

No. 10-290

In the Supreme Court of the United States

MICROSOFT CORPORATION,

Petitioner,

v.

14I LIMITED PARTNERSHIP AND
INFRASTRUCTURES FOR INFORMATION, INC.,

Respondents.

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

**BRIEF OF APOTEX, INC.,
AS *AMICUS CURIAE*
IN SUPPORT OF PETITIONER**

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**BRIEF OF APOTEX, INC., AS *AMICUS CURIAE*
IN SUPPORT OF PETITIONER**

INTEREST OF *AMICUS CURIAE*¹

Apotex, Inc., is the largest pharmaceutical company in Canada and a leading worldwide manufacturer and distributor of generic pharmaceuticals. Founded in 1974, Apotex manufactures approximately 300 generic drugs and sells those products worldwide. Apotex's customers include physicians, hospitals, and patients in the United States.

Apotex frequently files Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market generic versions of brand-name drugs. ANDAs must address the status and effect of each patent that a brand-name manufacturer has claimed covers a particular drug. Apotex and other generic manufacturers frequently include in their ANDAs a certification stating that one or more of those patents are invalid or inapplicable; by law, such a certification constitutes an act of patent infringement. Consequently, Apotex is often a defendant in patent infringement suits brought by brand-name drug manufacturers. Because Apotex asserts patent invalidity as a defense to such actions, it is directly and adversely affected by the Federal

¹ The parties' letters of consent to the filing of this brief have been filed with the Clerk. Pursuant to this Court's Rule 37.6, *amicus curiae* states that no counsel for a party wrote this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to this brief's preparation or submission.

Circuit's rule that challengers must establish invalidity by clear and convincing evidence, even when the Patent Office did not consider the prior art on which the invalidity defense rests. Accordingly, Apotex has a valuable perspective to contribute to this case and a substantial interest in the correct resolution of the important issue presented.

INTRODUCTION AND SUMMARY OF ARGUMENT

Section 282 of the Patent Act creates a presumption of validity for every patent issued by the U.S. Patent and Trademark Office, stating that the “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 Federal Circuit reads Section 282 to add, *sub silentio*, an additional requirement: that a challenger must carry the statutory burden of proof by clear and convincing evidence, rather than by a preponderance of the evidence. That judge-made rule finds no support in the text or legislative history of Section 282 and undermines the core purpose of patent law by inhibiting rather than promoting innovation.

I. The Framers sought to ensure that “free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989). The Patent Clause, U.S. CONST. Art. I, § 8, Cl. 8, therefore has long been understood to contain an important limitation on the power to grant a federal patent: “Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to

restrict free access to materials already available.” *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966). As the Framers, Congress, and this Court all have recognized, granting a monopoly on information that is already available to the public exacts substantial social costs and undermines the Patent Clause’s central goal of promoting innovation. Accordingly, since the first Patent Act of 1790, the public use or sale of an article has served as an absolute bar to its patentability.

Determining whether an invention is already in the public domain, however, is seldom an easy task. The universe of prior-art references is vast, comprising not only books and articles published anywhere in the world (and in any language), but also public uses and sales that are not formally documented at all. 35 U.S.C. § 102. Such undocumented prior art can be extremely difficult for patent examiners—who review patent applications *ex parte*—to discover. Defendants in patent infringement suits, by contrast, are well positioned (and highly motivated) to identify pertinent prior-art references. For that reason, both this Court and Congress affirmatively *encourage* competitors of patent holders to put dubious patents to the test by challenging their validity in court.

The rule applied below—that defendants must prove invalidity by clear and convincing evidence—hinders the corrective function that litigation serves by making it vastly more difficult to weed out invalid patents. The Federal Circuit’s rule therefore undermines the central purpose of the Patent Clause by protecting those “inventions” that remove existing knowledge from the public domain.

II. The Federal Circuit’s rule finds no support in the text of the statute. Section 282 codifies the former common-law presumption of validity and shifts the burden to the challenger to rebut that presumption. It says nothing, however, about the quantum of proof necessary to discharge that burden. That silence speaks volumes; under settled rules of statutory construction, the traditional preponderance-of-the-evidence standard applies in civil cases unless Congress says otherwise. Congress has not done so in Section 282. This Court should therefore reject the Federal Circuit’s rule that the statutory presumption of validity can be rebutted only by clear and convincing evidence.

The Federal Circuit’s interpretation of Section 282 cannot be saved by appealing to general notions of administrative deference. To begin with, even most formal agency determinations that enjoy a statutory presumption of validity are nevertheless rebuttable by a mere preponderance of the evidence. There is no reason to depart from that general rule in the patent context, and there are many good reasons not to.

