

No. 10-290

In The
Supreme Court of the United States

MICROSOFT CORPORATION,

Petitioner,

v.

i4i LIMITED PARTNERSHIP AND
INFRASTRUCTURES FOR INFORMATION, INC.,

Respondents.

On Writ Of Certiorari To
The United States Court of Appeals
For The Federal Circuit

BRIEF OF GENENTECH, INC., CALIFORNIA
HEALTHCARE INSTITUTE, ROCHE DIAGNOSTICS
OPERATIONS, INC. AND ROCHE MOLECULAR
SYSTEMS, INC. AS *AMICI CURIAE*
IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*¹

Founded in 1976, *Amicus* Genentech, Inc. was the first biotechnology company, and today is the leading manufacturer of biotechnology-derived products (“biologics”). Genentech’s growth is mirrored by that of the biotechnology sector of the pharmaceutical industry. In 1989, biologics represented only 0.5% of the market share for drugs. Today, more than six hundred biotechnology medicines are in development. *See* PHRMA, REPORT 2008: BIOTECHNOLOGY MEDICINES IN DEVELOPMENT 1 (Sept. 2008), *available at* <http://www.phrma.org/sites/default/files/422/biotech2008.pdf>; Biotechnology Industry Organization, GUIDE TO BIOTECHNOLOGY 2008 2 (2008), *available at* <http://bio.org/speeches/pubs/er/BiotechGuide2008.pdf>. Genentech believes the patent system, including the appropriate enforcement of patent rights, is crucial to the continuing development of innovative, lifesaving and life-enhancing drugs.

In order to develop safe, innovative and effective products, Genentech must necessarily undertake significant commercial risks, involving substantial investments of time, resources, energy and scientific expertise. Genentech has invested literally tens of billion of dollars over the past 34 years in the research and development of biologics, and has discovered and introduced more than a dozen significant therapies for serious and life-threatening

¹The parties have filed letters with the Clerk providing their blanket consent to the filing of *amicus* briefs. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored any part of this brief, and no person or entity other than *amici* and its counsel made a monetary contribution to the preparation or submission of this brief.

diseases, including cancer, heart disease, stroke and pulmonary disease.

In 1985, for example, Genentech received approval to market the synthetic human growth hormone Protropin®, one of the first biologics manufactured and marketed in the United States. This was followed by the approval of Activase®, a human tissue plasminogen activator for use in dissolving blood clots in patients suffering from acute myocardial infarction. Since then, Genentech has developed and received approval for numerous breakthrough products, including Pulmozyme®, the first new therapy for management of cystic fibrosis in 30 years; Herceptin® for treatment of patients with specific types of breast cancer and certain metastatic gastric cancer; Xolair® for treatment of moderate to severe asthma; and Avastin® for use in treatment of multiple types of cancer including lung cancer, renal cell carcinoma, glioblastoma and metastatic colorectal cancer.

The level of investment necessary to make these breakthroughs possible would not have been available without the assurance afforded by strong, enforceable patents. Back in 1980, Genentech filed its first *amicus* brief in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), asking the Court to recognize the patent eligibility of certain types of inventions related to living organisms. As a consequence of the Court's decision in that case, and the resulting patent protection it afforded innovations in biologics, Genentech has progressed from startup to an industry leader. Importantly, during this time Genentech has frequently been on both sides of patent infringement litigation, and therefore is qualified to offer an informed perspective on the proper balance between the need to promote innovation through a

meaningful presumption of validity while simultaneously providing accused infringers the necessary procedural safeguards against improvidently granted patents. For the reasons set forth below, the existing “clear and convincing evidence” standard—as applied in this case by the Federal Circuit—is the appropriate test that best serves both of these objectives.

Amicus California Healthcare Institute (“CHI”) is a non-profit public policy research organization for California’s biomedical research and development industry. CHI represents more than 275 leading biotechnology, medical device, diagnostics, and pharmaceutical companies, and public and private academic biomedical research organizations. CHI’s mission is to advance responsible public policies that foster medical innovation and promote scientific discovery.

As a global leader in healthcare, *amicus* Roche Diagnostics offers a broad portfolio of tools that help healthcare providers in the early detection, prevention, diagnosis and treatment of diseases like congestive heart failure, HIV, hepatitis and diabetes, as well as other medical conditions, such as fertility and blood coagulation. These products and services are used by researchers, physicians, patients, hospitals and laboratories worldwide to help improve people’s lives. Specifically, Roche offers healthcare solutions in the fields of: diabetes care (handheld blood glucose monitors for physicians and patients); point-of-care testing (handheld and benchtop monitoring devices for hospitals, clinics and physician offices); centralized diagnostics (clinical chemistry and immunoassay analyzers for laboratories); molecular diagnostics (PCR systems for blood screening, infectious disease testing and genetic testing); and applied science

(genome sequencing, genetic variation and gene expression detection for research).

