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 PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

DAVID E. KORN
PHARMACEUTICAL
RESEARCH AND
MANUFACTURERS OF
AMERICA
950 F St., N.W.
Washington, D.C. 20004
(202) 835-3400

HARRY J. ROPER
Counsel of Record
JENNER & BLOCK LLP
353 N. Clark Street
Chicago, IL 60654
(312) 222-9350
HRoper@jenner.com

PAUL M. SMITH
ELAINE J. GOLDENBERG
LEAH J. TULIN
JENNER & BLOCK LLP
1099 New York Avenue, N.W.
Suite 900
Washington, D.C. 20001
(202) 639-6000

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS

LEGISLATIVE MATERIALS

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading research-based biopharmaceutical companies. In 2010, PhRMA members invested approximately $49.4 billion (of an industry total of approximately $67.4 billion) in discovering and developing new medicines, *see* Burrill & Co., Analysis for PhRMA (2011) (industry total includes PhRMA research associates and nonmembers); PhRMA, Annual Member Survey (Washington, DC: PhRMA, 2010-2011), and in the past decade they have invested more than $380 billion, *see* PhRMA, *Pharmaceutical Industry Profile 2010*, at 44 (2010). Those expenditures translate into huge benefits to the public. For example, new medicines accounted for 40 percent of the increase in life expectancy between 1986 and 2000. *See* Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data from 52 Countries, 1982-2001*, 5 Int'l J. of Health Care Fin. & Econ. 47, 71 (2005).

Resolution of the question presented in this case will have a significant impact on PhRMA's

---

[1] The parties have consented to the filing of this brief. 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 to its preparation or submission.

members.[2] Because members find themselves on both sides of patent litigation, PhRMA has a balanced perspective on the effect and desirability of the clear-and-convincing standard of proof that an alleged infringer must satisfy in order to invalidate a patent in litigation.

In PhRMA's view, a ruling lowering that standard of proof would dramatically diminish incentives for innovation. This chilling effect would disproportionately affect PhRMA's members, who rely on the incentives provided by strong patent protection when they choose to make extraordinary investments in research and development. A 2004 Department of Commerce study estimated that the average cost of bringing a new drug to market is approximately $1.3 billion, when the cost for unsuccessful drugs is taken into account. *See* U.S. Dep't of Commerce, Int'l Trade Admin., *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation* 30-31 (Dec. 2004), *available at* http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf. Patent protection provides an important way for PhRMA's members to recoup these costs, thus permitting reinvestment in further research. *See, e.g.*, Michael Meehan, *Increasing Certainty and Harnessing Private Information in the U.S. Patent System: A Proposal for Reform*, 2010 Stan. Tech. L. Rev. 1, 5 ("Given that the cost of researching and developing drugs dwarfs the production costs for drugs, companies rely primarily

[2] A list of PhRMA members can be found at http://www.phrma.org/about/member-companies.

on strong patent protection, and not manufacturing efficiencies, to maintain profits."); James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 Lewis & Clark L. Rev. 1, 10 (2005) (reporting on research indicating that the financial value of patent protection is greatest in the pharmaceutical industry).

If a mere preponderance of the evidence were to suffice to invalidate a patent in litigation, then the incentive to invest the time and money required to discover and develop new medicines would be substantially reduced, because the risk of erroneous invalidation would be substantially higher and those investments would be substantially less secure. This dampening of innovation would harm not only PhRMA's members, but also the public, which has a vital interest in ensuring that promising research for new life-saving treatments continues to take place.

SUMMARY OF ARGUMENT

When Congress declines to specify the standard of proof applicable to a claim or defense, the courts are tasked with dictating the appropriate standard. Pursuant to this Court's long-standing precedent, the Federal Circuit (like its predecessor court) has long required clear-and-convincing proof that a patent is invalid, and Congress has not sought to prescribe a different standard by statute. The clear-and-convincing standard, moreover, is justified by the vitally important public interest – reflected both in the Constitution and in the statutory presumption of patent validity created by 35 U.S.C. § 282 – of

promoting innovation and protecting the legitimate expectations of innovators. Applying a lower standard not only would give short shrift to the technical expertise and judgment of the Patent and Trademark Office ("PTO"), but also would decrease the reliability of patent protection and thereby create serious disincentives for inventors to invest time, effort, and money in research and development.

Lowering the standard of proof for invalidating a patent would be especially damaging to the innovation incentives of PhRMA's members, who pour billions of dollars into discovering life-saving treatments and medications that benefit society as a whole. Because the public has a vital interest in spurring new biopharmaceutical developments, a change in the standard of proof would work a particular public harm.

The so-called "dual standard" – under which a preponderance standard would replace the clear-and-convincing standard where the patent examiner is not shown to have considered the prior art alleged to demonstrate invalidity – is no solution, and should not be adopted. Such a standard would cause undue disruption to the patent system. It would increase the complexity and difficulty of resolving patent cases, increase the volume of patent litigation in federal court, and discourage use of reexamination procedures as an alternative option. It would also overwhelm the PTO by encouraging patent applicants to submit as much prior art to the patent examiner as possible, regardless of its real relevance.

ARGUMENT

I. A Clear-and-Convincing Standard for Proving That A Patent Is Invalid Is Necessary To Protect The Public's Interest In Promoting Innovation.

