In the Supreme Court of the United States

MICROSOFT CORPORATION,

Petitioner;

v.

I4I LIMITED PARTNERSHIP AND INFRASTRUCTURES FOR INFORMATION INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATED COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF AMICI CURIAE OF TEVA PHARMACEUTICALS USA, INC., GENERIC PHARMACEUTICAL ASSOCIATION, AND CISCO SYSTEMS, INC., IN SUPPORT OF PETITIONER

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September 29, 2010

232555



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Warner-Lambert Co. v. Teva Pharms. USA, Inc., 418 F.3d 1326 (Fed. Cir. 2005)
Statutes
21 U.S.C. § 355
35 U.S.C. §§ 101 et seq
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Cited Authorities

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Other Authorities	
37 C.F.R. §1.56	7, 9
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 (3d prtg. 2007)	10
David Hricik, Wrong About Everything: The Application by the District Courts of Rule 9(b) to Inequitable Conduct, 86 Marq. L. Rev. 895 (2003)	14
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INTEREST OF AMICI CURIAE¹

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. Amicus curiae Generic Pharmaceutical Association ("GPhA") represents more than sixty companies that manufacture and sell generic pharmaceuticals. GPhA has submitted briefs amicus curiae on many occasions to address patent law issues that affect the generic drug industry. As explained below, Teva and GPhA have a deep interest in the legal standards that govern challenges to patent validity.

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

^{1.} Counsel of record for all parties received notice at least 10 days prior to the due date of the *amici curiae*'s intention to file this brief. 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 to its preparation or submission.

^{2.} For example, GPhA submitted a brief on the merits in support of petitioner in *MedImmune*, *Inc.* v. *Genentech*, *Inc.*, 549 U.S. 118 (2007).

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 sixmonth 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 alone has been involved in scores of such cases since the enactment of the Hatch-Waxman Act. In many of these cases, the challenger identifies significant prior art or other material information that was never disclosed to the patent examiner during the prosecution of the patentsin-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).

Amicus curiae Cisco Systems, Inc. ("Cisco") is one of the world's largest technology companies. It designs and sells consumer electronics, and networking and communications technology and services. Cisco's Internet-Protocol-based networking solutions constitute the foundation for computer networks across the globe. Cisco holds thousands of patents that have been prosecuted in compliance with the Patent Act, 35 U.S.C. §§ 101 et seq. Cisco is also a frequent target of infringement lawsuits based on patents of questionable validity. In many instances, prior art that should have

resulted in denial of the patent application was not disclosed during prosecution. In such cases, Cisco faces a difficult burden of proving invalidity by clear and convincing evidence, even though the information on which its invalidity argument is based was never even considered by a patent examiner.

As explained below, the Federal Circuit's requirement for clear and convincing proof of invalidity in all circumstances creates a powerful incentive for patent applicants to conceal potentially invalidating prior art and other material information from the patent examiner during patent prosecution. This incentive is particularly powerful in the pharmaceutical area because the owner of a patent covering a pharmaceutical product, simply by commencing an infringement action, can delay FDA approval of a competing generic drug product for 30 months without any showing that it is likely to succeed on the merits of its claim.

This perverse incentive is also powerful in the hightechnology industry, which currently faces a great many patent infringement lawsuits brought by entities who abuse the litigation process by knowingly asserting invalid or unenforceable patents to extract quick settlements and licensing fees. The inequitable conduct defense creates a limited counterbalance but establishing that defense is, if anything, more difficult than proving invalidity by clear and convincing evidence.

Moreover, applicants can often reduce the risk of a successful inequitable conduct defense by making no attempt to research whether their invention truly is novel before filing a patent application. Discovering relevant prior art before or during prosecution trigger's the applicant's duty to disclose it to the examiner, failing which the patent may be unenforceable. But if no search is done and the relevant art not found, then there is no disclosure obligation and the likelihood that the patent will be invalidated over that art in later litigation is reduced because of the clear and convincing hurdle. The Federal Circuit's rule thereby creates a perverse incentive not to investigate the novelty of an invention before or during prosecution.

