

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 TEVA PHARMACEUTICALS USA,
INC. AS *AMICUS CURIAE* SUGGESTING
VACATION**

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INTEREST OF *AMICUS CURIAE*¹

Amicus curiae Teva Pharmaceuticals USA, Inc. (“Teva”) is a wholly-owned U.S. subsidiary of Teva Pharmaceuticals Industries Ltd., the largest generic pharmaceutical company in the world. Teva sells a wide range of proprietary and generic pharmaceutical products.

Teva has a deep interest in the legal standards that govern challenges to patent validity as those challenges profoundly affect when generic pharmaceuticals can be made available to the public. Rapid introduction of generic drugs is critical to national health policy. Congress enacted the Hatch-Waxman Act in 1984 to accelerate the introduction of less costly generic pharmaceuticals in a manner consistent with the *legitimate* rights of owners of pharmaceutical patents. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670, 676-78 (1990). The Act encourages generic companies to challenge the validity of pharmaceutical patents by rewarding the first company to do so, whether successful or not, with a six-month period of marketing exclusivity. 21 U.S.C. §355(j)(5)(B)(iv).

As Congress intended, generic pharmaceutical companies frequently challenge the validity of pharmaceutical patents in litigation. Teva has been involved in scores of such cases since the enactment of the Hatch-Waxman Act. In many of these cases, Teva

1. Petitioner’s and respondents’ counsel have lodged with the clerk of the Court consent to the filing of amicus briefs in support of either party or of neither party. No counsel for a party authored this brief in whole or in part and no person other than the *amici curiae* made a monetary contribution intended to fund its preparation or submission.

has identified significant prior art or other material information that was never disclosed to the patent examiner during the prosecution of the patents-in-suit. Even in such cases, however, the Federal Circuit requires that invalidity be proven by clear and convincing evidence, notwithstanding this Court's observation that the rationale for such deference to the decision of the Patent Office "seems much diminished" when material information was not before the patent examiner. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007).

Teva shares with the public a vital interest in having both patentability and later invalidity challenges fairly assessed under appropriate standards in light of all relevant information. For the reasons set forth below, that interest will be best served by a rule that permits proof of invalidity by a preponderance of the evidence for any invalidity challenge based on any material, non-cumulative information that was not before the Patent Office during examination of the patent-in-suit.

SUMMARY OF ARGUMENT

The system for examining patent applications in the United States is deeply dependant on applicants bringing to the attention of the examiner prior art and other information that examiners are unlikely otherwise to uncover. However, the Federal Circuit's requirement that invalidity be proven in patent infringement litigation by clear and convincing evidence discourages applicants from searching for such information and from disclosing any such information to the examiner. A rational patent applicant will recognize the advantages of having such information considered for the first time, if at all, by a

judge or jury that will give it far less weight because of the heavy burden placed on the challenger to prove invalidity by clear and convincing evidence.

Although the deliberate concealment of material information known to the applicant creates a risk that the resulting patent will be ruled unenforceable under the inequitable conduct doctrine, this risk creates only a weak deterrent to patent applicants. First, patent applicants have no duty to conduct prior art searches, and the inequitable conduct defense does not apply to information unknown to the applicant. Second, even if the applicant concealed known material information, the inequitable conduct defense is very difficult to establish. The defendant must prove actual intent to deceive the examiner by clear and convincing evidence where direct evidence of such intent is rarely available, and, under Federal Circuit case law, the inference of intent must be the single most reasonable inference able to be drawn from the evidence. Moreover, the Federal Circuit is now considering *en banc* whether to require the defendant to prove that the withheld information would have prevented issuance of the patent to constitute inequitable conduct. Such a ruling would effectively eliminate any incentive to disclose potentially invalidating prior art to the examiner.

For these and other reasons articulated by Microsoft and other *amici*, accused infringers should be able to establish patent invalidity by a preponderance of the evidence where the invalidity argument is based, in whole or in part, on material, non-cumulative evidence that was not before the patent examiner. However, where the challenger relies only on evidence that was before the examiner, the burden of proving invalidity should

be higher. A higher burden of proof is warranted by the deference due to a fully informed decision by the Patent Office and by the incentives that such a higher burden would create for patentees to uncover and disclose to the examiner information material to patentability. Such a dual standard of proof presents no significant manageability issues.

