No. 10-290

IN THE
Supreme Court of the United States

MICROSOFT CORPORATION,
Petitioner,

v.

I4I LIMITED PARTNERSHIP AND INFRASTRUCTURES FOR INFORMATION, INC.,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

BRIEF OF *AMICI CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION, ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, AND CROPLIFE INTERNATIONAL IN SUPPORT OF RESPONDENTS

Thomas DiLenge
General Counsel
Hans Sauer
Deputy General Counsel for Intellectual Property
BIOTECHNOLOGY INDUSTRY ORGANIZATION
1201 Maryland Ave., S.W.
Washington, D.C. 20024

Patricia A. Millett
Counsel of Record
AKIN GUMP STRAUSS HAUER & FELD LLP
1333 New Hampshire Ave., NW
Washington, DC 20036
(202) 887-4000
pmillett@akingump.com

Michael C. Small
AKIN GUMP STRAUSS HAUER & FELD LLP
2029 Century Park East
Suite 2400
Los Angeles, CA 90067
(310) 229-1000

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Constitution and Statutes

Rules

Legislative Materials

Other Authorities

INTEREST OF *AMICI CURIAE*[1]

The Biotechnology Industry Organization ("BIO") is the principal trade association of the biotechnology industry in the United States. BIO has more than 1,100 members, including corporations, nonprofit entities, and academic institutions. While some of BIO's corporate members are Fortune 500 companies, 90% of its members are small or mid-size businesses, with annual revenues of less than $25 million. All of BIO's members share a strong commitment to the stability of the Nation's patent system and, indeed, for most members the reliability and durability of patents is vital to their ability to raise the investment capital that funds their research and product development efforts.

The Association of University Technology Managers ("AUTM") is a nonprofit organization with an international membership of more than 3,000 technology managers and business executives. The field of technology management in which AUTM operates is one of the most active growth sectors of the international economy. AUTM members come from more than 300 universities, research institutions, and teaching hospitals, as well as

[1] The parties have consented to the filing of this brief in letters on file with the Clerk's office. Pursuant to Supreme Court Rule 37.6, *amici* represent that no counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amici* themselves made a monetary contribution to the preparation and submission of this brief.

businesses and governmental organizations that are involved with managing and licensing innovations derived from academic and nonprofit research.

CropLife International is a global federation that represents the plant science industry. CropLife promotes the international development of crop protection, seeds, agricultural biotechnology, and sustainable agriculture in an effort to assist farmers and consumers, as well as to protect the environment. Through those activities, CropLife works closely with those interested in the future of food production and farming.

Amici have a substantial interest in this Court's continued adherence to the long-settled principle that the invalidity of patents must be proven in litigation by clear and convincing evidence.

SUMMARY OF ARGUMENT

The stability of patents drives the innovation that the patent system is intended to promote. Central to that stability are the presumption in 35 U.S.C. § 282 that patents are valid and the concomitant requirement that litigants challenging patent validity in court show by clear and convincing evidence that the patent is invalid. Together, the strong presumption of validity and the demanding clear and convincing evidence standard for proving invalidity furnish inventors and investors with the stability and confidence needed to disclose their discoveries and to invest labor and resources in innovations that promote the public interest, but that require long-term commitments of resources to come to fruition.

Petitioner's campaign to discard the clear and convincing standard defies a century's worth of precedent that Congress codified when it enacted Section 282. Nothing in the statutory text or legislative history says that Congress wanted to change the uniform judicial and scholarly recognition that challengers to the validity of a patent must demonstrate invalidity by a heightened showing, or wanted to permit the presumption of validity to be overcome by jurors under a mere preponderance standard. Quite the opposite, petitioner's position would read the first sentence of Section 282 right out of the statute because, if Section 282 as a whole does nothing more than assign the burdens of proof and production to the plaintiff, the presumption is rendered meaningless.

The courts' longstanding application of the clear and convincing evidence standard to patent invalidity claims, and Congress's endorsement of that settled law, make sense. That same clear and convincing standard has historically been used to protect property rights that have a special need for security and stability, and those property interests that are imbued with a significant public interest. It also enforces the presumption of regularity that applies to governmental processes. In reliance on the strength of the property right conferred through the government's issuance of a patent, countless individuals and businesses have formed legitimate investment-backed expectations about the stability of the patent system.

Reliance on the stability of the patent system has had special force in the context of biotechnology innovation. Indeed, strong patent protections have

been the lifeblood of the dramatic and remarkable biotechnological innovations that have saved and enhanced millions of lives over the past three decades. The areas of health, agriculture, energy, and environmental protection have all been transformed by these profound advancements. Because the development of biotechnological products is extraordinarily time-consuming, capital-intensive, and uncertain, such innovations would not have been possible without a strong system of patent protection. Stable patents have spurred the massive investment of labor and money necessary to bring biotechnological products to market. And stable patents are the foundation for scores of public-private licensing arrangements, many of which involve universities and other research institutions, that have facilitated the development of biotechnological products. Lowering the standard for proving patent invalidity will destabilize the security of the patent system on which a broad swath of business and research organizations depends. And the expectations of inventors and investors who already have committed the resources towards innovation in reliance on well-established principles will be profoundly shaken.

Given the substantial property and reliance interests at stake, any changes to the standard should come from Congress, not the judiciary. Congress has the institutional capacity to best assess in what ways the current patent system should be changed and to assess the impact of the current patent system on *all* industries, not just on the parties to one particular lawsuit. This distinction between the vantage point of Congress and that of a

court cautions against judicial intervention in an area where Congress is and has been active, especially because there are pronounced industry-specific differences over the importance of strong patent protections.

In fact, Congress has already dealt with the policy concerns about which petitioner complains. Congress, however, addressed the issue of questionable patents not by withdrawing the presumption of validity for *all* patents in litigation, but by strengthening the Patent and Trademark Office's ("PTO") examination and reexamination processes and authorizing an administrative preponderance standard only on congressionally prescribed terms. That approach appropriately focuses the inquiry on specific questionable patents, rather than categorically devaluing patents across the board as petitioner would do. In declining to change the litigation standard for patent validity, Congress determined that expert evaluation of patents at the PTO is not fungible with lay jury evaluation of patents in a trial, and to equate the two by lowering the proof standard in litigation to a mere preponderance would upset the careful balance that Congress struck.

