention disclosures to WARF—inventors’ write-ups for patent counsel to use in preparing patent applications—had fallen to barely one per month and what few disclosures there were had fallen in quality. The situation improved somewhat when Institutional Patent Agreements (IPAs) were negotiated with (what is now) the Department of Health and Human Services in 1968 and the National Science Foundation in 1973. These IPAs gave WARF (and other universities) the right to elect to take title to inventions made with funds from those two agencies.

Since the enactment of Bayh-Dole, invention disclosures to WARF have mushroomed. Today, WARF (a) manages over 800 pending and 1,000 issued U.S. patents on UW-Madison technologies, as well as over 2,000 foreign

equivalents; (b) offers more than 1,000 technologies for licensing; (c) maintains more than 500 active commercial license agreements, as well as about 460 academic licenses; (d) has over 160 license agreements with Wisconsin companies; and (e) holds equity in 40 UW-Madison spin-off companies. WARF's most important patents include the blood anticoagulant Warfarin, a coating process making pills easier to swallow, treatments for osteoporosis and cancer, magnetic resonance techniques, and a discovery known as the "Wisconsin Solution" that prolongs the use of transplant organs.

Research Corporation Technologies ("RCT"), is a technology investment and management company whose mission of commercializing inventions from research institutions dates to 1912. RCT currently provides early-stage funding and development for biomedical companies and technologies from universities and research institutions worldwide. RCT has participated in the commercialization of a number of landmark university-derived technologies the products of which have enhanced the lives of millions of patients. These include the anticancer agents cisplatin and carboplatin from Michigan State University, the PSA blood test to detect prostate cancer from Roswell Park Memorial Institute, the heart imaging agent Cardiolite® from work originating at the University of Cincinnati and most recently the antiepileptic agent, Vimpat®, from discoveries made at the University of Houston. With more than \$300 million in assets derived from commercializing these discoveries, RCT continues to advance university-derived technology development through venture investment, partnerships, and special licensing programs. Its investments have initiated over a dozen start-up companies based on university technology.

RCT's specialized licensing programs include the following technologies: granulocyte macrophage stimulation factor (Ludwig Institute for Cancer research); mRNA transport enhancer (University of Connecticut); bovine growth hormone polyadenylation signal (Case Western Reserve University); viral-mediated gene transfer systems (University of Michigan); ultrasound tissue harmonic imaging (University of Rochester). RCT has no financial interest in any of the parties to the current action.

SUMMARY OF ARGUMENT

In the United States, universities are perhaps the most significant force driving the advancement of technology. Because patents are critical for securing private investment in university research and for commercializing university technologies, the clear and convincing standard is essential.

During the ten years from 1996-2007 alone, new university-developed technologies contributed an estimated \$187 billion to U.S. gross domestic product, increased the gross industrial output by \$457 billion, and created 279,000 new jobs. University research has advanced medicine, cured diseases, and saved lives. The system that produces these innovations depends upon strong, enforceable patents.

Weakening patents ultimately harms universities' ability to partner with commercial entities otherwise willing to sponsor research or license university technologies. Not only does this result frustrate one of the main university goals—transferring research and technology to the public—it impacts universities' licensing

revenues. These monies are used to fund further research that, in turn, may lead to additional breakthroughs.

History confirms that patents would be found invalid at a much higher frequency if the clear and convincing evidence standard were lowered to the preponderance of the evidence standard. The consequent uncertainty would likely undermine the profound progress achieved since the advent of the Federal Circuit and its adoption of the clear and convincing standard. Indeed, the rate of validity for litigated patents increased from 35% (before the Federal Circuit) to 55% (after the Federal Circuit).

Regardless, there is no justification for broadly maligning the United States patent system. The United States Patent and Trademark Office (“USPTO”) statistics on the outcome of patent reexamination proceedings demonstrate not only that the vast majority of patents are valid, but also that jury trials applying the clear and convincing standard and USPTO reexamination proceedings applying the preponderance of the evidence standard reach consistent results, and thereby validate each other.