Roche Diagnostics' North American headquarters, located in Indianapolis, is home to U.S. research and development, laboratory, manufacturing, distribution, information technology and administrative operations. It supports five distinct business areas: Diabetes Care; Professional Diagnostics–Hospital; Professional Diagnostics–Physician Office Laboratory; Molecular Diagnostics; and Applied Science.

Amicus Roche Molecular Systems, Inc. (“RMS”), based in Pleasanton, California, develops, manufactures and supplies a wide array of innovative medical diagnostic products, services, tests, and platforms based on the company's Nobel prize winning polymerase chain reaction (“PCR”) and now industry-standard real-time PCR technologies. With its broad portfolio in the areas of oncology, virology, microbiology and blood screening, RMS's business serves researchers, physicians, patients, hospitals, laboratories and blood banks around the world.

INTRODUCTION AND SUMMARY OF ARGUMENT

To obtain a patent is to enter into a bargain with the public: in exchange for disclosing its invention and demonstrating to the Patent Office that the invention is a new, useful and non-obvious advancement over the prior art, the patent applicant receives the right to exclude others from practicing that invention in the United States for a limited time. For companies like Genentech, Roche Diagnostics and RMS, a critical feature of this bargain is that when the Patent Office issues a patent, the patentee receives an intangible property right on which it can

reasonably rely in deciding to dedicate millions of dollars to pursue a patentable technology and even greater amounts to develop a patented product.

In this way, the examination system is more than just an administrative step; it provides patentees with the necessary level of certainty to support their decisions on whether to invest in new ideas. In our patent system, that certainty is the presumption of validity as manifested in the “clear and convincing” evidence standard of proof.

Without a heightened standard of proof, the presumption of validity would be of little practical consequence and the issued patent scarcely more than an advisory opinion of a patentee’s rights on which reliance would be perilous. To the contrary, the uncertainty created by the lower standard would exacerbate the existing “cloud” on the patentee’s intangible property right that can never truly be cleared, even if the patent is eventually litigated and found valid.² As a result, any change to the existing standard of proof would only discourage investment in—and disclosure of—new technologies, thwarting the Constitution’s directive that the patent system “*promote* the Progress of Science and useful Arts.” U.S. CONST. art. I, §8, cl. 8 (emphasis added).

Moreover, a lower standard would encourage judicial challenges to already issued patents and simultaneously frustrate Congress’s efforts over the last thirty years to promote the administrative review of patents in the Patent and Trademark Office (“PTO” or “Patent Office”). Since establishing the reexamination system in 1980, Congress has

²As discussed below (*see* Part I(B), *infra*), unlike judgments of *invalidity*, a jury’s determination of patent *validity* is not binding in subsequent litigation.

repeatedly made it easier for third parties to bring “substantial new questions of patentability” to the attention of the PTO. As recently as 2002, Congress amended these reexamination statutes with the express goal of reducing invalidity litigation by creating attractive administrative alternatives within the Patent Office.

By arguing that the appropriate standard for challenges to patent validity should be a preponderance of the evidence, Petitioner ignores the central role the “clear and convincing” evidence standard plays in our patent system: both in encouraging investment and reinforcing the PTO’s role as the primary gatekeeper on patentability issues. At most, any implementation of a lower standard should be limited to those rare occasions where the PTO is unable—either through a reexamination or whatever other procedure Congress may provide—to address the specific patentability question raised in litigation.

ARGUMENT

I.

LOWERING THE EXISTING STANDARD OF PROOF WOULD DISCOURAGE FUTURE INVESTMENT IN INNOVATION.

As the Court has recognized, “the ultimate goal of the patent system is [to encourage innovators] to bring new designs and technologies into the public domain through disclosure” (*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989)), which can most effectively and efficiently occur where the rights granted by the patent are predictable and certain. *Markman v. Westview*

Instruments, 517 U.S. 370, 390 (1996) (“[t]he limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public”) (quoting *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938)). The current patent system achieves this certainty in many ways, not the least of which through the heightened standard of proof required to invalidate a patent in a subsequent infringement suit. See Br. of *Amicus Curiae*, American Intellectual Property Law Ass’n 14-20. Indeed, the heightened standard of proof constitutes a “necessary part of the bargain” between the patentee and the public, “providing an incentive to disclose inventions while reducing the risks of a patent challenge that invariably accompany public disclosure.” *Id.* at 20.

Like many other innovators, the life sciences *amici* rely on their patent portfolios as a major factor in making decisions on whether, and how much, to invest in a particular endeavor. Accordingly, their willingness and ability to invest depends heavily on the enforceability of the patents protecting the underlying technology. Yet no matter how thoroughly companies like Genentech, Roche Diagnostics and RMS conduct the examination process, any patents that result are ultimately susceptible to being found invalid by a lay jury, even with the heightened standard of proof in place.³ Lowering the preponderance standard would exacerbate many of the existing business risks patentees like Genentech, Roche

³Indeed, “patents are invalidated roughly *half the time* in litigation,” even with a clear and convincing standard of proof. Resp’t Br. 37 (emphasis in original).

Diagnostics and RMS already face and would undermine the system of incentives on which the entire United States patent system is based.

