

No. 10-290

In the Supreme Court of the United States

MICROSOFT CORPORATION, PETITIONER

v.

14I LIMITED PARTNERSHIP, ET AL.

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

**BRIEF FOR THE UNITED STATES
AS AMICUS CURIAE SUPPORTING RESPONDENTS**

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QUESTION PRESENTED

The Patent Act of 1952 states that “[a] patent shall be presumed valid,” and that “[t]he burden on establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. 282. The Patent Act further provides that “[i]nvalidity of the patent” is a defense to an infringement action. 35 U.S.C. 282(1). The question presented in this case is as follows:

Whether, when the defendant in an infringement suit asserts as a defense that the relevant patent is invalid, the defendant must prove invalidity by clear and convincing evidence.

TABLE OF CONTENTS

	Page
Interest of the United States	1
Statement	1
Summary of argument	6
Argument	8
I. Section 282 codified a pre-existing judge-made presumption of validity that had long included a heightened standard of proof	8
A. In enacting Section 282 in the Patent Act of 1952, Congress intended to codify the existing presumption of validity	8
1. Before 1952, this Court applied a presumption of validity that required a party who challenged an issued patent to satisfy a heightened burden of proof	9
2. Section 282 codified the presumption of validity as it had previously been defined and applied by this Court	15
B. Congress’s acquiescence in the Federal Circuit’s longstanding construction of Section 282 further supports the clear-and-convincing-evidence standard	17
II. Applying the clear-and-convincing-evidence standard to all validity challenges best accommodates the competing interests implicated by such challenges and is most consistent with administrative-law principles	20
A. Challenges to the validity of an issued patent implicate administrative-deference and reliance interests	20
1. A validity challenge seeks to overturn the considered decision of the PTO	20

IV

Table of Contents—Continued:	Page
2. Invalidity challenges implicate substantial reliance interests	25
B. The clear-and-convincing-evidence stan- dard should apply in all cases, including those involving “new” evidence of invalidity	26
Conclusion	33

TABLE OF AUTHORITIES

Cases:

<i>Aluminum Fabricating Co. v. Season-All Window Corp.</i> , 259 F.2d 314 (2d Cir. 1958)	27
<i>American Hoist & Derrick Co. v. Sowa & Sons, Inc.</i> , 725 F.2d 1350 (Fed. Cir.), cert. denied, 469 U.S. 821 (1984)	<i>passim</i>
<i>Auer v. Robbins</i> , 519 U.S. 452 (1997)	22
<i>Blonder-Tongue Labs., Inc. v. University of Ill. Found.</i> , 402 U.S. 313 (1971)	25
<i>Cantrell v. Wallick</i> , 117 U.S. 689 (1886)	9, 13
<i>Chase Bank USA, N.A. v. McCoy</i> , 131 S. Ct. 871 (2011)	22
<i>Citizens to Preserve Overton Park, Inc. v. Volpe</i> , 401 U.S. 402 (1971)	31
<i>Coffin v. Ogden</i> , 85 U.S. (18 Wall.) 120 (1873)	9
<i>Consolo v. Federal Mar. Comm’n</i> , 383 U.S. 607 (1966) . .	27
<i>Cosmetic Ideas, Inc. v. IAC/Interactivecorp</i> , 606 F.3d 612 (9th Cir.), cert. denied, 131 S. Ct. 686 (2010)	27
<i>Dickinson v. Zurko</i> , 527 U.S. 150 (1999)	3, 27

Cases—Continued:	Page
<i>Eagle Comtronics, Inc. v. Arrow Commc'n Labs, Inc.</i> , 305 F.3d 1303 (Fed. Cir. 2002), cert. denied, 537 U.S. 172 (2003)	24
<i>Etter, In re</i> , 756 F.2d 852 (Fed. Cir.), cert. denied, 474 U.S. 828 (1985)	3, 23
<i>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.</i> , 535 U.S. 722 (2002)	29
<i>Florida Power & Light Co. v. Lorion</i> , 470 U.S. 729 (1985)	29, 30
<i>Gaddis v. Calgon Corp.</i> , 506 F.2d 880 (5th Cir. 1975)	18
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966) . . .	2, 8, 20, 21
<i>Graver Tank & Mfg. Co. v. Linde Air Prods. Co.</i> , 336 U.S. 271 (1949)	14
<i>Herman & MacLean v. Huddleston</i> , 459 U.S. 375 (1983)	20
<i>Hunt v. Armour & Co.</i> , 185 F.2d 722 (7th Cir. 1950)	16
<i>Hyatt v. Kappos</i> , 625 F.3d 1320 (Fed. Cir. 2010)	28
<i>INS v. Orlando Ventura</i> , 537 U.S. 12 (2002)	29
<i>John R. Sand & Gravel Co. v. United States</i> , 552 U.S. 130 (2008)	17
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007) . . .	31, 32
<i>Kewanee Oil Co. v. Bicron Corp.</i> , 416 U.S. 470 (1974) . . .	25
<i>Kumar, In re</i> , 418 F.3d 1361 (Fed. Cir. 2005)	24
<i>Lincoln Eng'g Co. v. Stewart-Warner Corp.</i> , 303 U.S. 545 (1938)	14
<i>Long Island Care at Home, Ltd. v. Coke</i> , 551 U.S. 158 (2007)	22
<i>Marconi Wireless Tel. Co. v. United States</i> , 320 U.S. 1 (1943)	14

VI

Cases—Continued:	Page
<i>Mathews v. Eldridge</i> , 424 U.S. 319 (1976)	32
<i>McClintock v. Gleason</i> , 94 F.2d 115 (9th Cir. 1938)	16
<i>Mead Corp. v. Tilley</i> , 490 U.S. 714 (1989)	16
<i>Meyer v. Holley</i> , 537 U.S. 280 (2003)	22
<i>Milner v. Department of the Navy</i> , No. 09-1163 (Mar. 7, 2011)	16
<i>Morgan v. Daniels</i> , 153 U.S. 120 (1894)	<i>passim</i>
<i>Mumm v. Jacob E. Decker & Sons</i> , 301 U.S. 168 (1937)	12, 13, 14
<i>Muncie Gear Works, Inc. v. Outboard, Marine & Mfg. Co.</i> , 315 U.S. 759 (1942)	14
<i>Pfaff v. Wells Elec., Inc.</i> , 525 U.S. 55 (1998)	21, 26
<i>Radio Corp. of Am. v. Radio Eng'g Labs., Inc.</i> , 293 U.S. 1 (1934)	<i>passim</i>
<i>Rains v. Niaqua</i> , 406 F.2d 275 (2d Cir.), cert. denied, 395 U.S. 909 (1969)	18
<i>Santosky v. Kramer</i> , 456 U.S. 745 (1982)	31
<i>Smith v. Hall</i> , 301 U.S. 216 (1937)	13, 14
<i>Star Fruits S.N.C. v. United States</i> , 393 F.3d 1277 (Fed. Cir. 2005)	22
<i>The Barbed Wire Patent</i> , 143 U.S. 275 (1892)	13
<i>Tokai Corp. v. Easton Enters., Inc.</i> , No. 2010-1057, 2011 WL 308370 (Fed. Cir. Jan. 31, 2011)	18
<i>Universal Oil Prods. Co. v. Globe Oil & Ref. Co.</i> , 322 U.S. 471 (1944)	14
<i>Westinghouse Elec. & Mfg. Co. v. De Forest Radio Tel. & Tel. Co.</i> , 21 F.2d 918 (3d Cir. 1927), aff'd, 278 U.S. 562 (1928)	12