ARGUMENT

THE CLEAR AND CONVINCING EVIDENCE STANDARD FOR PROVING PATENT INVALIDITY IS CRITICAL TO INNOVATION.

A. Durable And Stable Patents Are Vital To Promoting Innovation.

The Constitution invests Congress with broad authority to formulate legislation that "promote[s] the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const., art. I, § 8, cl. 8. The "policy of stimulating invention that underlies the entire patent system runs * * * deep" in our history. *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 221 (1980). By giving "Inventors" the incentive and security to develop their innovations and to share them with the public, the Nation's patent laws are critical to furthering the "Progress of * * * useful Arts."

More specifically, the patent laws offer inventors "a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989). In exchange for revealing their innovations to the public, the inventors' investment of labor and funds is rewarded with "the exclusive right to practice the[ir] invention for a period of years." *Id.* at 151.

Ensuring that the patent laws provide appropriate security and reward to inventors is critical because, without such protection, inventors will be unable to bear the financial, intellectual, and resource costs of bringing their innovations to public use. The grant of a patent thus is "compensation to the inventors for their labor, toil, and expense in making the inventions." *Seymour v. Osborne*, 78 U.S. 516, 533 (1870).

"The public good," moreover, "fully coincides" with that protection of the "inventors'" exclusive rights in their "useful inventions." THE FEDERALIST NO. 43 (JAMES MADISON) (Clinton Rossiter ed. 1961). Indeed, this Court repeatedly has recognized that the "productive effort" of inventors has "a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). *See Kendall v. Winsor*, 62 U.S. 322, 328 (1858) (the "primary object" of patents is to "benefit the public").

B. The Clear And Convincing Standard For Patent Invalidation Provides The Patent System The Reliability And Stability Upon Which Innovation Depends.

1. The Clear and Convincing Standard is Deeply Rooted in the Law.

The "clear and convincing" standard for proving patent invalidity in litigation that petitioner seeks to discard (Pet. Br. 14-18) is deeply anchored in this Court's precedent. As early as 1844, Justice

Story set "beyond a reasonable doubt" as the threshold for a jury to find patent invalidity "because the plaintiff has a right to rest upon his patent for his invention, till its validity is overthrown." *Washburn v. Gould*, 29 F. Cas. 312, 320 (C.C.D. Mass. 1844) (No. 17,214) (Story, J.. Circuit Justice).

In the century that preceded Congress's enactment of 35 U.S.C. § 282 in 1952, this Court repeatedly echoed Justice Story, holding that a heightened showing is required to prove patent invalidity. For example, this Court held unanimously in *RCA v. Radio Engineering Laboratories, Inc.*, 293 U.S. 1 (1934), that a patent's "presumption of validity" is "not to be overthrown except by clear and cogent evidence," *id.* at 2, and "an infringer who assails the validity of a patent * * * bears a heavy burden of persuasion," beyond a "dubious preponderance." *Id.* at 8.

Likewise, in *Washburn & Moen Manufacturing Company v. Beat 'Em All Barbed-Wire Company,* 143 U.S. 275 (1892), this Court observed that "almost every important patent, from the cotton gin of Whitney to the one under consideration, has been attacked" by individuals "who imagined they had made similar discoveries long before the patentee had claimed to have invented his device," so much so that "the popular impression" has arisen "that the inventor may be treated as the lawful prey of the infringer," *id.* at 284-285. For that reason, this Court required that proof of invalidity "shall be clear, satisfactory, and beyond a reasonable doubt." *Id.* at 284.

As respondents explain (Br. 13, 18), those holdings were part of a precedential pattern, cutting

across a variety of invalidity claims and forms of evidence, in which the common thread was this Court's uniform insistence that a heavy burden—not a mere preponderance—be imposed on those seeking to overthrow the presumption of validity. *See Smith v. Hall*, 301 U.S. 216, 233 (1937) (challenger bears a "heavy burden of persuasion" when seeking to invalidate a patent by "showing prior use"); *Mumm v. Jacob E. Decker & Sons*, 301 U.S. 168, 171 (1937) (The "burden is a heavy one, as it has been held that every reasonable doubt should be resolved against him."); *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 60 (1923) (evidence of invalidity must be "clear and satisfactory"); *Adamson v. Gilliland*, 242 U.S. 350, 353 (1917) ("requiring the defendant to prove his case beyond a reasonable doubt"); *Deering v. Winona Harvester Works*, 155 U.S. 286, 301 (1894) (invalidity must be proven "by evidence so cogent as to leave no reasonable doubt in the mind of the court"); *Cantrell v. Wallick*, 117 U.S. 689, 696 (1886) ("every reasonable doubt should be resolved against" invalidity); *Brown v. Guild (The Corn-Planter Patent)*, 90 U.S. 181, 227 (1874) (requiring "conclusive evidence" of invalidity); *Coffin v. Ogden*, 85 U.S. 120, 124 (1873) ("every reasonable doubt should be resolved against" invalidity).

The law of the circuit courts was also uniform at the time of Section 282's enactment. Relying on decisions of this Court such as *RCA* and *Smith,* the circuits had consistently held that the party seeking to establish the invalidity of a patent had to meet a heightened standard of proof. *See, e.g.*, Resp. Br. 22 (citing *Charles Peckat Mfg. v. Jacobs*, 178 F.2d 794, 801 (7th Cir. 1949); *Insul-Wool Insulation Co. v.*

Home Insulation, 176 F.2d 502, 504-505 (10th Cir. 1949); *Murdock v. Murdock*, 176 F.2d 434, 437 (4th Cir. 1949); *Lever Bros. v. Procter & Gamble Mfg.*, 139 F.2d 633, 640 (4th Cir. 1943); *Williams Mfg. v. United Shoe Mach. Corp.*, 121 F.2d 273, 277 (6th Cir. 1941), *aff'd*, 316 U.S. 364 (1942); *Wisconsin Alumni Research Foundation v. George A. Breon & Co.*, 85 F.2d 166, 167 (8th Cir. 1936).