As Petitioner asserts, 35 U.S.C. § 282 states that "[a] patent shall be presumed valid," but does not explicitly discuss the standard of proof required to defeat this statutory presumption of validity. *See* Microsoft Br. 14. Under these circumstances, it is the well-established role of the courts to determine the applicable standard. *See Herman & MacLean v. Huddleston*, 459 U.S. 375, 389 (1983) ("Where Congress has not prescribed the appropriate standard of proof and the Constitution does not dictate a particular standard, we must prescribe one."); *cf. Steadman v. SEC*, 450 U.S. 91, 95 (1981) ("Where Congress has not prescribed the degree of proof which must be adduced by the proponent of a rule or order to carry its burden of persuasion in an administrative proceeding, this Court has felt at liberty to prescribe the standard, for '[i]t is the kind of question which has traditionally been left to the judiciary to resolve.'" (quoting *Woodby v. INS*, 385 U.S. 276, 284 (1966))).

Precedents from this Court dating back to the nineteenth century have consistently endorsed the application of a clear-and-convincing standard to challenges based on the alleged invalidity of a patent. As this Court explained in *Radio Corp. of America v. Radio Engineering Laboratories*, 293 U.S. 1 (1934), "[t]hrough all the verbal variances, . . .

there runs this common core of thought and truth, that one otherwise an infringer who assails the validity of a patent . . . bears a heavy burden of persuasion, and fails unless his evidence has more than a dubious preponderance." *Id.* at 8; *see also id.* at 2 ("Even for the purpose of a controversy with strangers, there is a presumption of validity, a presumption not to be overthrown except by clear and cogent evidence."); *Smith v. Hall*, 301 U.S. 216, 233 (1937) (discussing the "heavy burden of persuasion which rests upon one who seeks to negative novelty in a patent by showing prior use"); *The Barbed Wire Patent*, 143 U.S. 275, 285, 292 (1892) (acknowledging that "the doubts we entertain [regarding validity] . . . should be resolved in favor of the patentee" because "it was [he], beyond question, who first published the device . . . and gave it to the public"). The Federal Circuit, too, like its predecessor court, has long applied the clear-and-convincing standard of proof to invalidity claims. *See, e.g.*, *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60 (Fed. Cir. 1984) (citing *Radio Corp.*, 293 U.S. 1; *Morgan v. Daniels*, 153 U.S. 120, 125 (1894)); *Astra-Sjuco, A.B. v. U.S. Int'l Trade Comm'n*, 629 F.2d 682, 688 (C.C.P.A. 1980) (presumption of validity "can be overcome only by clear and convincing evidence"); *Solder Removal Co. v. U.S. Int'l Trade Comm'n*, 582 F.2d 628, 632-33 (C.C.P.A. 1978); Gerald Sobel, *Examining the Extra Burden Imposed on a Patentee Who Seeks a Preliminary Injunction*, 32 Am. U. L. Rev. 985, 995 (1983) (noting application of clear-and-convincing standard before creation of Federal Circuit).

That long-standing standard is necessary to protect the important public interests that are implicated by patent litigation, and is further justified by the deference to the technical expertise of the PTO reflected in § 282's presumption of validity. Congress has not altered that standard, and adopting a new standard that would suddenly permit lay juries to invalidate a patent by a preponderance of the evidence would destabilize the expectations of inventors and seriously jeopardize the rights of legitimate patent holders. The instability and unpredictability caused by such a rule would, in turn, create higher risk for companies such as PhRMA's members that depend on strong patent protection to maintain financial viability, and thereby disincentivize innovation.

1. In *Addington v. Texas*, 441 U.S. 418, 423 (1979), this Court explained that the "[t]he function of a standard of proof . . . is to 'instruct the factfinder concerning the degree of confidence our society thinks he should have in the correctness of factual conclusions for a particular type of adjudication.'" *Id.* (quoting *In re Winship*, 397 U.S. 358, 370 (1970) (Harlan, J., concurring)). The clear-and-convincing standard, which "is no stranger to civil law," *id.* at 424 (quoting *Woodby*, 385 U.S. at 285), shifts the risk of error to one party where important interests or rights are at stake. *See Grogan v. Garner*, 498 U.S. 279, 286 (1991) (quoting *Herman & MacLean*, 459 U.S. at 389-90).

Contrary to the suggestion of Petitioner and its *amici*, this Court has never held that the clear-and-convincing standard may apply only when the

important interests at stake are *liberty* interests. *See* Microsoft Br. 16; Google Br. 9. And although this Court has said that the preponderance standard generally suffices in "the typical civil case involving a monetary dispute between private parties," *Addington*, 441 U.S. at 423, a patent case is far from the "typical civil case" involving a monetary dispute. The vital importance of patents in promoting progress is reflected in the text of the Constitution. *See* U.S. Const. art. I, § 8 ("Congress shall have power to . . . promote 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."). Ensuring that inventors continue to innovate, and that investors have the confidence to invest in development of such innovations, is vital to the success of the Nation, and protecting these goals falls squarely within the realm of important interests that justify the imposition of a heightened standard of proof. *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 815-16 (1945) ("The possession and assertion of patent rights are 'issues of great moment to the public.' A patent by its very nature is affected with a public interest." (citations omitted)); *Seymour v. Osborne*, 78 U.S. (2 Wall.) 516, 533-34 (1870) (describing patents as "public franchises" granted to inventors "as matter of compensation to the inventors for their labor, toil, and expense in making the inventions, and reducing the same to practice for the public benefit, as contemplated by the Constitution and sanctioned by the laws of Congress"); *infra* pp. 14-22 (discussing particularly

strong public interest in protection of pharmaceutical patents).