Even if principles of administrative deference could justify a heightened standard of proof in some circumstances, those principles do not warrant the onerous standard of review that the Federal Circuit applies to validity determinations made by the Patent Office. That is especially true when, as in the present case, the Patent Office has not even considered the prior art in question. Courts accord no deference to an agency’s factual determination when the agency “failed to consider an important aspect of the problem.” *Motor Vehicle Mfrs. Ass’n of United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43

(1983). Thus, as this Court observed in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007), “the rationale underlying the presumption [of validity]—that the PTO, in its expertise, has approved the claim—seems much diminished” when the agency has not passed on the prior art. At a minimum, then, this Court should clarify that the presumption of validity can be rebutted by a preponderance of the evidence when the prior art on which the invalidity defense rests was not considered by the Patent Office.

ARGUMENT

I. THE CLEAR-AND-CONVINCING-EVIDENCE STANDARD UNDERMINES THE PURPOSES OF THE PATENT ACT BY INHIBITING RATHER THAN ADVANCING INNOVATION

A. The Framers Recognized That The “Embarrassment of the Exclusive Patent” Is Justified Only If An Invention Was Not Already Known To The Public

“[A] patent is an exception to the general rule against monopolies and to the right to access to a free and open market.” *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). The Framers possessed an “instinctive aversion to monopolies.” *Graham v. John Deere Co.*, 383 U.S. 1, 7-9 (1966). They nevertheless believed that a limited patent monopoly could, in some circumstances, serve as “an inducement . . . to bring forth new knowledge.” *Id.* at 9. Accordingly, the Patent Clause carefully balances “the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of

Science and useful Arts.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (quoting U.S. CONST. Art. 1, § 8, Cl. 8).

Consistent with those competing goals, the federal patent laws, from their inception, have sought to “draw[] a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.” *Bonito Boats*, 489 U.S. at 148 (quoting 13 WRITINGS OF THOMAS JEFFERSON 335 (Memorial ed. 1904)). Although drawing that line is sometimes difficult, the Patent Clause establishes one bright-line rule: “Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.” *Graham*, 383 U.S. at 6. That fundamental limitation reflects the Framers’ determination that the creation of a monopoly on information already known to the public “would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use.” *Bonito Boats*, 489 U.S. at 148.

Indeed, Thomas Jefferson—the first administrator of the federal patent system and author of the second Patent Act—“viewed a grant of patent rights in an idea already disclosed to the public as akin to an *ex post facto* law, ‘obstruct[ing] others in the use of what they possessed before.’” *Bonito Boats*, 489 U.S. at 147 (quoting 13 WRITINGS OF THOMAS JEFFERSON 327); see *Graham*, 383 U.S. at 7 (describing Jefferson’s views on the limitations of the “patent monopoly” as “worthy of note”). The Patent Act of 1790 addressed that concern by expressly restricting the patent monopoly to those innovations “not before known or

used.” 1 Stat. 109, 110. That limitation was derived from the English Statute of Monopolies, which targeted abusive practices whereby the Crown would issue letters patent “granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public.” *Graham*, 383 U.S. at 5. Although it generally dismantled such monopolies, the English Statute carved out a limited exception permitting grants of exclusive rights to “new manufactures”—but only if such inventions were not already in public use. *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 20 (1829) (quoting 21 Jac. 1, c. 3 (1623)). The first Patent Act adopted that restriction, which Congress continued in the Patent Act of 1793. 1 Stat. 318, 319 (restricting patents to technologies not “known or used before the application”).²

The prior-use and on-sale bars—now codified in 35 U.S.C. § 102—have thus been a central fixture of U.S. patent law since the first Congress. And those statutory bars are a crucial corollary to the bargain that lies at the heart of the Patent Clause—namely, that an inventor may receive a limited monopoly on an invention only in return for disclosing it to the public. See *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186-87 (1933). Because the animating purpose of that *quid pro quo* is to induce inventors to communicate new knowledge to the public, the “embarrassment of an exclusive patent,” as Jefferson put it, is plainly unjustified when that knowledge is already in the public domain. See, *e.g.*,

² In *Pennock v. Dialogue*, 27 U.S. (2 Pet.) at 19-20, this Court interpreted the “known or used” bar to encompass prior sales as well. See also Patent Act of 1836, 5 Stat. 117, 123 (codifying *Pennock*’s on-sale bar).

Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 64 (1998) (public-use and on-sale bars reflect “reluctance to allow an inventor to remove existing knowledge from public use”); *Envirotech Corp. v. Westech Eng’g Inc.*, 904 F.2d 1571, 1574 (Fed. Cir. 1990) (same).

That is particularly true when—as is the case here, Pet. App. 15a—an applicant commercially exploits an invention by using or selling it and *then* seeks to extend that benefit by securing a patent to the invention. In *Pennock*, this Court explained:

If an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention; if he should for a long period of years retain the monopoly, and make, and sell his invention publicly, and thus gather the whole profits of it, relying upon his superior skill and knowledge of the structure; and then, and then only, when the danger of competition should force him to secure the exclusive right, he should be allowed to take out a patent, and thus exclude the public from any farther use than what should be derived under it during his fourteen years; it would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries.