The views of leading treatises were of the same accord. *See, e.g.*, Albert Walker, TEXT-BOOK OF THE PATENT LAWS OF THE UNITED STATES OF AMERICA § 76 (1st ed. 1883) ("[T]he burden of proving want of novelty is upon him who avers it, and every reasonable doubt should be resolved against him.").

That is the settled legal backdrop against which Congress enacted Section 282's rule that "[a] patent shall be presumed valid." Again and again, that solid wall of authority had mandated that the presumption of validity could not be overthrown by a mere preponderance of the evidence. And that rule is what Congress carried forward when it enacted Section 282 without a legislative word of complaint about the settled standard of proof. "When all (or nearly all) of the relevant judicial decisions have given a term or concept a consistent judicial gloss, [this Court] presume[s] Congress intended the term or concept to have that meaning when it incorporated it into a later-enacted statute." *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1082 (2011). Indeed, the legislative record avowed its intent to codify "the existing presumption of validity." H.R. Rep. No. 82-1923, at 29 (1952); S. Rep. No. 82-1979, at 2422 (1952).

Petitioner cites (Br. 24) a handful of district court cases that it says "question[ed] whether *any* presumption of validity was warranted" before Section 282 was enacted. But Congress answered that question quite emphatically and directly by preserving and codifying the existing presumption of validity long recognized by *this* Court. That is why, even after 1952, petitioner cannot find a single decision of this Court holding or stating that the presumption of validity can be overcome by a mere preponderance of the evidence. Not one. In fact, this Court continued to recognize that Section 282 made patentees "heavily favored" in validity challenges. *Blonder-Tongue Labs. v. University of Illinois Foundation*, 402 U.S. 313, 335 (1971) (discussing high evidentiary burden imposed on party seeking to establish patent invalidity).

Petitioner also notes (Br. 34) that some pre-1952 circuit decisions held that "the presumption of validity was, at minimum, 'weakened' when the PTO did not consider relevant prior art." But that proves *amici's* and respondents' point. Absent a heightened standard of proof, there would be nothing to "weaken." One speaks of defeating, not weakening, claims that are subject to ordinary preponderance invalidation in litigation. In any event, Congress did nothing in 1952 that remotely resembles the adoption of a two-tiered system of presumptive validity, and petitioner's pre-1952 circuit decisions merely foreshadowed the Federal Circuit's rule that, in cases involving prior art that was not considered by the PTO, "the patent challenger's burden may be more easily carried" as an empirical and factual matter.

See Connell v. Sears, Roebuck & Co., 722 F.3d 1542, 1549 (Fed. Cir. 1983).

Most telling is what petitioner does not and cannot say: it cites not a whisper from Congress in 1952 or since criticizing the heightened showing of patent invalidity consistently required by this Court. Indeed, even modern patent reform proposals leave untouched the presumption of validity and its "consistent judicial gloss," *Bruesewitz, supra*, imposing a heightened standard of proof. *See* America Invents Act, S. 23, 112th Cong. (passed by Senate, March 8, 2011). Petitioner's case, in other words, is less about statutory construction and more about its quest to obtain from this Court what patent challengers could not in 1952 and have not since been able to obtain from Congress.

2. The Statutory Text Comports with Past Precedent.

Petitioner's effort to read the settled jurisprudential backdrop out of a statute that was enacted to codify that law fails. To begin with, if petitioner is right that the issuance of a patent has no bearing on the standard for proving its invalidity, then there was no reason for Congress in 1952 to enact both sentences of Section 282. Specifically, petitioner posits that Section 282 was all about assigning the burdens of production and proof to the infringer challenging the patent's validity. But if that is all Congress wanted to do—in flat rejection of *RCA* and the unbroken line of precedent of this Court—then Congress needed only to enact the second sentence of Section 282: "The burden of establishing invalidity of a patent or any clam thereof shall rest on the party asserting such invalidity."

Congress could have skipped the first sentence ("A patent shall be presumed valid.") altogether. The second sentence would have assigned both the burden of proof and production to the challenger. And nothing more would need to have been said. This Court, however, does not read statutory text to make 50% of its content surplusage. *See Corley v. United States*, 129 S. Ct. 1558, 1566 (2009) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.").

Nor, if it wanted the two sentences of Section 282 to tagteam the burdens of proof and production, would Congress in subsequent amendments have separated the two sentences by multiple lines of new text. Instead, Congress's more extended discussion of the presumption of validity in the current text of Section 282 underscores that the presumption of validity in the first sentence was meant to be one of legal substance operating in the real world where inventors and investors make decisions, not just a procedural rule for courthouse litigation.

Petitioner's argument (Br. 20-21) that the presumption of validity merely assigns a burden of production fails for another reason. In the normal course, "the determination that a defendant has met its burden of production" is important not just because it "rebut[s] any legal presumption," but also because it shifts the burden to the plaintiff, who ultimately bears the burden of proving its claim. *St. Mary's Honor Ctr. v. Hicks*, 509 U.S. 502, 509-510 (1993); *see Schaffer v. Weast*, 546 U.S. 49, 56 (2005) ("The ordinary default rule [is] that plaintiffs bear the risk of failing to prove their claims."). But no

such burden shifting occurs under Section 282, because the second sentence of the statute imposes the entire burden of proving invalidity on the party asserting invalidity. As this Court stated in *Blonder-Tongue*, under Section 282, the party seeking to establish invalidity must "*both* introduce proof to overcome the presumption *and* attempt to rebut whatever proof the patentee offers to bolster the claims." 402 U.S. at 335 (emphases added).

And even if petitioner were correct that the first sentence of Section 282 imposes a burden of production, that would simply beg the question of what evidentiary showing the party challenging validity must make to carry its burden-of-proof under Section 282. That question is answered both by this Court's century-worth of pre-1952 precedents, codified in Section 282, requiring a showing of clear and convincing evidence, and by *Blonder-Tongue*'s recognition that "patentees are *heavily favored* as a class of litigants by the patent statute." 402 U.S. at 335 (emphasis added).

3. The "Clear and Convincing" Standard Provides Indispensable Security to Inventors, Developers, and Investors.

As if the dearth of legislative direction and judicial precedent were not enough, the arguments of petitioner and its *amici* ignore the "clear and convincing" standard's critical contribution to the stability and reliability of patent rights. Most basically, patent law cannot make inventors "secur[e]" in their interests and cannot actually "promote the progress of science," U.S. Const., art. I, § 8, cl. 8, if their patents are at perpetual risk of

being cast aside in any lawsuit anywhere at any time in the inherently unpredictable civil litigation process.