A. Obtaining A Patent Already Entails Significant Business Risks For Genentech.

The first such risk, of course, is the enormous cost of research and development. For pharmaceutical and biotechnology companies like Genentech, for example, “the process of discovery, development, and regulatory approval” for new, lifesaving drugs “is lengthy, risky, and very costly.” Benjamin Zycher *et al.*, *The Truth About Drug Innovation: Thirty-Five Summary Case Histories on Private Sector Contributions to Pharmaceutical Science*, 6 MED. PROGRESS REP. 1, 5 (2008); *see also* Christopher P. Adams & Van V. Brantner, *Spending On New Drug Development*, 19 J. HEALTH ECON. 130, 138 (2010) (estimating the average cost to develop a new drug to be \$1.2 billion). First, Genentech must invest considerable sums to develop an invention to the point of patentability and apply for a patent. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 J. MANAGERIAL & DECISION ECON. 469, 475 (2007) (estimating the average “preclinical” capitalized costs for a new biologic to be \$615 million). Then, in reliance on the validity of the patents that issue many years later, Genentech must make further investments to develop a product suitable for submission to the FDA for approval, and then incur even greater expense undergoing the regulatory approval process itself.⁴

⁴On top of these sunk costs, if Genentech wants to seek a patent in most other countries, it must permit the patent

(continued . . .)

See id. (estimating the average capitalized costs for a new biologic during the clinical period to be \$626 million).

Genentech, and companies like it, must take this leap of faith even though the enormous investment could be for naught if the patent that results is later invalidated in court. This risk is currently mitigated by the rule that a court will not invalidate any issued patent absent “clear and convincing evidence” of invalidity. Without this assurance, Genentech would be far more cautious in disclosing its inventions to the public and making the investments that have led to many useful scientific advancements.

Genentech’s Herceptin® product for treating certain types of cancer provides an apt illustration of a lifesaving drug that might never have been developed without definite, enforceable patents supporting the investment necessary to bring it to market. Herceptin has been in continual development for almost two decades, and many years after the original launch of the product, Genentech has been able to continue to invest money in seeking approval for additional treatments for cancer patients. Among the many patents supporting the numerous facets of innovation behind Herceptin are U.S. Patent Nos. 5,677,171 (filed Aug. 5, 1994), 6,339,142 (filed Jan. 15, 2000) and 6,407,213 (filed June 18, 2002).

Genentech’s research and development path for Herceptin began in 1981—some seventeen years before obtaining regulatory approval—when Genentech scientists John McGrath and Arthur

(. . . continued)

application containing its trade secrets to be published within 18 months of filing, regardless of whether the application is granted. *See* 35 U.S.C. §122(b).

Levinson cloned and sequenced a portion of the human HER2 gene, the product's ultimate target. *See* Genentech, Herceptin Development Timeline, www.gene.com/gene/products/information/oncology/herceptin/timeline.html (last visited March 16, 2011). At the time, Genentech and other research labs across the US were engaged in extensive exploration for cancer-causing genes. Yet it took another four years after the initial discovery of the HER2 sequence before the full-length gene was cloned and still another five years before Genentech had fully engineered the compound which later became the Herceptin product. *Id.* This year, over 200,000 women will be diagnosed with breast cancer in the United States, of whom approximately 25 percent will be HER2-positive. Herceptin is the only targeted biologic therapy approved for use in women with both the early and advanced stages of HER2-positive breast cancer. The seventeen-year saga that resulted in this revolutionary treatment for breast cancer reflects hard work and dedication in the face of challenging odds.

The concomitant “patent” story for Herceptin has not been an easy one for Genentech. Genentech has faced at least four patent lawsuits seeking royalties on Herceptin based on patents held by third parties (including two currently pending cases, over a decade after the product's original launch). Yet because it could rely on its own intellectual property with some level of comfort against the possibility of copycats or imitators, Genentech was able to spend hundreds of millions of dollars during the critical years of development—when it could not collect a penny in revenues—in order to make Herceptin a reality for patients.

The experience of Genentech is representative of the challenges faced by the life sciences *amici*, requiring millions of dollars in development prior to commercializing a product without any guarantee the product will ultimately reach the market. As the Court has noted, “the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.” *Pfaff v. Wells Elecs.*, 525 U.S. 55, 63 (1998). In order for Genentech (and similar companies) to obtain the necessary benefit of this bargain that would justify the costs incurred in bringing a product like Herceptin to market, the presumption of validity that attaches to an issued patent must amount to more than the meager “burden-shifting” device that Petitioner urges. *See* Pet’r Br. 21.

B. The Collateral Estoppel Rules Subject Genentech To Perpetual, Conclusive Validity Challenges.

Exacerbating the investment risk, Genentech also knows that under present law any accused infringer may challenge a patent’s validity regardless of how many times it was previously held valid in court. On the other hand, under *Blonder-Tongue Laboratories v. University of Illinois Foundation*, 402 U.S. 313, 350 (1971), once one accused infringer is successful in its invalidity challenge, the resulting judgment will have collateral estoppel effect in *all* subsequent suits involving the same patent claims, effectively rendering them worthless. As a result, invalidity litigation creates far higher stakes for the patentee than the challenger: while a finding that the patent is valid

only forces the accused infringer to rely on other defenses, a finding that certain patent claims are invalid permanently precludes the patentee from ever being able to enforce those claims again.