27 U.S. (2 Pet.) at 19.

To give force to that essential principle, the second Patent Act created a defense to an infringement action if a patented invention “had been in use, or had been described in some public work anterior to the supposed discovery of the patentee.” 1 Stat. at 322; see also Patent Act of 1836, 5 Stat. 117, 123

(codifying the on-sale defense to infringement). The anticipation defense therefore serves the important purpose of preventing a patentee from securing a monopoly on knowledge already in the public domain. As discussed below, the Federal Circuit’s rule that a challenger must prove invalidity by clear and convincing evidence—even when the Patent Office never considered anticipatory prior art—undermines that foundational goal of patent law.

B. The Clear-and-Convincing-Evidence Standard Undermines The Crucial Corrective Role Litigation Plays In Weeding Out Invalid Patents

Far from disfavoring challenges to patent validity (as the clear-and-convincing-evidence standard necessarily does), this Court has affirmatively encouraged such litigation. In *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969), for example, the Court observed that litigants “may often be the only individuals with enough economic incentive to challenge the patentability of an inventor’s discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification.”³

³ See also *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 349-50 (1971) (noting the Court’s “consistent view” that “the holder of a patent should not be insulated from the assertion of defenses and thus allowed to exact royalties for the use of an idea that is not in fact patentable or that is beyond the scope of the patent monopoly granted”); *Edward Katzinger Co. v. Chicago Metallic Mfg. Co.*, 329 U.S. 394, 400 (1947) (stressing “the necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid”); *Pope Mfg. Co. v.*

This Court's emphasis on the salutary role of the invalidity defense is not surprising. Numerous commentators have highlighted the growing number of questionable patents awarded by the PTO.⁴ As this Court has long recognized, invalid patents exact tremendous social costs by hindering competition and undermining the incentive structure of the patent system. See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402 (2007) ("Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress."); *Bonito Boats*, 489 U.S. at 146 (invalid patents "stifle innovation"); *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("competition should not be repressed by worthless patents"). The problem stems, in large part, from several well-known structural constraints on the Patent Office's ability to identify invalid patents. As discussed in greater detail below, patent examiners have limited time and resources to evaluate the deluge of applications received each year; prior-art references (particularly prior uses and

Gormully, 144 U.S. 224, 235 (1892) (recognizing that the right to challenge a patent "is not only a private right to the individual, but is founded on public policy, which is promoted by his making the defense, and contravened by his refusal to make it").

⁴ See, e.g., Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763 (2002); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U.L. REV. 1495 (2001); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577 (1999); Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521 (2005); Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 MINN. J.L. SCI. & TECH. 1 (2007); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305 (2001).

sales by third parties) are often extraordinarily difficult to detect; and the examination process is conducted *ex parte*, thus depriving examiners of the benefit of an adversary to present opposing views and evidence.

Given those deficiencies, patent litigation constitutes the best—and, once a patent has been issued, the most efficient—protection against patent monopolies that “remove[] existing knowledge from public use.” *Bonito Boats*, 489 U.S. at 148. As the Federal Trade Commission has explained, “[l]itigation is a mechanism for focusing enhanced attention on those patents that are most likely to hold commercial significance and for weeding out from this group those patents that should not have been granted.” FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 5, at 28 (Oct. 2003) (“FTC Report”), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>. Litigants have vastly more time and money to devote to questions of validity than do patent examiners. Defendants to patent infringement suits are also supremely motivated to search for potentially invalidating prior art such as public uses and sales. See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U.L. REV. 1495, 1510 (2001).

For those reasons, Congress has sought to encourage patent validity challenges. The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), for example, incentivizes generic drug manufactures to challenge the validity of questionable brand-name patents by rewarding the first challenger with an extremely valuable 180-day period of generic market exclusivity.

See 21 U.S.C. §§ 355(j)(2)(A)(vii), 355(j)(5)(B)(iv). That statutory scheme reflects Congress's determination that dubious pharmaceutical patents deter full and fair competition and that potential infringers are best positioned to attack such patents successfully. See *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008) (Hatch-Waxman provides incentive to challenge "suspect" patents); *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008).

The Federal Circuit's onerous standard of proof, however, hinders the corrective role that patent litigation serves. By "distort[ing] the litigation process," the clear-and-convincing-evidence standard shields such patents from the cleansing light of litigation, creating the "serious potential for judicially confirming unnecessary, potentially competition-threatening rights to exclude." FTC Report, ch. 5, at 28.