The reliability and durability of patent grants from the federal government are indispensable to the fluid disclosure of innovation and to providing the structural support for turning innovative ideas into usable and marketable products for the public. For a broad swath of businesses and industries—biotechnology, military and heavy equipment, and durable consumer goods—research, development, and bringing products to market take substantial time and long-term investment. Only a reliable and stable patent system, in which the government's grant of a patent right provides meaningful protection, can make that publicly beneficial innovation possible.

More specifically, the heightened standard for invalidation fuels innovation by limiting risk and providing a measure of predictability for patentees and all affected entities. It furnishes the inventor, as well as private business, venture capitalists and others who contribute to the research and development process, with the confidence that the expenditure of time, energy, and money will result in a durable patent—one that lasts long enough to develop and apply the patent in public uses and provide a reasonable return. The heightened standard also promotes the liberal licensing and transfer of patented technology in pro-competitive arrangements, frequently involving private and public sector partnerships, including thousands of university/industry licensing arrangements. Those arrangements rest critically on the expectation that the validity of the patent will not be easily upset.

Changes to the patent system that cause parties to technology licensing agreements to question the strength, and thus the value, of an issued patent will significantly undermine such arrangements.

Applying the "clear and convincing" standard to the protection of property interests that are of such public and private magnitude hews closely to precedent in two respects.

First, this Court's adoption of the "clear and convincing" evidence standard in *RCA* and other cases reflects the profound public and private interests at stake in the limited property right that a patent creates. "[P]atents are matters concerning far more than the interest of the adverse parties; they entail the public interest." *S&E Contractors, Inc. v. United States*, 406 U.S. 1, 15 (1972). Courts have long applied the "clear and convincing" standard to property rights in which there is a distinct societal need for stability and certainty. For example, only clear and convincing proof can contest a will,[2] reform a deed,[3] establish adverse possession,[4] obtain a prescriptive easement,[5] revoke a broadcaster's

---

[2] *See, e.g., Lutz v. Orinick,* 401 S.E.2d 464, 467 (W.Va. 1990); *In re Last Will and Testament of Melson*, 711 A.2d 783, 788 (Del. 1998); *Evans v. Liston*, 568 P.2d 1116, 1118 (Ariz. Ct. App. 1977).

[3] *See Thirty and 141 v. Lowe's Home Centers*, 565 F.3d 443, 446 (8th Cir. 2009); *In re Kentucky Processing Co.*, 282 Fed. Appx. 371, 373-374 (6th Cir. 2008).

[4] *See, e.g., United States v. Tobias,* 899 F.2d 1375, 1378 (4th Cir. 1990)*; Pueblo of Santa Ana v. Baca,* 844 F.2d 708, 712 (10th Cir. 1988).

[5] *See, e.g., Andrews v. Columbia Gas Transmission Corp.*, 544 F.3d 618, 631 n.13 (6th Cir. 2008); *United States v. Tobias* ,

license,[6] or revoke a professional license.[7] In those situations, only a heightened showing will provide the underlying property right sufficient security against loss through the vagaries of litigation.

Likewise here, a lawsuit seeking patent invalidation is not an ordinary commercial dispute over damages that affects only the interests of the parties; it strikes at the heart of the "delicate balance" Congress crafted between protecting inventors, promoting innovative development, and ensuring fair competition. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). Indeed, some of this Court's earliest cases applying a heightened standard of proof for patent invalidation stressed that the grant of a property right upon which both the grantee and the public reasonably rely should not be withdrawn lightly. *See, e.g.*, *Coffin*, 85 U.S. at 124 ("every reasonable doubt should be resolved against" invalidity, because the law in this area "requires not conjecture, but certainty").

Thus the "clear-and-convincing-evidence standard accommodates society's competing interests in increasing the stability of property rights and in putting resources to their most efficient uses,"

---

899 F.2d 1375, 1378 n.4 (4th Cir. 1990); *Pueblo of Santa Ana v. Baca,* 844 F.2d 708, 712 -713 (10th Cir. 1988).

[6] *See, e.g., Sea Island Broadcasting Corp. v. FCC*, 627 F.2d 240, 244 (D.C. Cir. 1980).

[7] *See, e.g.*, *Sandarg v. Dental Bd. of California*, 109 Cal. Rptr. 3d 826, 831 (Cal. App. 2010); *Columbus Bar Ass'n. v. Kiesling*, 925 N.E.2d 970, 976 (Ohio 2010); *Nguyen v. Department of Health Medical Quality Assurance Comm'n.*, 29 P.3d 689, 693 (Wash. 2001).

Colorado v. New Mexico, 467 U.S. 310, 316 (1984). As with other important property rights, the standard also allocates the risk of erroneous judgment between the litigants and underscores the public importance that society attaches to the decision to grant patent rights. Given the stakes in such cases, "[a] mere preponderance of evidence * * * is not enough." *Oriel v. Russell*, 278 U.S. 358, 362 (1929).

Second, the "clear and convincing" standard has long been employed to give governmentally-created property interests the legal force, effect, and durability needed to serve their public purposes. The "clear and convincing" standard of proof enforces "the respect due to a patent" and "the immense importance and necessity of the stability of titles dependent upon these official instruments." *United States v. Maxwell Land-Grant Co.*, 121 U.S. 325, 381 (1887) (land patent case). Indeed, the clear and convincing standard comports with the protection that the law has historically accorded to the holders of government-issued licenses, which, like patents, are generally regarded as a form of property right. *See Cleveland v. United States*, 531 U.S. 12, 26 n.4 (2000). Furthermore, this Court has long recognized that official actions of the federal government merit a presumptive legitimacy in judicial decisionmaking. *United States v. Armstrong*, 517 U.S. 456, 464 (1996); *United States v. Chemical Foundation*, 272 U.S. 1, 14-15 (1926).