ARGUMENT

I. Introduction

Petitioner, Microsoft Corp. (“Microsoft”) has presented compelling arguments why an accused infringer relying upon prior art or other information not before the patent examiner during prosecution should be able to establish an invalidity defense by a preponderance of the evidence. In this brief, we emphasize one particular reason for this position, *i.e.*, that the Federal Circuit’s requirement that patent invalidity be proven by clear and convincing evidence in all cases encourages practices that undermine the quality of patent examination. Under the Federal Circuit’s requirement, patent applicants have a powerful incentive neither to search for potentially invalidating prior art nor to disclose such prior art to the examiner. For that reason alone, in the circumstances presented here a preponderance of the evidence standard should apply to Microsoft’s invalidity defense.

It does not follow, however, that the preponderance of the evidence standard should be applied in all cases. While that standard may be the default standard for claims and defenses in federal civil actions, there are reasons to require that patent invalidity be proven by a higher

standard where all of the evidence on which the accused infringer relies to prove invalidity was before the patent examiner. The prospect of obtaining a favorable standard of review will provide incentives to patent applicants to assist the examiner by searching for, disclosing, and addressing potentially invalidating prior art. Moreover, where the patent examiner has conducted an examination on a complete record — currently a rare occurrence — it is appropriate to have a standard of review that reflects a measure of deference to the examiner’s determination.

II. Application of a clear and convincing standard to prove invalidity even where material, non-cumulative prior art was not before the Patent Office, encourages applicants to conceal such prior art from the Patent Office.

A. Informed patent examination often requires information that only the applicant will be in a position to supply.

An inventor is entitled to patent protection only when the invention claimed in the patent application satisfies the statutory requisites for patentability, including utility, novelty and non-obviousness. 35 U.S.C. §§101-103. For the system to work as intended, the examiner must be in a position to make a fully informed judgment as to the patentability of the claimed invention. “The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the [Patent] Office is aware of and evaluates the teachings of all information material to patentability.” 37 C.F.R. §1.56(a).

However, there are significant obstacles to achieving informed decision-making by the Patent Office. The patent prosecution process is *ex parte*. In contrast to litigation, no one involved in the prosecution of the patent has an economic incentive to bring to the patent examiner's attention information that may preclude patent issuance.

The examiners themselves theoretically are charged with searching the pertinent scientific literature to determine whether the claimed invention really is novel and non-obvious, as the patent applicant contends. But the reality is that examiners rarely have sufficient time or resources to undertake a comprehensive search themselves for prior art or other information that would preclude patentability. *See* Fed. Trade Comm'n, *To PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY* Ch. 5, at 1-10 (2003) ("FTC Innovation Report"); Lichtman & Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 *STAN. L. REV.* 45, 46, 53-54 (2007). The PTO itself has acknowledged that "the volume of patent applications continues to outpace our capacity to examine them. We have a pending application backlog of historic proportions."²

Moreover, some information that is highly material to patentability will not be available to the examiner.

2. U.S. PATENT & TRADEMARK OFFICE, 2007-2012 STRATEGIC PLAN 6 (2007) ("PTO Strategic Plan"), available at <http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012.pdf> (last visited Jan. 31, 2011) The PTO reports a five-fold increase in the number of pending applications between 1987 and 2007. U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT, FY 2007 table 3 (2007), http://www.uspto.gov/web/offices/com/annual/2007/50303_table3.html (last visited Jan. 31, 2011).

For example, 35 U.S.C. §112 obliges patent applicants to disclose “the best mode contemplated by the inventor of carrying out his invention.” Obviously, patent examiners cannot discover the best mode contemplated by inventors if inventors themselves fail to disclose it. Similarly, 35 U.S.C. §102(b) precludes patent issuance if the claimed invention was “in public use or on sale” in the U.S. more than one year before the patent application. The applicant is often in the only position to bring evidence of such prior sales to the examiner’s attention.

Because examiners need information that they are unlikely to obtain if the applicant does not supply it, the patent laws oblige “each individual associated with the filing and prosecution of a patent application” to “disclose to the [Patent] Office all information known to that individual to be material to patentability.” 37 C.F.R. §1.56(a).

B. The application of a clear and convincing standard of proof across the board exacerbates powerful incentives not to discover problematic prior art and not to disclose such prior art to the patent examiner.

Despite the disclosure obligation imposed on patent applicants, a rational patent applicant will recognize that the benefits of concealing material information often exceed the costs. The principal benefit is a higher likelihood of obtaining an issued patent.