VII

Constitution, statutes and regulations:	Page
U.S. Const. Art. I, § 8, Cl. 8 (Patent Clause)	1
Act of Nov. 1, 1995, Pub. L. No. 104-41, § 2, 109 Stat. 352	19
Act of Dec. 12, 1980, Pub. L. No. 96-35, 94 Stat. 3015	19
Administrative Procedure Act, 5 U.S.C. 701 <i>et seq.</i>	3
5 U.S.C. 706(2)(E)	27
Court of Federal Claims Technical and Procedural Improvements Act of 1992, Pub. L. No. 102-572, Tit. IX, § 902(b)(1), 106 Stat. 4516	19
Drug Price Competition and Patent Term Restora- tion Act of 1984, Pub. L. No. 98-417, Tit. II, § 203, 98 Stat. 1603	18
Optional Inter Partes Reexamination Procedure Act of 1999, Pub. L. No. 106-113, Div. B, § 1000(a)(9) [Tit. IV, subtit. F], 113 Stat. 1536, 1501A-567 (35 U.S.C. 311 <i>et seq.</i>)	19
35 U.S.C. 311	3, 19
35 U.S.C. 314	23
35 U.S.C. 314(b)(2)	4
35 U.S.C. 314(c)	4, 23
15 U.S.C. 1057(b)	27
17 U.S.C. 410(c)	27
35 U.S.C. 1 <i>et seq.</i>	1
35 U.S.C. 2(a)	20
35 U.S.C. 2(a)(1)	1
35 U.S.C. 101	2
35 U.S.C. 102	2
35 U.S.C. 102(b)	2, 5

VIII

Statutes and regulations—Continued:	Page
35 U.S.C. 103	8
35 U.S.C. 103(a)	2
35 U.S.C. 112	25
35 U.S.C. 122	2
35 U.S.C. 122(b)	23
35 U.S.C. 131	2
35 U.S.C. 131-132	22
35 U.S.C. 141	27
35 U.S.C. 141-145	3
35 U.S.C. 145	27, 28
35 U.S.C. 151	2
35 U.S.C. 271(a)	4
35 U.S.C. 281	4
35 U.S.C. 282	<i>passim</i>
35 U.S.C. 282(2)	4
35 U.S.C. 282(3)	4
35 U.S.C. 284	4
35 U.S.C. 301	3
35 U.S.C. 301-307	23
35 U.S.C. 302	3, 19
35 U.S.C. 302-307	19
35 U.S.C. 303	3
35 U.S.C. 304	3
35 U.S.C. 305	3, 4, 23
37 C.F.R.:	
Section 1.56(a)	22
Section 1.99	23

IX

Regulation—Continued:	Page
Section 1.104(a)	22
Miscellaneous:	
65 Fed. Reg. (2000):	
p. 54,604	22
p. 54,633	22
74 Fed. Reg. 65,098 (2009)	23
H.R. Rep. No. 1307, 96th Cong., 2d Sess. Pt. 1 (1980) ...	19
H.R. Rep. No. 1923, 82d Cong., 2d Sess. (1952)	8, 15, 17
Staff of the H.R. Comm. on the Judiciary, 81st Cong., 2d Sess., <i>Proposed Revision and Amendment of the Patent Laws: Preliminary Draft with Notes</i> (Comm. Print 1950)	16
U.S. Patent & Trademark Office, <i>Manual of Patent Examining Procedure</i> (8th ed. Rev. 8, July 2010)	2, 21, 23

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INTEREST OF THE UNITED STATES

Pursuant to the Patent Clause of the Constitution (Art. I, § 8, Cl. 8), Congress has charged the United States Patent and Trademark Office (PTO), an agency in the Department of Commerce, with responsibility for examining patent applications and issuing patents. See 35 U.S.C. 1 *et seq.* Because the practical effect of a successful challenge to the validity of a patent is to overturn the PTO's administrative decision, the United States has a substantial interest in the question presented.

STATEMENT

1. a. The PTO is “responsible for the granting and issuing of patents.” 35 U.S.C. 2(a)(1). When an inventor applies for a patent, the PTO undertakes an examination

process to determine whether a patent should issue. 35 U.S.C. 131. An examiner with expertise in the relevant technological fields analyzes the application and the invention it describes, as well as the prior art in the field, in order to determine whether the statutory requirements for patentability are satisfied. *Ibid.*; PTO, *Manual of Patent Examining Procedure* §§ 704-706, 903.08(e), 904-904.02 (8th ed. Rev. 8, July 2010) (*MPEP*). The examination process is conducted *ex parte*, without direct participation by third parties. 35 U.S.C. 122.

A number of statutory prerequisites must be satisfied before a patent may issue. *Inter alia*, an invention must be novel, see 35 U.S.C. 102, and it is not patentable if it was “in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States,” 35 U.S.C. 102(b). An invention also is not patentable if it does not consist of patent-eligible subject matter, 35 U.S.C. 101, or if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious * * * to a person having ordinary skill in the art.” 35 U.S.C. 103(a).

In applying these and other statutory requirements, the PTO may make a number of factual determinations. For instance, the question of obviousness is ultimately one of law, but it turns on “several basic factual inquiries,” including analysis of the scope and content of the prior art, the level of ordinary skill in the art, and the nature of the invention’s advancement over the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). After undertaking the necessary analysis, the PTO issues the patent “[i]f it appears that applicant is entitled to a patent under the law.” 35 U.S.C. 151. Once granted, “[a]

patent shall be presumed valid,” and “[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. 282.

If the examiner concludes that a patent should not be granted, the applicant may appeal the examiner’s decision within the PTO and may then seek judicial review. See 35 U.S.C. 141-145. Review of a PTO decision denying a patent application is conducted pursuant to the deferential standards set forth in the Administrative Procedure Act, 5 U.S.C. 701 *et seq.* See *Dickinson v. Zurko*, 527 U.S. 150, 154, 163-165 (1999).

b. Although the examination process is conducted *ex parte*, Congress has provided avenues through which third parties may petition the PTO to reexamine the validity of an issued patent. “Any person at any time may file a request for reexamination by the Office of any claim of a patent on the basis of” prior art reflected in another patent or a printed publication. 35 U.S.C. 302; see 35 U.S.C. 301. If the PTO determines that the cited art presents a substantial new question of patentability, it institutes a reexamination proceeding. 35 U.S.C. 303, 304. In that proceeding, the examiner considers patentability de novo, using the preponderance-of-the-evidence standard, in light of the newly introduced prior art. *In re Etter*, 756 F.2d 852, 857 (Fed. Cir.) (en banc), cert. denied, 474 U.S. 828 (1985). The patent holder has the opportunity to amend his claims in order to avoid invalidity. 35 U.S.C. 305. A third party may also seek *inter partes* reexamination of any patent for which the application was filed after November 1999, 35 U.S.C. 311, and in that reexamination process “the third-party requester shall have one opportunity [at each stage] to file written comments addressing issues raised by the action of the

Office or the patent owner's response thereto," 35 U.S.C. 314(b)(2). All reexamination proceedings must be conducted with "special dispatch." 35 U.S.C. 305, 314(c).

c. A patent holder may bring a civil action for infringement against any person who "without authority makes, uses, offers to sell, or sells any patented invention, within the United States." 35 U.S.C. 271(a), 281, 284. The defendant in an infringement suit may assert the invalidity of the patent as an affirmative defense. 35 U.S.C. 282(2) and (3). In order to establish that defense, the defendant must overcome the presumption of validity that inheres in an issued patent. 35 U.S.C. 282.