Those principles apply equally to the federal government's conferral of property rights in a patent. A challenge to a patent "is an application to the court to set aside the action of one of the executive departments of the government" that "gave to the

defendant the exclusive rights of a patentee." *Morgan v. Daniels*, 153 U.S. 120, 124 (1894). When a litigant seeks "to set aside the conclusions reached by the administrative department, and to give to the plaintiff the rights there awarded to the defendant," the claim "is not to be sustained by a mere preponderance of evidence." *Id*. *See also Dickinson v. Zurko*, 527 U.S. 150, 158-161 (1999) (discussing *Morgan*'s reach).

Thus, at two different levels—the distinctive public interest in protecting certain, significant property claims imbued with a public interest and heavy reliance interests, and the respect accorded to an expert federal agency's grant of patent property rights—the "clear and convincing" standard long embodied in precedent makes sense. Unless patents have meaningful force and durability for the inventors and developers who bring innovation to fruition—unless the United States' issuance of a patent property right has more force and respect in the law than a "dubious preponderance" determination of lay jurors, *RCA*, 293 U.S. at 8—the innovators' side of the balance is deeply diminished. Indeed, thousands upon thousands of inventors, financiers, licensees, private businesses, and public institutions have built strong reliance interests on the well-established principle that the validity of patents issued by the federal government can be overcome only upon clear and convincing evidence of invalidity. *See* Adam B. Jaffe & Josh Lerner, *Innovation and its Discontents*, 1 Capitalism and Society 22 (2006). Abandoning the clear and convincing standard would profoundly disturb those legitimate reliance interests. It also would

substantially increase the risk of erroneous jury invalidation, while pushing the risk of innovation disclosure, support, and investment to the breaking point. "A patent that costs a lot to get from the Patent Office, and a lot more to defend in unending reexamination, but that gives no advantage in court, is a patent that doesn't do much good to anyone."[8]

C. Innovation In The Biotechnology Industry Depends On The Stable And Durable Patent System That The Clear And Convincing Evidence Standard Fosters.

1. Biotechnology Innovation is Vital.

The biotechnology industry is a case in point for the importance of patent stability. The exceptionally "rapid pace of innovation in the biotechnology industry" in recent decades has led to innovations that have dramatically improved and even saved lives on a daily basis.[9] Biotechnology advancements provide life-saving medical treatments and diagnostic procedures, disease- and herbicide-resistant crops, and a host of promising scientific solutions for modern environmental, medical, agricultural, and energy challenges. Many of those products, moreover, find their origins on university campuses as the result of the critical research that

---

[8] F. Scott Kieff, *The Patent Process Run Amok*, DEFINING IDEAS (Hoover Institution) (Feb. 1, 2011), *available at* http://www.hoover.org/publications/defining-ideas/article/64956.

[9] *See* Federal Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy ("FTC Report"), Ch. 3, p. 21 (Oct. 2003), *available at* http:/www.ftc.gov/os/2003/10/innovationrpt.pdf.

they can be conducted only within the framework of a strong patent system.

In the health care arena, the biotechnology industry has brought to market more than 230 drugs, diagnostics, therapies, and vaccines for once untreatable diseases, such as cancer, diabetes, HIV/AIDS, and autoimmune disorders. Additionally, more than 400 therapeutic biotechnology products are currently in clinical trials being tested for their effectiveness in combating hundreds of diseases – including numerous common and rare forms of cancer, heart disease, Alzheimer's, Parkinson's, stroke, cystic fibrosis, multiple sclerosis, lupus, kidney disease, and liver disease.

Additionally, biotechnology research holds the promise of developing "personalized medicine," in which specialized biotech research tools will permit the affordable sequencing of an individual's own unique genetic code to identify that person's susceptibility to certain diseases and to enable customized medical treatments that are cheaper and more effective than the current "one-size-fits-all" approach.[10]

In the agricultural arena, biotechnological innovation is helping to feed a growing world and to combat hunger in areas challenged by drought, flooding, pestilence, and other inclement conditions. Among other things, biotechnology research and development has led to the emergence of disease-and herbicide resistant crops and a concomitant increase

---

[10] *See* Mayo Clinic, *Pharmacogenomics: When Medicine Gets Personal*, *available at* http://www.mayoclinic.com/health/personalized-medicine/CA00078.

in harvests. In 2006, more than 8 billion pounds of additional crops were grown in the United States with over 100 million fewer pounds of pesticides.[11] And in 2010, more than 14 million famers in China and India adopted insect-resistant cotton created in the United States as a means to grow their way out of poverty.[12] Such innovations have reduced the environmental impact of food production by as much as 32% for some crops.[13]

Furthermore, crops are being developed that will grow under adverse conditions, such as water or nitrogen deficiency. Indeed, "[b]iotech foods could improve food yields by up to 25 percent in the developing world and feed the more than three billion people to be born in the next three decades."[14]

Finally, biotechnology innovation helps reduce pollution and dependence on fossil fuels or imported sources of energy. It serves this vitally important

---

[11] *See* Sujatha Sankula, *Quantification of the Impacts on U.S. Agriculture of Biotechnology*, National Center for Food & Agriculture Policy (Nov. 2006), *available at* http://www.ncfap.org/documents/2005biotechExec Summary.pdf.

[12] Clive James, Global Status of Commercial Biotech/GM Crops: 2010, International Service for Acquisition, Agri-Biotech Applications Brief, 42-2010, *available at* http://www..isaaa.org/resources/publications/briefs42/executive summary/default.asp.

[13] *See* Graham Brookes & Peter Barfoot, *Plant Biotechnology Proven Promising*, PG Economics, at 1 (Oct. 11, 2005).

[14] Tommy G. Thompson, Secretary of Health & Human Services, "Biotechnology: Its Promise and Challenge in the New Century," Address at the Emerging Issues Forum on Biotechnology and Humanity at the Crossroads, *available at* http://www.hhs.gov/news/speech/2002/020211.html.

societal need by developing biofuels that efficiently convert non-food biomass (crop residues, switchgrass, and hybrid wood plants) into ethanol and other valuable materials.

2. Biotechnology Depends on Secure and Reliable Patents.

A stable and durable patent system, with the clear and convincing standard for proving patent invalidity as its centerpiece, is imperative to the biotechnology industry because it "is the most research and development-intensive and capital-focused industry in the world.[15] In fact, biotechnology research and development expenditures are more than double the average of the pharmaceutical industry, which itself is several times more intensive than any other industry. *See FTC Report* at pp. 15-16; Dan Burk & Mark Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1676 (2003) ("If any technology fits the criteria of high-cost, high-risk innovation, it is certainly biotechnology. Development of biotechnology products, particularly in the pharmaceutical sector, has been characterized by extremely long development times and high development costs.").