The presumption of validity set forth in § 282, which affirmatively shifts the balance toward patent holders when an alleged infringer contends that a patent is invalid, reflects not only a legal directive to generalist judges and lay juries to protect this vital public interest, but also a policy judgment by Congress that deference to the PTO's initial determination of patentability is warranted.[3] Indeed, as other *amici* have persuasively demonstrated, Microsoft's attempt to cast the Federal Circuit's application of a heightened standard as deference improperly derived from the Administrative Procedure Act ("APA") is misleading. A fair reading of *American Hoist*, 725 F.2d 1350, and its progeny make clear that the Federal Circuit's discussion of deference has nothing to do with the APA, but rather is grounded in the agency's expertise in the relevant field and familiarity "from their work with the level of skill in the art." *Id.* at 1359; *see also, e.g.*, IBM Br. 9-10 (explaining the underpinnings of the Federal Circuit's deference rationale).[4] Accordingly, the Federal Circuit's

---

[3] Petitioner and its *amici* devote pages upon pages of briefing to the argument that deference to the PTO is unjustified either on legal grounds or by the practical reality of the PTO's examination of patent applications. *See, e.g.*, Microsoft Br. 40-54; Google Br. 15-29. But those arguments miss the mark, because the principal source of authority for deference to the PTO's review process is in fact the statutory presumption itself.

[4] "The deference applied to validity challenges recognizes the expert process employed by the Agency, not the expertise applied in any particular instance." IBM Br. 12-13 (citing *W.*

application of a clear-and-convincing evidence standard to such claims gives effect to the statutory presumption, ensuring that the risk of error continues to lie with the party challenging the validity of a patent that has been issued by an agency with technical expertise. In contrast, applying a preponderance standard would undercut that presumption, and in so doing would both diminish the PTO's role as the agency with "the primary responsibility for sifting out unpatentable material," *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 18 (1966), and substantially increase the risk that legitimate patents are erroneously invalidated in litigation.

2. The clear-and-convincing standard has strong roots in this Court's decisions, and the Federal Circuit has consistently applied it for over twenty-five years. There is every reason to think that Congress had in mind just such a heightened standard when it established a presumption of validity. *See, e.g.*, *Am. Hoist*, 725 F.2d at 1359-60 (Rich, J.) (discussing the drafting of the Patent Act of 1952). In any event, however, in subsequent years

---

Elec. Co. v. Piezo Tech., Inc., 860 F.2d 428, 433 (Fed. Cir. 1988)). Notably, the Federal Circuit has held that deference is not a monolithic principle and that the *evidentiary* weight of a particular piece of prior art may vary based on the degree of consideration given to that art by the patent examiner, although the clear-and-convincing standard never changes. *See Am. Hoist*, 725 F.2d at 1359; *see also, e.g.*, *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304-05 (Fed. Cir. 2008); i4i Br. 43-44, 46; *cf.* IBM Br. 24-37 (discussing how jury instructions can be used to address the weight to be given such evidence under the clear-and-convincing standard).

Congress could have changed that standard if in its judgment a heightened evidentiary burden tipped the scales too far in favor of patent holders. The fact that Congress has declined to do so – despite having had the Patent Act before it on many occasions and making numerous changes to the Act – suggests that the current burden accords with Congress's view of the proper balance, and strongly counsels against altering the existing standard. *See, e.g.*, *Shepard v. United States*, 544 U.S. 13, 23 (2005) (noting that principles of *stare decisis* are given particular weight where Congress is free to alter the interpretation of a statute and declines to do so).

That is particularly true given that a change in the standard of proof required to invalidate a patent would seriously disrupt the expectations of legitimate patent holders. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 739 (2002) ("[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community. . . . Fundamental alterations in [the rules governing patent litigation] risk destroying the legitimate expectations of inventors in their property."). Courts should be very reluctant to undermine patent protections after they have incentivized inventors, such as members of PhRMA, to invest in developing new and useful inventions – the very purpose of extending patent protection in the first instance.

The *amicus* brief submitted in support of Google and others points to the clear-and-convincing standard explicitly provided for under 35 U.S.C. § 273(b)(4) as evidence that "when Congress intended

to impose a clear-and-convincing standard in the Patent Act, it knew how to do so." Google Br. 8. But the canon of interpretation on which the Google *amici* rely – that Congress is presumed to act intentionally when it omits language in one section of a statute but includes it in another section of the same statute – bears little or no weight where, as here, the two sections of the Act were enacted at different times. *See Bates* v. *United States*, 522 U.S. 23, 29-30 (1997) (applying canon to statutory provisions enacted at the same time); *INS v. Cardoza-Fonseca*, 480 U.S. 421, 432 (1987) (noting that the different emphasis of two standards for relief in the Immigration and Nationality Act was "significantly highlighted by the fact that *the same Congress*" simultaneously drafted one and amended the other (emphasis added)).

In addition, reliance on § 273(b)(4) proves too much. That provision, which provides a statutory defense to claims of business-method patent infringement, was passed in direct response to a Federal Circuit decision "intimat[ing that] business methods could be patented" and was targeted at "limit[ing] the potential fallout" from that decision. *Bilski v. Kappos*, 130 S. Ct. 3218, 3250 (2010) (Stevens, J., concurring in the judgment) (citing *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998)). The passage of the provision therefore clearly demonstrates that Congress has acted to amend the Patent Act where it concludes that Federal Circuit decisions have upset the balance of patent rights.