To be sure, some patents—*e.g.*, the much-derided peanut butter and jelly sandwich patent—would be invalidated under any standard of proof. See i4i BIO at 27-28 n.20. But the problem is not the existence of such obviously frivolous patents, which are unlikely to deter anyone from practicing the claimed invention. Rather, the problem (by definition) arises from those dubious patents that would survive the limited scrutiny of a clear-and-convincing-evidence standard but not the more stringent preponderance standard. Indeed, the cancellation rate in *inter partes* reexamination proceedings⁵ (where no

⁵ Pursuant to 35 U.S.C. § 311, third parties may request (and participate in) *inter partes* reexamination of a patent based on a

heightened standard of proof applies) is higher than the invalidity rate in litigation (where patents enjoy a presumption of validity rebuttable only by clear and convincing evidence). Roger Shang, *Inter Partes Reexamination and Improving Patent Quality*, 7 NW. J. TECH. & INTELL. PROP. 185, 192 (2009). That disparity suggests that the clear-and-convincing-evidence standard does in fact “judicially confirm[]” anticompetitive patent monopolies that would otherwise be rooted out by litigation. FTC Report, ch. 5, at 28; see 35 U.S.C. § 317(b) (final court decision that challenger failed to satisfy its burden of establishing invalidity bars *inter partes* reexamination).

Although respondents bemoan the settled expectations that would supposedly be upset by any departure from the heightened standard of proof, see i4i BIO at 17, they ignore the flip side of the coin: precisely *because* of the certainty it provides, the clear-and-convincing-evidence standard deters potential litigants from challenging a patent’s validity. “An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees.” *eBay Inc. v. MercExchange*, 547 U.S. 388, 396-97 (2006) (Kennedy, J., concurring) (highlighting the “potential vagueness and suspect validity” of some patents). The clear-and-convincing-evidence standard increases the likelihood that accused infringers would capitulate to exorbitant licensing demands rather than face the onerous standard of

comparison of the patent’s claims to the prior art. The preponderance-of-the-evidence standard applies in *inter partes* proceedings. See *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988).

proof applicable in an infringement action. Further stifling innovation, potential competitors may decline even to enter a market so as to avoid the minefield of questionable patents that could expose them to infringement liability. See John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 319-20 (2001).

Those deleterious consequences are exacerbated in industries—such as the computer hardware and software fields—that advance by incremental innovations that build on top of one another. The vast number of patents needed to practice such innovations can create “patent thickets” that generate prohibitive transaction costs for potential licensees and cripple competition. See FTC Report, Executive Summary, at 6. And the assertion of overly broad patents on foundational technologies—*e.g.*, patents covering online shopping, electronic voice communication, and digital video transmission—can block a vast swath of downstream innovations that depend on those technologies. See Mark Lemley, Doug Lichtman & Bhaven Sampat, *What to do About Bad Patents?*, 28 REGULATION 10, 12 (Winter 2005); James Gleick, *Patently Absurd*, N.Y. TIMES MAG., Mar. 12, 2000, at 48. Of particular concern to Apotex, such overreaching is all too common in the pharmaceutical industry, where a single invalid patent protecting a name-brand drug can cost U.S. patients billions of dollars annually. See John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 735-36 (2002) (comparing costs of generic vs. branded drugs).

In sum, the clear-and-convincing-evidence standard works as a steep disincentive to challenge the validity of patents—challenges that this Court and Congress have recognized benefit the public interest by serving a vital corrective function. It also distorts litigation outcomes by enabling invalid patents to survive such challenges. Contrary to the core purpose of the Patent Clause—and more than 400 years of Anglo-American patent law—the heightened standard of proof therefore permits the extraordinary patent monopoly to be bestowed on “inventions” that remove “existing knowledge from the public use.” *Bonito Boats*, 489 U.S. at 148.

II. THE CLEAR-AND-CONVINCING-EVIDENCE STANDARD IS UNJUSTIFIED, ESPECIALLY WHEN THE PATENT OFFICE DID NOT CONSIDER PRIOR ART INTRODUCED IN LITIGATION

A. The Presumption Of Validity Simply Allocates The Burden Of Proof And Does Not Raise The Quantum Of Proof Necessary To Invalidate A Patent

As relevant here, Section 282 of the Patent Act sets forth two straightforward rules. First, it provides that “[a] patent shall be presumed valid.” 35 U.S.C. § 282. Simply establishing a presumption of validity, however, does not necessarily define the nature of that presumption. Presumptions in the law take many forms. See 2 K. BROUN, MCCORMICK ON EVIDENCE § 342, at 495 (6th ed. 2006). Under the so-called bursting-bubble theory, for example, the creation of a presumption merely allocates the burden of production; the presumption vanishes upon

the introduction of evidence supporting the nonexistence of the presumed fact. *Id.* § 344, at 508; see *Texas Dep't of Community Affairs v. Burdine*, 450 U.S. 248, 255 n.8 (1981) (“The word ‘presumption’ properly used refers only to a device for allocating the production burden.”) (internal quotation marks omitted); see also Fed. R. Evid. 301. Although less common, other presumptions shift both the burden of production and the burden of persuasion to the party seeking to rebut the presumption.

Because a presumption can mean many things, Section 282 includes a second proviso defining the effect of the statutory presumption of patent validity: “The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. § 282. Although Section 282 allocates to the challenger the burden of persuading the factfinder of a patent’s invalidity, it says nothing whatsoever about the *quantum of proof* necessary to discharge that burden.