An issued patent is often extremely valuable even if the patent is ultimately found to be invalid. Patent litigation is time-consuming and expensive. Defending a

typical patent infringement case costs millions of dollars and diverts enormous time and energy from productive activity.³ Some patent owners exploit this by filing lawsuits against entire industries, hoping that at least some defendants will find it cheaper and less disruptive to license a patent of questionable validity rather than spend the time and money to invalidate the patent.⁴ The licensing of weak or invalid patents resulting from such coercive litigation tactics imposes a kind of private tax on legitimate businesses — enormous in the aggregate — that ultimately burdens consumers and the economy as a whole. *See* FTC Innovation Report, *supra*, Ch. 5, at 2-4; Adam B. Jaffe & Josh Lerner, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT, 115 (Princeton University Press, 3d prtg. 2007) (“Ultimately, if paying this kind of protection money comes to be seen as a routine cost of introducing new products, the whole process of innovation becomes more expensive. As a result, there will be less innovation and society as a whole will be worse off.”). *See also* FTC Innovation Report,

3. *See* James Bessen and Michael J. Meurer, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 131-33 (2008).

4. *See* Adam B. Jaffe & Josh Lerner, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 114 (Princeton University Press, 3d prtg. 2007) (“Even if an alleged infringer is convinced that it is in the right, given the uncertainty of the litigation process and the possibility of a very costly punishment, it may choose to settle. The result may be that a truly innovative firm, trying to bring a valuable new product to market, ends up taking a license to an invalid patent in order to implement its own technology without the cost and distraction of litigation.”).

Ch. 2 at 28-29 and Ch. 3 at 34-41 (discussing “patent thicket” that afflicts many technology companies); Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991 (2007).⁵

Under current Federal Circuit law, once a patent issues, potentially invalidating information concealed from the examiner becomes much less of a threat to the patent. If the applicant had disclosed potentially invalidating information during patent prosecution, the examiner would have considered that information *de novo*. If the examiner had finally concluded that the information precluded issuance of particular claims, the applicant would have faced the choice of either abandoning or narrowing the rejected claim or challenging the rejection on appeal.

5. Issued pharmaceutical patents are particularly valuable, regardless of validity, because by statute a pharmaceutical patentee can automatically restrain competition from generic drugs for at least two and a half years without any proof that its infringement claim is likely to succeed. If the generic drug company requests that FDA approve its generic product before the expiration of any patent identified by the manufacturer of the previously approved reference drug, the patentee can sue immediately for patent infringement. 35 U.S.C. §271(e)(2). If the patentee does so within 45 days of the generic company’s certification, the FDA may not approve the generic company’s Abbreviated New Drug Application (“ANDA”) for 30 months, whether or not the patent is valid (except in the rare case where the defendant proves invalidity or non-infringement in less than 30 months). 21 U.S.C. §355(j)(5)(B)(iii). Because a successful drug can generate billions of dollars in sales during those 30 months, the economic incentive to obtain by any possible means even an exceptionally weak patent covering a commercial drug product is very great indeed.

However, if the applicant conceals that information from the examiner and the patent issues, then the information will be considered for the first time by a judge or jury often lacking the scientific training and expertise of a patent examiner. More important, under the Federal Circuit rule challenged by Microsoft here, the judge or jury will apply a standard of proof that is highly favorable to the patentee. Unless the information concealed from the examiner *clearly and convincingly* establishes the invalidity of the patent, the invalidity challenge will fail. Because the challenger faces such a heavy burden, the potentially invalidating information will carry significantly less weight in the patentability analysis than it would have carried with the examiner. Accordingly, applying the clear and convincing standard of proof as to invalidity defenses based on information not before the examiner substantially enhances an already powerful incentive to conceal potentially invalidating prior art and other information during patent prosecution. It would be naïve to assume that applicants rarely succumb to such temptations.

This is true even if one also assumes that most patent lawyers and inventors will attempt to comply with their legal duty to disclose potentially invalidating information in their possession to the examiner, despite the powerful economic incentives to conceal. Initially, patent lawyers will be inclined not to perform, and to discourage clients from performing, prior art searches that may uncover obscure references that would jeopardize the application. There is no obligation to undertake such a search. *See American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1362 (Fed. Cir. 1984).