Given the imbalance of consequences created by the *Blonder-Tongue* rule, it is appropriate that the presumption of validity place the risk of error⁵ on the party seeking to invalidate the patentee's valuable property right⁶ that is the issued patent. Indeed, the Court in *Blonder-Tongue* explicitly recognized that, due to the presumption of validity, "patentees are heavily favored as a class of litigants." 402 U.S. at 335. Consequently, the Court held that it would not be unfair to bind patentees to adverse judgments regarding the validity of their patents. *Id.* ("If a patentee's expense [in defending his patent] is high though he enjoys the benefits of the presumption of validity, the defendant in an infringement suit will have even higher costs as he [must also] introduce[] proof to overcome the presumption"). Petitioner's contention that the presumption affects only the burden of production (*see* p.14, *infra*) is at odds with the Court's reasoning in *Blonder-Tongue*.

C. Final Validity Judgments Rest In The Hands Of Lay Juries With No Specialized Knowledge Of The Subject Matter.

Another source of uncertainty faced by companies like Genentech is the frequent placement of the

⁵The purpose of a standard of proof is to balance the importance of the interests at stake in any given determination with the appropriate allocation of the risk of error. *See Addington v. Texas*, 441 U.S. 418, 423 (1979).

⁶*See* 35 U.S.C. §261 ("Subject to the provisions of this title, patents shall have the attributes of personal property").

ultimate invalidity decision in the hands of lay jurors, not experts. As the Court has noted in the past, “the primary responsibility for sifting out unpatentable material lies in the Patent Office [as] to await patent litigation is—for all practical purposes—to debilitate the patent system.” *Graham v. John Deere Co.*, 383 U.S. 1, 18 (1966). Unlike patent examiners, jurors have no specialized knowledge in the subject matter covered by the patent, nor the wealth of experience and training in deciding validity issues. *See Dickinson v. Zurko*, 527 U.S. 150, 160 (1999) (recognizing “that the PTO is an expert body . . . that . . . can better deal with . . . technically complex subject matter”).

More importantly, reasonable juries are more inclined to disagree as to whether a patent is “more likely” invalid than they would be in finding a patent “clearly” invalid. As a result, lowering the standard would lead to more disparate jury verdicts and embolden subsequent infringers to try their hand at invalidating patents already upheld in court. Applying a lower standard of proof to invalidity decisions would not only exacerbate the existing uncertainty faced by patentees, but it would also disserve the important goal of uniformity in patent law by allowing juries even greater freedom to reach different conclusions about the validity of the same patent. *Cf. Markman*, 517 U.S. at 391 (the important goal of uniformity “would . . . be ill served by submitting issues of [claim] construction to juries”).

D. Any Change To The Existing Clear And Convincing Standard Will Fundamentally Upset The Current Patent System.

In light of the foregoing factors, any change to a preponderance of the evidence standard of proof would radically alter the risk calculations that innovators have relied on for decades in deciding whether to pursue a particular technology or allocate limited resources towards crafting solutions to a particular problem. These “settled expectation[s] . . . should not be disturbed by the courts.” Resp’t Br. 55.

Nor should the Court accept Petitioner’s invitation to render Section⁷ 282 meaningless. If Petitioner were correct,⁸ and the presumption of validity operates solely as “a procedural device for shifting the burden of production” (Pet’r Br. 21), then the provision would be of little practical consequence and would achieve nothing other than to “permit the [patentee] relying upon it to survive a motion for directed verdict.” 2 KENNETH S. BROUN, MCCORMICK ON EVIDENCE §344, at 508 (6th ed. 2006). In light of the myriad of prior art available to accused infringers motivated to avoid liability, the presumption would impose no meaningful burden at all. See *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983) (“there is virtually always ‘pertinent’

⁷Unless otherwise indicated, all references to Section, or Sections, refer to Title 35 of the United States Code.

⁸While one of several competing theories about the legal effect of presumptions, Petitioner’s asserted “Thayerian concept of a disappearing presumption has yet to win the day” in courts. 2 KENNETH S. BROUN, MCCORMICK ON EVIDENCE §344, at 520 (6th ed. 2006).

and ‘relevant’ art apparently unconsidered in the PTO and available to a patent challenger”).

Congress understood this when it enacted Section 282 to codify the existing heightened burden established by the Court’s precedents prior to 1952. *See* Resp’t Br. 14. Moreover, the Court has continued to articulate the presumption of validity as creating a substantive burden for challengers to overcome. *See, e.g., Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 94 n.15 (1993) (“Although [the] presumption [of validity] is obviously resurrected after the Federal Circuit vacates a finding of invalidity . . . the revived presumption *lacks some of its earlier strength*”) (emphasis added).