The Federal Circuit has long held that, in order to rebut the presumption of validity, the party challenging the patent must establish invalidity by clear and convincing evidence. See, *e.g.*, *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-1360, cert. denied, 469 U.S. 821 (1984). The court has applied that heightened standard even when the defendant introduces evidence of invalidity that was not before the PTO during the examination process. See *ibid.* The court has recognized, however, that "new" evidence may "carry more weight and go further toward sustaining the attacker's unchanging burden." *Id.* at 1360.

2. a. Respondents hold the patent at issue in this case, known as the '449 patent. Pet. App. 4a. The patent claims an improved method for editing documents containing "markup languages" by storing a document's contents and its tags separately. *Id.* at 5a-6a.

In 2007, respondents filed this infringement action, alleging that petitioner's manufacture and sale of certain Microsoft Word products infringed respondents' patent. Pet. App. 6a. Petitioner counterclaimed, seeking a dec-

laration that the '449 patent was invalid and unenforceable. *Ibid.* At trial, petitioner argued that the on-sale bar (35 U.S.C. 102(b); see p. 2, *supra*) applied because, beginning more than one year before respondents' patent application was filed, respondents had sold a software program known as "S4," which had not been before the PTO examiner who granted the '449 patent. Pet. App. 15a, 184a. Petitioner asserted that the S4 software was materially identical to the invention claimed in the '449 patent. *Id.* at 19a. Because the S4 source code had been destroyed, *id.* at 20a, the factual dispute largely turned on the testimony of S4's two creators, who testified that S4 did not practice the key innovation claimed in the '449 patent. *Id.* at 20a-21a; see J.A. 176a-177a.

Petitioner requested a jury instruction that petitioner's "burden of proof with regard to its defense of invalidity based on prior art that the examiner did not review * * * is by preponderance of the evidence." J.A. 124a n.8. The district court rejected petitioner's proposed instruction and instead instructed the jury that petitioner bore the "burden of proving invalidity by clear and convincing evidence." Pet. App. 195a. Petitioner was allowed to argue, however, that the jury need not defer to the examiner's grant of the patent because the examiner "didn't have a chance to look at" the most probative evidence of invalidity. J.A. 203a-204a. The jury found that the '449 patent was valid and that petitioner had willfully infringed it. Pet. App. 7a.

b. The court of appeals affirmed. Pet. App. 1a-57a. Petitioner argued that the jury instructions were erroneous because they required clear and convincing evidence of invalidity even though the evidence regarding S4 had not been before the PTO. The court rejected that contention, concluding that "the jury instructions

were correct in light of [Federal Circuit] precedent, which requires the challenger to prove invalidity by clear and convincing evidence.” *Id.* at 23a.

SUMMARY OF ARGUMENT

When the defendant in a patent infringement action asserts that the relevant patent is invalid, he must present clear and convincing evidence of invalidity in order to establish that defense. See 35 U.S.C. 282. That heightened standard applies even if the defendant relies on evidence of invalidity that was not before the PTO. See *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-1360 (Fed. Cir.), cert. denied, 469 U.S. 821 (1984). Evidence that was not before the examiner, however, may be given greater weight, making the defendant’s burden easier to satisfy. See *id.* at 1360. That approach—which the Federal Circuit has long followed—is consistent with congressional intent and with this Court’s precedents, and it best serves the administrative-deference and reliance interests implicated by challenges to a patent.

In enacting Section 282 in the 1952 Patent Act, Congress sought to codify the existing judge-made presumption of validity. This Court’s prior decisions had required the party asserting invalidity to prove it by “clear and satisfactory” evidence that was “more than a mere preponderance.” *Radio Corp. of Am. v. Radio Eng’g Labs., Inc.*, 293 U.S. 1, 8-10 (1934) (*RCA*). Although that heightened burden was rooted in the deference due the Patent Office’s exercise of its authority and its technical expertise, *Morgan v. Daniels*, 153 U.S. 120, 123-124 (1894), this Court made clear that it applied in all cases, even when the defendant’s proffered evidence of invalidity had not been before the agency, see *RCA*, 293 U.S. at

8. Section 282's directive that "[a] patent shall be presumed valid" therefore should be understood to incorporate the pre-existing rule that a litigant who challenges the validity of an issued patent bears a heightened burden of proof.

The clear-and-convincing-evidence standard best accommodates the interests implicated by validity challenges. A contention that a patent is invalid is in essence a collateral attack on the PTO's prior administrative action, and it therefore implicates principles of deference to agency authority and expertise. Invalidation challenges also implicate the inventor's reliance interests in a patent, which confers valuable property rights in return for the inventor's public disclosure of his invention. Requiring that invalidity be demonstrated by clear and convincing evidence serves both of these interests by ensuring that the jury has a high degree of confidence before it overturns the PTO's grant of a patent. Even when evidence suggesting invalidity was not before the PTO, and the administrative-expertise rationale therefore does not apply, the heightened burden of proof furthers the patent holder's reliance interests, and it is consistent with congressional intent and with this Court's precedents.

ARGUMENT

I. SECTION 282 CODIFIED A PRE-EXISTING JUDGE-MADE PRESUMPTION OF VALIDITY THAT HAD LONG INCLUDED A HEIGHTENED STANDARD OF PROOF**A. In Enacting Section 282 In The Patent Act Of 1952, Congress Intended To Codify The Existing Presumption Of Validity**

Enacted as part of the Patent Act of 1952, Section 282 provides that “[a] patent shall be presumed valid,” and that “[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. 282. The accompanying House Report explained that “Section 282 introduces a declaration of the presumption of validity of a patent, which is now a statement made by courts in decisions, but has had no expression in the statute.” H.R. Rep. No. 1923, 82d Cong., 2d Sess. 10 (1952) (*House Report*). Thus, “[t]he first paragraph [of Section 282] declares the existing presumption of validity of patents.” *Id.* at 29. Although Section 282 does not specify the degree of evidence needed to overcome the presumption of validity, the *House Report*’s reference to the “existing” presumption indicates that Congress intended to adopt the presumption as courts had applied it in the years leading up to 1952—including the judge-made requirement that the party asserting invalidity must satisfy a heightened burden of proof. Cf. *Graham v. John Deere Co.*, 383 U.S. 1, 3, 14-17 (1966) (noting the *House Report*’s statement that 35 U.S.C. 103 codified obviousness doctrine “which exists in the law”).

1. Before 1952, this Court applied a presumption of validity that required a party who challenged an issued patent to satisfy a heightened burden of proof

In the decades before the enactment of the Patent Act, this Court developed and applied a presumption that an issued patent is valid. Although the presumption was grounded initially in principles of deference to agency authority and expertise, it applied even when the challenger relied on evidence of invalidity that the Patent Office had not considered. And while the Court did not adhere to a uniform articulation of the challenger's evidentiary burden, it consistently made clear that invalidity must be proved by more than a preponderance of the evidence.

a. In *Morgan v. Daniels*, 153 U.S. 120 (1894), the Court identified the need for deference to the Patent Office's delegated authority and expert judgment as the primary rationale for the presumption of validity. *Morgan* involved a suit by a disappointed patent applicant who challenged the Patent Office's adverse priority determination and its consequent denial of the plaintiff's application. *Id.* at 121-122. The plaintiff's claim, the Court stated, was "closely" related to validity challenges raised as defenses in patent infringement suits, in that each type of challenge attacks the Patent Office's disposition of a patent application. *Id.* at 123. In an infringement suit, the Court explained, a patent is presumed valid, and "every reasonable doubt" is resolved against the party asserting invalidity. *Ibid.* (citing *Coffin v. Ogden*, 85 U.S. (18 Wall.) 120, 124 (1873), and *Cantrell v. Wallick*, 117 U.S. 689, 695 (1886)). Drawing on that precedent, the Court held that when an unsuccessful patent applicant seeks direct review of the Patent Office's action, he must establish the agency's error by

more than “a mere preponderance of evidence,” by proffering “testimony which in character and amount carries thorough conviction.” *Id.* at 125.

