

No. 10-290

In The
Supreme Court of the United States

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MICROSOFT CORPORATION, PETITIONER,

v.

14I LIMITED PARTNERSHIP, ET AL., RESPONDENTS

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

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**BRIEF OF SYNERX PHARMA, LLC AS AMICUS
CURIAE SUPPORTING PETITIONER**

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QUESTION PRESENTED

Whether the court of appeals erred in holding that Microsoft's invalidity defense must be proved by clear and convincing evidence.

RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, Synerx Pharma, LLC states that it is a Pennsylvania limited liability company whose principal offices are located in Newtown, Pennsylvania. Synerx Pharma, LLC is a private company, and no other privately or publicly held company owns 10% or more of the stock of Synerx Pharma, LLC. Synerx Pharma, LLC has no parent company.

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INTEREST OF AMICUS CURIAE

Synerx Pharma, LLC develops and commercializes select pharmaceutical products aimed at addressing unmet market needs, particularly those involving some combination of barriers to market entry.¹ Synerx Pharma, LLC focuses on developing cost effective specialty generic pharmaceutical and small brand products. Like many other generic pharmaceutical manufacturers, Synerx Pharma, LLC has filed Abbreviated New Drug Applications (ANDAs) under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984,² commonly known as the Hatch-Waxman Act.

Synerx Pharma, LLC is currently involved in patent litigation based on one of its ANDAs. In that litigation, Synerx Pharma, LLC has asserted

¹ No counsel for a party authored this brief in whole or in part, nor did such counsel or a party make any monetary contributions intended to fund the preparation or submission of this brief.

The docket reflects that in December 2010, counsel for each of the parties generally consented to the filing of amicus curiae briefs in support of either party or neither party.

² Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (collectively, the “Hatch-Waxman Act”).

invalidity of a pharmaceutical patent based on prior art. In addition, a number of products presently under development by Synerx Pharma, LLC are likely to involve a patent certification, commonly known as a “Paragraph IV Certification,” pursuant to 21 U.S.C. § 355(j)(2)(A)(iv). A Paragraph IV Certification asserts that a patent listed in the FDA’s “Orange Book” by a branded pharmaceutical manufacturer is invalid or will not be infringed by the manufacture, use, or sale of a particular drug in the United States. Within forty-five days after receiving a Paragraph IV Certification, the patent holder typically initiates a patent infringement lawsuit against the generic pharmaceutical manufacturer. As a result of these statutorily mandated procedures, Synerx Pharma, LLC expects to be involved in additional patent infringement litigation in the future.

While it is undoubted that many pharmaceutical patents disclose valuable innovations worthy of patent protection, large pharmaceutical patent holders often have sought and obtained patents of questionable validity on incremental “improvements” to an original drug product, in an effort to “evergreen” a single patented product, or “manage” its “life cycle.”

For all generic pharmaceutical manufacturers, the business decision to pursue a particular generic drug product is based in part on a rational assessment of the potential legal costs and the probability of success in any patent litigation. The Federal Circuit’s imposition of the clear and convincing evidence standard makes some patents

essentially unchallengeable in practice. Even patents of questionable validity, such as those often obtained in the process of “evergreening” or “life cycle management,” may be effectively unchallengeable, even if it is more likely than not that they are invalid in light of prior art, or more likely invalid for another reason. This is so simply because the cost of proving invalidity may be too high in relation to the possible profits from sales of the generic drug product, especially if the heightened Federal Circuit standard, rather than the preponderance standard, must be applied.

If a preponderance of the evidence is sufficient to bear the burden imposed upon a patent challenger to demonstrate that a patent is invalid, it is likely that generic pharmaceutical manufacturers would choose to challenge a larger number of questionable “Orange Book” listed patents and seek FDA approval for a larger number of generic drug products. Moreover, a preponderance of the evidence standard would likely lead generic pharmaceutical manufacturers to reach different judgments about the timing and terms of patent settlements, based upon altered appraisals of both litigation costs and the likelihood of success on the merits.

Synerx Pharma, LLC has a strong interest in the outcome of this case and in ensuring that judicial interpretation of the Patent Act does not unreasonably distort the limited monopoly granted by Congress to pharmaceutical patent owners.

SUMMARY OF ARGUMENT

The Federal Circuit has erroneously determined that the clear and convincing evidence standard should be applied in all cases in which patent validity is challenged. Congressional silence, when it enacted 35 U.S.C. § 282 to include the statement that “[a] patent shall be presumed valid,” is inconsistent with the view that a heightened standard of proof was intended.

Requiring proof of invalidity by clear and convincing evidence conflicts with this Court’s admonition that it is “as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.” *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1982). The preponderance standard most closely aligns with this evenhanded treatment of the competing societal interests.