The more reasonable interpretation—the one that furthers the patent system’s goal of encouraging investment in innovation—is that the presumption of validity provides a meaningful incentive for patentees to innovate by creating a significant burden for challengers to overcome in court. Were it otherwise, patentees would have less incentive to make productive use of their inventions—or improve upon them—until the validity of the patents underlying them could be tested in court.

II.

THE COURT SHOULD INTERPRET THE PRESUMPTION OF VALIDITY IN A MANNER CONSISTENT WITH THE REEXAMINATION STATUTES.

Petitioner argues that “[s]tatutory ‘silence’ on the requisite standard [of proof] is an impermissible basis for a court to conclude that ‘Congress intended

to require a special, heightened standard of proof.” Pet’r Br. 14 (citation omitted). Yet, over the past thirty years, Congress has been anything *but* silent with regard to the “problems” posed by invalid patents, and the appropriate mechanism for dealing with those problems. To the contrary, during this time Congress has created, and repeatedly promoted, a robust system of patent reexamination to encourage the resolution of validity disputes at the PTO, thereby weeding out invalid patents without undercutting investor confidence in the certainty and predictability of issued patents.

However, as detailed below, this system can only function as intended when a patent is more difficult to invalidate in court. Accordingly, interpreting Section 282 to apply a lower standard of proof for challenges to patent validity would be inconsistent with the purpose and structure of administrative reexamination that Congress has put into place. *See Kawasaki Kisen Kaisha Ltd. v. Regal-Beloit Corp.*, —U.S.—, 130 S. Ct. 2433, 2447 (2010) (“Where the text permits, congressional enactments should be construed to be consistent with one another”); *see also Bilski v. Kappos*, —U.S.—, 130 S. Ct. 3218, 3228–29 (2010) (patent statutes should not be interpreted to render other provisions meaningless, “even when Congress enacted the provisions at different times”).

To the extent any change in the existing standard of proof is warranted where a challenger substantially relies on evidence not previously considered by the Patent Office, the rule adopted by the Court should be consistent with Congress’s legislatively expressed preference for reexamination. At most, the Court should limit the application of the lower standard to situations where the prior art is not a patent or printed publication that could have been

brought to the attention of the Patent Office in a reexamination proceeding. Any broader reduction in the standard of proof would inherently frustrate Congress's stated purpose in the reexamination statutes to create incentives for raising validity issues in the PTO first, thereby *boosting* investor confidence and *reducing* litigation.

A. In Passing The Reexamination Statutes, Congress Expressed A Policy Preference For Having Validity Issues Resolved By Experts At The Patent Office.

In 1980—some 28 years after the passage of Section 282—Congress enacted the original reexamination statutes in order to encourage the resolution of patent validity issues in the Patent Office, rather than in the courts.

Under the *ex parte* reexamination provisions, “[a]ny person at any time” may cite pertinent prior art, consisting of patents or printed publications, to the Patent Office and request a reexamination of patent based on that prior art. 35 U.S.C. §§301, 302. If the request raises “a substantial new question of patentability,” the Patent Office will order a reexamination of the patent to proceed in the same manner as the original examination, including introduction by the patentee of new or amended claims. *Id.* §§304, 305. The statute further directs the PTO to conduct reexamination proceedings “with special dispatch within the Office.” *Id.* §305.

Reexamination, therefore, allows the PTO to “start over’ [and] *re* examine the claims . . . as they would have been considered if they had been originally examined in light of all the prior art of record in the reexamination proceeding.” *In re Etter*, 756 F.2d 852, 856-57 (Fed. Cir. 1985) (emphasis in

original). As a result, the presumption of validity has no effect during reexamination and patentees may even amend and narrow their claims in order to distinguish prior art cited by the examiner. *Id.* at 858. In this fashion, Congress has created a system for sifting out invalid patents that is effectively “neutral, the patentee and the public having an equal interest in the issuance and maintenance of valid patents.” *Id.* at 856. Moreover, while a District Court has discretion to stay litigation pending the outcome of a reexamination (*see Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1329 (Fed. Cir. 2001)), the PTO has no parallel authority to suspend reexamination proceedings and “preclude[] access to the forum where there is no presumption of validity.”⁹ *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988).

By designating the Patent Office as the forum for new “substantial questions of patentability,” the reexamination statutes reflect Congress’s avowed preference for having the Patent Office decide important issues of validity whenever possible:

The U.S. Patent and Trademark Office (PTO) is the agency that examines applications for a patent, reviews the applicable evidence (e.g., “prior art”), and makes decisions to award the

⁹Unlike litigation, where the parties may vigorously dispute the proper scope of the claims, during reexamination “[c]laims are given their broadest reasonable interpretation, consistent with the specification,” permitting the PTO to address *all* potential invalidity issues, rather than just those raised by the District Court’s construction. *In re Swanson*, 540 F.3d 1368, 1377-78 (Fed. Cir. 2008) (citation and internal quotation marks omitted). Because the examiner on reexamination “is conducting a subjective examination of claims in the light of prior art” and not “attacking the validity of a patent,” reexamination also provides a more useful and equitable mechanism for correcting errors made by the Patent Office. *Etter*, 756 F.2d at 857-58.

