No. 10-290

In the Supreme Court of the United States

MICROSOFT CORPORATION, PETITIONER

v.

I4I LIMITED PARTNERSHIP, ET AL.

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

BRIEF FOR BAYER AG
AS AMICUS CURIAE SUPPORTING RESPONDENTS

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INTEREST OF AMICUS CURIAE

Bayer AG[1] is one of the world's largest producers of pharmaceutical, agricultural, and other scientific products. For more than a hundred years, Bayer and its scientists have invented products that improve the daily

[1] Pursuant to Rule 37.6, Bayer affirms that no counsel for a party authored this brief in whole or in part; no such counsel or a party made a monetary contribution to fund its preparation or submission; and no person other than Bayer or its counsel made such a monetary contribution. The parties have entered blanket consents to the filing of amicus briefs, and copies of their letters of consent are on file with the Clerk's Office.

lives of millions of people. Bayer is represented in almost every country around the globe. In each of those countries, it relies on local intellectual property laws to safeguard its inventions.

In 1897, Bayer employee Felix Hoffmann first synthesized acetylsalicyclic acid in an effort to treat his father's arthritis pain. Bayer marketed that medicine under the trade name of aspirin—and, in 1900, Dr. Hoffmann received a U.S. patent for his invention. Although the patent for aspirin has long since expired, Bayer today holds U.S. patents for a variety of inventions across all of its product lines. It also holds patents on potential products that are in development but have not yet been offered to the public. In 2010 alone, Bayer spent more than $4.2 billion on research and development.

Bayer heavily depends on intellectual property laws, particularly patent laws, to protect its inventions as they are developed into safe, marketable products, and to ensure that those products return sufficient revenues to fuel the development of additional products. At the same time, Bayer relies on intellectual property laws to protect it from unfounded claims that its products infringe rights belonging to others. In light of its strong interest in the fair and efficient administration of the patent laws, Bayer files this amicus brief to bring to the Court's attention the risks that petitioner's proposed standard for invalidity would pose to innovation.

SUMMARY OF ARGUMENT

In their brief, respondents amply demonstrate why this Court should reject petitioner's invitation to overturn decades of settled precedent and lower the clear-and-convincing-evidence standard for proving patent invalidity. Bayer respectfully submits this brief in order to highlight two points: first, that petitioner's approach

would have stifling effects on innovation in the pharmaceutical sector, and second, that such an approach would lead to further divergence between the American patent system and other leading patent systems.

A. Pharmaceutical companies such as Bayer require staggering amounts of capital to develop new drugs. But once a company develops a drug and obtains approval from the Food and Drug Administration (FDA)—a process that can take a decade or more—other companies can imitate the drug relatively easily and produce it at a low marginal cost. Once a so-called "pioneer drug" loses its patent protection, competitors can free-ride off the original manufacturer's research and development efforts by introducing a generic version of the drug. Unburdened by the substantial fixed costs required initially to bring a drug to market, competitors can afford to undercut the original manufacturer's prices—thereby reducing that manufacturer's market share and rendering it more difficult for the manufacturer to recoup its investment.

In the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Hatch-Waxman Act or the Act), Congress recognized the critical role that patent protections play in encouraging innovation in the pharmaceutical industry, while at the same time seeking to balance the interests of manufacturers of pioneer and generic drugs. Eliminating the clear-and-convincing-evidence standard would disrupt that balance, rendering it easier for generic manufacturers to prevail in patent litigation and giving generic manufacturers a structural advantage that Congress could not have anticipated when it enacted the Hatch-Waxman Act. The inevitable consequence will be reduced investment in research and development in this vital area.

B. The American patent system is something of an international outlier, because it assigns questions of patent validity to generalist judges and lay juries. In other leading patent systems, that task is delegated instead to patent specialists or to specialized courts. Inventors in those countries thus do not face the risk that their patents will be invalidated by individuals who lack specialized knowledge of patent law or of the relevant prior art. In practice, the clear-and-convincing-evidence standard for challenges to validity has minimized the potential for divergent outcomes between the American system and other leading systems. Under that standard, generalist judges and lay juries do not lightly second-guess decisions made by the Patent and Trademark Office (PTO)—the specialized agency with responsibility for issuing patents. Lowering the standard for proving invalidity would inevitably render the PTO's determinations on validity less relevant, weakening American patent protection and exacerbating disparities with rival systems.