Patent lawyers will also be inclined to withhold material information on any colorable rationale. Disclosing problematic information that the examiner would be unlikely to discover independently is difficult to square with the professional obligation of zealous representation, unless there is no colorable argument whatever that the information need not be disclosed. Accordingly, all possible doubts will be resolved against disclosure. And some inventors will be experienced enough in the patenting process to know that if they fail to bring potentially invalidating prior art or other information to the attention of their patent lawyer, there will rarely be any serious adverse consequence, and a valuable patent will likely result.

C. The inequitable conduct defense does little to reduce the incentives to conceal problematic prior art.

The perverse incentives for the applicant to conceal material information during patent examination are not significantly affected by the risk that such concealment might render the patent unenforceable under the inequitable conduct doctrine. Under current Federal Circuit law, if an inventor, a patent attorney or some other person involved with the filing or prosecution of the application (i) conceals material information from the examiner or makes a material misrepresentation to the examiner, and (ii) does so with an intent to deceive the examiner, the patentee may not enforce the resulting patent. *E.g., Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313 (Fed. Cir. 2008). However, the inequitable conduct defense provides only a very weak deterrent to concealing problematic information during patent prosecution.

First, the inequitable conduct defense only applies to information known to the applicant because the obligation to disclose is limited to what the applicant knows. If the applicant fails to undertake a comprehensive prior art search, the applicant's failure to disclose even highly material prior art that such a search would uncover would not support an inequitable conduct defense.

Second, inequitable conduct is, if anything, harder to establish than invalidity. To establish the inequitable conduct defense, the defendant must first prove both materiality and deceptive intent by clear and convincing evidence. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).⁶ Moreover, even where the defendant has adduced clear and convincing evidence of both materiality and intent to deceive, the district court retains discretion to reject the inequitable conduct defense if the conduct is insufficiently "egregious." *Id.*

The intent requirement presents the more formidable obstacle. The Federal Circuit has ruled that even grossly negligent concealment of material information does not constitute inequitable conduct. *See, e.g., Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc* in relevant part). While direct evidence of intent, which is rarely available, is not required, *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1134-35 (Fed. Cir. 2006), circumstantial proof of intent generally

6. Of course, if this Court rules that the preponderance of the evidence standard is the default rule for affirmative defenses in patent cases, the requirement of clear and convincing proof of inequitable conduct would need to be reconsidered.

requires proof that highly material information, known to the applicant, was concealed or misrepresented, and that the patentee cannot articulate a credible excuse for the concealment, *see id.*; *Praxair*, 543 F.3d at 1313-14. Since most of the conversations between inventors and patent counsel during the actual prosecution will be protected by the attorney-client privilege, contemporaneous evidence of actual motivation will often not be discoverable, and the ability of patentees to articulate plausible post hoc rationalizations for decisions made years earlier during patent prosecution makes proof of intent to deceive by clear and convincing evidence a formidable task for any defendant.⁷

In addition, the Federal Circuit is currently considering *en banc* whether to make it even more difficult to establish inequitable conduct. In *Therasense, Inc. v. Becton Dickinson Co.*, Nos. 2008-1511, -1512, -1513, -1514, -1595 (Fed. Cir.), the Federal Circuit has requested briefing on several questions going to the foundations of the inequitable conduct defense, including: “Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?”

7. *See, e.g., Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1342-47 (Fed. Cir. 2005) (affirming finding of no inequitable conduct where inventors testified they failed to appreciate the materiality of prior art compounds); *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, 464 F.3d 1339, 1346 (Fed. Cir. 2006) (same where patentee’s president testified that he did not believe the material prior art reference was material); *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1226-27 (Fed. Cir. 2006) (same where inventor testified he did not believe disclosure of information found to be material was necessary).

Id. (Order dated April 26, 2010). If the Federal Circuit answers this question in the affirmative, then establishing the inequitable conduct defense will effectively require proof of invalidity, and the defense will then provide no incentive whatever to discover and disclose potentially invalidating prior art.⁸

* * * * *

In short, the Federal Circuit's requirement that invalidity be proven by clear and convincing evidence, even where material, non-cumulative information was not before the examiner, encourages patent applicants to ignore or conceal information critical to informed patent examination. For that reason alone, this Court should vacate the judgment below and remand the case with instructions to apply the preponderance of the evidence standard to the retrial of Microsoft's invalidity defense.