The heightened respect for patents reflected by the clear and convincing standard has produced overwhelmingly positive results for the country, serving as a foundation pillar of the knowledge economy. In the United States, technology transfer offices are key actors in the knowledge economy, through assessing of a technology’s patentability, applying for and maintaining patents, and negotiating material transfer and licensing agreements for material access and intellectual property use. Universities, research sponsors, and investors have

relied on the presumption of validity as evidenced by the tens of thousands of license agreements executed by American universities. These partnerships are vital to funding research and development, to rewarding innovation, and to supporting educational programs.

ARGUMENT

Reversal of the district court could seriously weaken the presumption of validity that attaches to millions of patents in force in the United States. The Court should not alter the balanced regime that has prevailed for decades, by sharply tipping the scales in favor of accused infringers and thereby regressing to the weak patent system that existed prior to the Federal Circuit's creation.

I. STRONG PATENTS ARE VITAL TO MODERN RESEARCH UNIVERSITIES.

Patents are vitally important for securing private investment in university research and for developing and licensing of university inventions. Between 2000 and 2008, American universities “received 147,515 invention disclosures, filed 83,988 new patent applications, and signed 41,598 license and option agreements, of which 4,566 were with startup companies based on university research.” Arundeeep S. Pradhan, *Defending the University Tech Transfer System*, Bloomberg Businessweek, Feb. 19, 2010, available at http://www.businessweek.com/smallbiz/content/feb2010/sb20100219_307735.htm. In 2009 alone, 12,109 new patent applications were filed and 3,417 patents were issued to research institutions. See, e.g., Association of University Technology Managers, *AUTM U.S. Licensing Activity Survey Summary: FY2009* (Robert Tieckelmann *et al.* eds., 2010). In fact, American

universities are responsible for about 20% of all patents in the biotechnology sector. *See* David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 Tex. 1677, 1687 & n.44 (2007).

The clear and convincing standard is a key component of a strong patent system. This strength is essential to the efforts of the universities to transfer technology and to launch startup companies. The United States patent system was the vehicle chosen by Congress under the Bayh Dole Act of 1980 to transfer the results of basic research conducted with federal funds within the university sector to the public for its use and benefit through appropriate licensing arrangements. Patents supply the foundation for achieving that end.

Patents are also fundamental to protect the results of research and development sponsored in the university sector by and for the private sector. The private sector relies upon the strength of patents as reflected in the presumption of validity (and implemented by the clear and convincing standard) to serve as an incentive to motivate the often expensive development of the technology embraced by the patent(s). The strength of a patent is a key component of the private sector's evaluation of the risk/rewards criteria driving, or detracting from, the economic benefits to be derived through a licensing arrangement. Any change that reduces the perceived ability of the patent holder to enforce its rights erodes the willingness of private companies to seek a patent license or to sponsor research at a university.

Universities are perhaps the most important force driving the advancement of technology in the United

States. During the ten years from 1996-2007 alone, new university-developed technologies contributed an estimated \$187 billion to U.S. gross domestic product, increased the gross industrial output by \$457 billion, and created 279,000 new jobs.

University research has advanced medicine, cured diseases, and saved lives. It is directly responsible for drugs for HIV treatments, cancer therapeutics, and technologies that allow scientists to identify and to understand the genetic causes of countless diseases, including cancer, cystic fibrosis, and Parkinson's disease. In driving our world toward a more sustainable future, university research has resulted in innovative new energy solutions, drought and disease-resistant agricultural crops, and high-efficiency water purification systems. Indeed, university research pervades our day-to-day lives, as it is responsible for countless innovations we take for granted in the Internet age, such as Google's search engine. The system that produces these innovations depends upon patents, which are the chosen vehicle for technology transfer under the Bayh-Dole Act of 1980.

The uniformity and clarity provided by the clear and convincing standard imparts the predictability, strength and value of patent rights required by the private sector. University-derived technology transferred to the private sector is responsible for 18% of the United States GDP. Universities, however, do not produce goods or utilize processes themselves—except for research and development purposes. Rather, they develop dynamic new technologies, patent them, and partner with companies (through licensing and sponsored-research agreements) that have the wherewithal to reach the marketplace

through the risk of product and market development. Patent licensing programs provide an opportunity to reward innovation, generate royalty revenue, and directly fund additional research and development and educational programs. The investment in domestic innovation ultimately creates jobs and enhances the American economy on both local and national level and helps the United States achieve and maintain a dominant position in the global economy.