patent grant. Since the PTO is the Federal agency with the expertise and “first look” at a patent’s validity and scope, Congress decided that the PTO was the proper agency with the necessary expertise to take a “second look” at a patent’s validity in certain cases when new information became available. In 1980, Congress created an *ex parte* reexamination system for this purpose. (H.R. REP. NO. 107-120, at 3 (2001))

Nor has the PTO shied away from this responsibility. Since instituting the *ex parte* procedure in 1981, the Patent Office has granted 92% of the over eleven thousand requests for *ex parte* reexamination. UNITED STATES PATENT AND TRADEMARK OFFICE, *EX PARTE* REEXAMINATION FILING DATA – DECEMBER 31, 2010 1 (2011), *available at* http://www.uspto.gov/patents/stats/EP_quarterly_report_Dec_2010.pdf. Of the patents reexamined, less than a quarter have survived completely intact, with 65% resulting in amended claims and 12% leading to cancellation of all claims outright.¹⁰ *Id.* at 2.

B. The Reexamination Statutes Reflect Congress’s Primary Concern With Restoring Confidence And Certainty To The Patent System.

As the legislative history confirms, Congress created the reexamination system in response to many

¹⁰The results for *inter partes* reexamination (*see* pp.21-24, *infra*) have been even more drastic. UNITED STATES PATENT AND TRADEMARK OFFICE, *INTER PARTES* REEXAMINATION FILING DATA – DECEMBER 31, 2010 (2011), *available at* http://www.uspto.gov/patents/stats/IP_quarterly_report_Dec_2010.pdf (96% of *inter partes* reexaminations requests granted with 47% cancelling all claims, 43% amending at least one claim and only 10% confirming all claims).

of the same concerns identified by *amici* (see pp.7-8, *supra*) about the value of issued patents in the absence of sufficient certainty as to their validity. H.R. REP. NO. 96-1307, pt. 1, at 4 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6462-63 (“Reexamination will permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation . . . [which], in turn, will promote industrial innovation by assuring the kind of certainty about patent validity which is a necessary ingredient of sound investment decisions”); see also 1980 U.S.C.C.A.N. at 6462 (“[This act] strengthens investor confidence in the certainty of patent rights by creating a system of administrative reexamination of doubtful patents”). Accordingly, Congress intended the new reexamination procedure to achieve three principal benefits: (1) the ability to *settle* validity disputes more quickly and less expensively than litigation; (2) to allow courts to refer patent validity questions to an agency with *expertise* in both patent law and technology; and (3) reinforce *investor confidence* by giving the PTO an opportunity to review doubtful patents. H.R. REP. NO. 107-120, at 3 (2001); *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 602 (Fed. Cir. 1985).

However, if a heightened standard of proof were not required when challenging a reexamined patent, Congress would have achieved none of these stated benefits. *First*, the proceeding would not truly “settle” any dispute as to validity, because accused infringers would be no more deterred from attacking a patent upheld following reexamination than they would have been beforehand. *Second*, the reexamination would still leave courts free to disregard the PTO’s expertise and render their own judgment on validity *de novo*. See pp.12-13, *supra*. *Third*,

reexamination would not “reinforce investor confidence” because the procedure would leave reexamined patents just as vulnerable to attack—and, therefore, just as uncertain (*see* pp.4-5, *supra*)—as before.

Congress could not have expected to meet these goals unless, in passing the reexamination statutes, it believed: (1) that the presumption of validity made it easier to overturn patents in the PTO; and (2) that any patent surviving reexamination would become even more difficult to invalidate. This understanding is entirely consistent with the view taken by the Federal Circuit several years later. *See, e.g., Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 973-74 (Fed. Cir. 1986) (where patent has been reexamined “after consideration by the PTO of [prior] art not considered during the original prosecution, the presumption of validity remains intact, and the challenger’s burden of proof imposed by that presumption, as an evidentiary matter, is usually more difficult to sustain”); *see also Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 961 (Fed. Cir. 1986) (District Court must give credence to fact that challenger’s burden of proving invalidity is “made heavier” when the patent has already been reexamined and reissued by the PTO).

C. Recent Amendments To The Reexamination Statutes Reinforce Congress’s Preference For Fixing Patent Mistakes Within The PTO Itself, Rather Than In Litigation.

Congress’s recent addition of an *inter partes* reexamination procedure nearly twenty years after the Federal Circuit began applying a “clear and convincing” standard to invalidity challenges (*see* Optional Inter Partes Reexamination Procedure Act, PUB. L.

No. 106-113, tit. IV, subtit. F, §§4601-08, 113 Stat. 1501, 1501A-567 to 1501A-572 (1999)) strongly supports the inference that Congress believes the presumption of validity imposes a heightened burden of proof. *Merck & Co. v. Reynolds*, —U.S.—, 130 S. Ct. 1784, 1795 (2010) (The Court “normally assume[s] that, when Congress enacts statutes, it is aware of relevant judicial precedent”); *accord*, *South Dakota v. Yankton Sioux Tribe*, 522 U.S. 329, 351 (1998); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 184-85 (1988).