8. Oral argument in *Therasense* took place on November 9, 2010.

III. The standard of proof required to establish invalidity should be preponderance of the evidence unless the trial court finds that all of the prior art and other information on which the accused infringer relies was before the patent examiner.

A. Where all material, non-cumulative prior art was before the examiner, a higher standard of proof for invalidity defenses will encourage full disclosure by applicants and appropriately defer to informed administrative action.

There is no justification for requiring clear and convincing proof of invalidity where, as here, the invalidity argument turns on information not before the patent examiner. However, it does not follow that the preponderance of the evidence standard should apply across the board.

Where *all* of the information on which a defendant bases an invalidity argument was before the examiner, there are at least two reasons to require a higher standard of proof. First, as this Court noted in *KSR*, the rationale for the statutory presumption of validity is based on the fact “that the PTO, in its expertise, has approved the claim.” 550 U.S. at 426. The Federal Circuit’s adoption of the clear and convincing standard was based on the same rationale:

When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to

have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

American Hoist, 725 F.2d at 1359.

The Federal Circuit’s error in this case was its application of a deferential standard when the rationale for such deference was not present. As this Court recognized in *KSR*, the material incompleteness of the record considered by the examiner “diminishes” the extent to which the decision to approve the patent is entitled to deference. But it also follows from that rationale that fully informed decision-making by the examiner warrants the observance of such deference.

The second reason for preserving the clear and convincing standard for invalidity challenges that rely only on information that had been before the examiner is that such a rule would encourage patent applicants to conduct prior art searches and to bring problematic information to the examiner’s attention. As explained above, applying a clear and convincing standard across the board discourages such behavior. But if the clear and convincing standard were applied only if the applicant took these steps to enhance the quality of patent examination, the incentives would be significantly altered for the better.⁹

9. Professors Lichtman and Lemley have advocated a version of this approach whereby patent applicants would have a chance to “gold-plate” their patents by “funding and submitting

B. Applying a clear and convincing standard only where the invalidity challenge is based on information that was before the examiner is workable.

In opposing the petition in this case, respondents suggested that applying the preponderance standard only as to information not before the examiner would impose unreasonable burdens on applicants, the Patent Office, and courts. *See* Brief in Opposition to Certiorari at 21-22. Since respondents are likely to elaborate on those arguments in their merits briefs, we briefly address them here.

Respondents argued in their opposition to certiorari that the cost of a dual standard of proof would outweigh the benefits because it will effectively make patent prosecution more expensive — a burden said to fall particularly hard on small business and individual applicants — and will lead to a significant increase in the volume of information submitted to “already-overtaxed patent examiners.” *Id.* at 22. These arguments are both wrong.

First, not all inventors will feel compelled to undertake comprehensive prior art searches that are not currently required. Under the approach that Teva proposes, they would have no obligation to do so. Inventors, together with their corporate assignees and financing sources,

to a vigorous review process in the PTO,” getting in return “a significant presumption in favor of patent validity.” Lichtman & Lemley, *supra*, at 50. If a patent applicant had brought to the examiner’s attention all of the information on which an accused infringer relies to prove invalidity, its patent should at least be “silver-plated” by being insulated from invalidation absent clear and convincing proof.

will face an economic choice whether the investment of time and money to present a complete description of the pertinent prior art to the examiner to obtain a patent less vulnerable to challenge makes economic sense. Sometimes the investment will be worth it; sometimes not. But if the applicant chooses not to make that investment, there is no reason why invalidity challenges to any resulting patent should not be judged under the preponderance of the evidence standard that generally applies to affirmative defenses in federal cases.

Second, applying the default preponderance standard for invalidity arguments predicated on information not before the examiner need not result in applicants “dumping” vast additional numbers of references. Both case law and Patent Office regulation clearly relieve the applicant of any obligation to disclose “cumulative” information. 37 C.F.R. §1.56 (the duty to impose information material to patentability only imposes a duty to disclose information that “is not cumulative to information already of record or being made of record in the application”); *Halliburton Co. v. Schlumberger Technology Corp.*, 925 F.2d 1435, 1440 (Fed. Cir. 1991) (“a patentee has no obligation to disclose an otherwise material reference if the reference is cumulative or less material than those already before the examiner”). If an invalidity argument is predicated on references that merely repeat information already before the examiner, then the patent should enjoy a heightened presumption of validity.¹⁰

10. The greater risk may be that applicants that seek to earn the application of the clear and convincing standard by disclosing problematic references will attempt to “bury” such references in a large volume of references in the hope that the examiner does not find or focus on the problems. While this is a

Respondents also argue that if “patent trials ... include both prior art that the PTO had and had not considered, requiring juries to apply different burdens of proof to different pieces of evidence relevant to the same question in the same trial.” Brief in Opposition to Certiorari at 22. Respondents overstate the difficulties in applying a dual standard of proof.