Reduction in the strength of a patent will harm universities' ability to partner with commercial entities otherwise willing to sponsor research or license university technologies. This result frustrates one of the main university goals: transferring research and technology to the public. Universities use licensing revenues—and the strong patents that induce them—to fund further research that, in turn, may lead to additional breakthroughs. If this Court reverses decades of settled law and adopts Microsoft's position, the value of university patent portfolios will fall, leading directly to a reduction in the private investment that universities rely upon to further their long tradition of innovation.

II. LOWERING THE STANDARD WILL INCREASE THE NUMBER OF PATENTS INVALIDATED.

Empirical studies and judicial history teach that patents would be found invalid at a much higher frequency if the clear and convincing evidence standard were discarded. The consequent uncertainty would likely undermine the profound progress achieved since the advent of the Federal Circuit.

Congress created the Federal Circuit in 1982, understanding that a single appellate court would establish uniformity in the patent laws and eliminate the substantial regional differences in interpretation of the patent laws by the 12 regional courts of appeal.

The Federal Circuit remarked on its founding and mission:

The purpose of this Court's enabling act, the Federal Courts Improvement Act of 1982 . . . is to provide a forum that will increase doctrinal stability in the field of patent law. . . . [To that end the] Hruska Commission singled out patent law as an area in which the application of the law to the facts of a case often produces different outcomes in different courtrooms in substantially similar cases. Furthermore . . . the patent bar indicated that uncertainty created by the lack of national law precedent was a significant problem. . . . The testimony received by the committee also supported the basic objective of providing for uniformity of doctrinal development in the patent area. . . . The creation of the Court of Appeals for the Federal Circuit will produce desirable uniformity in this area of the law.

Panduit Corp. v. All States Plastic Mfg. Co., 744 F.2d 1564, 1573-74 (Fed. Cir. 1984) (quoting S. Rep. 97-975, 97th Cong., 1st Sess.) (internal quotation marks omitted). Before then, patents were held invalid about 60 to 70 percent of the time, and, when combined with cases where the patents were held valid but not infringed, the patent

owner lost about 80 percent of the time. See Alfred J. Mangels, *The Quiet Revolution in Patents*, 31 Res Gestae 356, 356 (1988).

Barely two years after its inception, the Federal Circuit adopted the clear and convincing standard in *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1358-1361 (Fed. Cir. 1984). From 1982 through 1987, the Federal Circuit upheld 89% of district court decisions of patent validity, and reversed or vacated 45% of district court decisions finding patents obvious over prior art. See Donald R. Dunner, *Special Committee on CAFC*, 1988 A.B.A. Sec. Pat., Trademark & Copyright L. Rep. 314, 325. When Professor Lemley analyzed all written, final validity decisions by either district courts or the Federal Circuit reported in the United States Patents Quarterly from early 1989 through 1996, he observed:

Of the 300 final validity decisions in the data set, 162 (54%) found the patent valid, and 138 (46%) found the patent invalid. . . . This result is broadly consistent with other recent work on overall patent validity, which has generally found that courts determining the validity of patents since creation of the Federal Circuit adjudge approximately 55% of them to be valid. As those prior studies have noted, this validity rate is significantly higher than it was before the Federal Circuit was created. . . . Before creation of the Federal Circuit, studies had found that only about 35% of litigated patents were held valid on average. The percentages were similar in the district courts and the courts of appeal. . . . At the court of appeals level, validity rates

varied widely among circuits, ranging from around 10% to over 55%.

John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-206 and nn.51-53 (1998) (internal citations omitted).

Thus, the rate of validity for litigated patents increased from 35% (before the Federal Circuit) to 55% (after the Federal Circuit). Undeniably, the Federal Circuit has substantially reduced nonuniformity across the circuits and their district courts; the Federal Circuit's reversal rate in patent cases overall is roughly the same as or lower than reversal rates for complex cases in other circuits. See Ted Sichelman, *Myths of (Un)Certainty at the Federal Circuit*, 43 Loy. L.A. L. Rev. 1161, 1163 (2010).