By contrast, Congress has not amended § 282 to explicitly prescribe a particular standard of proof, even though it must have been aware that the clear-and-convincing standard has long been the rule for establishing invalidity.[5] Notably, Congress has made a number of other amendments to this section over the years. *See, e.g.*, Pub. L. No. 104-41, § 2, 109 Stat. 351, 352 (1995) (adding provision to clarify relationship between presumption of validity and obviousness defense); Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, § 203, 98 Stat. 1585, 1603 (adding provision to clarify that invalidation of a patent term extension constitutes defense to infringement suit during that extension period). Indeed, the Hatch-Waxman Act, which was enacted after the clear-and-convincing standard was well established in the law and which addresses patent validity challenges mounted by manufacturers of generic drugs, provided an obvious opportunity for Congress to clarify or change the

---

[5] Of course, Congress is presumed to be aware of this Court's decisions. *See, e.g.*, *North Star Steel Co. v. Thomas*, 515 U.S. 29, 34 (1995); *Cannon v. University of Chicago*, 441 U.S. 677, 696-98 (1979). In addition, when Congress created the Federal Circuit in 1982 and chose to give it exclusive jurisdiction over patent appeals, it must have understood that the new court would adopt its predecessor's precedent as its own. *Cf. Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc) (decision of newly established Eleventh Circuit, just prior to Federal Circuit's creation, to adopt existing precedent of the Fifth Circuit, from which it had been split off). Congress's entrustment of patent law to the Federal Circuit therefore serves as an implicit approval of the existing clear-and-convincing standard. *See supra* pp. 6, 11.

standard of proof for establishing invalidity – but Congress chose not to do so.[6]

In short, the fact that Congress has not recalibrated the balance struck by the well-settled clear-and-convincing standard for establishing invalidity counsels against disrupting that rule.

3. A change in the standard of proof required to invalidate a patent during litigation would have a particularly harmful impact on PhRMA's members, who rely on the stability and relative predictability of the patent system when deciding to invest billions of dollars every year in the research and development of life-saving medicines. Indeed, although the public certainly has an important interest in promoting innovation in all fields of discovery, nowhere are the public interest in innovation and the rights of inventors more closely aligned than in the field of biopharmaceutical patents.

---

[6] The Hatch-Waxman Act "allow[s] pioneers to reclaim a portion of the patent term lost to FDA review" of a pharmaceutical patent, while substantially relaxing the testing requirements imposed on generic manufacturers and allowing them to piggyback on data developed by the pioneer after a certain time. Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 Antitrust L.J. 585, 585, 590 (2003). The Act also establishes a set of special procedures for the resolution of patent infringement and invalidity claims in the context of generic drugs. *See generally* 21 U.S.C. § 355(j) (generic applicant may certify in drug application that product will not infringe patent or that patent is invalid; if patent holder sues for infringement within 45 days, it obtains a 30-month stay of FDA approval of the generic drug while infringement suit is pending).

The development of new medications and the discovery of new uses for existing medications have played a critical role in curing disease and improving patient quality of life for centuries. Since 1980, new medical treatments for cancer have contributed to the increase in life expectancy of cancer patients by approximately three years, with medicines specifically accounting for 50 to 60 percent of the increase in survival rates of cancer patients since 1975. *See* E. Sun *et al.*, Abstract, *The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database*, 26 J. Clinical Oncology 6616 (supp. 2008), *available at* http://meeting.ascopubs.org/cgi/content/abstract/26/15_suppl/6616; Frank R. Lichtenberg, *The Expanding Pharmaceutical Arsenal in the War on Cancer* 2 (Nat'l Bureau of Econ. Research, Working Paper No. 10328, Feb. 2004). Likewise, the discovery and development of highly active antiretroviral treatments have brought about a more than 75% reduction in deaths from HIV/AIDS since they were first approved by the FDA in 1995. *See, e.g.*, Edward L. Murphy *et al.*, *Highly Active Antiretroviral Therapy Decreases Mortality and Morbidity in Patients with Advanced HIV Disease*, 135 Annals of Internal Medicine 17, 22 (2001). Simply put, the societal benefit from such innovation – and the public interest in the encouragement and continuation of such work – is difficult to overstate.

The stark reality, however, is that the development of a new medicine is extremely costly and time-consuming. As noted above, PhRMA

members invested over $49 billion to discover and develop new medicines in 2010 alone. *See supra* p. 1. Because of the difficulty of developing new medicines and the high safety and effectiveness standards that they must meet, relatively few research avenues are successful. Thus, of every 5,000 to 10,000 compounds that are screened, only 1 results in a new medicine. PhRMA, *Innovation by the Numbers*, innovation.org, http://www.innovation.org/index.cfm/ToolsandResources/FactSheets/Innovation_by_the_Numbers#6- (last visited Mar. 16, 2011) (citing data from Tufts University, Tufts Center for the Study of Drug Development (1995)). Even if a compound is determined to be safe enough to test on humans, there must be three phases of clinical testing to determine safety and efficacy before the FDA can give final approval for marketing. *See* 21 C.F.R. §§ 312.21, 314.50(d)(5). As a result, the development and commercialization of a drug is a very lengthy and uncertain process that on average takes ten to fifteen years. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 475-76 (2007).

Because of this difficult process, the average cost of bringing a new medicine to market is approximately $1.3 billion when the cost of unsuccessful efforts is taken into account. *See* U.S. Dep't of Commerce, Int'l Trade Admin., *Pharmaceutical Price Controls in OECD Countries*, *supra*, at 30-31. And this cost must be recouped in a patent term that is effectively much shorter than the statutory term – because the ten to fifteen years of

development cut into the patent term and reduce a medicine's years of effective patent life. *See* Sheila R. Shulman *et al.*, *Patent Term Restoration: The Impact of the Waxman-Hatch Act on New Drugs and Biologics Approved 1984-1995*, 2 J. Biolaw & Bus. 63, 65-66 (1999). Even drugs that make it to market do not generally cover their development costs. *See* John A. Vernon, Joseph H. Golec, & Joseph A. Dimasi, *Drug Development Costs When Financial Risk is Measured Using the Fama-French Three-Factor Model*, 19 Health Econ. 1002, 1004 (2010) (finding that only 2 of 10 approved medicines produce revenues that exceed average research and development costs).