Teva, GPhA, Cisco, and the public have a vital interest in reducing these perverse incentives, in having both patentability and later invalidity challenges fairly and realistically assessed under appropriate standards in light of all relevant information, and in ensuring that invalid patents are not used to stifle legitimate innovation and new products.

SUMMARY OF ARGUMENT

The Petitioner in this case rightly notes that the Federal Circuit's insistence on applying its "clear and convincing evidence" rule even where information material to patentability was not before the patent examiner disregards this Court's decision in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), conflicts with the pre-1982 rulings of all twelve regional circuits, and is inconsistent with well-established principles of administrative law.

There is, however, an additional reason why this case presents a question of exceptional importance, warranting this Court's review. The Federal Circuit's rule encourages patent applicants to forego any search for potentially invalidating prior art and to conceal from patent examiners such prior art and any other information that could undermine their applications. Rational patent applicants will recognize that because litigants face a heavy burden of proving invalidity by clear and convincing evidence, it is to their advantage if problematic information is considered for the first time in patent litigation, and not by the examiner during patent prosecution. Because of the challenger's heavy burden of proof in patent litigation, such evidence will carry less weight than it would have carried with the patent examiner. On the other hand, if patent applicants know that the clear and convincing test will apply only to patent challenges based on information actually before the examiner³ — and that a preponderance of the evidence standard will apply in cases involving previously undisclosed information — the incentives to willful ignorance and active deception created by the Federal Circuit's rule would be significantly reduced.

^{3.} The Federal Trade Commission and respected scholars have argued that the "clear and convincing" standard of proof should not be applied even where all material, non-cumulative information was available to the examiner, because the extraordinary time and resource constraints on patent examination make such deference to examiners' decisions unwarranted. See U.S. Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy Ch. 5, at 26-28 (2003) ("FTC Innovation Report"); Doug Litchman & Mark A. Lemley, Rethinking Patent Law's Presumption of Validity, 60 Stan. L. Rev. 45, 46-59 (2007). Amici take no position on this issue. The FTC Innovation Report is available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf (last visited Sept. 27, 2010).

The incentive to suppress material information is not significantly counterbalanced by the inequitable conduct defense. Although an accused infringer can defeat an infringement claim by proving that the patent applicant concealed material information during prosecution with intent to deceive the examiner, this inequitable conduct defense is even more difficult to establish than invalidity. The modest risk of being found to have intentionally deceived the PTO will not often discourage patentees from concealing problematic information.

REASON FOR GRANTING THE PETITION

The question presented is exceptionally important because the Federal Circuit's rule creates incentives for patent applicants to conceal material information from the PTO.

The Federal Circuit's rule requiring proof of invalidity by clear and convincing evidence even if material information was concealed from the patent examiner encourages willful ignorance and deception by patent applicants. This results from the practical and legal constraints on the patent application process, the enormous economic value of many patents (even patents ultimately found to be invalid), and simple human nature. Concealing material adverse information from the patent examiner increases the likelihood that a patent will issue for an unpatentable invention, and the Federal Circuit's rule significantly increases the likelihood that the patentee will get away with such concealment.

A. The Patent Office must rely on patent applicants for accurate information during patent prosecution.

A patent applicant seeks to persuade the patent examiner that the invention claimed in the application satisfies various 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 an 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 fully 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 quite different, as Petitioner has demonstrated in the Petition. See Petition at 19-21. It is widely recognized that examiners have insufficient time and resources to undertake a comprehensive search for prior art that would preclude patentability. See FTC

Innovation Report, *supra* note 3, Ch. 5, at 1-10; Litchman & Lemley, *supra* note 3, at 46, 53-54. 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."

Moreover, some information that is highly material to patentability will not be available to the examiner if the applicant fails to disclose it. For example, examiners commonly reject as prima facie obvious claims to chemical compounds that are structurally similar to compounds disclosed in the prior art unless the applicant can show that the claimed compound has unexpectedly superior properties. See In re Dillon, 919 F.2d 688, 692-93 (Fed. Cir. 1990) (en banc). The applicant is often the only source for test data to demonstrate such superiority. If the applicant "cherry picks" favorable data to suggest a superiority that the applicant's unpublished data as a whole would not support, there is little chance that the examiner will discover the unfavorable data or be able to make an informed assessment of the claimed compound's ostensible superiority. See Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1365-66 (Fed. Cir. 2007).