But why? Federal Circuit Judge Richard Linn pointed to the adoption of the clear and convincing standard as exemplary of the Federal Circuit's "mission to bring understanding and uniformity to judicial interpretations of the patent statutes." Honorable Richard Linn, *Foreword: The Future Role Of The United States Court Of Appeals For The Federal Circuit Now That It Has Turned 21*, 53 Am. U.L. Rev. 731, 732 (2004) (citing *American Hoist*); see also Gerald Sobel, *The Court of Appeals for the Federal Circuit: A Fifth Anniversary Look at Its Impact on Patent Law and Litigation*, 37 Am. U.L. Rev. 1087 (1988). Judge Linn reflected on the importance of rulings like *American Hoist*:

As a consequence, the Federal Circuit was soon perceived to be a pro-patent court. That perception may have been justified. Comparative statistics from the years just

before and just after the court's establishment show that patentees stood a better chance of enforcing their patents after the formation of the Federal Circuit than they did before.

Linn, *supra*, at 733 (citing Allison *et al.*, *supra*, at 206 (percentage of patents held valid rose from 35% in the 1970s to 54% in the early 1990s) and Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 Cal. L. Rev. 805, 821 (1988) (noting that between 1982 and 1985, the Federal Circuit invalidated only 44% of the patents it adjudicated on appeal from trial courts, a marked contrast to the prior invalidation rate of approximately 66%).

The heightened respect for patents had a profoundly positive effect on the knowledge economy. Again, Judge Linn:

The precise role the Federal Circuit played in the successes of the U.S. economy following the formation of the court has not, to my knowledge, been quantified. This remains to be determined by future scholars. But I think it is fair to conclude that the Federal Circuit played an important part. To me, it is clear that inventors and corporations are more likely to seek and enforce patents when there is *greater clarity in the applicable legal standards and greater certainty in the outcome of litigation*. Likewise, corporations are more inclined to license patents if they and their attorneys are better able to evaluate the chances that those patents will withstand a legal challenge.

Linn, *supra*, at 734 (emphasis added). Indeed, a study of United States multinational firm behavior in sixteen middle-income countries during 1990s found that royalty payments received for technology and research and development spending by the firm's local affiliates all increased in response to the strengthening of their patent systems, especially if the firm in question was already a heavy patent user and therefore presumably dependent upon patents to secure returns to innovation. See Bronwyn H. Hall & Christian Helmers, *The Role of Patent Protection in (Clean/Green) Technology Transfer*, 26 Santa Clara Computer & High Tech. L.J. 487, 496 (2010).

If this Court adopts the preponderance of the evidence standard, courts will invalidate patents more frequently as they did before the Federal Circuit adopted the clear and convincing evidence standard. Building on the research of Professors Allison and Lemley, Professor Arti K. Rai observed:

John Allison and Mark Lemley's study of judicial patent decisions between 1989 and 1996 does indicate that during this period courts held patents invalid in approximately 50% of the cases where validity was at issue and decided. In contrast, in the pre-Federal Circuit era, courts upheld the validity of patents in approximately 30-40% of the cases where validity was at issue. This data suggests that if the Federal Circuit were to reverse course and establish a preponderance of the evidence standard for challenging patent grants, lower courts might well invalidate patents more frequently.

Arti K. Rai, *Allocating Power Over Fact-Finding in the Patent System*, 19 Berkeley Tech. L.J. 907, 920 (2004). This contention—that changing to a preponderance of the evidence standard would significantly increase the frequency with which patents are found invalid—is hardly controversial. This is precisely the result that Microsoft and the Amici supporting it want. But they are myopic in wanting this result.

Microsoft’s and its Amici’s unstated premise, only thinly-veiled, is that an overwhelming number of United States patents are issued by mistake and that this Court ought to make it easier to invalidate them. Ironic indeed for companies built on the strong intellectual property laws of the United States. There is no basis for broadly maligning the United States patent system. Microsoft has no reliable study that would justify its self-serving perspective.

The USPTO’s statistics on the outcome of patent reexamination proceedings demonstrate not only that the vast majority of patents are valid, but also that USPTO examiners following the preponderance of the evidence and juries following the clear and convincing standard reach consistent results, and thereby validate each other. These statistics certainly do not support Microsoft’s contention that a substantial number of patents are mistakenly granted.