The cost of bringing a new medicine to market can be justified financially only if PhRMA's members can rely on strong, reliable patent protection to permit them to recoup their extraordinary up-front investments in research and development. As a result, patent protection is particularly crucial to spur innovation in this field. *See, e.g.*, Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents*, 11 B.U.J. Sci. & Tech. L. 1, 47 (2005) ("The promise of full patent rights for successful discovery is important motivation for inventors entering the unpredictable, competitive biopharmaceutical area."); John P. Walsh *et al.*, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in Patents in the Knowledge-Based Economy* 285, 286-87 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) ("There is widespread consensus that patents have long benefited biomedical innovation. A forty-year empirical legacy

suggests that patents are more effective, for example, in protecting the commercialization and licensing of innovation in the drug industry than in any other.").

Thus, even scholars who advocate narrow patent rights in some contexts recognize the importance of patent rights for biopharmaceutical patents. One such scholar explains:

> In the specific context of the biopharmaceutical industry, the claim that broad, monopoly-conferring rights on nascent invention can provide a necessary spur to further innovation may well have merit. As matters currently stand, the research path from initial discovery of a potentially relevant DNA sequence or receptor to identification of a drug that is ready for clinical testing can be quite risky, lengthy, and expensive.

Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 Berkeley Tech. L.J. 813, 828-29 (2001) (footnotes omitted).

In addition to providing incentives for invention, patent protection also helps ensure quick disclosure of actual inventions, accelerating innovation by making it easier for inventors to understand the work of those who have gone before them. *See Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945). The PTO reports that as a result of the American Inventor Protection Act of 1999, Pub. L.

No. 106-113, 113 Stat. 1501, 1501A-552, "roughly 90 percent of all pending patent applications are published at eighteen months." FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 1, at 26 (Oct. 2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf (discussing testimony of PTO personnel). Testimony from pharmaceutical and biotech representatives, including those from generic pharmaceutical firms, makes clear that patent disclosures lead to further innovations. Companies rely on patent disclosures to develop advances that build on patented technology; they also rely on such disclosures to guide efforts to design around patents by developing new and potentially superior ways to obtain similar results. *Id.*, ch. 3, at 1-2, 4.

Because patent protection plays such an important role in sustaining incentives for pharmaceutical research and development, any substantial erosion in the strength of patent rights risks altering the investment calculus and ultimately harming the public by choking off the development of life-saving medicines. Empirical research indicates that society benefits from robust protection of patents on medicines because "innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection." *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1617 (2003) ("Strong patent rights are necessary to encourage drug companies to expend large sums of money on research years before the product can be released to the market."); *see also* James W. Hughes *et al.*,

"Napsterizing" Pharmaceuticals: Access, Innovation, and Consumer Welfare 3-4 (Nat'l Bureau of Econ. Research, Working Paper No. 9229, 2002) (finding that eliminating patent protection on pharmaceuticals would cost future consumers three dollars in lost innovation benefits for every dollar saved in reduced drug prices). After gathering evidence on the costs and benefits of patent protection, a Federal Trade Commission report explained that "[p]articipants in the Hearings overwhelmingly expressed the view that patent rights for pharmaceuticals are essential for brand-name companies to prevent free riding and recoup their significant investments." FTC, *To Promote Innovation*, *supra*, ch. 3, at 9. Indeed, when a generic drug becomes available for the first time, it can capture as much as 84% to 94% of the market within the first month. *See* Medco, *The Great Healthcare Debates: Prescriptions for Meaningful Reform*, 11 Drug Trend Report 1, 22 (2009), *available at* http://medco.mediaroom.com/file.php/177/2009+DRUG+TREND+REPORT.pdf. It is unsurprising, then, that "pharmaceutical industry participants reported that 60% of inventions would not have been developed and 65% would not have been commercially introduced absent patent protection." FTC, *To Promote Innovation*, *supra*, ch. 2, at 11 (citing Edwin Mansfield, *Patents and Innovation: An Empirical Study,* 32 Mgmt. Sci. 173, 175 (1986)).[7]

---

[7] For instance, the first semi-synthetic penicillins like ampicillin, used to overcome staphylococci resistant to biological penicillins, owed both their development and their availability to strong patent protection. *See* C.T. Taylor & Z.A.

The lowered standard of proof of invalidity could have a powerful negative impact on these incentives and ultimately stunt innovation in the medical field. Because the validity of biopharmaceutical patents is frequently litigated, the procedural protections provided in that litigation necessarily factor into business decisions regarding how to invest and where to focus limited resources. *See* James E. Bessen & Michael J. Meurer, *The Private Costs of Patent Litigation* 25, 36 tbl.7 (Boston Univ. Sch. of Law Working Paper Series, Law & Econ., Working Paper No. 07-08, 2008), *available at* http://papers.ssrn.com/abstract=983736 (estimating that patent litigation costs constitute approximately 14% of pharmaceutical companies' research and development costs); John R. Allison *et al.*, *Valuable Patents*, 92 Geo. L.J. 435, 471-72 (2004) (noting that biopharmaceutical and medical device patents are "far more likely to be litigated than their numbers in the general population [of issued patents] would suggest").

Silbertson, *The Economic Impact of the Patent System: A Study of the British Experience* 258-59 (1973). Lacking experience in large-scale pharmaceuticals manufacturing, the original British inventor – which had relied on obtaining effective patent protection when it initially invested in its research – partnered with a more experienced American pharmaceutical company to develop manufacturing techniques, exchanging information and licenses. *Id.* at 258. "[H]ad effective sole patent protection been unavailable in the U.S.A.," however, "it would have been extremely difficult to persuade [the American company] to divulge its manufacturing know-how," delaying or even imperiling the life-saving antibiotic's global distribution. *Id.* at 259.