That burden of proof, the Court explained, was higher than the burden ordinarily placed on an appellant who challenges a presumptively correct judgment. See *Morgan*, 153 U.S. at 123-124. The heightened burden is warranted, the Court held, because a litigant who asserts that an issued patent is invalid seeks to have the courts “set aside the action of one of the executive departments of the government,” made by “[t]he one charged with the administration of the patent system” after “finish[ing] its investigations and ma[king] its determination.” *Id.* at 124-125. Because the plaintiff in *Morgan* sought to relitigate “a question of fact which ha[d] once been settled by a special tribunal, intrusted with full power in the premises,” *id.* at 124, the heightened burden ensured that if the evidence was “doubtful, the decision of the Patent Office must control,” *id.* at 125.

b. Four decades later, in *RCA*, an infringement suit in which the defendant argued that the patent was invalid, this Court synthesized earlier decisions applying the presumption of validity in infringement actions, and it reaffirmed that the presumption can be overcome only by “convincing evidence of error.” 293 U.S. at 7. The Court explained that the requirement of clear evidence to establish an invalidity defense is “little more than another form of words” for *Morgan*’s requirement that a party directly challenging the PTO’s decision must present “evidence sufficient to carry thorough conviction to the mind.” *Id.* at 9. Thus, the Court explained, “the presumption of validity shall prevail against strangers as well as parties [who previously litigated priority in a

PTO interference proceeding] unless the countervailing evidence is clear and satisfactory.” *Ibid.*

In discussing the strength of the presumption of validity, the Court canvassed earlier decisions that had applied the presumption in infringement suits—including *Coffin* and *Cantrell*, on which the Court in *Morgan* had previously relied. The Court explained that, although the presumption had “found varying expression in this and other courts,” *RCA*, 293 U.S. at 7, a “common core of thought and truth” ran through the decisions, *id.* at 8, to the effect that “one otherwise an infringer who assails the validity of a patent fair upon its face bears a heavy burden of persuasion, and fails unless his evidence has more than a dubious preponderance.” *Id.* at 7-8. The Court in *RCA* thus rejected the preponderance standard, just as the *Morgan* Court had rejected that standard in the context of a direct action challenging the PTO’s decision. See *Morgan*, 153 U.S. at 124.

The *RCA* Court also stated that “[i]f it is true [that the presumption applies] where the assailant launches his attack with evidence different, at least in form, from any theretofore produced in opposition to the patent, it is so a bit more clearly where the evidence is even verbally the same.” *RCA*, 293 U.S. at 8. That statement reflected the Court’s understanding that, while the rationale for a heightened evidentiary standard is particularly strong when an invalidity challenge rests on information that the agency previously considered, the clear-evidence standard should apply even when the challenge is based on information that was not before the examiner. And while the Court pointed out that “[t]he evidence in this suit for an infringement is a repetition, word for word, of the evidence” presented in earlier lawsuits challenging the PTO’s determination of priority, *id.*

at 6, the evidence in the earlier suits had included “new testimony produced to overcome the evidential effect” of the PTO’s administrative interference ruling. See *Westinghouse Elec. & Mfg. Co. v. De Forest Radio Tel. & Tel. Co.*, 21 F.2d 918, 927 (3d Cir. 1927), *aff’d*, 278 U.S. 562 (1928). The Court thus made clear that the presumption of validity can be rebutted only by “clear and satisfactory” evidence even if the challenger presents evidence of invalidity that was not before the agency. 293 U.S. at 9.¹

c. After *RCA*, the Court reaffirmed that a party challenging the validity of a patent in an infringement action must satisfy a heightened burden of proof, regardless of the character of the evidence or the procedural posture of the suit.

In *Mumm v. Jacob E. Decker & Sons*, 301 U.S. 168 (1937), for example, the Court rejected the argument that the plaintiff in an infringement action must plead

¹ Petitioner argues (Br. 28-29) that *RCA* did not establish a generally applicable standard of proof because the case presented issues that had been litigated in previous suits and that had been the subject of an *inter partes* interference proceeding before the PTO. The Court nowhere suggested, however, that the “heavy burden of persuasion” was limited to cases having those characteristics. See *RCA*, 293 U.S. at 7-9. The heightened standard was not based on *res judicata* concerns, as the Court observed that when it had *first* considered the validity issues in the context of an earlier direct challenge to the PTO’s decision, it had concluded that “the evidence was insufficient to overcome the presumption of * * * validity in any clear or certain way.” *Id.* at 10. The Court’s statement that “[a] patent regularly issued, and even more obviously a patent issued after a hearing of all the rival claimants, is presumed to be valid until the presumption has been overcome by convincing evidence of error,” *id.* at 7, likewise indicates that the Court intended the heightened standard to apply to patents issued after *ex parte* examinations as well as those issued after contested interference proceedings.

that the patent had not been anticipated by earlier inventions. *Id.* at 169. The Court held that such allegations were unnecessary because invalidity is an “affirmative defense.” *Id.* at 171. The Court further observed that “[n]ot only is the burden to make good this defense upon the party setting it up, but his burden is a heavy one, as it has been held that ‘every reasonable doubt should be resolved against him.’” *Ibid.* (citing *Cantrell* and *Coffin*). The Court offered that unqualified statement of the defendant’s burden even though, at the motion-to-dismiss stage, it was not yet clear what evidence of invalidity the defendant would present, or whether that evidence had been before the PTO. Similarly in *Smith v. Hall*, 301 U.S. 216 (1937), the Court relied on *RCA* in requiring the defendant to present “convincing evidence” of anticipation. *Id.* at 232-233. After evaluating the oral and documentary evidence, the Court concluded that the entire record was sufficient to “support the heavy burden of persuasion which rests upon one who seeks to negative novelty in a patent.” *Id.* at 233; *id.* at 221-222.

d. Petitioner contends (Br. 25-28) that this Court applied the heightened standard only when the evidence of invalidity took the form of oral testimony, which was considered less reliable. Although some of the early decisions applying the heightened standard emphasized the oral nature of the evidence, see, *e.g.*, *The Barbed Wire Patent*, 143 U.S. 275, 284 (1892), others involved oral testimony but stated the heightened burden without qualification, see, *e.g.*, *Cantrell*, 117 U.S. at 695-696. The Court made clear in *RCA* that the heightened burden was not limited to invalidity defenses resting on oral testimony by citing the earlier cases for the unqualified proposition that a defendant must prove invalidity by

“more than a dubious preponderance.” 293 U.S. at 7-9. Subsequent decisions applied the *RCA* standard without regard to whether the evidence was oral. See *Smith*, 301 U.S. at 233; *id.* at 221-222; *Mumm*, 301 U.S. at 171.