The USPTO will grant a request for reexamination only if an interested party submits new prior art that raises a substantial new question of patentability. 35 U.S.C. §§ 303, 312; see *In re Swanson*, 540 F.3d 1368, 1375, 1380 (Fed. Cir. 2008) (“Congress intended reexaminations to

provide an important ‘quality check’ on patents that would allow the government to remove defective and erroneously granted patents.”) (citations omitted). This condition, of course, mirrors the circumstance that Microsoft says should justify application of the preponderance of the evidence standard, i.e., when new prior art is offered at trial. However, the USPTO statistics do not support the hypothesis that consideration of “new” prior art will likely invalidate an issued patent. On the contrary, the reported statistics suggest that the overwhelming majority of patents are valid.

Even though requests for *ex parte* reexamination were granted in 92% of the 10,705 requests since 1981, the USPTO cancelled all claims in only 12% of the cases. *See* Ex Parte Reexamination Filing Data—December 31, 2010, *available at* http://www.uspto.gov/patents/stats/EP_quarterly_report_Dec_2010.pdf. The statistics for *inter partes* reexamination are even more interesting. Since 1999, the USPTO has granted 90% of the 1115 requests for *inter partes* reexamination, 70% of which involved parties in litigation. *See* Inter Partes Reexamination Filing Data—December 31, 2010, *available at* http://www.uspto.gov/patents/stats/IP_quarterly_report_Dec_2010.pdf. Even though there is no presumption of validity and, therefore, no clear and convincing standard in such proceedings,² the patents at issue were cancelled entirely (or disclaimed) in *only* 47% of the cases. *See id.* We say “only” because this rate is roughly equivalent to the

2. The USPTO uses the preponderance of the evidence standard in reexamination proceedings. Manual of Patent Examining Procedure, §§706 (comment I) and 2280; 37 C.F.R. 1.555(b)(2)(ii).

invalidity rate in federal court litigation where the clear and convincing standard applies, i.e. 46%. See Allison *et al.*, *supra*, at 205-206 and nn.51-53.

This rough equivalence suggests that the use of the clear and convincing standard in litigation does not shield patents from invalidation; rather, it apparently buffers the jury trial process. By contrast, the higher invalidity rates experienced in the years before the Federal Circuit adopted the clear and convincing standard would indicate an anomaly. If the patent system is functioning properly, one would expect the USPTO and juries to invalidate patents at roughly the same rate. That is precisely what the reexamination statistics indicate: a healthy system in which the USPTO in *inter partes* reexamination proceedings invalidates at roughly the same rate as juries following the clear and convincing instruction.

History teaches that adoption of the preponderance of the evidence standard would significantly increase the frequency with which juries would invalidate patents. This would lead to an unacceptable discrepancy between the rate of invalidation by juries and the USPTO in reexamination proceedings. This discrepancy would be empirical proof that either the reexamination office or juries was “wrong.” They cannot both be correct. The current system, which produces relatively consistent results, indicates a healthy system that works.

III. THE CLEAR AND CONVINCING STANDARD OF PROOF HAS BEEN POSITIVE.

Inventors and corporations are more likely to seek and enforce patents when there is greater clarity in the applicable legal standards and greater certainty in the outcome of litigation. Likewise, corporations are more inclined to license patents if they and their attorneys are better able to evaluate the chance that those patents will withstand a legal challenge.

The heightened respect for patents that the clear and convincing standard reflects has produced overwhelmingly positive results for the country, serving as a foundation pillar of the knowledge economy. Most intellectual property scholars point to the 1980s as the trigger point for the growing interest in patenting and indeed, for the increase of Technology Transfer Offices (“TTOs”) at universities. That was the year that saw two fundamental changes in the patent laws: (1) the decision of this Court in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), which permitted the patenting of living organisms; and (2) the passage of the University and Small Business Patent Procedures Act (the Bayh-Dole Act), which changed the presumption of title to inventions made in whole or in part with federal funding from the government to universities and small businesses and established a uniform government patent policy. These two separate and distinct events are universally accepted as providing the primary motivation for establishing TTOs. In the United States, TTOs are key actors in the assessment of a technology’s patentability, applying for and maintaining patents, and the negotiation of material transfer and licensing agreements for material access and intellectual property use. And the number of

TTOs in the United States grew from around 21 in 1980 to 176 in 2002 and today to about 300. *See Ass'n of Univ. Technology Managers, Canadian Licensing Activity Survey: FY2007 Survey Summary, Data Appendix: Summary of FY 2005-07.*

Sponsorships such as the BMW Endowed Chair in Systems Integration,³ the Halliburton Endowed Chair in Engineering,⁴ the Electronic Arts Interactive Entertainment Program,⁵ the Mars, Inc. Endowed Chair in Developmental Nutrition,⁶ and the CVS/Pharmaceutical Endowment⁷ confirm the symbiotic relationship between today's universities and industry. In fact, in 2007 alone, universities received over two

3. *See* Press Release, Clemson Univ., *Clemson Hires Industry Leader as Fourth Endowed Chair for CU-ICAR Automotive Engineering Program* (July 24, 2008), available at http://www.clemson.edu/newsroom/articles/2008/july/BMW_chair.php5.