A preponderance standard would substantially increase the likelihood that PhRMA's members could erroneously lose valuable patent protection and be unable to recoup their research and development costs. At a minimum, the standard would prevent biopharmaceutical research companies from determining with any certainty how much protection has been provided by a patent. Without any confidence that a patent actually will assure market exclusivity, and anticipating that patents will be of lower financial value, pharmaceutical companies might well be dissuaded from making investments in research and development. So too might the investors who fund small inventors and start-up businesses in this field. This Court should therefore endorse the clear-and-convincing standard that has been consistently applied to invalidity challenges and that appropriately accounts for the public's vital interest in promoting robust investment in innovation.

II. The Clear-And-Convincing Standard Should Apply Regardless Of Whether The Prior Art Is Proven To Have Been Considered By The PTO.

Applying a clear-and-convincing standard of proof in cases where the PTO is shown to have considered the prior art that forms the basis of the invalidity argument and a preponderance standard in all other cases – the so-called "dual standard" – would introduce troublesome practical difficulties into patent litigation and prosecution, both of which are already highly complicated. In litigation, determining what evidence in fact was "considered" by the expert patent examiner would simply not be

feasible. Moreover, a dual standard of proof would increase the incentive to litigate invalidity in the first place, by raising the chances that such an argument might prevail, and would decrease the chances that parties will use the PTO's reexamination procedures to address validity issues rather than burdening the courts with them.

The effects on patent prosecution would be equally deleterious. The most serious of these is the "over-disclosure" incentive: the risk that patent applicants will cite to as much prior art as possible, even where that art is only marginally relevant to the patent claims or cumulative of other prior art already cited, to lower the risk that invalidity issues will be decided under a preponderance standard in any subsequent litigation. Patent applicants are already under pressure to over-disclose due to the frequency with which patentees face inequitable conduct allegations. Applying a dual standard would exacerbate this problem. The result would be to place further pressure on an agency that is tasked with complex work and operating with limited resources.

A. A Dual Standard Would Have Harmful Effects On Patent Litigation

1. Attempting to determine whether the patent examiner actually considered particular pieces of prior art, in order to determine which standard of proof to apply to an invalidity claim, would inject a whole new set of practical problems into the resolution of such claims during litigation. While it is possible to examine the written record of the

prosecution to see what references a patent examiner has *cited* in reaching his expert conclusion that a given invention is patentable, it is much less clear what the examiner may have *considered* in the course of reaching that conclusion.

This is so for a number of reasons. While examiners routinely note their searches of multiple classes or subclasses of pertinent patents, they typically choose to list in the patent file only a limited number of patents that are representative of those searched, and to cite even fewer of these in rejecting a patent. *See, e.g.*, Manual of Patent Examination Procedures ("MPEP") § 904.03 ("The examiner is not called upon to cite all references that may be available."). In addition, because examiners are organized into technological sub-specialties, they develop expertise that extends far beyond that reflected in the record of any given examination. *See, e.g.*, *id.* § 904.02 (discussing the requirement for "examiners to acquire specialized skills needed to determine an appropriate field of search in their specific arts"). This expertise derives from their formal technical training, which often includes a graduate degree in a relevant scientific field; from spending their careers reviewing publications, patents, and patent applications pertaining to their assigned sub-specialties; from actually examining hundreds of applications within the same sub-specialty; from routinely interacting with patent applicants in doing so, both in writing and in personal interviews pertaining to their inventions; and from consulting with supervisory examiners prior to taking official action. Thus, when a patent

examiner, acting on behalf of the public, determines that an invention is nonobvious, he or she is bringing to bear a great deal of knowledge that is not catalogued in a particular patent file. *See, e.g.*, IBM Br. 19-20 ("There is no way to know from the public record how carefully an examiner read, digested, and evaluated a reference that is of record, and no way to rule out whether an examiner 'considered' a reference that is not of record.").

A dual standard would place the factfinder in the position of attempting to determine precisely what prior art was given sufficient "consideration" by the patent examiner, and then trying to categorize (potentially voluminous) prior art references accordingly. That task would be well-nigh impossible – especially where an alleged infringer's defense was based on an argument that a combination of prior art references rendered the patent invalid. But the need to make some attempt to carry it out would create a new layer of litigation, including additional attorneys' fees and discovery costs. It also would distract judges and juries from the resolution of the dispositive factual and legal questions in the case: whether the patent is actually valid and, if so, whether it was infringed. And to the extent that those judges and juries mistakenly concluded that an examiner was unaware of something that actually fell within the scope of his or her experience and expertise, they would be applying a standard of proof on validity that affords the examiner no deference at all, and simply substitutes a layperson's judgment – arrived at based solely on whatever the parties place in the trial record – for

the considered judgment of a specialist in the field. That increases the risk of an erroneous result.

2. In addition, adopting a standard of proof for litigation of validity issues that varies based on whether the patent examiner considered prior art might well increase the volume of litigation and the burden on federal courts. Because the standard for demonstrating invalidity would sometimes be easier to meet, parties that might otherwise be inclined to seek a license from a patentee would now be emboldened to simply engage in infringing activity and force the patent holder to sue.[8]

The litigation pull would be especially strong in the area of pharmaceutical patents, where the Hatch-Waxman procedures permit a generic drug manufacturer to seek FDA approval of a potentially infringing drug and notify the patent holder of an invalidity claim by way of a so-called "Paragraph IV certification" that the patent is invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). In addition to giving generic drug manufacturers a mechanism to seek early entry into the market, the Act further encourages such validity challenges by providing the first generic manufacturer to file a Paragraph IV certification with 180 days of marketing exclusivity against subsequent challengers. *See id.* § 355(j)(5)(B)(iv).