Petitioner also argues (Br. 30-31) that this Court must not have viewed *RCA* and *Morgan* as adopting a generally applicable standard of proof because its later decisions sometimes addressed validity issues without discussing the burden of persuasion. It would be highly unusual, however, for the Court to have *sub silentio* overruled *RCA*'s unequivocal clear-and-satisfactory-evidence requirement. The decisions on which petitioner relies are therefore best understood as involving circumstances in which identification of a specific standard of proof was unnecessary to resolve the case. See, e.g., *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949) (lower courts' factfindings demonstrated validity “as a matter of law”); *Muncie Gear Works, Inc. v. Outboard, Marine & Mfg. Co.*, 315 U.S. 759, 766-767, 768 (1942) (respondent effectively conceded prior use, and the Court found “inescapable” the conclusion that such use had occurred); *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 487 (1944) (claim was “on its face too obvious to constitute patentable invention”); *Lincoln Eng'g Co. v. Stewart-Warner Corp.*, 303 U.S. 545, 549 (1938) (prior decision was “controlling” on validity question); cf. *Marconi Wireless Tel. Co. v. United States*, 320 U.S. 1, 34 (1943) (finding that invalidity had been established by “convincing proof”).

2. Section 282 codified the presumption of validity as it had previously been defined and applied by this Court

a. In enacting Section 282 to codify “the existing presumption of validity,” *House Report 29*, Congress acted against the backdrop of this Court’s precedents. Section 282’s directive that “[a] patent shall be presumed valid,” without qualification or condition, should be understood to incorporate *RCA*’s requirement that invalidity be established in all cases by “clear and satisfactory” evidence, *RCA*, 293 U.S. at 9—in modern terminology, clear and convincing evidence. See *id.* at 8-9.

Although Section 282 does not specify the standard of proof necessary to overcome the presumption of validity, this Court had previously made clear that a heightened evidentiary standard is the presumption’s defining attribute. *RCA*, 293 U.S. at 7-9; see *American Hoist*, 725 F.2d at 1360 (presumption and burden are “different expressions of the same thing—a single hurdle to be cleared”). The presumption of validity reflected this Court’s recognition that, because an alleged infringer’s invalidity defense is in effect a collateral attack on the PTO’s decision to grant a patent, it implicates administrative-deference principles to the same extent as a suit directly challenging the agency’s action. See *Morgan*, 153 U.S. at 123; *RCA*, 293 U.S. at 9; *American Hoist*, 725 F.2d at 1359 (“Behind it all, of course, was the basic proposition that a government agency such as the [PTO] was presumed to do its job.”). The Court viewed the deference due the PTO’s expert judgment and authority as requiring the party attacking the PTO’s action to shoulder a burden of proof *higher* than that usually placed on a plaintiff or an appellant challenging a previous decision. *Morgan*, 153 U.S. at 123-125. The pre-

sumption of validity would not serve its intended purpose if it could be rebutted by a preponderance of the evidence.²

b. Petitioner contends (Br. 23-24, 33-36) that because lower courts had not uniformly applied the heightened standard mandated by *RCA* in the years before 1952, Section 282 cannot be viewed as codifying any judicial consensus that the heightened standard should apply in all cases. As petitioner observes, some lower courts had diverged on the strength of the presumption of validity and the extent to which it applied when the evidence of invalidity had not been before the agency. Compare, *e.g.*, *Hunt v. Armour & Co.*, 185 F.2d 722, 726 (7th Cir. 1950) (presumption strengthened if evidence was not new), with *McClintock v. Gleason*, 94 F.2d 115, 116 (9th Cir. 1938) (presumption weakened if the evidence was new). But the fact that some lower courts had not followed *RCA* does not lessen the clarity of this Court's precedent, or the inference that Congress was aware of this Court's leading decisions on the issue. To the contrary, Section 282 served the dual purpose of codifying the *RCA* rule and abrogating those lower-

² As petitioner observes (Br. 19), a preliminary draft of the Patent Act specified that invalidity should be established by "convincing proof." Staff of the H.R. Comm. on the Judiciary, 81st Cong., 2d Sess., *Proposed Revision and Amendment of the Patent Laws: Preliminary Draft with Notes* 68 (Comm. Print 1950). The omission of that language from the enacted version does not suggest that Congress intended to prescribe a preponderance standard. See *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989) (the "unexplained disappearance of one word from an unenacted bill" is "not [a] reliable indicator[] of congressional intent") (internal citation and quotation marks omitted); see also *Milner v. Department of the Navy*, No. 09-1163 (Mar. 7, 2011), slip op. 8-9.

court decisions that had failed to follow *RCA*. See *American Hoist*, 725 F.2d at 1359.³

Petitioner also relies (Br. 14-23) on default rules governing the construction of statutory presumptions where evidence of congressional intent is lacking. Those default principles are not relevant here, however, because Congress did not write on a clean slate when it enacted Section 282. Rather, Congress codified a pre-existing presumption of validity long recognized by this Court, part and parcel of which was the heightened evidentiary standard that governed invalidity challenges. Particularly because the clear-and-convincing-evidence standard is grounded in agency-deference principles that were thought to require a heightened standard, see *Morgan*, 153 U.S. at 124-125, Congress would not likely have divorced the presumption from the heightened burden of persuasion necessary to overcome it—and doing so certainly would not have codified the “existing presumption of validity.” *House Report 29*.

B. Congress’s Acquiescence In The Federal Circuit’s Long-standing Construction Of Section 282 Further Supports The Clear-And-Convincing-Evidence Standard

Congress’s intent to codify the requirement that invalidity be proved by clear and convincing evidence is further evidenced by its acquiescence in the Federal Circuit’s decades-old precedent to that effect. See *John R.*

³ Petitioner is therefore wrong in arguing (Br. 20) that Section 282’s express placement of the burden of persuasion on the party asserting invalidity would be superfluous if Congress had intended the presumption of validity to include a heightened burden. Because some lower courts had placed the burden on the patent holder to prove the patent’s validity, see *American Hoist*, 725 F.2d at 1359, Congress could reasonably have decided to abrogate those decisions explicitly.

Sand & Gravel Co. v. United States, 552 U.S. 130, 139 (2008). In 1984, shortly after the Federal Circuit was vested with exclusive appellate jurisdiction in patent cases, Judge Rich (who had helped draft the Patent Act of 1952) wrote an opinion for the court addressing the burden of proof under Section 282. See *American Hoist*, 725 F.2d at 1359-1360. Relying on *RCA*, the court held that a party challenging the validity of a patent has the burden of presenting “clear and convincing evidence” of invalidity. *Ibid.* The court emphasized that this heightened burden “is constant and never changes,” and that “new prior art not before the PTO” may “carry more weight” but “has no effect on the presumption” or the burden of proof. *Ibid.* Accordingly, for more than 25 years, parties asserting invalidity in infringement actions have been required to satisfy the clear-and-convincing-evidence standard. See, e.g., *Tokai Corp. v. Easton Enters., Inc.*, No. 2010-1057, 2011 WL 308370, at *6 (Fed. Cir. Jan. 31, 2011).