The costs of biotechnological innovation are staggering. Biotechnology companies in the United States invest more than $30 billion annually in research and development, virtually all of which

---

[15] *See* National Institute of Health: Moving Research from the Bench to the Bedside: Hearings Before the House Comm. on Energy and Commerce, Subcomm. On Health 108th Cong. 47 (2003) (Phyllis Gardner, M.D.) ("NIH Gardner Testimony").

comes from private sources.[16] The average capitalized cost of bringing a biologic from the laboratory to human clinical trials exceeds $600 million. Subsequent human testing mandated by the Food and Drug Administration costs another $624 million. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial and Decisions Economics, 469-479 (2007).

The length of time it takes to bring a biotechnological product to fruition is equally daunting. Clinical development of biologics typically lasts more than eight years. DiMasi& Grabowski, 28 Managerial and Decisions Economics at 469-479. And the average for vaccine products may be ten years or longer. *See* Yann Jolly, *et al.*, Regulatory Approval For New Pharmacogenomic Test: A Comparative Overview, 66 Food and Drug L.J. 1, 3 (2011).

The challenge of biotechnology innovation is heightened further by the sheer uncertainty of the development process. The costly and time-consuming research and development of biotechnology products frequently meets with failure. For every successful pharmaceutical product, thousands of products are studied but then rejected. Only a small minority of

---

[16] NIH Gardner Testimony at 49*; see also* Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing, Hearing Before the House Comm. on the Judiciary Subcomm. on Courts, the Internet and Intellectual Property, 110th Cong. 3 (2007) (Jeffrey P. Kushan).

drugs that advance to human clinical trials obtain FDA approval.[17]

The enormous cost, time-commitment, resource-investment, and uncertainty inherent in biotechnology development can almost never be borne by any one person or entity alone. For that reason, biotechnology innovation depends on partnerships between numerous stakeholders, including research universities, public institutions, private industry, and investors. *See* Stewart J.H. Graham, *et al.*, *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 Berkeley Tech. L. J. 1255, 1317 (2009); Ashley J. Stevens *et al.*, *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, New Eng. J. Med., Feb. 10, 2011, at 535-541 (153 new FDA-approved drugs, vaccines, or new uses for existing drugs were discovered through research carried out at public sector research institutions). For example, a university scientist might discover a new protein linked to certain cancers. After patenting the relevant technology, the university might then license a biotech business or university spin-off company to begin the time-intensive process of developing standardized tools for further research, as well as diagnostic methods, therapeutic treatments, and other real-world applications for the discovery.

Such licensing arrangements are mutually beneficial. They provide the licensee with the exclusive rights needed to attract capital for research

---

[17] *See* Tommy G. Thompson, Secretary of Health and Human Services, Remarks as Prepared for the Milken Institute's Global Conference (April 26, 2004), *available at* http://www.hhs.gov/news/speech/2004/040426.html.

and development, while providing the university with revenue to support further academic research. Indeed, in fiscal year 2009, 596 new companies were formed as a result of university research, and 595 were formed in 2008. AUTM, LICENSING ACTIVITY SURVEY: FY09 (Dec. 2010). The symbiotic relationship between different entities engaged in biotechnological research and development is crucial both to ensuring the continued viability of small and publicly funded biotechnology research entities, which cannot afford expensive licensing fees or sale prices, and to allowing inventors to navigate successfully the long and resource-intensive road to the commercial and public use of their products.[18]

Since this Court first held three decades ago that genetically-engineered organisms were patent-eligible, *see Diamond v. Chakrabarty,* 447 U.S. 303, 310 (1980), and since Congress authorized in the Universities and Small Business Patent Protection Act of 1980 the licensing of biotechnology innovations funded by the government, 35 U.S.C. § 200 *et seq*., patents have become the primary asset, and often the lifeblood, of the biotechnology industry. *See FTC Report,* Ch. 3*,* at 29 ("Biotechnology innovation is

---

[18] Under the University and Small Business Patent Procedures Act, 35 U.S.C.§ 200 *et seq*., universities that conduct research with federal funds may retain title to resulting inventions and may license them to other parties. The availability of liberal licensing of biotechnological products has provided enormous benefits to society, including life-sustaining medical and agricultural innovations. *See* Birch Bayh, Joseph P. Allen, and Howard W. Bremer, *Universities, Inventors and Bayh-Dole*, 79 Pat., Trademark & Copyright J. 167, 169 (2009).

heavily dependent on the patent rights that have been available for biotechnology inventions since 1980."); Burk & Lemley, 89 Va. L. Rev. at 1687 ("[M]ost biotechnological and chemical inventions require broad patent protection because of their high costs and uncertain development process."); Graham, 24 Berkley. Tech. L. J. at 1278, 1280, 1307 (discussing importance of patents to start-up biotechnology companies and their investors). That is because only strong, stable, and durable patent protection can support the investment of billions of dollars in biotechnology research and development. *FTC Report* at 15. Without those investments, the capital-intensive and time-consuming advancements in biotechnology simply could not proceed.

Lowering the standard for proving patent invalidity in litigation will significantly chill biotechnological innovation. The necessary commitment of time, energy, and money to bring a biotechnological product to market simply may not be worth it to inventors and investors if, at some point down the road after a patent is obtained, a lay jury can wrest the patent away upon a finding of invalidity under the mere preponderance standard. And lowering the standard also will unsettle the existing expectations of countless inventors and investors who have expended time, energy, and money in reliance on the principle that the patents obtained from their efforts will not be lightly withdrawn by civil litigation.

Finally, the heightened evidentiary standard facilitates investment in biotechnology not only for the patentee. Businesses commonly plan development strategies based on a careful analysis of

the patent landscape in their fields. Assuming patents to be enduring legal instruments that benefit from a strong presumption of validity, competing businesses often decide to "design around" a competitor's patent, or to incorporate non-infringing alternative features that ultimately result in additional options for consumers. In this way, a system of strong patent rights facilitates a market in which alternative products compete on their own merits, with more consumer choices, and more options for patients, doctors, and farmers—as opposed to a market in which ever cheaper copies of the same product compete on price alone.