Applying a dual standard would also increase litigation volume by effectively removing any incentive for parties to seek reexamination by the

[8] Of course, the adoption of a preponderance standard for *all* invalidity challenges would have the same effect.

PTO as an alternative to litigation. Currently, one of the primary advantages of reexamination is the lower standard of proof, which recognizes the expertise of the decision-maker but arguably creates a relatively higher chance of prevailing. *See* MPEP § 2280. If that advantage disappeared because the standard of proof for invalidity in litigation was also preponderance of the evidence, then potential infringers would be left with only the drawbacks of the reexamination procedure, such as the risk of estoppel in a separate civil action. *See* 35 U.S.C. § 315(c). Under those circumstances, they would likely choose litigation as a safer avenue of attack.[9] Moreover, even to the extent that the potentially lower cost of reexamination might continue to appeal to a potential infringer, such cost savings would likely be offset by the increased value of litigation as a tool to extract a settlement from a patentee facing a riskier, more complex court case. Accordingly, the dual standard would channel validity challenges into the courts and away from the PTO, thus depriving the agency of the opportunity to apply its expertise to correct any errors internally.

---

[9] To be sure, reexamination can never be a complete substitute for litigation, in part because certain patentability issues cannot be addressed in reexamination proceedings. *See* MPEP §§ 2258, 2658. Nonetheless, to the extent that reexamination currently offers an attractive alternative to litigation in some circumstances, removing the incentive to pursue that approach would result in an associated increase in the burden on overloaded federal court dockets. *See* J. Steven Baughman, *Reexamining Reexaminations: A Fresh Look at the Ex Parte and Inter Partes Mechanisms for Reviewing Issued Patents*, 44 Bloomberg Corp. L.J. 44, 49-51, 58 (2007) (discussing reexamination as an alternative to litigation).

B. A Dual Standard Would Have Harmful Effects On Patent Prosecution

The dual standard would have equally harmful effects at the patent prosecution stage. Adoption of such a standard could lead patent applicants to flood the PTO with marginally relevant prior art, straining the PTO's limited resources. Applicants would have an incentive to do so in an effort to ensure that in any subsequent litigation the factfinder would conclude that the examiner considered the prior art relied on by an invalidity challenger, and would therefore apply a clear-and-convincing standard to the invalidity question. *See* IBM Br. 22 (discussing "incentives for the patent applicant to 'launder' as much prior art as possible"); AIPLA Br. 34 n.8 (noting "the torrent of paper likely to arrive on the agency's doorstep"). That kind of increase in the volume of applicants' filings would create additional difficulties for an agency that is already facing a backlog of applications. *See, e.g.*, *USPTO Oversight: Hearing Before the H. Comm. on the Judiciary*, 111th Cong. 3 (2010) (statement of David J. Kappos, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office) (discussing the "mounting backlog of unprocessed applications"), *available at* http://judiciary.house.gov/hearings/pdf/Kappos100505.pdf.

Contrary to the suggestion of *amici* supporting Microsoft, *see* Teva Br. 5-11, there is no existing incentive for *concealment* of prior art from the PTO that the dual standard would somehow "correct." Of course, even if there *were* a legitimate reason to

think that patent applicants were not citing enough prior art during prosecution, changing the standard of proof that applies during litigation of invalidity is a curiously indirect and wholly unsuitable way to address that concern. But, in any event, just the opposite is true – the dual standard would have the effect of making an existing issue of over-disclosure even worse.

There are a number of reasons why concealment of prior art is not an actual problem. As an initial matter, applicants face sanctions if they fail to comply with the PTO rules that require them to disclose all material prior art of which they are aware. *See, e.g.*, 37 C.F.R. § 1.56(a) ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.").

Applicants who fail to comply with this obligation also risk a finding of inequitable conduct, a claim that is frequently asserted by alleged infringers.[10] *See, e.g.*, *Burlington Indus. Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (lamenting that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague"). Such a finding has harsh consequences, including the unenforceability of the patent (and potentially

[10] Notably, in this case, Microsoft tried to establish inequitable conduct, but failed, Pet. App. 183a-188a – a result that Microsoft does not now challenge.

even of related patents) and the risk of follow-on antitrust claims and treble damages. *See, e.g.*, *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1235-36 (Fed. Cir. 2007) (affirming decision that fifteen of inventor's patents were unenforceable due to inequitable conduct); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1242 (Fed. Cir. 2003) (affirming decision that a patent for a chemotherapy agent was unenforceable based on inequitable conduct); *Agfa Corp. v. Creo Products, Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006) (discussing unenforceability of related patents); *cf. Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070-73 (Fed. Cir. 1998) (upholding district court's imposition of more than $9 million in treble damages based on jury's verdict in favor of defendant's counterclaim that the plaintiff had violated the antitrust laws by fraudulently obtaining a patent and then bringing a sham infringement suit to interfere with a competitor's business). The inequitable conduct doctrine thus serves as a powerful counterweight to any concealment incentive that might otherwise arise.[11]

---

[11] Of course, the application of a clear-and-convincing standard to inequitable conduct charges makes them more difficult to prove, but that standard is perfectly appropriate given the serious nature of those allegations. *See Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting) ("The allegation of inequitable conduct opens new avenues of discovery; impugns the integrity of [a] patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a