During that period, Congress has not altered the statutory presumption of validity, even though Congress has repeatedly amended other aspects of Section 282.⁴ See, e.g., Drug Price Competition and Patent Term Res-

⁴ Petitioner notes (Br. 38-40) that Congress also did not act to overrule decisions of the regional courts of appeals interpreting Section 282 between its enactment in 1952 and the Federal Circuit’s decision in *American Hoist*. Congress’s inaction during that period raises no inference that it acquiesced in any particular standard of proof, however, because there was no clear consensus among the courts of appeals. Compare, e.g., *Gaddis v. Calgon Corp.*, 506 F.2d 880, 885 (5th Cir. 1975) (new evidence “weakens” presumption, but “[n]evertheless,” “clear and cogent evidence” that is “more than a dubious preponderance” is necessary; citing *RCA, supra*), with *Rains v. Niaqua*, 406 F.2d 275, 278 (2d Cir.) (preponderance standard in all cases), cert. denied, 395 U.S. 909 (1969).

toration Act of 1984, Pub. L. No. 98-417, Tit. II, § 203, 98 Stat. 1603; Court of Federal Claims Technical and Procedural Improvements Act of 1992, Pub. L. No. 102-572, Tit. IX, § 902(b)(1), 106 Stat. 4516; Act of Nov. 1, 1995, Pub. L. No. 104-41, § 2, 109 Stat. 352. Over approximately the same period, Congress has also addressed directly the problem of invalid patents by expanding the PTO's authority to conduct administrative reexaminations of issued patents—rather than by adjusting the ease of proving in litigation that a patent is invalid. See 35 U.S.C. 302-307; Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015. Congress created the reexamination procedure, which permits third parties to request that the PTO reconsider a granted patent based on published prior art, 35 U.S.C. 302, in order to channel a subset of validity challenges to the PTO.

In Congress's view, enabling the agency to apply its expertise to certain new evidence in the first instance would both increase the reliability of patents and lessen the prevalence of validity challenges in the context of infringement suits. H.R. Rep. No. 1307, 96th Cong., 2d Sess. Pt. 1, at 3-4 (1980). In the years since *American Hoist* was decided, Congress has expanded the reexamination procedure, including by creating *inter partes* reexamination proceedings. See 35 U.S.C. 311; Optional Inter Partes Reexamination Procedure Act of 1999, Pub. L. No. 106-113, Div. B, § 1000(a)(9) [Tit. IV, subtit. F], 113 Stat. 1536, 1501A-567 (35 U.S.C. 311 *et seq.*). Thus, while Congress has left untouched the evidentiary standard used in litigated challenges, it has specifically provided for third-party validity challenges by channeling many of those challenges to the expert agency.

II. APPLYING THE CLEAR-AND-CONVINCING-EVIDENCE STANDARD TO ALL VALIDITY CHALLENGES BEST ACCOMMODATES THE COMPETING INTERESTS IMPLICATED BY SUCH CHALLENGES AND IS MOST CONSISTENT WITH ADMINISTRATIVE-LAW PRINCIPLES

When the defendant in an infringement suit asserts the affirmative defense that the patent is invalid, he raises what is in practical effect a collateral attack on the PTO's prior decision to grant the patent. Accordingly, a validity challenge implicates both the deference due the PTO's expert factual judgments, made in the exercise of its statutory authority, and the patent holder's reliance interests in its patents. Because a standard of proof "serves to allocate the risk of error between the litigants and to indicate the relative importance attached to the ultimate decision," the amount of evidence necessary to overcome the presumption of validity should reflect and accommodate the competing interests at stake. *Herman & MacLean v. Huddleston*, 459 U.S. 375, 389-390 (1983). The *American Hoist* approach of applying the clear-and-convincing-evidence standard in all cases, while allowing the factfinder to accord greater weight to evidence that was not before the PTO examiner, best accommodates these interests.

A. Challenges To The Validity Of An Issued Patent Implicate Administrative-Deference And Reliance Interests

1. A validity challenge seeks to overturn the considered decision of the PTO

a. Congress has vested the PTO with authority to issue patents. See 35 U.S.C. 2(a); *Graham*, 383 U.S. at 18. The issuance of a patent represents the agency's decision that the invention satisfies the statutory prerequisites for patentability, and that the inventor there-

fore should receive potentially valuable intellectual property rights in return for his disclosure of the invention to the public. *Id.* at 6; *Pfaff v. Wells Elec., Inc.*, 525 U.S. 55, 63 (1998). In deciding whether to grant a patent, a PTO examiner with specialized expertise in the relevant scientific or technical fields analyzes the application and relevant material, and determines whether the invention satisfies the statutory requirements for patentability. See *MPEP* §§ 704-706, 903.08(e), 904-904.02; *American Hoist*, 725 F.2d at 1359. The examiner's decision to grant a patent thus reflects the technical expertise necessary to evaluate the invention; knowledge of the state of the art in relevant fields; and experience in applying the statutory requirements.

When the defendant in subsequent infringement litigation asserts that a patent is invalid, it seeks to have set aside a decision made by the PTO in the exercise of its statutory authority and technical expertise. See *Morgan*, 153 U.S. at 124. By asking the jury to review the PTO's factfindings and its ultimate determination of patentability, the challenger places the correctness of the PTO's administrative action in issue. The preponderance standard that petitioner advocates, under which the expert agency's decision would be subject to de novo reconsideration by a lay jury, is inconsistent with basic administrative-law principles.

b. Petitioner contends (Br. 41-43) that administrative-deference principles are inapposite here because infringement suits do not involve direct judicial review of agency action. It is not unusual, however, for the resolution of disputes between private parties to turn on the correctness of prior agency action. In such cases this Court has routinely accorded agency action the deference to which it is otherwise entitled. See, *e.g.*,

Chase Bank USA, N.A. v. McCoy, 131 S. Ct. 871, 880-881 (2011); *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 171-174 (2007); *Meyer v. Holley*, 537 U.S. 280, 287-288 (2003); *Auer v. Robbins*, 519 U.S. 452, 461 (1997). When the defendant in an infringement suit attempts to overturn the PTO's prior patenting decision by asserting an invalidity defense, resolution of that defense involves the kind of challenge to the agency's expert judgment that implicates the essential rationale for agency deference.

c. Petitioner also suggests (Br. 46-51) that deference is unwarranted because the PTO's examination procedures are "structurally biased" (Br. 47) in favor of patent applicants. Petitioner is incorrect.

The *ex parte* nature of the procedure does not prevent a rigorous and effective examination. The examination process consists of iterative exchanges between the examiner and the applicant, as claims are amended in response to initial rejections and invalidity concerns are addressed. 35 U.S.C. 131-132. Examiners are required to undertake a "thorough study" of the patent and a "thorough investigation" of the prior art in all relevant fields. 37 C.F.R. 1.104(a). An applicant must disclose to the PTO "all information known to that individual to be material to patentability." 37 C.F.R. 1.56(a). Examiners also have broad authority to request that applicants provide any information relating to any potential ground for denying the patent. 65 Fed. Reg. 54,604, 54,633 (2000); see *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281-1283 (Fed. Cir. 2005) (upholding PTO's authority to request information about potential on-sale bar).

Although petitioner suggests (Br. 49-50) that patents are often granted without consideration of the most relevant prior art, examiners conduct prior-art searches

pursuant to detailed PTO policies, see *MPEP* § 904-904.02, and rely on their expertise in the field and their access to extensive patent and non-patent resources. See 74 Fed. Reg. 65,098 (2009). And despite the *ex parte* nature of the proceedings, there are several mechanisms by which third parties may provide the PTO with relevant prior art. Patent applications are generally published 18 months after they are filed, see 35 U.S.C. 122(b), and third parties may then submit prior art references they consider relevant to the PTO's decision. 37 C.F.R. 1.99. After issuance, any party may seek reexamination of the patent on the basis of published prior art, 35 U.S.C. 301-307, and third parties may present arguments to the PTO in *inter partes* reexamination proceedings, 35 U.S.C. 314.