^{4.} 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 Sept. 27, 2010) The PTO reports a fivefold 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 Sept. 27, 2010).

Because patent examiners cannot uncover all of the information needed to make an informed assessment of patentability, the patent system is deeply dependent upon patent applicants themselves to bring potentially invalidating prior art and other information to the attention of the examiner. Accordingly, Patent Office rules impose on each person involved in prosecuting a patent application "a duty to disclose to the [Patent] Office all information known to that individual to be material to patentability " 37 C.F.R. § 1.56(a).⁵

Those rules, however, impose no duty on applicants to conduct a search for material prior art. See FTC Innovation Report, supra note 3, Ch. 5, at 7-8. There is very little reason for applicants to do so. If scrutiny of the pertinent professional literature uncovers publications, however obscure, that disclose or suggest the claimed invention, the applicant will face an obligation to disclose them to the examiner and thereby jeopardize the patent application.

Moreover, patent applicants face powerful incentives to conceal potentially invalidating information, however discovered, from the Patent Office, as explained in the next section of this brief.

^{5.} The regulation defines materiality in terms of non-cumulative information that either "establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim," or "refutes, or is inconsistent with" a position taken by the applicant in opposing an unpatentability argument raised by the Patent Office or in asserting an argument supporting patentability in, for example, prosecuting a foreign patent application covering the same invention. 37 C.F.R. §1.56(b).

B. The requirement of clear and convincing proof of invalidity exacerbates already powerful temptations to conceal problematic information from the Patent Office.

A rational patent applicant will recognize that the benefits of concealing material information will often exceed the costs. The principal benefit, of course, 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. Some patent owners exploit this by filing lawsuits against entire industries, hoping that some defendants will find it cheaper and less disruptive to license a patent of questionable validity rather than spend the time and money to attempt to invalidate the patent. The licensing of weak or invalid patents resulting from

^{6.} See James Bessen and Michael J. Meurer, Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk 131-33 (2008).

^{7.} 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 (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.").

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 note 3, Ch. 5, at 2-4; Jaffe and Lerner, supra note 7, at 115 ("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.").

This "tax" is especially burdensome in the information technology industry, where a product can be covered by hundreds, if not thousands, of patents. The costs required to defend against weak and invalid patents stifles innovation and diverts resources that could otherwise be spent on research and development and job creation. See generally FTC Innovation Report, Ch. 2 at 28-29; 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).

Issued pharmaceutical patents are also particularly valuable, regardless of validity, because by statute the patentee can automatically restrain generic competition for at least two and a half years. 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.

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 the patent, the applicant would have faced the choice of either abandoning the application or challenging the rejection on appeal.

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 Petitioner 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 likely 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 even as to information not before the examiner substantially enhances an already powerful incentive to conceal potentially invalidating prior art and other information. It would be naïve to assume that applicants rarely succumb to such temptations.

Moreover, even if one also assumes that most patent lawyers and inventors will attempt to comply with their legal duty to disclose potentially invalidating information to the examiner, despite the powerful economic incentives to conceal, they will also be inclined to withhold material information on any colorable rationale. Indeed, 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 plausible argument whatever that the information need not be disclosed. Any colorable doubt 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 or the Patent Office, there will rarely be any serious adverse consequence, and a valuable patent may result.

On the other hand, if the failure to disclose potentially invalidating prior art or other information had the effect of reducing the burden of proving invalidity in later patent litigation, applicants would have some incentive both to discover problematic information before filing and to submit it to the examiner. If an applicant thought the examiner could be persuaded that the information did not render the claimed invention unpatentable, or if the claim itself could be refined to avoid the effect of the information, the resulting patent would be far less vulnerable to subsequent challenge. Under the Federal Circuit's current jurisprudence, however, such incentives to improve the quality of information available to the examiner do not exist.

C. The inequitable conduct defense provides only a weak disincentive to concealing potentially invalidating information from the examiner.