Under settled rules of statutory construction, that “silence is inconsistent with the view that Congress intended to require a special, heightened standard of proof.” *Grogan v. Garner*, 498 U.S. 279, 286 (1991). In civil cases, the traditional preponderance-of-the-evidence standard applies unless Congress expressly provides otherwise or “particularly important individual interests or rights are at stake.” *Ibid.* (internal quotation marks omitted). Patent rights, however, are a far cry from the types of fundamental individual interests this Court has held justify a heightened standard of proof—*e.g.*, an individual’s interests in her involuntary commitment, termination of parental rights, or deportation. See

Herman & MacLean v. Huddleston, 459 U.S. 375, 389-90 (1983) (noting that the preponderance standard suffices even for imposition of severe civil sanctions that would expose a party to criminal prosecution). The plain text of Section 282, properly interpreted, therefore establishes a preponderance-of-the-evidence standard—nothing more.

Nor does Section 282's legislative history lend any support to the elevated standard of proof demanded by the Federal Circuit. The presumption of validity was originally a judicial creation. The case law, however, "was far from consistent—even contradictory—about the presumption and, absent statutory restraint, judges were free to express their individual views about it." *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). Some courts took the extreme position that the presumption was actually "the other way around"—*i.e.*, that there was a presumption of *invalidity*, with the burden on the *patentee* to demonstrate an issued patent's validity. *Ibid.* (internal quotation marks omitted). By enacting Section 282, Congress sought to correct that misapprehension by codifying the presumption of validity and clarifying that the burden rested with the challenger and not the patentee. But that is all Congress did. It did not take the additional—and extraordinary—step of requiring a heightened standard of proof to discharge that burden. The Federal Circuit's rule that Section 282 implicitly creates such a special standard of proof simply conflates the presumption of validity with the

quantum of proof required to rebut that presumption.⁶

Congress has expressly provided for a heightened standard of proof elsewhere in the Patent Act. Section 273 of Title 35, which creates a prior-use defense to infringement of business method patents, requires the defendant to establish the defense by clear and convincing evidence. 35 U.S.C. § 273(b)(4) (“A person asserting the defense under this section shall have the burden of establishing the defense by clear and convincing evidence.”). That statutory command is clearly expressed, removing any doubt that, when Congress seeks to increase the standard of proof for an infringement defense, it says so. Moreover, Section 273’s heightened standard is justified by the fact that the prior-use defense shields a defendant from liability even when it has infringed a *valid* patent.

⁶ Indeed, the Federal Circuit’s early decisions seemingly acknowledge that Section 282’s presumption of validity is a burden-shifting mechanism only. In *In re Etter*, 756 F.2d 852, 858-59 (Fed. Cir. 1985), for example, the court explained that “the § 282 presumption is a rule of procedure placing the burden of persuasion on him who attacks a patent’s validity.” See *Lannom Mfg. Co., v. ITC*, 799 F.2d 1572, 1575 (Fed. Cir. 1986) (the “presumption [of validity] assigns the burden of proof to the challenger”); *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 885 (Fed. Cir. 1984) (“The presumption of patent validity found in 35 U.S.C. § 282 is but a procedural device which places on a party asserting invalidity the initial burden of going forward to establish a prima facie case on that issue.”); see also *Solder Removal Co. v. ITC*, 582 F.2d 628, 632-33 n.8 (C.C.P.A. 1978) (noting that the last sentence of Section 282 simply serves to shift the burden of persuasion to the challenger).

A comparison to the closely related fields of trademark and copyright law is informative. See *eBay*, 547 U.S. at 392 (looking to copyright law for guidance in interpreting the Patent Act). Proof of registration of a trademark with the PTO gives rise to a “strong presumption” that the mark is valid. *Zobmondo Entm’t, LLC v. Falls Media, LLC*, 602 F.3d 1108, 1113 (9th Cir. 2010) (internal quotation marks omitted); see 15 U.S.C. §§ 1057(b) (registration of mark constitutes prima facie evidence of its validity), 1115(a) (same). Nevertheless, that presumption merely shifts to the defendant the burden of proving *by a preponderance of the evidence* that the mark is not protectable. *Zobmondo*, 602 F.3d at 1114. Importantly, the preponderance standard suffices to rebut the presumption of validity even though trademark registration decisions—just like patent approval determinations—are made by PTO officials who possess “special expertise” to make such “fact-intensive” determinations. *Lahoti v. Vericheck, Inc.*, 586 F.3d 1190, 1199 (9th Cir. 2009). Registration of a copyright with the U.S. Copyright Office similarly confers a presumption of validity; that presumption is also rebuttable by less than clear and convincing evidence. See 17 U.S.C. § 410(c); *Palladium Music, Inc. v. EatSleepMusic, Inc.*, 398 F.3d 1193, 1196 (10th Cir. 2005).⁷

The fact that Section 282 creates a presumption of validity is therefore insufficient to raise the quantum