ARGUMENT

THIS COURT SHOULD RETAIN THE CLEAR-AND-CONVINCING EVIDENCE STANDARD FOR PROVING PATENT INVALIDITY

A. The Clear-And-Convincing-Evidence Standard Is Necessary To Ensure Innovation In The Pharmaceutical Industry

1. a. There is perhaps no industry that relies on the protections afforded by the patent system as heavily as the pharmaceutical industry. As commentators have noted, "[w]ithout patents[,] * * * the large majority of drugs likely would not be developed, and the health gains they produce might never be realized." Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 Tex. L. Rev. 503, 505 (2009) (Roin). One sur-

vey indicated that some 65% of new drugs would not have been introduced in the absence of patent protection. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Mgmt. Sci. 173, 174-175 (1986).

Patent protection is particularly critical to the pharmaceutical industry because of the astronomical investment required to bring a product to market. Estimates of the investment required for a new pharmaceutical product range from $800 million to over $1 billion per drug. See, *e.g.*, Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 475 (2007); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 180-183 (2003). Bayer's pharmaceutical and consumer-health divisions spent more than $2.8 billion in research and development in 2010 alone. Research and development costs in the industry are only increasing, both because pharmaceutical companies are developing treatments for ever more complex and intractable conditions and because the FDA is placing a higher premium on safety in the approval process. See Ronald J. Vogel, *Pharmaceutical Economics & Public Policy* 87 (2007) (Vogel). Not surprisingly, therefore, one commentator has described patent protection as "the basic backbone for incentives for the expensive research and development (R&D) activities that drive competition in the industry." *Id.* at xix.

Once a drug has been developed and approved, it is easy to imitate and relatively cheap to produce. In contrast to the approximately $1 billion that it takes for a pharmaceutical company such as Bayer to launch a pioneer drug, a manufacturer may spend as little as $2 million to obtain FDA approval for a generic version of the drug—and, once it does so, the marginal cost to the

manufacturer of producing the generic version is extremely low. See William M. Landes & Richard A. Posner, *The Economic Structure of Intellectual Property Law* 313 (2003) (Landes & Posner); *Big Generic Pharma*, Economist, July 30, 2005, at 58. Once generic manufacturers enter the market, therefore, the market share for the branded version of the drug considerably drops. In fact, within two years of generic entry, the typical branded drug loses as much as 80 percent of its market share, with corresponding effects on the profit margins of the original manufacturer. See Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, in *Science and Cents: Exploring the Economics of Biotechnology* 87 (John V. Duca & Mine K. Yücel eds. 2002); see *Sanofi-Synthelabo* v. *Apotex Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (recognizing the "irreversible price erosion" that results when generic manufacturers enter the market).

Accordingly, pharmaceutical companies rely on the exclusive right to market a drug during the life of the patent to generate sufficient revenue to cover research and development costs. And, given the protracted nature of the FDA approval process, the effective life of patents in the pharmaceutical industry is shorter than in less regulated industries. The time lag between the filing of a patent application and FDA approval is approximately 9½ years. See Vogel 140. Although manufacturers can reclaim some of the time lost to the approval process by applying for an extension of the patent term pursuant to the Hatch-Waxman Act, see pp. 10-11, *infra*, regulatory delay reduces the effective life of a pharmaceutical patent from the statutory 20 years, see 35 U.S.C. 154(a)(2), to an average of 12 or 13 years, see F.M.

Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 New Eng. J. Med. 927 (2004).

It is all the more important to afford vigorous patent protection to drugs that successfully run the FDA gauntlet because those drugs represent only a small fraction of the overall investment that the pharmaceutical industry makes in research and development. For every 10,000 drugs tested on animals, only five are tested on humans, and only one receives FDA approval and ultimately reaches the market. See Government Accountability Office, *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts* (Nov. 2006) <tinyurl.com/gaodrugs>. Companies such as Bayer therefore rely on revenue streams generated from the few drugs that reach the market and are commercially successful to compensate for losses on the hundreds of others that do not. Without vigorous patent protection, "pharmaceutical companies cannot recoup their R&D costs in the competitive market." Roin 505.