4. *See* Halliburton Foundation *Endows Million-Dollar Engineering Chair at Texas A&M* (September 29, 2009), available <http://engineering.tamu.edu/news/2009/09/29/halliburton-foundation-endows-million-dollar-engineering-chair-at-texas-am/>.

5. *See* Press Release, Sch. of Cinematic Arts, Univ. of S. Cal., *Tracy Fullerton Named EA Endowed Chair* (Dec. 5, 2008), <http://cinema.usc.edu/about/news/usc-school-of.htm>.

6. *See* University of California at Davis, College of Agricultural and Environmental Sciences, *The Mars, Inc. Endowed Chair in Developmental Nutrition*, <http://caes.ucdavis.edu/giving/endowed-chairs>.

7. *See* University of Florida Foundation, *CVS/Pharmacy Endowment*, <http://www.uff.ufl.edu/EndowedFunds/EndowedFundInfo.asp?eFund=008879>.

billion dollars in licensing revenue from various inventions that academic researchers created. *See* Association of University Technology Managers, *AUTM U.S. Licensing Activity Survey: FY2007* 138, 142 (Robert Tieckelmann et al. eds., 2008).

The United States patent system exists to provide incentives to “promote the Progress of Science and useful Arts.” U.S. Const. art. I, § 8, cl. 8. The uniformity and clarity provided by the Court’s venerable precedent affords the predictable disposition of patent rights and the ability of the patent holder to enforce the rights granted. It thus affords incentive for private sector or venture capital investment in invention development that are critical for innovation and the resulting domestic job creation and economic growth.

Technological innovation is widely seen as responsible for much of the economic growth and increased standard of living in modern societies. Patent rights give inventors, or other patent owners, exclusive control over the use of their inventions for about 20 years, which, in turn, promotes commercialization of new ideas and allows inventors to profit from their ideas. Patent ownership encourages the additional, and often substantial, investment of time and money needed to transform the technological innovations developed in the laboratory into goods, services, and processes available in the marketplace. Patent owners—including individuals, companies, and universities—may grant licenses to one or more businesses to complete this transformation and, in return, receive payments in the form of license fees or royalties.

Our patent system is the strongest in the world. It promotes innovation by facilitating the investment necessary for small businesses to form and grow, and for more established businesses to continue competing and thriving in an increasingly competitive global marketplace. Our patent system helps ensure that the United States can continue to reap the benefits of advances in technology, through innovation, which creates jobs and growth opportunities in every state and every sector of our economy.

From 1948 to 1985, nearly 70 percent of the growth in United States industrial output was attributable to the combined effects of technical progress and capital growth, with technology alone accounting for approximately 50 percent of the growth. *See* John W. Schlicher, 1 *Patent Law, Legal and Economic Principles* § 2:3 (2d ed.). Over that period, output grew at an average annual rate of 3.1 percent. *See id.* Over the period roughly 1957 to 1985, the relative contributions of capital, labor, and technical progress in France, West Germany, Japan, and the United Kingdom shows that technical progress is by far the most important source of economic growth, accounting for half or more for Japan and three quarters for the European countries. *See id.*

From 1953 to 1984, estimates for the total annual United States research and development (“R&D”) investment range between 1.40 to 2.66 percent of gross national product (“GNP”). Schlicher, *supra*, at § 2:4. In 1985, total nondefense R&D expenditures were 1.8 percent of the United States’ GNP (about \$74 billion). *See id.* The bulk of R&D investment is by private companies: private R&D investment was about 54 percent of that total R&D

(1.44 percent of GNP) in 1984 and 64 percent of that total R&D (2.4 percent of GNP) in 1987. *See id.* In 1990, the private sector provided \$138 billion for R&D—about 66 percent of total worldwide R&D investment. *See id.*