⁷ Courts have suggested that the presumption of validity in copyright law serves only to shift the burden of production to the challenger. See *Palladium Music*, 398 F.3d at 1196; *Lamps Plus, Inc. v. Seattle Lighting Fixture Co.*, 345 F.3d 1140, 1144 (9th Cir. 2003).

of proof required to rebut that presumption. Indeed, the Federal Circuit has acknowledged as much with respect to other statutes very similar to Section 282. For example, 28 U.S.C. § 2639 provides that certain decisions by the Customs Bureau are “presumed to be correct,” and that “[t]he burden of proving otherwise shall rest upon the party challenging such decision.” 28 U.S.C. § 2639(a)(1). The statute is silent, however, on the quantum of proof required to rebut that presumption of correctness. In the face of that silence, the Federal Circuit has “conclude[d] that the higher ‘clear and convincing’ burden of persuasion is inappropriate” and that “section 2639(a)(1) requires [challengers] to overcome the presumption of correctness accorded Customs’ decisions . . . by a preponderance of the evidence.” *Fabil Mfg. Co. v. United States*, 237 F.3d 1335, 1340 (Fed. Cir. 2001) (quoting *St. Paul Fire & Marine Ins. Co. v. United States*, 6 F.3d 763, 769 (Fed. Cir. 1993)) (first alteration in original). In reaching that conclusion, the court expressly relied on the interpretive rule—equally dispositive in the present case—that the “‘preponderance of the evidence’ formulation is the general burden assigned in civil cases for factual matters.” *St. Paul*, 6 F.3d at 769 (citing VAUGHN C. BALL ET AL., *MCCORMICK'S HANDBOOK OF THE LAW OF EVIDENCE* § 339 (Edward W. Cleary ed., 2d ed. 1972)).

Two lessons can be drawn from those statutory presumptions. First, a presumption of validity—even one tethered to an express burden-shifting mechanism—does not in and of itself create a special, heightened standard of proof. Rather, the traditional preponderance-of-the-evidence standard is sufficient to rebut statutory presumptions of validity unless Congress says otherwise.

Second, even when agency factual determinations are granted “deference” by reviewing courts, any such deference serves only to justify the presumption of validity and the allocation of the burden to the challenger; it does not also elevate the quantum of proof necessary to rebut the presumption. See *Lahoti*, 586 F.3d at 1199 (noting that courts accord significant “deference” to PTO trademark validity determinations but that such determinations are nevertheless rebuttable by a preponderance of the evidence); *Lone Star Steakhouse & Saloon, Inc. v. Alpha of Va., Inc.*, 43 F.3d 922, 934 (4th Cir. 1995) (courts give “due regard” to PTO trademark determinations). Thus, although Section 282’s presumption of validity stems from the recognition that the Patent Office is “presumed to do its job,” *Am. Hoist & Derrick Co.*, 725 F.2d at 1359, that presumption of administrative correctness simply justifies the presumption of validity now codified in Section 282; it does not support the Federal Circuit’s interpretation of Section 282 as establishing a clear-and-convincing-evidence standard of proof. As discussed below, however, even if the general notion of agency deference can justify a heightened standard of proof in some circumstances, it plainly cannot do so when the Patent Office has not even passed on the prior art forming the basis of an invalidity defense.

B. Bedrock Principles Of Administrative Law Weigh Against Deference To The Patent Office’s Validity Determination When The Patent Office Did Not Consider The Prior Art Raised In Litigation

The clear-and-convincing-evidence rule is often defended on two related grounds: (1) patent exami-

ners have the requisite experience and ability to make patentability determinations, and (2) patent approval is a species of administrative determination warranting deference. *Baumstimler v. Rankin*, 677 F.2d 1061, 1066 (5th Cir. 1982); see *KSR*, 550 U.S. at 426 (rationale for presumption of validity is that “the PTO, in its expertise, has approved the claim”).⁸ Neither rationale supports the Federal Circuit’s rule that invalidity must be proven by clear and convincing evidence even when the challenger produces evidence of prior art that the Patent Office did not consider.

To begin with, although patent examiners undoubtedly possess technical expertise, this Court has recognized that they operate under significant constraints. As early as 1966, the Court observed that “the Patent Office is confronted with a most difficult task.” *Graham*, 383 U.S. at 18 (noting that more than 100,000 patent applications were filed each year). That task has grown more difficult since *Graham*: in 2010 alone, the PTO received more than 500,000 patent applications, with a total backlog running well over one million applications. U.S. Patent & Trademark Office, *Performance and Accountability Report, FY 2010*, 125-27, available at http://www.uspto.gov/about/stratplan/ar/2010/USPTO_FY2010PAR.pdf. As a result, patent examiners “have from 8 to 25 hours to read and understand each application, search for prior art, evaluate patentability, communicate with the applicant, work

⁸ Because an infringement action does not constitute direct review of an agency decision, the judicial review framework of the Administrative Procedure Act, 5 U.S.C. § 706, does not apply.

out necessary revisions, and reach and write up conclusions.” FTC Report, Executive Summary, at 10.