b. Given the economic realities of the industry, uncertainty about the scope of patent protection is the bane of pharmaceutical innovation. Under the prevailing clear-and-convincing-evidence standard for challenges to patent validity, pharmaceutical companies understand that, once the PTO issues a patent, the patent will be vulnerable to attack in court only when there is a serious basis for doubting its validity. Pharmaceutical companies often receive the patent for a pioneer drug before the drug is even submitted for FDA approval. See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food & Drug L.J. 187, 192-193 (1999). Thus, before making all of the substantial expenditures necessary to bring a new drug to market, pharmaceutical companies

will often have a fair degree of confidence that they will be able to market the drug exclusively for a period of time long enough to recoup their investment.

If the Court lowers the standard of proof for invalidity, that confidence will disappear, and the consequences for the pharmaceutical industry could be severe. A generation's worth of investment decisions have been made on the assumption that issued patents will remain intact except when there is a compelling (*i.e.*, clear and convincing) case for invalidity. If this Court overturns that assumption, the value of patent portfolios held by pharmaceutical companies will drop, and the expected return from current and future research efforts will fall as well. The inevitable consequence will be less investment in new pharmaceutical products—and, ultimately, fewer life-saving innovations.[2]

2. Technology companies such as petitioner and its amici operate in a completely different environment from pharmaceutical companies. For starters, "[t]he archetypal software invention is one made by two people working in a garage." Dan L. Burk & Mark A. Lemley,

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[2] For its part, petitioner has now largely abandoned the "hybrid" approach it advanced in its petition for certiorari: *viz.*, that the standard of proof for invalidity challenges should depend on whether the challenger is relying on prior art that was considered by the PTO. If adopted by this Court, however, that approach would be unfair to pharmaceutical companies that have followed the PTO's rules regarding the disclosure of prior art. The PTO encourages inventors to file streamlined patent applications that do not disclose cumulative prior art references. See 37 C.F.R. 1.98(c). Under the "hybrid" approach, a company that took the PTO's advice and refrained from submitting additional prior art on which a challenger subsequently relies would be unable to avail itself of the clear-and-convincing-evidence standard, whereas a company that flooded the PTO with every conceivable piece of prior art would.

Policy Levers in Patent Law, 89 Va. L. Rev. 1575, 1622 (2003). In the pharmaceutical industry, by contrast, "innovation is generally directed at producing a discrete product covered by a small number of patents," and a pharmaceutical company will not make the massive investment necessary to bring a new product to market unless it is confident that its patents will protect the product. Federal Trade Commission, *The Evolving IP Marketplace* 55-56, 79 & n.33 (2011) (FTC Report).

To be sure, in the technology industry, "manufacturers face an additional challenge in trying to identify and clear patent rights due to the large number of patents that cover most [technology] products." FTC Report 55-56. But any disadvantage is offset by the tremendous benefits that accrue to first movers in the technology industry that are actually able to bring products to market. See Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849, 850 (2002). In particular, when it comes to products ranging from software to search engines, first movers benefit from so-called "network effects" that occur when large numbers of customers begin using their products (and thereby increase the utility that other customers derive from those products). See, *e.g.*, *United States* v. *Microsoft Corp.*, 253 F.3d 34, 49 (D.C. Cir. 2001) (discussing "network effects" more generally); Oren Bracha & Frank Pasquale, *Federal Search Commission? Access, Fairness and Accountability in the Law of Search*, 93 Cornell L. Rev. 1149, 1181 (2008) (discussing "network effects" in the specific context of search engines). It is therefore unsurprising that large technology companies such as Microsoft and Google have taken the position they have with regard to the standard for proving patent invalidity: they do not need the patent system to protect their products, and on the whole are more likely to view

patents as a hindrance than a help. See Landes & Posner 312 (noting that, in the technology industry, companies "do not rely heavily on patents as a method of preventing free riding on inventive activity").

3. This is not to suggest that there is no role for competition in the pharmaceutical industry, or that pharmaceutical companies should benefit from invalid patents. In order to maximize consumer welfare, however, the patent system must operate in a way that balances the need for competition with incentives to innovate. Congress sought to achieve such a balance for pharmaceutical patents through the enactment of the Hatch-Waxman Act. A decision by this Court to lower the standard of proof for invalidity challenges will disrupt that carefully calibrated balance.