More generally, there is no doubt that many applicants are motivated to cite relevant prior art in order to anticipate the patent examiner's arguments for non-patentability and affirmatively address those potential issues in early stages of the prosecution – both to expedite the examination process and to increase the odds of obtaining a valuable patent that will withstand scrutiny if later challenged. *Cf.* John R. Allison *et al.*, *Valuable Patents*, *supra*, at 453; *see also* John R. Allison, Mark A. Lemley, & Joshua Walker, *Extreme Value or Trolls on Top?: The Characteristics of the Most-Litigated Patents*, 158 U. Pa. L. Rev. 1, 15 n.31 (2009) ("[T]he more citations that are considered during prosecution by the examiner, the less likely it is that some prior art exists that will invalidate the patent. The more prior art considered, in other words, the more likely a patent is to survive subsequent litigation.").[12]

In the biopharmaceutical arena, which is exactly where abandonment of the clear-and-convincing standard would have the most devastating effects for patentees and for the public, that motivation to disclose prior art to the PTO during patent prosecution is particularly strong. As noted above, because of the cost of development and the length of

---

case without the rigors of claim construction and other complex patent doctrines."), *cert. denied*, 129 S. Ct. 2053 (2009).

[12] The availability of *ex parte* and *inter partes* reexamination procedures reinforces the incentive to disclose relevant prior art. Because reexamination is available when "a substantial new question of patentability affecting any claim of a patent is raised" by a third party, *see* 35 U.S.C. §§ 304, 312, an applicant can head off such a challenge by ensuring that the patent examiner has all information relevant to patentability.

the FDA approval process, obtaining a strong patent is crucial to being able to recoup investments in research and development. *See* John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 Vand. L. Rev. 2099, 2125-26 (2000) (surmising that the higher mean of refilings in the pharmaceutical industry may signal that these applicants are willing to "fight harder" to get claims issued because of the stakes involved). And empirical evidence indicates that applicants for biopharmaceutical and medical device patents – who stand to lose as much as a billion dollars if an invention is deemed unpatentable – are especially likely to cite prior art references in their patent applications, including non-patent prior art. *See id.* at 2130-31 (comparing citation statistics between industries and noting that biopharmaceutical and medical device patents lead the field in citations to prior art, both with respect to patent and non-patent prior art references). Biomedical patents also tend to be more rigorously scrutinized and undergo more revision during patent prosecution than patents in other fields. *See id.* at 2126-27 (noting that biopharmaceutical patents are based on more applications and refilings and spend more time in the prosecution process than other types of patents).[13]

---

[13] *Amicus* Teva suggests that pharmaceutical companies have a unique "economic incentive to obtain by any possible means even an exceptionally weak patent" because of the provision in the Hatch-Waxman Act that allows a patentee to obtain a stay of FDA approval for the generic drug for 30 months while the litigation is pending. Teva Br. 9 n.5; *see* 21 U.S.C.

In light of all of these compelling reasons for applicants to disclose relevant prior art to the PTO, there is plainly no need to force additional disclosure by adopting a dual standard that would penalize a patentee if the PTO could not be proven to have considered a particular reference. Indeed, the incentives to disclose prior art during patent prosecution are already so high as to create a significant problem of *over-disclosure*, which is bogging down the examination system. *See* S. Rep. No. 110-259, at 32 n.152 (2008) (noting that the inequitable conduct doctrine frequently leads patent applicants to "dump" things on the PTO); Duty of Disclosure & Practitioner Misconduct, 54 Fed. Reg. 11,334, 11,334 (Proposed Rules Mar. 17, 1989) (to be codified at pts. 1 & 10) (acknowledgement in proposed rule by PTO that the inequitable conduct doctrine leads to unproductive use of resources by the agency); *see also* Changes to Information Disclosure Statement Requirements & Other Related Matters, 71 Fed. Reg. 38,808, 38,809 (Proposed Rules

---

§ 355(j)(5)(B)(iii). But the rationale for this argument – that a drug can generate enough money in sales during those 30 months to make the drug profitable even if the patent is later invalidated – stands in stark contradiction to the reality of PhRMA members' business models. Indeed, it can take the entire lifetime of a drug's patent to recover the development process once unsuccessful attempts are accounted for, and many drugs that make it to market do not even cover their development costs. *See* FTC, *To Promote Innovation*, *supra*, ch. 3, at 5; F.M. Scherer, *The Link Between Gross Profitability & Pharmaceutical R&D Spending*, 20 Health Affairs 216, 216 (2001), *available at* http://content.healthaffairs.org/content/20/5/216.full.pdf.

July 10, 2006) (to be codified at 37 C.F.R. pt. 1) (recognition by PTO of the burdens associated with over-disclosure). The dual standard would only worsen that problem, without any concomitant benefit.

CONCLUSION

The application of a heightened standard of proof to claims that a patent is invalid has a long history in both the Federal Circuit and this Court. That standard reflects not only Congress's judgment that patents should be presumed valid, but also the important public interest in promoting innovation. Applying a lower standard of proof would destabilize the expectations of legitimate patent holders and chill innovation in the costly and vital realm of biopharmaceutical research. Because the risk of upsetting this delicate balance is too great and because the weighing of such competing interests is best left to Congress, this Court should affirm the Federal Circuit's decision.

Respectfully submitted,

DAVID E. KORN
PHARMACEUTICAL
RESEARCH AND
MANUFACTURERS OF
AMERICA
950 F St., N.W.
Washington, D.C. 20004
(202) 835-3400

HARRY J. ROPER
Counsel of Record
JENNER & BLOCK LLP
353 N. Clark Street
Chicago, IL 60654
(312) 222-9350
HRoper@jenner.com

PAUL M. SMITH
ELAINE J. GOLDENBERG
LEAH J. TULIN
JENNER & BLOCK LLP
1099 New York Avenue, N.W.
Suite 900
Washington, D.C. 20001
(202) 639-6000