Under these provisions, “[a]ny third-party requester at any time” has the option of requesting an *inter partes* reexamination based on the same prior art used to trigger an *ex parte* reexamination. 35 U.S.C. §311. Like the *ex parte* procedure, the Patent Office will initiate a reexamination only upon finding that the request raises a “substantial new question of patentability.” *Id.* §312. But unlike the *ex parte* procedure, an *inter partes* reexamination provides the third party an “opportunity to file written comments addressing issues raised by [any] action of the [Patent] Office or the patent owner’s response thereto” (*id.* §314) and gives third parties the right to appeal “any final decision favorable to patentability.” *Id.* §315.

By providing third parties the “opportunity to argue their case for patent invalidity in the USPTO,” Congress hoped *inter partes* reexamination would provide an even greater incentive¹¹ to “reduce expen-

¹¹So concerned was Congress with providing the necessary incentives for parties to engage in *inter partes* reexamination, rather than patent litigation, that it further amended the statutes to give third parties the right to appeal reexamination decisions to the Federal Circuit. Appeals in Inter Partes Reexamination Proceedings, PUB. L. NO. 107-273, div. C.,

(continued . . .)

sive patent litigation in U.S. district courts.” H.R. REP. NO. 106-464, at 133 (1999) (Conf. Rep.); *see also* H.R. REP. NO. 106-287, pt. 1, at 57 (1999) (originally referring to the new chapter as the “Patent Litigation Reduction Act”). Given the statute’s purpose of creating an incentive to reduce patent litigation,¹² Congress must have thought that reexamination would be a more attractive option for challenging patent validity than litigation, where the presumption of validity must be *overcome*. *Cf. Ethicon*, 849 F.2d at 1427 (staying reexamination proceedings in favor of litigation would, contrary to legislative intent, “preclude[] access to the forum where there is no presumption of validity”). Yet, if the preponderance of the evidence standard applies in *both* forums, the ability to participate would provide little, if any, incentive for third parties to rely on reexamination as a useful method for challenging invalidity, especially given that challengers who instigate an *inter partes* reexamination are estopped from asserting invalidity in a later infringement proceeding on grounds it “raised or could have raised” during reexamination. *See* 35 U.S.C. §§315(c), 317(b); *see also* USPTO REPORT TO CONGRESS ON *INTER PARTES* REEXAMINATION, ¶1 at 6 (2004) (citing the “high risk of estoppel” as the most frequently

(. . . continued)

tit III, subtit. A, §13106, 116 Stat. 1758, 1901 (2002) (codified as amended at 35 U.S.C. §315).

¹²In fact, during the hearings on the *inter partes* bill, one lawmaker went so far as to suggest that Section 282 be amended to make reexamination “a mandatory process before pursuing a patent validity dispute in a district court.” *Patent Reform and the Patent and Trademark Office Reorganization for Fiscal Year 2000, Hearing Before the Subcomm. on Courts and Intellection Property of the Comm. on the Judiciary*, 106th Cong. 9-10 (1999) (statement of Rep. Dana Rohrabacher).

identified deterrent facing third parties considering an *inter partes* reexamination request).

Congress further expressed its preference for reexamination as the forum for patent validity issues in 2002 by amending Sections 303(a) and 312(a) to expressly state that “[t]he existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.” Determination of Substantial New Question of Patentability in Reexamination Proceedings, PUB. L. NO. 107-273, div. C., tit III, subtit. A, §13105, 116 Stat. 1758, 1900 (2002). In so doing, Congress meant to overturn the Federal Circuit’s decision in *In re Portola Packaging, Inc.*, 110 F.3d 786 (Fed. Cir. 1997), which, in Congress’s view, “impos[ed] an overly-strict limit that reache[d] beyond the text of the Patent Act.” H.R. REP. NO. 107-120, at 2 (2001).

In *Portola Packaging*, the Federal Circuit held that examiners could *not* issue rejections during reexamination based solely on prior art previously before the PTO because such evidence could not, by definition, create a “substantial *new* question of patentability.” 110 F.3d at 791 (emphasis added). In essence, the decision categorically barred the PTO from relying on already cited prior art during reexamination “based on a presumption that the [original] examiner had properly discharged his duties and thus had considered all question of patentability raised by any reference before him.” *Swanson*, 540 F.3d at 1380 (citing *Portola Packaging*, 110 F.3d at 790). In amending Section 303(a)—and its *inter partes* analogue, Section 312(a)—Congress “rejected this presumption” that an examiner fully considers all possible questions of patentability

raised by the particular reference, and instead required “a more context-specific approach that is based on an analysis of what the PTO actually did.” *Swanson*, 540 F.3d at 1380; *see also* H.R. REP. NO. 107-120, at 3 (2001) (“The appropriate test . . . should not merely look at the number of references or whether they were previously considered or cited,” but determine whether the reference is being viewed in a new light for a substantially different purpose).