These R&D investments reveal the commercial significance of technology. In many industries, the private share of total R&D costs is considerable. For example, privately-financed expenditures in the chemical, food and beverage, and petroleum products industries exceeded 98 percent of total expenditures in 1990. *See id.* Many companies invest up to ten percent of their current revenue in research and development. *See id.* Thousands of small privately funded startup companies invest in R&D amounts that are several hundred percent greater than their revenue. *Id.* For all these companies, these investments only work if they pay off, and pay off an amount several times larger the investment. *See id.*

Private investment in R&D, however, is predicated on the ability of businesses to rely on the strength and presumed validity of issued patents for product development, innovation, partnering, and licensing decisions. The public, likewise, has an expectation that patents that were examined and granted by the USPTO confer valid rights that should be respected and on which it can rely.

University patent licensing has produced astounding economic benefits—from 1996 to 2007, university licensing contributed an estimated \$187 billion to United States gross domestic product, achieved a \$457 billion impact on United States gross industrial output, and created 279,000 new jobs. *See The Better World Report, The Positive*

Impact of Academic Innovations on Quality of Life at viii (2010), available at <http://www.betterworldproject.org/AUTM2010BWR.pdf>. During the same time, more than 6,000 new United States companies were formed from university inventions, 4,350 new university-licensed products are in the market, and 5,000 active university-industry licenses are in effect, mostly with small companies. *See id.*

The opportunities available to universities to realize a portion of the benefits that their technological advancements provide to society are only as valuable as the patent rights that universities are now free to license to the private sector. Thus, the continued success of the statutory structure is predicated on the ability of patentees and their licensees effectively to enforce their patent rights. If universities cannot offer their licensees the certainty of patent validity, the private sector will have little incentive to form partnerships with universities. The result would be detrimental to our nation's economy and the public interest.

The societal benefits of university research are substantial. In the area of life sciences, the following innovations (among many others) are attributable to university research:

- hepatitis B vaccine (University of California and University of Washington);
- vitamin D metabolites and derivatives (University of Wisconsin);
- recombinant engineering co-transformation process (Columbia University);

- synthetic penicillin (Massachusetts Institute of Technology);
- Citracal calcium supplement (University of Texas Southwestern Medical Center);
- Cisplatin and carboplatin cancer therapeutics (Michigan State University);
- a new lithium-ion battery technology that makes batteries more energy efficient and affordable (The University of California's Lawrence Berkeley National Laboratory);
- Leustatin chemotherapy for hairy cell leukemia (Brigham Young University); and
- metal oxide process for Taxol antitumor cancer treatment (Florida State University).

See Michael J. Remington, *The Bayh-Dole Act at Twenty-Five Years: Looking Back, Taking Stock, Acting for the Future* at 3, available at www.infodev.org/en/Document.644.pdf. Additional university-based advances include:

- gene trapping technology by Dr. Mario Capecchi, who was awarded Nobel Prize for Physiology in 2007 (University of Utah);
- cochlear implant for restoring hearing loss (University of California, San Francisco);
- the GlucoWatch Biographer glucose monitoring device (University of California, San Francisco);

- the nicotine patch (University of California, Los Angeles);
- Lamivudine (3TC), a breakthrough HIV and hepatitis drug (Emory University);
- human cytomegalovirus promoter, a fundamental tool used in the biotechnology industry (University of Iowa);
- retinal imaging technology that could make health care more affordable while protecting diabetes patients at risk of losing their eyesight (Indiana University);
- BluePro water filtration system (University of Idaho);
- permeable reactive barriers for removing groundwater contaminants (University of Waterloo);
- the Honeycrisp apple (University of Minnesota);
- the prostate-specific antigen test (Roswell Park Cancer Institute);
- the Google search engine (Stanford University);
- treatment for Chagas' disease (University of Washington and Yale University);
- Replacement Therapy that can eliminate dental cavities (University of Florida);