ARGUMENT**The Burden of Persuasion Placed Upon a Party Who Asserts the Invalidity of a Claimed Invention, Based Upon Prior Art, Should be Satisfied by a Preponderance of Evidence.****A. The Patent Clause Strikes An Even Balance.**

A patent creates a publicly sanctioned monopoly—a right to exclude others from making, using or selling a claimed invention. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 149, 150 (1989); 35 U.S.C. § 154 (2006). The Patent Clause grants Congress only limited power to create patent monopolies. U.S. Const. art. I, § 8, cl. 8; see *Bonito Boats*, 489 U.S. at 146 (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” (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 5 (1966))).

Implicit in the Patent Clause is the principle that “free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception.” *Bonito Boats*, 489 U.S. at 151. At least as early as *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850), the Court has said that a putative invention that would have been obvious from existent knowledge is free for all to use. *Graham*, 383 U.S. at 11 (“*Hotchkiss*, by positing the condition that a patentable invention evidence more ingenuity and skill than that possessed by an ordinary

mechanic acquainted with the business, merely distinguished between new and useful innovations that were capable of sustaining a patent and those that were not.”). The Court has said that taken together, “the novelty and nonobviousness requirements express a congressional determination that the purposes behind the Patent Clause are best served by free competition and exploitation of that which is either already available to the public, or that which may be readily discerned from publicly available material.” *Bonito Boats*, 489 U.S. at 150.

The underlying policy of the patent system, this Court has stated, is that ‘the things which are worth to the public the embarrassment of an exclusive patent,’ as Jefferson put it, *must* outweigh the restrictive effect of the limited patent monopoly.” *Graham*, 383 U.S. at 10–11 (emphasis added).³ That policy gives no greater weight to the interests of those who claim to be inventors than to the interests of the public. It is “as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly” *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) (quoted with approval in *Lear, Inc. v. Adkins*, 395 U.S. 653, 664 (1969) (referring to “Pope’s powerful argument.”)).

The fulcrum for the balance of private and

³ See also *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007) (noting that granting patent protection to advances that would occur in the ordinary course without real innovation retards progress).

public interests is thus placed in the middle, not shifted off-center to give greater leverage to the claim of the inventor. Such a different balance would relegate to inferior status the constitutional policy that the public interest is “best served by free competition and exploitation of that which is ... already available to the public.” That different balance would likewise give undue weight to the claimed innovation of the ordinary mechanic, suppressing competition in spite of his insubstantial contribution.

B. The Preponderance Standard Allocates The Risk of Error In Line With The Competing Societal Interests.

The preponderance standard is appropriate in light of the dual purposes embodied in the Patent Clause. The parties in patent infringement litigation, in effect, represent competing societal interests: on the one hand, to encourage innovation by awarding a limited monopoly, and on the other hand, to ensure that competition is not repressed by unmerited patents. To serve both of these purposes, it is reasonable to allocate the risk of error roughly equally between litigants and to require no more than a preponderance of the evidence to prove a patent invalid.

While a patent is the result of an agency action, patent infringement litigation is not simply a lawsuit seeking judicial review of agency action, in which deference is accorded to lawful administrative determinations that are supported by substantial evidence. In patent infringement litigation, the

issue is whether an accused product infringes a valid patent, not whether the agency was correct in issuing the patent in the first place.

An accused infringer is able to present evidence that was never considered by the patent examiner and to argue that prior art that was considered by the examiner should be viewed differently. Patent infringement litigation can thus illuminate with more intense light the fundamentally judicial inquiry of whether a patent is valid. The importance of such new or different evidence was highlighted in an analogous context in *Dickinson v. Zurko*, 527 U.S. 150 (1999), where the Court considered whether a “court/agency” or “court/court” standard of review is appropriate when a PTO decision is being reviewed. The Court’s opinion strongly suggested that it is not a review of agency action when the Court goes beyond the administrative record. *See id.* at 164 (“The presence of such new or different evidence makes a factfinder of the district judge. And nonexpert judicial factfinding calls for the court/court standard of review.”)⁴

The clear and convincing evidence standard used by the Federal Circuit in patent cases shifts the fulcrum for judicial weighing of evidence away from

⁴ *See also Hyatt v. Kappos*, 625 F.3d 1320, 1339 (Fed. Cir. 2010) (*en banc*) (district court entertaining civil action brought by unsatisfied patent applicant to review PTO denial of his application is free to consider evidence outside administrative record and is then required to review new evidence *de novo*).

true center. Importantly, the use of the clear and convincing evidence standard does not increase the likelihood that the court will weigh accurately; it only redistributes unevenly the risk of judicial mistake. *Cooper v. Oklahoma*, 517 U.S. 348, 366 (1996) (“A heightened standard [of proof] does not decrease the risk of error, but simply reallocates that risk between the parties.”)