That tight schedule makes it especially difficult for examiners to ferret out pertinent prior art—already a daunting task even under the best of circumstances. Some types of prior-art references are relatively easy to find—previously issued patents, for example. But, as the present case well illustrates, much of the prior art takes the form of undocumented uses or sales likely to be overlooked by examiners. See Merges, 14 BERKELEY TECH. L.J. at 589-90. Even documented prior art can be difficult to find, as PTO databases often do not include relevant trade publications, industry-specific journals, or technical manuals. In *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975, 977-78 (Fed. Cir. 2010), for example, a promotional catalogue for a computerized system to track car repair parts constituted the anticipating prior art. How would a PTO examiner locate such material in the limited time allotted? That is particularly true with respect to new and complex fields such as the computer and software industries, where little of the prior art resides in published patents and other readily accessible sources. See Julie E. Cohen, *Reverse Engineering and the Rise of Electronic Vigilantism: Intellectual Property Implications of “Lock-Out” Programs*, 68 S. CAL. L. REV. 1091, 1177-78 (1995).

Business competitors, of course, are better informed of undocumented prior art—and more highly motivated to search for it. But “the Patent Office is often obliged to reach its decision in an ex parte proceeding, without the aid of the arguments

which could be advanced by parties interested in proving patent invalidity.” *Lear*, 395 U.S. at 670; *In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996) (recognizing that, “[i]n the ex parte process of examining a patent application, . . . the PTO lacks the means or resources to gather evidence” going toward the obviousness inquiry). Confidentiality requirements, moreover, prevent examiners from consulting outside experts better able to access and understand the prior art in complex and fast-evolving fields. See Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 MINN. J.L. SCI. & TECH. 1, 19 (2007). It is therefore no surprise that examiners often overlook key prior-art references raised for the first time in litigation.

As a result of the significant limitations inherent in the patent examination process, patent applications can be (and often are) approved without examiners bringing their full expertise to bear. See Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law’s Presumption of Validity*, 60 STAN. L. REV. 45, 47 (2007). Consequently, the first rationale for deference—that PTO examiners are technical experts—is substantially weakened by the practical constraints on examiners’ ability to do their jobs.

The second justification for deference to PTO validity determinations—that patent approvals are a type of administrative decision warranting deference—is also unavailing. The patent examination process differs markedly from traditional agency decisionmaking accorded deference by courts. Most significantly, Section 102 of the Patent Act provides that “[a] person shall be entitled to a patent *unless*” certain invalidating conditions are present. 35 U.S.C.

§ 102 (emphasis added). The Federal Circuit and its predecessor have interpreted that provision to place the burden on the *examiner* to show *invalidity*; if the examiner fails to do so by a preponderance of the evidence, the patent must issue. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992); *In re Warner*, 379 F.2d 1011, 1016 (C.C.P.A. 1967); see 37 C.F.R. § 1.56(b); Manual of Patent Examining Procedure § 716.01(d).⁹ In other words, the moment that a patent application is filed, there is *presumed to be an invention*. “He who seeks to build a better mousetrap today” may in fact have “a long path to tread before reaching the Patent Office”; once he gets there, however, the path is decidedly downhill every step of the way. *Graham*, 383 U.S. at 19.¹⁰

That baseline presumption—that every applicant in a bona fide inventor—is all the more remarkable

⁹ Patent examiners have the burden of demonstrating unpatentability even when the corresponding statutory requirement lacks the “entitled . . . unless” language. Examiners, for example, have the burden of making out a prima facie case of obviousness under 35 U.S.C. § 103. See Manual of Patent Examining Procedure § 2142.

¹⁰ Commentators have suggested that the patent review process favors patent grants over denials in other ways. See, e.g., Merges, 14 BERKELEY TECH. L.J. at 609 (arguing that the Patent Office’s bonus system incentivizes examiners to award patents); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 324-25 (2001) (observing that it is easier for an examiner to dispose of an application by awarding rather than denying a patent). It bears mentioning, moreover, that issuing patents generates the fees that fund PTO’s operations—while a rejected patent application yields no revenue, a successful patent application results in an issuance fee and maintenance fees at the 3-, 7-, and 11-year marks. See 35 U.S.C. § 41(b).

given this Court's recognition that patents confer the extraordinary "*privilege* of an exclusive right" and therefore should not be handed out lightly. *Pennock*, 27 U.S. (2 Pet.) at 19 (emphasis added); see *Bonito Boats*, 489 U.S. at 151 ("[F]ree exploitation of ideas will be the rule, to which the protection of a federal patent is the exception."). When an applicant seeks a license, benefit, or other government privilege, the burden typically rests with the applicant to justify his request. That general principle is codified in Section 7(c) of the Administrative Procedure Act, which states, "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d); see *Director, OWCP v. Greenwich Collieries*, 512 U.S. 267 (1994) (rejecting Department of Labor rule shifting the burden of persuasion to the party opposing a benefits claim).