The Hatch-Waxman Act was designed to facilitate the entry into the marketplace of low-cost generic drugs while preserving the incentives of pioneer manufacturers to innovate. See *Glaxo, Inc.* v. *Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). Recognizing the "divergent and sharply differing" nature of those interests, Congress sought to strike an appropriate balance. 130 Cong. Rec. 24,425-24,427 (1984) (statement of Rep. Waxman); see 130 Cong. Rec. 15,847 (1984) (statement of Sen. Hatch) (describing the Act as creating a balance through the "placement of weights along the beam").

The various provisions of the Hatch-Waxman Act reflect that balance. Title I provides a streamlined process for manufacturers to obtain FDA approval of generic versions of a previously approved drug, and allows manufacturers to begin that process before the patent on the previously approved drug has even expired. See 21 U.S.C. 355(j). By contrast, Title II provides a mechanism whereby an original manufacturer may obtain an extension of its patent term for up to five years to account

for time lost during the FDA approval process. See 35 U.S.C. 156.

Other provisions of the Hatch-Waxman Act set forth detailed rules applicable to patent litigation between pioneer and generic manufacturers. If the patent on a previously approved drug has not yet expired, a generic manufacturer must certify either that it will not seek to market the drug during the patent term, see 21 U.S.C. 355(j)(2)(A)(vii)(III), or that it believes the patent is either invalid or not infringed by its generic version, see 21 U.S.C. 355(j)(2)(A)(vii)(IV). If the generic manufacturer takes the latter position, it must provide notice to the patent holder, which has 45 days to bring an infringement action. See 21 U.S.C. 355(j)(5)(B)(iii). If the patent holder files an action for infringement, FDA's approval is automatically stayed for 30 months (unless the patent expires or a court holds the patent invalid or not infringed). See *ibid.* The Act further provides a substantial incentive for generic drug manufacturers to challenge the validity of weak patents: the first generic manufacturer to take the position that a patent is either invalid or not infringed by its generic version is afforded a 180-day exclusivity period if it is successful, and no other generic manufacturer may enter the market during that period. See 21 U.S.C. 355(j)(5)(B)(iv).

When Congress enacted the Hatch-Waxman Act in 1984, it was aware of then-existing Federal Circuit case law. Indeed, one of the Act's most significant intended effects was to overturn a Federal Circuit decision holding that it constituted infringement for a generic manufacturer to perform tests on a patented drug as part of the FDA approval process. See H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. II, at 28 (1984) (citing *Roche Prods., Inc.* v. *Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984)). By the time Congress enacted the Hatch-Waxman Act,

the Federal Circuit had definitively adopted the clear-and-convincing-evidence standard. See, *e.g.*, *American Hoist & Derrick Co.* v. *Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984). It is therefore reasonable to conclude that the balance Congress struck in the Hatch-Waxman Act was predicated, at least in part, on the assumption that a generic manufacturer could overturn the PTO's decision to issue a patent to a pioneer manufacturer only upon a showing of clear and convincing evidence.

In addition to disrupting the balance Congress intended to strike, an opinion by this Court adopting a preponderance standard would turn what has been a steady but manageable stream of Hatch-Waxman litigation into a torrent. Generic manufacturers will have greater incentives to pursue challenges to validity even when those challenges are weak on the merits—incentives that are already large enough in light of the economic bonanza that results from invalidation. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlements as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1580 (2006) (noting that "the level of sales for a best-selling drug likely justifies a challenge [to validity] with a prospect of success of just one percent").

If Congress had anticipated that this Court would eventually relax the standard for proving patent invalidity, the final version of the Hatch-Waxman Act may have looked very different. Regardless of that, however, it cannot seriously be disputed that a change in the standard of proof for invalidity would alter the balance established by the Act in a way that favors generic manufacturers, with the result that incentives for investment in research and development would accordingly erode. Petitioner has offered an insufficient justification for dis-

rupting the settled expectations of the pharmaceutical industry in that manner—to say nothing of expectations in other industries. This Court should reaffirm decades of settled precedent and uphold the clear-and-convincing-evidence standard for invalidity.