Several features of the reexamination process enhance the PTO's ability to undertake a thorough analysis of published prior art in reexamination proceedings. Because the presumption of validity does not apply, *In re Etter*, 756 F.2d 852, 855-859 (Fed. Cir.) (en banc), cert. denied, 474 U.S. 828 (1985), the PTO is able to evaluate the new art using the preponderance-of-the-evidence standard, unconstrained by its previous issuance of the patent. The examiner also interprets the patent using the "broadest reasonable construction," which permits the examiner to invalidate the patent based on a wider range of prior art. *Id.* at 858. The patent holder may respond by amending his claims, thereby permitting the PTO to consider whether the prior art demands the invalidation of the entire patent, or whether a more nuanced solution that preserves some of the patent holder's rights is possible. 35 U.S.C. 305, 314(c).

Petitioner also emphasizes (Br. 48-49) that, when a patent application is filed, the initial burden rests on the examiner to identify potential obstacles to patentability. The requirement that the examiner establish a prima facie case of unpatentability, however, is simply a “procedural tool” to regulate the interaction between examiner and applicant. *In re Kumar*, 418 F.3d 1361, 1366 (Fed. Cir. 2005). Once the examiner establishes a prima facie case of invalidity, the burden shifts to the applicant to demonstrate that the invention is patentable. *Ibid.* The PTO has informed this Office that in the vast majority of examination proceedings, the examiner issues an initial rejection of some or all claims in the application, thus shifting the burden to the applicant.

Finally, the examination process reflects Congress’s conclusion that an *ex parte* procedure would simultaneously serve two interests: the need for searching agency review of patent applications, and applicants’ interest in avoiding premature disclosure of their not-yet-patented inventions. See *Eagle Comtronics, Inc. v. Arrow Commc’n Labs., Inc.*, 305 F.3d 1303, 1314 (Fed. Cir. 2002), cert. denied, 537 U.S. 1172 (2003). A fully adversarial proceeding, in which third parties (likely the applicant’s competitors) are permitted to submit any and all evidence they can obtain in an attempt to prevent the patent from issuing, would likely provide a greater degree of certainty that the PTO has before it all relevant evidence of invalidity. Cf. Pet. Br. 49-51. Congress has determined, however, that the potentially increased accuracy of such an adversarial proceeding is outweighed by other interests. Congress’s decision to strike that balance provides no sound basis for construing Section 282 to allow lay juries to review the PTO’s patent grants de novo, in derogation both of usual

administrative-law principles and of this Court's decisions preceding Section 282's enactment.

2. *Invalidity challenges implicate substantial reliance interests*

The PTO's issuance of a patent creates a property right that engenders, and is intended to engender, significant reliance interests. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-481 (1974). Patent holders invest considerable sums of money in developing patentable inventions in return for the exclusive right to exploit their inventions for a period of time. The expected value of these patents—and hence the incentive to invest in new innovations—depends in part on the perceived likelihood that any patent the inventor may obtain can be successfully enforced in infringement litigation. Once issued, moreover, a patent gives rise to significant reliance interests, as the patent holder will organize its operations around the patents it holds.

Even a single invalidity challenge can subvert those interests by extinguishing the value of a patent. If the jury in an infringement suit finds the patent invalid and its verdict is sustained on appeal (under the deferential standard governing sufficiency challenges to jury determinations), the preclusive effect of that determination will prevent the patent holder from judicially enforcing the patent against any other alleged infringer, leaving the patent with no practical value. See *Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313, 349-350 (1971). In addition, a crucial part of the patent bargain is that in exchange for the property rights conferred by a patent, an inventor must disclose to the public “a written description of the invention, and of the manner and process of making and using it.” See 35

U.S.C. 112; *Pfaff*, 525 U.S. at 63. Because such disclosure eliminates the inventor’s option of maintaining that information as a trade secret, an inventor whose patent application is granted but later declared invalid may be placed in a worse position than if he had never sought a patent in the first place. In sum, if patents are too easy to invalidate, the risk of invalidation—as well as the prospect that every infringement suit will be met with a burdensome validity challenge—may raise the cost of enforcing a patent to the point where the expected value of the patent cannot justify the outlays entailed in innovation.

B. The Clear-And-Convincing-Evidence Standard Should Apply In All Cases, Including Those Involving “New” Evidence Of Invalidity

The rationale for the clear-and-convincing-evidence standard is strongest when the party asserting invalidity relies, in whole or in part, on evidence that was before the PTO when it issued the patent. Section 282 is properly read to incorporate that heightened evidentiary standard, however, even when the defendant in an infringement suit relies solely on evidence that was not before the examiner.

1. The clear-and-convincing-evidence standard reflects deference to the agency’s authority and expertise by ensuring that, when the factual questions on which validity turns are “doubtful, the decision of the Patent Office must control.” *Morgan*, 153 U.S. at 125. That rule makes particular sense because validity issues arising in infringement suits are decided by lay juries who lack technical expertise and specialized knowledge of the relevant fields. A jury should not be permitted to overturn the considered decision of the PTO when the evi-

dence is substantially in equipoise, but rather should be allowed to take that step only if it possesses a high degree of confidence that the PTO erred.⁵ In this respect, the clear-and-convincing-evidence standard serves largely the same purpose as the substantial-evidence standard that governs a court’s review of an agency’s factfindings under the Administrative Procedure Act. See 5 U.S.C. 706(2)(E); *Consolo v. Federal Mar. Comm’n*, 383 U.S. 607, 620-621 (1966) (substantial-evidence review “places a premium upon agency expertise” and “minimize[s] the opportunity for reviewing courts to substitute their discretion for that of the agency”).

Petitioner contends (Br. 18) that more searching review is necessary to bring “balance” to the patent system because the PTO’s procedures are biased in favor of granting patents. In fact, requiring clear and convincing evidence under Section 282 provides symmetry in judicial review of the PTO’s decisions. When the PTO *denies* a patent application, its factual findings are reviewed under the deferential standards established by the APA. See 35 U.S.C. 141, 145; *Dickinson v. Zurko*,

⁵ As petitioner observes (Br. 23), courts have held that a litigant may establish the invalidity of a registered trademark or copyright by a preponderance of the evidence. The statutory provisions governing registered trademarks and copyrights, however, are worded differently from Section 282. See 15 U.S.C. 1057(b) (trademark registration “shall be prima facie evidence of the validity of the registered mark”); 17 U.S.C. 410(c) (copyright registration “shall constitute prima facie evidence of the validity of the copyright”). And the relevant trademark- and copyright-law provisions are intended primarily to encourage registration, rather than to recognize the agencies’ expertise. See *Cosmetic Ideas, Inc. v. IAC/Interactivecorp*, 606 F.3d 612, 619 (9th Cir.), cert. denied, 131 S. Ct. 686 (2010); *Aluminum Fabricating Co. v. Season-All Window Corp.*, 259 F.2d 314, 316 (2d Cir. 1958).

527 U.S. 150, 158, 165 (1999).⁶ Applying the clear-and-convincing-evidence standard when the validity of an issued patent is challenged in an infringement suit would thus place comparable burdens on the parties seeking to overturn the PTO's decision to grant or deny a patent.