- Altoprane for early diagnosis of Parkinson's disease and attention deficit hyperactivity disorder (Harvard University);
- the InstaTrak system, an electromagnetic, image-guided surgical technology (Boston University and Brigham and Women's Hospital);
- the Rheo Knee, a microprocessor that sends signals to magnetic fluid in the artificial joint and allows below-the-knee amputees to enjoy active lives (Massachusetts Institute of Technology);
- a robotic elbow brace allows stroke victims to recover the use of their arms (Massachusetts Institute of Technology);
- new hybrid drugs for treating malaria (Portland State University);
- the cystic fibrosis gene (The Hospital for Sick Children and University of Michigan);
- the Osteomark technology for early detection and protection against osteoporosis (University of Washington);
- TRICKS, a three-dimensional imaging technique (University of Wisconsin-Madison);
- a water treatment filter that has the potential to provide safe drinking water to reduce 3.4 million deaths worldwide (University of Delaware);

- human papillomavirus vaccine (Indiana University);
- Caldolor®, an intravenous formulation of ibuprofen (Vanderbilt University);
- a therapeutic treatment that relieves the intensely painful disease of shingles (University of Colorado);
- Amevive, a treatment for psoriasis (Harvard University's Dana-Farber Cancer Institute); and
- Periostat for periodontal disease (SUNY Stony Brook).

See, e.g., The Better World Project, supra.

Technological advances developed and patented by universities in the United States have been licensed to industry for commercialization into products and processes that benefit society through the efficient promotion of high-value jobs in high-tech industries. For example, a recent study found that, through their technology transfer programs, American universities create more than two startup companies each working day. *See* Arundeeep S. Pradhan, *Defending the University Tech Transfer System*, Bloomberg Businessweek, Feb. 19, 2010, *available at* http://www.businessweek.com/smallbiz/content/feb2010/sb20100219_307735.htm. In 2009, academic research was responsible for the creation of 658 new commercial products, 596 new companies, and two startup companies each working day. *See, e.g., Association of University Technology Managers, AUTM U.S. Licensing Activity Survey Summary: FY2009* (Robert Tieckelmann *et al.* eds., 2010). More broadly, since

1980, American universities have created more than 5,000 companies through licensing their intellectual property. *See, e.g.*, Association of University Technology Managers, *AUTM U.S. Licensing Activity Survey Summary: FY2006* (Robert Tieckelmann *et al.* eds., 2007).

The revenue generated by the tens of thousands of license agreements signed by American universities is an important adjunct to public funding of research and development, as universities use the royalty revenue generated by their licensing programs to reward innovation and fund further research and educational programs. *See, e.g.*, 35 U.S.C. § 202(c)(7) (requiring that a nonprofit organization use the balance of any royalties, after the payment of expenses (including payments to inventors), to support further scientific research or education). Ohio State University, for example, attracted \$42.8 million in capital and created over 120 jobs in the last three years alone. *See OSU Tech Drives New Ventures, available at* <http://fisher.osu.edu/centers/tlc>. In 2010, Ohio State's total research expenditures were \$756 million, with its funded research program's estimated annual economic impact is more than \$4 billion. *See Ohio State's Research Profile, available at* <http://research.osu.edu/osu-research/profile/>.

If the law impairs the effective enforcement of patentee's rights, then an exclusive license is of little value. In other words, weak or weakened property rights that would not support rigorous patent enforcement, would tend to stifle innovation. Universities, research sponsors, and investors have relied on the presumption of validity.

The heightened burden of proof in litigation benefits the public by providing inventors and potential inventors with a strong incentive to invest the substantial resources necessary for innovation, and then to disclose their inventions to the public. It provides this incentive by assuring inventors that their patents will not be invalidated (by lay judges and juries) based on what the Supreme Court long ago labeled “a dubious preponderance” of evidence. *Radio Corp. of Am. v. Radio Eng’g Labs., Inc.*, 293 U.S. 1, 8 (1934).

Permitting infringers to invalidate patents on a lower standard of evidence could thus frustrate decades of settled expectations under which large investments were made in reliance on patents that were believed to carry a strong presumption of validity. Shifting the law to a weaker presumption of validity could also deeply affect the prospective investment and product development decisions of innovative businesses, affect public-private technology transfer, and profoundly change the behavior of patent applicants and litigants.

CONCLUSION

The University Patent Owners and Licensees Amici respectfully submit that the current “clear and convincing” standard should remain undisturbed. The heightened standard is of critical importance for domestic innovation, job creation, and our technological leadership internationally and preserves the American economy.

Respectfully submitted,

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