The patent process turns that rule on its head, placing the burden on the government to show why the patent monopoly should *not* be granted. Patent examination therefore represents a dramatic departure from traditional agency decisionmaking in that the scales are tilted heavily in favor of the applicant, as a matter of both law and practice. Patent approvals, after all, may result simply from the failure of an examiner—acting with limited information—to meet his burden of identifying and applying anticipatory prior art. See Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269, 318-19 (2007) (arguing that patent approvals are necessarily the result of less thorough agency review than patent denials). Unless the doctrine of *Chevron U.S.A. Inc.*

v. *NRDC*, 467 U.S. 837 (1984), applies, the extent to which a court defers to an agency determination “depend[s] upon the thoroughness” of the agency’s “consideration.” *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). The systematic deficiencies in the examination process and the uniform presumption in favor of patentability therefore suggest that little if any deference is due to validity determinations made by the Patent Office—certainly no deference that goes beyond the basic presumption of validity required by the first sentence of 35 U.S.C. § 282.

That conclusion is inescapable when—as in the present case—the agency has not even passed on the prior art at issue. It is a bedrock principle of administrative law that an agency decision receives no deference if the agency “failed to consider an important aspect of the problem.” *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); see *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (agency decision is arbitrary and capricious unless “based on a consideration of the relevant factors”). The PTO has failed to “consider an important aspect of the problem” when it has not even looked at the very prior art that would render the patent invalid. In other words, when the PTO has not considered a patent’s validity in light of the prior art, there is simply *no agency decision to defer to*. That is the important insight reflected in this Court’s statement in *KSR* that “the rationale underlying the presumption [of validity]—that the PTO, in its expertise, has approved the claim—seems much diminished” when the agency has not vetted the prior art in dispute. *KSR*, 550 U.S. at 426.

The Federal Circuit has acknowledged that commonsense principle but has failed to recognize its proper consequences. In *American Hoist*, the leading Federal Circuit decision articulating the policy rationale for the presumption of validity, the court conceded that “[d]eference is due the Patent and Trademark Office decision to issue the patent with respect to evidence bearing on validity which it considered *but no such deference is due with respect to evidence it did not consider.*” *Am. Hoist*, 725 F.2d at 1360; see also *id.* at 1359 (there is “*no reason to defer to the PTO*” when a challenger presents prior art not considered by the agency). The court nevertheless insisted that the standard of proof remains unaltered when a challenger relies on prior art not considered by the Patent Office. *Id.* at 1360. But it is fundamentally incoherent to assert simultaneously that administrative deference justifies the presumption of validity, and that the heightened standard of proof remains intact even when such deference is concededly no longer warranted.

Indeed, the Federal Circuit’s clear-and-convincing-evidence rule conflicts with its approach to review of PTO determinations in other contexts. In *Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010), for example, the *en banc* court held that applicants who directly challenge PTO decisions in district court pursuant to 35 U.S.C. § 145 can introduce new evidence of patentability, even if the challenger reasonably could have provided that evidence to the agency. When such evidence is presented for the first time in the district court, however, the factfinder reviews that evidence without any “deference to agency findings.” *Id.* at 1337. Rather, the district court “must make de novo fact findings with respect to factual issues to

which the new evidence relates.” *Id.* at 1336. There is no reason to depart from that principle in the context of an infringement action.

Respondents have asserted (i4i BIO at 21) that it would be “impossible” to ascertain “whether the PTO considered a particular piece of prior art.” Not so. Courts could safely assume that the only prior art considered by the PTO is that cited by the examiner. See Manual of Patent Examining Procedure § 1302.12 (requiring examiner to list prior art cited by examiner during prosecution). Although respondents have suggested that the examiner could conceivably have relied on prior art not cited in the prosecution history, courts generally do not give agencies that benefit of the doubt. See *State Farm*, 463 U.S. at 43 (1983) (the “agency must examine the relevant data and *articulate* a satisfactory explanation for its action including a rational *connection* between the facts found and the choice made”) (internal quotation marks omitted) (emphasis added).

In any event, as shown above, the clear-and-convincing-evidence standard is unwarranted even when the agency had, in fact, considered the prior art in question. Thus, if this Court were to determine that it would be difficult for courts to identify prior art relied on by the examiner, the solution is nonetheless to hold that the preponderance-of-the-evidence standard applies to invalidity challenges across the board. Although this Court need not do so to resolve the present case, that uniform approach would be most consistent with the plain text of Section 282 and with the purposes of patent law generally.

* * * *

In sum, the judge-made rule that the presumption of validity must be rebutted by clear and convincing evidence runs counter to four centuries of history and practice. It also finds no support in either the text or legislative history of Section 282. That should be the end of the matter. But even if principles of agency “deference” could somehow justify a departure from the plain text of Section 282 in some circumstances, it certainly cannot do so when the question of validity turns on prior art that the Patent Office has never seen. Consistent with its observation in *KSR*, this Court should therefore clarify that the presumption of validity may be rebutted by a preponderance of the evidence when the Patent Office did not consider the prior art in question.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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