The clear-and-convincing-evidence standard also furthers the reliance interests created by a patent grant by affording the patent holder enhanced protection against an erroneous jury finding of invalidity. The heightened burden increases the strength of patents and is thus a historical component of the system that Congress created to encourage innovation. See pp. 25-26, *supra*. By allowing a lay jury to second-guess the PTO's judgment even in close cases, the preponderance standard would diminish the expected value of patents and would reduce future inventors' incentives to innovate and to disclose their inventions to the public. And with respect to *existing* patents, a repudiation of the heightened standard that has historically governed infringement suits would alter the patent bargain by reducing the value of the rights that inventors have received in exchange for disclosing their innovations. If any such

⁶ An unsuccessful patent applicant may seek review of the PTO's decision in the Federal Circuit under 35 U.S.C. 141 or in district court under 35 U.S.C. 145. The Federal Circuit recently held that the plaintiff in a Section 145 action may present any new evidence of patentability to the court, whether or not that evidence could have been presented to the PTO, and that the court may then review the PTO's findings de novo. See *Hyatt v. Kappos*, 625 F.3d 1320 (2010) (en banc). Because that holding deviates from administrative-review principles and creates an unjustified disparity between review under Section 141 and under Section 145, see *id.* at 1344-1349 (Dyk, J., joined by Gajarsa, J., dissenting), the Acting Solicitor General has authorized the filing of a petition for a writ of certiorari to review the *Hyatt* decision.

change is to be made, it should come from Congress rather than from this Court. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002).

2. Rather than altering the evidentiary standard that governs validity challenges raised in infringement suits, Congress has created and expanded PTO reexamination procedures, which address validity concerns based on published prior art while minimizing the impact on patent holders' reliance interests. The potential for the expert agency to reconsider its own decision may diminish to some degree the value of an issued patent by increasing the likelihood that the patent will later be found invalid, but it does not create the same uncertainty as would the potential for a lay jury's invalidation based on a bare preponderance of the evidence. In addition, reexamination gives the patent holder an opportunity to respond to new evidence of invalidity by amending his claims. Unlike an invalidity challenge in litigation, which may completely and permanently extinguish a patent's value, reexamination provides a more nuanced mechanism that takes reliance interests into account.

When the defendant in an infringement suit asserts invalidity based on evidence that was not before the examiner who issued the patent, but that could have been made the basis for a reexamination proceeding, the clear-and-convincing evidence standard furthers Congress's intent to channel such challenges to the expert agency. Where it is available, use of the reexamination procedure is consistent with the principle that an agency should have the opportunity to reconsider its prior decisions in light of new evidence. See, e.g., *INS v. Orlando Ventura*, 537 U.S. 12, 16-17 (2002) (per curiam); *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985).

Permitting an alleged infringer to invoke the PTO's prior inability to consider the new evidence as a justification for lowering the standard of proof even though he has forgone an opportunity to initiate the reexamination process would lessen the incentive to use the reexamination procedure, thereby undermining the system that Congress has created.

3. When an invalidity challenge rests solely on evidence that was not before the PTO and that could not have been the subject of administrative reexamination, the appropriate standard of proof for determining invalidity is less obvious.⁷ Ordinarily, when a court reviewing agency action concludes that the agency's decision was based on incomplete evidence, the proper course is to remand to the agency. See *Lorion*, 470 U.S. at 744. In an infringement suit, however, that option is not available, and both of the options before the court are in

⁷ Infringement cases may often arise in which some of the evidence relevant to an assessment of the patent's validity was before the PTO examiner, while other evidence bearing on validity was not. If the heightened evidentiary standard were treated as a sort of "bursting bubble" that converts to a preponderance standard if the defendant introduces *any* new evidence of invalidity, the exception would swallow the rule, since the party who asserts that the patent is invalid will almost always be able to identify *some* arguably relevant prior art that was not presented to the PTO examiner. Alternatively, any regime under which the jury attempts to apply different standards of proof to different evidence bearing on the same ultimate question would likely prove unworkable in practice. And even if the defendant in an infringement suit relied *exclusively* on materials that were not before the PTO examiner, difficult questions might arise as to whether those materials differed substantively from information that the examiner *did* consider. Any regime in which the standard of proof turns on whether particular evidence was before the PTO could also hinder the examination process by encouraging applicants to indiscriminately submit prior art references to the PTO, without regard to relevance.

some tension with usual administrative-law principles. Applying the preponderance standard that petitioner advocates would permit the jury to determine for itself what the PTO would or should have done had it considered the new evidence, while the clear-and-convincing-evidence standard has the practical effect of according deference to an agency decision that did not consider potentially material facts. Cf. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007).

As between those alternatives, applying the clear-and-convincing-evidence standard across the board reflects the better reading of Section 282 in light of that provision's text, history, and purposes. Most importantly, the text of Section 282 does not suggest that the standard of proof governing questions of patent validity varies depending on the nature of the evidence that a challenger introduces. Such a variable-proof regime, moreover, would reflect a substantial departure from the way in which evidentiary burdens typically operate. Although juries routinely give different *weight* to different types of evidence, petitioner identifies no statute under which the standard of proof governing a particular determination depends on the type of evidence that the parties introduce. The Federal Circuit's longstanding approach to the question presented here, under which evidence that was not before the PTO "may * * * carry more weight and go further toward sustaining the attacker's unchanging burden," *American Hoist*, 725 F.2d at 1360, is thus much more consistent with the usual application of evidentiary burdens than is a regime under which the introduction of new evidence changes the standard of proof itself. Cf. *Santosky v. Kramer*, 455 U.S. 745, 757 (1982) ("Standards of proof * * * 'are

shaped by the risk of error inherent in the truth-finding process as applied to the *generality of cases*, not the rare exceptions.’”) (quoting *Mathews v. Eldridge*, 424 U.S. 319, 344 (1976)) (emphasis in original).

Applying the heightened standard in all cases, while permitting the jury to take into account the PTO’s lack of opportunity to consider particular evidence of invalidity, is also more consistent with the case-law backdrop against which Congress enacted and amended the relevant Patent Act provisions. This Court’s pre-1952 decisions, while recognizing that the heightened standard is more clearly justified when the Patent Office has already considered the relevant evidence, made clear that the standard applies even when the defendant relies on evidence that was not before the examiner. See pp. 11-12, *supra*. And since its 1984 decision in *American Hoist*, the Federal Circuit has consistently held that the PTO’s lack of opportunity to consider particular information goes to the weight the factfinder may appropriately give that evidence rather than to the applicable standard of proof. Congress’s failure expressly to establish a variable-proof regime, even as it has amended Section 282 in other respects and expanded the opportunities for PTO reexamination, strongly indicates that it intended the clear-and-convincing-evidence standard to apply across the board.

Finally, petitioner relies (*e.g.*, Br. 52) on this Court’s observation that “the rationale underlying the presumption [of validity]—that the PTO, in its expertise, has approved the [patent] claim—seems much diminished” when the evidence suggesting invalidity was not before the agency examiner. *KSR*, 550 U.S. at 426. But while the administrative-expertise rationale for the presumption does not apply in these circumstances, the Federal

Circuit's approach accounts for that fact by allowing the factfinder to accord greater weight to new evidence. The clear-and-convincing-evidence standard also still serves to protect the patent holder's reliance interests, and it respects Congress's decision to vest the PTO, rather than courts or lay juries, with primary responsibility for resolving factual issues bearing on patentability. Congress could reasonably conclude, moreover, that the uncertainties and potential for jury confusion that a variable-proof regime might entail outweighed any benefits that such a regime could be expected to produce. See note 7, *supra*.

CONCLUSION

The decision of the court of appeals should be affirmed.

Respectfully submitted.

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