In other instances, strong patent rights can result in products becoming available sooner. Biotechnology companies often compete for limited clinical and developmental resources, especially in efforts to combat rare diseases that affect small, underserved patient populations. A biotechnology company's strong patent position may well persuade its competitors to defer or redirect their research and development efforts rather than fight over scarce clinical resources. In that way, a strong presumption of validity contributes to an "ordering" function of patents that encourages the development of alternative competing products where the market will bear them, and the conservation of public development resources where such resources are limited.

D. Allegations Of Undisclosed Prior Art Do Not Alter Application Of The "Clear and Convincing" Standard Of Proof.

In arguing for wholesale reversal of this Court's multiple decisions applying a heightened showing for patent invalidation, petitioner has largely turned its back on the issue it brought to this Court for certiorari review: whether there is an exception to the "clear and convincing evidence" rule when "the prior art on which the invalidity defense rests was not considered by the Patent and Trademark Office prior to the issuance of the asserted patent." Pet. i. Petitioner has abandoned its argument for a two-tiered standard of proof for good reason.

First, it is entirely unhinged from statutory text, which nowhere supports such claim-by-claim bifurcation of the presumption of validity.

Second, the very argument for an exception to the rule confesses the error of petitioner's newfound premise that no clear and convincing rule has ever existed at all. If no heightened showing were required in the first place, there would be no need for an exception to that rule when undisclosed prior art is at stake.

Third, the hybrid standard originally advocated by petitioner (Pet. 15) – one standard for prior art that was considered and another for prior art that was not considered – is unworkable in practice. It would overload the patent examination process at the PTO because applicants would confront a system in which the presumed validity of

their patent would depend on the sheer amount of prior art that was made part of the patent examination file. Applicants would have little choice but to overload patent examiners with every conceivable and identifiable past reference to preempt the patent's easy invalidation by lay juries operating under a mere preponderance standard. That is of particular concern for patent applications coming from industries like the biotechnology industry that already pour extensive resources and work into their patent applications.

Fourth, the hybrid standard would be dysfunctional in court. Litigation would devolve into collateral skirmishes over whether the newly identified prior art was truly considered by the PTO, or whether it was immaterial or redundant of art that was considered. The standard of proof would change case by case, and perhaps patent claim by patent claim, in contravention of the basic tenet that a standard of proof should be uniform. *See Santosky v. Kramer*, 455 U.S. 745, 757 (1982) (the "proper standard of proof" should not be a "case-by-case determination"). Juror confusion in what is already a highly technical area would be accentuated if the jury had to apply differing standards of proof, ratcheting the standard up and down within the same case based on the particular type of invalidity argument presented.

E. Any Change In The Standard For Proving Invalidity Should Come From Congress.

1. Stare Decisis Principles and the Reliance of Third Parties on Court Decisions Weigh Against a Judicial Unsettling of the Standard of Proof.

In asking this Court to lower the standard for proving patent invalidity and thereby jettison its unanimous decision in *RCA* and the line of precedents that preceded and followed it, petitioner and its *amici* run headlong into the doctrine of stare *decisis*, which operates at its "acme" in this case because it involves both "property * * * rights, where reliance interests are involved," *Payne v. Tennessee*, 501 U.S. 808, 828 (1991), and "statutory construction, where Congress is free to change this Court's interpretation of its legislation." *Burlington Indus. v. Ellerth*, 524 U.S. 742, 764 (1998).

Indeed, in any patent case in which a litigant seeks to upset long-standing rules on which firm reliance interests have been built, the judiciary "must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo*, 535 U.S. at 739. In this context in particular, "[t]he responsibility for changing [such rules] rests with Congress [because] [f]undamental alterations in [them] risk destroying the legitimate expectations of inventors in their property." *Id.*; *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32 n.6 (1997) ("To change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when

issuing * * * patents which have not yet expired and which would be affected by our decision.").

2. Congress Has Prescribed its Own Solution for Questionable Patents.

The fact that Congress, despite extensive legislative study and action in the patent area, has never altered the standard of proof for patent invalidity should be dispositive. After all, this case is fundamentally about how best to strike the "delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." *Festo*, 535 U.S. at 731. That is precisely the type of policy decision that the Constitution charges Congress, not the courts, with making. U.S. Const. art. I, §8, cl. 8. And it is precisely the type of policy decision that is best made through the comprehensive study of all competing interests that Congress is institutionally situated to conduct, rather than through the microcosm of record-constrained two-party litigation.

Congress, unlike petitioner and its *amici* and unlike courts, "has no responsibility to confine its vision to the facts and evidence adduced by particular parties," and, indeed, "its special attribute as a legislative body lies in its broader mission to investigate and consider all facts and opinions that may be relevant to the resolution of an issue." *Fullilove v. Klutznick*, 448 U.S. 448, 502-503 (1980) (Powell, J., concurring); *see Bush v. Lucas*, 462 U.S. 367, 389 (1983) (Congress "may inform itself through factfinding procedures such as hearings that are not available to the courts.").

Congress thus can canvass the impact of the current patent system, including the "clear and convincing" standard for patent invalidity, on a wide spectrum of business sectors and industries nationwide. Congress can also evaluate a body of empirical evidence that cuts across the entire economy, and can take into account the views of all the affected parties, including inventors, investors, venture capitalists, licensees, research laboratories, universities, and public institutions. Indeed, Congress has undertaken just such reviews in considering changes to the patent laws in recent years, including changes to the clear and convincing standard for proving patent invalidity. *See* Hearing Before the Subcomm. on the Courts, Internet, and Intellectual Property of the House Comm. on the Judiciary, 110th Cong. (2007); Hearing Before the Subcomm. on Intellectual Property of the Senate Judiciary Comm., 109th Cong. (2005). But Congress has never lowered the standard, despite calls from some quarters to do just that.