First, as Microsoft has demonstrated in its brief, before the creation of the Federal Circuit, circuit courts generally applied a different burden of proof when the alleged infringer relied on information not before the examiner. *See, e.g., Mfg. Research Corp. v. Graybar Elec. Co., Inc.*, 679 F.2d 1355, 1360-61 (11th Cir. 1982) (generally, an “alleged infringer must demonstrate the patent’s invalidity by clear and convincing evidence to succeed in this defense . . . however, when pertinent prior art was not considered by the Patent Office in its review of patent applications . . . the burden upon the challenging party is lessened, so that he need only introduce a preponderance of the evidence to invalidate a patent.”). Indeed, the Federal Circuit itself recently recognized that in some circumstances the standard of review of a rejection of patentability depends on whether the applicant relies on evidence that was before the examiner. *See Hyatt v. Kappos*, 625 F.3d 1320, 1336-37 (Fed. Cir. 2010) (*en banc*) (“the dual standards of review . . . maintain an appropriate level of deference to agency findings, while preserving to the court its role as factfinder with respect to new

real risk, the Patent Office can protect itself against such tactics by prohibiting cumulative filings and/or requiring the applicant to provide a “readers guide” for the examiner or otherwise to direct the examiner’s attention to the most significant references.

evidence”). Nothing in these cases suggests any practical difficulty in applying such a dual standard at trial.

Second, respondents incorrectly assume that the district court would apply (or instruct the jury to apply) different standards of proof to different pieces of prior art. We suggest that that is not how district courts would operate under a dual standard scheme. If this Court rules that a clear and convincing burden of proof will apply if, *but only if*, all of the information on which the defendant relies to prove invalidity was before the examiner, the trial judge will have to make an initial determination whether the accused infringer relies on any information that was not before the examiner. That is typically a matter of examining the prosecution history. If the accused infringer relies on such undisclosed information, and if that undisclosed information was both material to patentability and non-cumulative, then the judge will apply, or instruct the jury to apply, a preponderance standard. If not, the judge will apply, or instruct the application of, a clear and convincing standard.

This was the approach in the circuits before the Federal Circuit directed that a clear and convincing standard apply across the board. For example, in *Futorian Mfg. Corp. v. Dual Mfg. & Engineering, Inc.*, the First Circuit upheld a trial court’s instructions to a jury that the “burden of proof in establishing invalidity was . . . by a preponderance of the credible evidence,” as opposed to the “clear and convincing’ standard,” because “the examiner’s attention, so far as any record reveals, was called to only eight” out of “twenty relevant prior art patents” and the court determined that the “omissions cannot be said to be insignificant.” 528 F.2d 941, 942 (1st Cir. 1976).

In *Mfg. Research Corp.*, the Eleventh Circuit held that “the district court erred” when it instructed “the jury to apply a clear and convincing evidence standard to the defense of invalidity,” because the alleged infringer “introduced into evidence relevant prior art that was not cited by either the patent applicant or the examiner.” 679 F.2d at 1364. The Eleventh Circuit concluded that the new evidence was “quite probative” of relevant issues and “not cumulative,” held that the district court should have instructed the jury that the alleged infringer “is only obligated to show invalidity by a preponderance of the evidence.” *Id.*

District courts are experienced in making these materiality determinations because they are required to make them in resolving the inequitable conduct defense, which, as an equitable defense, is tried to the court. In resolving that defense, the district court must decide whether the patent applicant concealed material, non-cumulative information from the examiner.

In sum, applying a clear and convincing evidence standard of proof to invalidity defenses *if, but only if*, all of the prior art or other information on which the defendant relies was before the patent office, presents no significant management problems for courts in patent infringement cases. Such a rule reflects a rational calibration and allocation of the risks of erroneous adjudication to encourage behavior by patent applicants that advances the goals of the patent system.

CONCLUSION

The Federal Circuit's judgment should be vacated and the case remanded for retrial under a preponderance of the evidence standard.

Respectfully submitted,

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