As in this case, *Cooper* involved a rule that required a defendant to overcome a presumption by clear and convincing evidence. This Court earlier ruled, in *Medina v. California*, 505 U.S. 437 (1992), that a state may presume that a defendant is competent to stand trial and require the defendant to prove his incompetence by a preponderance of evidence. At issue in *Cooper* was an Oklahoma procedural rule that went further and required a defendant to overcome this presumption by clear and convincing evidence. *Cooper* held the Oklahoma rule unconstitutional because it invaded “the fundamental right to stand trial while competent.” *See id.* at 369

Cooper pointed out the central importance of determining who will bear the disproportionate risk of judicial error. *See id.* at 366 (“In cases in which competence is at issue, we perceive no sound basis for allocating to the criminal defendant the large share of the risk which accompanies a clear and convincing evidence standard.”). In *Cooper*, Oklahoma’s putative justification for the rule (“the state’s interest in the efficient operation of its criminal justice system,” *id.* at 367) did not justify

the infringement upon the defendant's fundamental right.

Use of the clear and convincing evidence standard is appropriate “when the individual interests at stake in a state proceeding are both ‘particularly important’ and ‘more substantial than mere loss of money.’” *Santofsky v. Kramer*, 455 U.S. 745, 756 (1982) (citing *Addington v. Texas*, 441 U.S. 418, 423 (1979)). Unlike the important right implicated in *Santofsky*,⁵ however, the issuance of a patent grants an interest akin to Oklahoma's interest, because it is largely a matter of money. An inventor's interest in a patent is, at bottom, an economic interest—worthy of protection, as the Patent Clause makes clear, but only if an inventor has actually contributed to the “the progress of science and useful arts.” See U.S. Const. art. I, § 8, cl. 8.

⁵ In *Santofsky v. Kramer*, the Court dealt with the “fundamental liberty interest of natural parents in the care, custody, and management of their child.” *Santofsky*, 455 U.S. at 756. The Court held unconstitutional a New York statute that provided that the “State may terminate, over parental objection, the rights of parents in their natural child upon a finding that the child is ‘permanently neglected,’ when only a “fair preponderance of the evidence” supports that finding. The Court also held that the clear and convincing evidence standard “adequately conveys to the fact finder the level of subjective certainty about his factual conclusions necessary to satisfy due process.” *Id.* The Court left to the legislature the choice whether to adopt that standard or the still more stringent “beyond a reasonable doubt” standard.

Use of the clear and convincing evidence standard in patent cases implies a judgment that this economic interest justifies shifting onto the patent defendant the disproportionate risk of error. Here, as in *Cooper*, there is no sound basis for doing so because the public interest in free competition is as fundamental as the patentee's economic interest.

The *Cooper* court concluded its reasoning: "Because Oklahoma's procedural rule allows the state to put to trial a defendant who is more likely than not incompetent, the rule is incompatible with the dictates of due process." *Id.* at 369. While the issue in this appeal does not implicate due process, the gap between a "preponderance" of evidence standard and a "clear and convincing" evidence standard makes it more likely than not that a constitutionally protected interest is being eroded in this case, as well – the public's freedom from monopolies unsupported by the scientific advance required by the Patent Clause.

The clear and convincing standard changes the result only where the patent challenger has demonstrated that a patent is more likely than not invalid, but has not reached that heightened threshold of proof. In this class of cases, the patent is probably invalid but competition is still suppressed. Stated another way, the clear and convincing evidence standard makes it more likely than not in those cases – *the only cases where the standard makes a difference* – that *Pope's* "worthless patents" are being allowed to suppress competition.

Such solicitude for the interests of patent holders is inconsistent with “*Pope’s* powerful argument” that the public’s interest in being free of restriction by an invalid patent is just as important as an inventor’s interest in upholding his individual monopoly. The choice of a “clear and convincing” evidentiary standard where patent validity is challenged thus effects a value choice that is not consistent with the Patent Clause, because that heightened standard gives greater weight to a patentee’s interest in a patent than to the public’s interest in ensuring that existent knowledge is free for all to use.

“Because the preponderance-of-the-evidence standard results in a roughly equal allocation of the risk of error between litigants, we presume that this standard is applicable in civil actions between private litigants unless ‘particularly important individual interests or rights are at stake.’” *Grogan v. Garner*, 498 U.S. 279, 286 (quoting *Herman & MacLean v. Huddleston*, 459 U.S. 375, 389–390 (1983)). That presumption should apply here.

C. The Language and Legislative History of 35 U.S.C. § 282 Do Not Require Application of the Clear and Convincing Standard.

Section 282 states that a “patent shall be presumed valid.” The language of the statute does not prescribe any standard of proof to overcome the presumption, let alone a requirement of proof by

clear and convincing evidence.⁶ The legislative history of § 282 likewise reveals no intent to impose a heightened standard of proof. The Senate report issued prior to enactment of the 1952 Patent Act simply states:

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. The defenses to a suit for infringement are stated in general terms, changing the language in the present statute, but not materially changing the substance.