B. If Adopted By This Court, Petitioner's Approach Would Exacerbate Disparities Between The American Patent System And Other Leading Patent Systems

When compared with other leading patent systems, the American patent system is something of an outlier as to the way in which challenges to existing patents are adjudicated. Some countries commit the decision on patent validity to experts, who play no role in deciding whether a product infringes the patent. Other countries commit the decisions both on validity and on infringement to specialized courts with expertise in patent matters.

In both cases, however, those countries fundamentally differ from the United States, which is unique among the world's leading patent systems in allowing generalist judges and lay juries to decide both validity and infringement issues. As a practical matter, the clear-and-convincing-evidence standard minimizes the potential for divergent outcomes, because it effectively results in deference to decisions made by the PTO—the specialized agency with responsibility for issuing patents. Replacing that standard with a lower preponderance standard would weaken American patent protection and exacerbate disparities with other leading patent systems.

1. a. In many countries, including the two jurisdictions that have the most patent litigation after the United States, only specialized courts or agencies can hear challenges to the validity of issued patents. In Germany—where Bayer is headquartered and where more than

half of the patent litigation in Europe takes place[3]—"questions of infringement and patent validity are strictly separated." Eberhard Körner et al., *Germany*, in *International Patent Litigation: A Country-By-Country Analysis*, at DE-13 (Michael N. Meller & William O. Hennessey eds., 2009) (*International Patent Litigation*). Challenges to validity can be heard either by an expert agency (the Federal Patent Office) or by an expert court (the Federal Patent Court). *Ibid.* In either case, "courts hearing infringement matters deal exclusively with infringement of the patent—they are not competent to decide on the validity of a patent." Bernd Allekotte & Ulrich Blumenröder, *Germany*, in *Patents in Europe 2010/2011*, at 41 (2010). At most, courts can stay litigation on infringement while awaiting a ruling on validity. See *Germany*, in *International Patent Litigation*, at DE-13.

In China—the other jurisdiction with the most patent litigation[4]—the Patent Reexamination Board has sole jurisdiction over the validity of a patent, even if a lawsuit alleging infringement has already been filed. See J. Benjamin Bai et al., *What Multinational Companies Need To Know About Patent Invalidation and Patent Litigation in China*, 5 Nw. J. Tech. & Intell. Prop. 449, 450 & n.3 (Summer 2007). As in Germany, a court can stay litigation on infringement while awaiting a decision from

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[3] See *Towards An Enhanced Litigation System and A Community Patent—How To Take Discussions Further*, Annex at 23 (Working Party on Intellectual Property (Patents), Council of the European Union No. 11622/07, July 12, 2007) (*Working Party Paper*).

[4] See *Courts Gather 30K New IP Civil Trial Cases in 2009*, China IP News (Mar. 8, 2010) <tinyurl.com/chinaipnews>.

the Patent Reexamination Board. See Jianyang Yu, et al., *China*, in *International Patent Litigation*, at CN-5.

Other countries in Europe and Asia have similar systems. In Austria, an expert administrative office alone decides validity issues, whereas a civil court has exclusive jurisdiction over infringement issues. See Helmut Sonn & Rainer Beetz, *Austria*, in *International Patent Litigation*, at AT-8 to AT-9; *Towards An Enhanced Litigation System and A Community Patent—How To Take Discussions Further*, Annex at 10 (Working Party on Intellectual Property (Patents), Council of the European Union No. 11622/07, July 12, 2007) (*Working Party Paper*). And in Korea, an expert administrative court known as the Intellectual Property Tribunal hears challenges to validity in the first instance, whereas district or branch courts hear infringement claims. See Yoon Bae Kim, *Republic of Korea*, in *International Patent Litigation*, at KR-7, KR-10.

b. Other countries with significant amounts of patent litigation allow validity and infringement issues to be adjudicated together, but centralize that litigation in specialized courts. In the United Kingdom, complex or higher-value patent suits in England and Wales are brought in the Patents High Court, which is part of the Chancery Division of the High Court; less complex or lower-value suits are brought in the Patents County Court. See Morag Macdonald, *United Kingdom*, in *International Patent Litigation*, at GB-3. The judges on the Patents High Court are scientists or experienced patent litigators, and they decide questions of validity and infringement together. See Arty Rajendra & David Lancaster, *United Kingdom*, in *Patents in Europe 2010/2011*, at 85.