As this example demonstrates, Congress has long understood that examiners often make mistakes by “not properly understand[ing]” or “not consider[ing]” appropriate references when rendering a decision on patentability. H.R. REP. NO. 107-120, at 3. Yet, rather than make it easier for challengers to invalidate patents in litigation by overturning the Federal Circuit’s “clear and convincing evidence” standard, Congress’s response to such mistakes has been to repeatedly promote the use of reexamination as the vehicle for correcting errors¹³ made by the PTO because it better provides certainty and predictability to our patent system. In other words, Congress has recognized that “the primary responsibility for sifting out unpatentable material lies in the Patent Office.”¹⁴ *Graham v. John Deere Co.*, 383 U.S. 1, 18 (1966).

¹³Of course, reexamination is not a complete substitute for litigation, as the PTO currently has no authority to correct its mistakes in certain circumstances, such as when the invalidity claim is based on allegations of prior use or the on-sale bar.

¹⁴Contrary to the arguments of Petitioner, whether and how to address the Patent Office’s capability to exercise this responsibility is a question for the other branches of government, not the Court. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) (responsibility for addressing changes that disrupt the settled expectations of the inventing community “rests with Congress”).

D. At Most, The Preponderance Standard Should Only Apply Where The Invalidity Challenge Is Based On Evidence That Could Not Be Brought Before The Patent Office On Reexamination.

Throughout the text and legislative history of the reexamination statutes runs a core theme: that Congress believes the patent system is better served when substantial new questions of validity are left to experts at the PTO and not to the courts,¹⁵ at least where such questions arise from “earlier patents and printed publications—grounds that are well-suited for consideration in PTO proceedings.” H.R. REP. NO. 106-287, part 1, at 58 (1999). Accordingly, should the Court find it necessary to lower the standard of proof in some instances, it should do so only where the PTO had—and would have—no opportunity to make the initial patentability determination—*i.e.*, where the validity question rests on prior art that was not before the examiner *and* does not consist of patents or printed publications that *could* have been brought to the attention of the Patent Office in a reexamination proceeding.

This rule would strike the proper balance between the need to rein in improvidently granted patents and the legislative judgment that the preferred forum for doing so resides in the Patent Office, not the courts. Consistent with Congress’s legislative

¹⁵Indeed, several of the patent reform bills currently being considered by Congress would go even farther by creating a comprehensive post-grant opposition procedure that would provide third parties an adversarial mechanism for challenging patents within the PTO soon after they issue. Resp’t Br. 41 (citing S. 23, 112th Cong., §5(d) (2011)).

response to the Federal Circuit's *Portola Packaging* decision, such a rule would reduce the required standard of proof based not on whether the examiner actually *did* consider the issue of patentability in light of the newly cited prior art, but on whether the Patent Office *could* address the patentability question, in light of the newly cited prior art, for the first time—either through a reexamination or whatever other administrative procedure Congress may authorize in the future.

This approach would also address the practical difficulties inherent in a hybrid standard of proof. Petitioner and its *amici* ask the Court to implement a rule applying a lower standard of proof whenever a challenger introduces relevant prior art that was not “considered by” or “presented to” the Patent Office.¹⁶ As a practical matter, however, the record will never fully reflect what the Patent Office “considered” because examiners are not required to cite prior art they reviewed but on which they did not rely. *See, e.g., Solder Removal Co. v. U.S. Int'l Trade Comm'n*, 582 F.2d 628, 633 n.9 (C.C.P.A. 1978) (“a mere failure to cite certain prior art does not necessarily mean it was not considered by the examiner, who may have considered it unworthy of citation”). A rule based on what prior art was actually “presented,” on the other hand, will create incentives to shower the Patent Office with cumulative prior art, which would frustrate the purpose of the patent laws, not to mention

¹⁶As the Federal Circuit has noted, any implementation of this purportedly bright line rule would likely operate to eliminate the “clear and convincing” standard of proof altogether. *See Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983) (observing that “there is virtually always ‘pertinent’ and ‘relevant’ art apparently unconsidered in the PTO and available to a patent challenger”).

the proper functioning of the PTO. H.R. REP. NO. 107-120 at 2 (2001) (noting that the *Portola Packaging* decision led “to abuse by patent agents and lawyers who . . . include hundreds of prior art references [in their applications], knowing that the PTO examiner has only a few precious hours to review the application before she is required to make a decision on its grant”).

By contrast, a rule lowering the standard of proof based on whether the prior art “could have been” presented to the Patent Office turns on clear rules and does not incentivize bad behavior during the patent prosecution process. The proposed rule would be fair to all constituencies: the Patent Office, the patent holder and the challenger.

CONCLUSION

For the foregoing reasons, the Court should uphold the clear and convincing evidence standard as the appropriate burden for proving patent invalidity. At the very least, the Court should not lower the

standard of proof where the validity challenge is based on prior art that could have been considered by the Patent Office in a reexamination proceeding.

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