In fact, Congress has chosen a different path. Its monitoring and calibration of the patent system and invalidity challenges to patents is already embodied in its authorization of the PTO to reexamine the validity of patents under a preponderance standard. 35 U.S.C. §§ 302, 311; *see In re Swanson*, 540 F.3d 1368, 1377-1378 (Fed. Cir. 2008). Rather than empty *all* patents of the stability and durability enforced by the presumption of validity under the clear and convincing standard, Congress has allowed challengers to seek review under a preponderance standard, *but only on Congress's terms*. The preponderance standard must

be (i) applied by an expert agency empowered both to modify and invalidate patents; (ii) confined to issues that the PTO has not already adjudicated; and (iii) prior art must take the form of objective, inherently reliable, or self-authenticating evidence like prior patents and printed publications. *See* 35 U.S.C. §§ 301, 303(a), 312(a). Microsoft plainly disagrees with Congress's choice. But it is not the role of courts to re-legislate. Tearing away the judicial backdrop against which Congress legislated and suddenly reformulating the litigation standard to mirror the standard in the reexamination process, without any of Congress's limitations, would unravel the calibrated incentive system for agency processes that Congress designed.

Notably, that congressional sentiment has been expressed again in a bill that recently passed the Senate. *See* America Invents Act, S.23, 112th Cong., 1st Sess. (passed March 8, 2011). The purpose of this legislation is to "establish a more efficient and streamlined patent system," 157 Cong. Rec. S1348-02 (March 8, 2011) (Sen. Leahy), not by lowering the standard of proof in litigation, but by enhancing the "inter partes" patent reexamination process through codification of the PTO's preponderance standard in reexaminations. *See* S.23, § 5.

In asking this Court to chart a different path, petitioner ignores the fact that the Constitution charges Congress with writing the patent laws. This Court has long recognized that Congress has tasked the PTO, not courts and not civil litigants, with the primary responsibility for "sifting out unpatentable material." *Graham v. John Deere Co.*, 383 U.S. 1, 18

(1966). While some mistakes are inevitable in a process that involves thousands of patent applications annually, that certainly does not prove that lay jurors with no technical expertise, no larger framework for analysis, and no background exposure to the patent system are better suited for the task.

3. Congress Has Canvassed a Broad Range of Vantage Points in Preserving the Clear and Convincing Standard.

Stripped to its essentials, petitioner and its *amici* ground their plea for a change in the law on the argument that the patent system is broken, and citing the "clear and convincing" standard as emblematic of the problem. But whether the patent system is in need of repair, and whether and to what extent the "clear and convincing" evidence standard for proving patent invalidity is part of the problem, are questions that depend very much on vantage point. Respecting Congress's comprehensive vantage point is thus critical because the impact of the patent system and its importance to business shows pronounced industry-specific differences. "The systematic variation in R&D expenditures across industries naturally affects the need for patent protection; industries that must spend more time and money in R&D generally have a greater need for patent protection." Burk & Lemley, 89 Va. L. Rev. at 1583. *See also* Graham, 24 Berkeley Tech. L. J. at 1262 ("[T]he usefulness of patents to technology entrepreneurs is driven by industry characteristics.").

The software industry—the industry of petitioner and many of its *amici*—is neither as capital- nor as time-intensive in bringing innovation

to market as many other sectors of the economy are. Today, in the software industry, "it is still possible to hire a team of programmers to write a new applications program for less than a million dollars," and "[w]hile debugging a new program is still a significant undertaking, writing such a program takes considerably less time than developing a new drug[.]" Burk & Lemley, 89 Va. L. Rev. at 1582-1583. Strong patent protection is thus far less important for software inventions, with their "quick, cheap, and fairly straightforward post-invention development cycle," short lead time to bring the invention to market, and "relatively low" capital investment needs. *Id.* at 1687-1688. *See id.* at 1622-1623 ("The need for strong patent protection is somewhat less for software inventions than it is in other industries. Software patents are important, but the relatively low fixed costs associated with software development, coupled with other forms of overlapping intellectual property protection for software, mean that innovation in software does not depend critically on strong, broad protection.").

In contrast, "broad patent protection" is more important for biotechnology innovations, "because of their high cost and uncertain development process." Burk & Lemley, 89 Va. L. Rev. at 1687. *See* Graham, 24 Berkeley Tech. L. J. at 1262 ("So while we find that patents help many startups compete in the market with their technology, this role tends to be much more pronounced among biotechnology and hardware companies * * *. Conversely, patents are much less important as a means by which most software firms—the majority of which hold no

patents—capture competitive advantage from their innovations.").

Importantly, the need for stability and endurance in patent protection that the biotechnology industry illustrates is *not* confined to that industry. It is, instead, representative of a need that cuts across a broad cross-section of business and industry, ranging from defense contractors to heavy machinery, to household and office products.

The evidence shows that industry-specific distinctions carry over to financing: venture capitalists funding biotechnology products consider patents more important than do venture capitalists funding software products. Graham, 24 Berkeley Tech. L. J. at 1307. Not surprisingly therefore, "[a]fter founding, venture-backed biotechnology and medical device companies * * * are more likely than software and [i]nternet firms to file patent applications." *Id.* at 1283.

That is not to say that there should be industry-specific patent rules. The patent laws, which universally apply to the diverse inventive community, should be industry neutral. Rather, the evidence of industry-specific variations simply underscores that the perspective that petitioner and its *amici* have on the workings of the patent system and the solutions Congress has prescribed is just that—one perspective. But the effect of adopting their proposed rule for patent validity would apply to all industries and all sectors. The patent rules that might appear to promote software development would be devastating for resource- and time-intensive biotechnology research and innovation that seek to create agricultural tools to feed a hungry world, to

develop renewable fuels that limit pollution and reduce dependence on foreign sources of energy, and to discover medical treatments that save lives. That is a balance that only Congress can and should draw.

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

Thomas DiLenge
General Counsel
Hans Sauer
Deputy General Counsel for Intellectual Property
BIOTECHNOLOGY INDUSTRY ORGANIZATION
1201 Maryland Ave., S.W.
Washington, D.C. 20024

Patricia A. Millett
Counsel of Record
AKIN GUMP STRAUSS HAUER & FELD LLP
1333 New Hampshire Ave., NW
Washington, DC 20036
(202) 887-4000
pmillett@akingump.com

Michael C. Small
AKIN GUMP STRAUSS HAUER & FELD LLP
2029 Century Park East
Suite 2400
Los Angeles, CA 90067
(310) 229-1000

March 18, 2011