S. Rep. No. 1979 (1952).⁷

Contemporary commentators said little more. See P.J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1, 54-55 (1954).⁸ In short, the language and legislative history of 35 U.S.C. § 282 suggest that Congress intended its enactment of

⁶ Compare 35 U.S.C. § 273(b)(4) (2006) (imposing a burden on a person defending a patent infringement claim for a method of doing business to establish that defense by “clear and convincing evidence”).

⁷ See also H.R. Rep. No. 1923, at 10 (1952).

⁸ See *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1358–59 (Fed. Cir. 1984); see also L.J. Harris, *Some Aspects of the Underlying Legislative Intent of the Patent Act of 1952*, 23 Geo. Wash. L. Rev. 658, 680–83 (1954); Editorial Note, *The New Patent Act and the Presumption of Validity*, 21 Geo. Wash. L. Rev. 575 (1953).

§ 282 to be no more than a codification of “a statement made by courts in decisions” that issued patents are entitled to a presumption of validity.⁹

Prior to enactment of the 1952 Patent Act, the House Judiciary Committee circulated a preliminary draft of proposed amendments of the patent laws. See Staff of H.R. Comm. on the Judiciary, 81st Cong., *Proposed Revision and Amendment of the Patent Laws: Preliminary Draft with Notes* (Comm. Print. 1950), available at http://www.ipmall.info/hosted_resources/lipa/patents/patentact/file9.pdf. The preliminary draft contained a proposal for what became 35 U.S.C. § 282, which provided, in relevant part:

A patent shall be presumed to be valid unless and until it has been held invalid by the final judgment of a court of competent jurisdiction from which no appeal is or can be taken and the *burden of establishing invalidity by convincing proof* shall rest on any person asserting invalidity of the patent.

Id. at 68 (proposal for 35 U.S.C. § 79) (emphasis added). In the final language, the requirement that invalidity be shown by “convincing evidence” was

⁹ See S. Rep. No. 1979 (1952) (stating that “[t]he major changes or innovations in the title consist of incorporating a requirement for invention in § 103 and the judicial doctrine of contributory infringement in § 271”). Noteworthy is the absence of mention of § 282 as a “major change or innovation,” further supporting the conclusion that § 282 effected no change in the law.

removed. One inference that may be drawn from this change is that Congress intentionally refrained from prescribing a burden of proof, leaving it to the courts to determine.¹⁰

The Federal Circuit at one point recognized that the presumption in 35 U.S.C. § 282 is properly understood as a procedural device:

The presumption, like all legal presumptions, is a procedural device, not substantive law. It does require the decision maker to employ a decisional approach that starts with acceptance of the patent claims as valid and that looks to the challenger for proof of the contrary. Thus the party asserting invalidity not only has the procedural burden of proceeding first and establishing a prima facie case, but the burden of persuasion on the merits remains with that party until final decision. The party supporting validity has no initial burden to prove validity, having been given a procedural advantage requiring that he come forward only after a prima facie case of invalidity has been made. With all the evidence in, the trial court must determine whether the party on which the statute imposes the burden of persuasion has carried that burden.

¹⁰ See also Editorial Note, *supra*, 21 Geo. Wash. L. Rev. at 575, n.1.

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983).

In light of the Patent Clause, the presumption of validity set forth in § 282 should be understood as determining the placement of the burden of proof, and not the weight of that burden. “Analogous to the presumption of validity is a tennis match, wherein § 282 determines who will serve first, but does not regulate the height of the net.”¹¹ So understood, the presumption of validity would ensure that there is no burden on the patentee to establish validity, and that the party asserting invalidity “not only has the procedural burden of proceeding first and establishing a prima facie case, but [also] the burden of persuasion on the merits . . . until final decision.” *Stratoflex*, 713 F.2d at 1534. That burden of persuasion, however, should be met by a preponderance of the evidence.

¹¹ C.E. Phipps, *The Presumption of Administrative Correctness: The Proper Basis for the Clear and Convincing Evidence Standard*, 10 Fed. Bar. J. 143, 148 (2000).

CONCLUSION

The two equally important purposes embodied in the Patent Clause are advanced by placement of a burden on patent challengers to prove the invalidity of patent claims by prior art with a preponderance of the evidence. The silence of Congress when it enacted 35 U.S.C. § 282 is inconsistent with the view that Congress intended the constitutionally suspect requirement of a heightened standard of proof.

It is respectfully submitted that the Court should reverse the decision of the Federal Circuit in this case, and instruct the lower courts that in all future cases in which the validity of a patent is challenged on the ground that the claimed invention is anticipated or obvious from the prior art, the patent challenger must prove invalidity by a preponderance of the evidence.

Respectfully submitted,

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