France—which has more patent litigation than any other European country except Germany[5]—recently adopted a similar system. Previously, seven regional courts possessed jurisdiction over French patent cases. See *Working Party Paper*, Annex at 31. In 2009, however, the French government conferred exclusive jurisdiction over patent suits on the Paris Court of First Instance; the judges on that court have expertise in patent law and receive additional training. See *ibid.*; Herbert Lewitter et al., *France*, in *Patents in Europe 2010/2011*, at 36. Moreover, the court has the authority to appoint an independent expert to assist it in understanding any technical issues in the cases it hears. See *Working Party Paper*, Annex at 31.

Other European countries, including the Netherlands and Sweden, have single courts that are responsible for all patent matters. In the Netherlands, patent cases go to the Hague District Court; judges on that court develop special expertise in patent matters. See Addick A.G. Land, *Netherlands*, in *Patents in Europe 2010/2011*, at 61. The Dutch court also requires an opinion from the Dutch patent office whenever a party challenges the validity of a patent. See *Working Party Paper*, Annex at 26; Willem A. Hoyng & Bart J. van den Broek, *Netherlands*, in *International Patent Litigation*, at NL-13. In Sweden, patent cases go to the District Court of Stockholm; that court uses four trial judges, two of whom have technical backgrounds. See Ragnar Lundgren, *Sweden*, in *International Patent Litigation*, at SE-1.

In Asia, Japan has a strikingly similar specialized court system. As part of a national campaign to improve patent protections, Japan enacted legislation in 2003 that

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[5] See *Working Party Paper*, Annex at 31.

confers exclusive jurisdiction for all patent matters on two district courts. See Toshiko Takenaka, *Success or Failure? Japan's National Strategy on Intellectual Property and Evaluation of Its Impact From the Comparative Law Perspective*, 8 Wash. U. Global Stud. L. Rev. 379, 387 (2009) (Takenaka). Those two courts already had special divisions devoted to intellectual property cases. See *ibid.*[6] Judges in those two courts have technical assistants known as *chosa-kan*, who are experienced patent attorneys sent from the Japanese Patent Office. See *ibid.*

2. In all of the countries discussed above, it is up to specialists to make the ultimate decisions on challenges to the validity of already issued patents. In the United States, by contrast, inventors risk losing their patents based on determinations made by generalist judges and lay juries. The clear-and-convincing-evidence standard substantially mitigates the potential for arbitrary outcomes, because it effectively encourages the factfinder to afford deference to decisions made by the PTO.[7]

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[6] In fact, before 2000, Japan used a system like Germany's, in which the Japanese Patent Office had sole jurisdiction over validity issues. See Takenaka 391. In 2000, however, the Supreme Court of Japan held that invalidity could be asserted as a defense in any infringement suit, see *Fujitsu Ltd.* v. *Texas Instruments, Inc.*, Saiko Saibansho [Sup. Ct.] Apr. 11, 2000, Heisei 10 (O) 364, 54 Saiko Saibansho Minji Hanreishu [Minshu] 1268 (Japan), and district courts thereafter had the authority to consider validity issues.

[7] As commentators have noted, "[p]atent law cases can turn almost entirely on an understanding of the underlying technical or scientific subject matter." Stephen Breyer, Introduction, *Federal Judicial Center Reference Manual on Scientific Evidence* 3 (2d ed. 2000). Accordingly, it has long been understood that patent cases pose particular difficulties for generalist judges and lay juries. See,

Petitioner's proposed preponderance standard, by contrast, would entirely eliminate that effective deference. The practical consequence of adopting that standard would be to create a much more substantial disparity between the United States and other leading nations in the way in which validity challenges are adjudicated. Adoption of that standard would also leave American inventors with less certain protection for their patented inventions—and thus less incentive to innovate—than their peers in other leading jurisdictions.

By preserving a meaningful role for the PTO in determining the validity of patents, the clear-and-convincing-evidence standard is a linchpin of the American patent system. This Court should uphold that settled standard and affirm the judgment of the Federal Circuit.

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e.g., William W. Schwarzer, Introduction, *Federal Judicial Center Reference Manual on Scientific Evidence* 1 (1st ed. 1994).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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