Under the Federal Circuit's requirement for clear and convincing proof of invalidity under all circumstances, the only significant factor discouraging the concealment of potentially invalidating prior art or other information from the examiner is the inequitable conduct defense to patent infringement. As the Federal Circuit currently defines the elements of that defense, if an inventor, a patent attorney or some other person involved with the filing or prosecution of the application

^{8.} While persons involved in actual fraud in patent prosecution face the theoretical risk of criminal prosecution, and patent lawyers face additional risks of professional discipline, it is fanciful to think that such matters constitute high priorities for prosecutors and disciplinary authorities. "[N]o one but the accused infringer has the legal and practical resources, as well as the opportunity and incentive, to thoroughly investigate the candor and honesty of the applicant." David Hricik, Wrong About Everything: The Application by the District Courts of Rule 9(b) to Inequitable Conduct, 86 Marq. L. Rev. 895, 933 (2003).

(i) concealed material information from the examiner or made a material misrepresentation to the examiner, and (ii) did 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). At least in theory, if an accused infringer can prove that the patent applicant deliberately concealed material information, then it may avoid liability for infringement, even if it cannot meet the clear and convincing burden of proving invalidity.

However, the effectiveness of this judge-made defense⁹ in encouraging compliance with the patent applicant's disclosure obligations is significantly diminished by the difficulty that defendants face in proving inequitable conduct. If anything, inequitable conduct is harder to prove than invalidity.¹⁰

Under current Federal Circuit case law, before a district court can rule a patent unenforceable because of inequitable conduct in obtaining the patent, it must

^{9.} The defense evolved from decisions of this Court ruling that "fraud or other inequitable conduct" in the procurement or enforcement of patents constitutes a defense to patent infringement claims under the "unclean hands" doctrine. See Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806, 814-16 (1945); Keystone Driller Co v. General Excavator Co., 290 U.S. 240, 244-47 (1933).

^{10.} Petitioner asserted an inequitable conduct defense in this case but was unable to overcome the heavy burden of establishing materiality and intent. See i4i Ltd. Partnership v. Microsoft Corp., 670 F. Supp. 2d 568, 605-606 (E.D. Tex. 2009) aff'd as modified, 589 F.3d 1246 (Fed. Cir. 2009) petition for cert. filed, 79 USLW 3128 (U.S. Aug. 27, 2010)(No. 10-290).

first find 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). 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. Review by the Federal Circuit is highly deferential. The findings on materiality and intent are reviewed for clear error, while the ultimate conclusion is reviewed for abuse of discretion. E.g., Purdue Pharma L.P. v. Endo Pharms. Inc., 438 F.3d 1123, 1128-29 (Fed. Cir. 2006).

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, 438 F.3d at 1134-35, circumstantial proof of intent generally requires at a minimum proof that highly material information, known to the applicant, was concealed or misrepresented, and that the patentee is unable to 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. The Federal Circuit has ruled that the inference of deceptive intent "must... be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard." Star Scientific, 537 F.3d at 1366.

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 the following: "Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?" *Id.* (Order dated April 26, 2010).

If the Federal Circuit answers this question in the affirmative, as the *Therasense* appellant and many *amici* in that case have urged, then the deterrent effect of

^{11.} 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).

the inequitable conduct defense on the concealment of material information will effectively vanish. As a practical matter, the defendant would have to prove by clear and convincing evidence that the patent is invalid by virtue of the information concealed or misrepresented during prosecution in order to establish the inequitable conduct defense. If the Federal Circuit requires proof of invalidity by clear and convincing evidence to assert the inequitable conduct defense, it will always be easier for the patentee to address potentially invalidating information in patent litigation, than to persuade the examiner in the first instance that the information does not preclude patent issuance. A patent applicant would face no risk that the concealment of potentially invalidating information would prevent the enforcement of an otherwise valid patent. This would leave patent applicants with virtually nothing to lose, and much to gain, from concealing problematic information from the examiner.

In short, the Federal Circuit's requirement that invalidity be proven by clear and convincing evidence, even as to information not before the examiner, encourages patent applicants to play "hide the ball" with the Patent Office. There is very little to discourage them from doing so. These are not incentives calculated to maintain the integrity of a patent system that is wholly dependent upon the candor of patent applicants.

CONCLUSION

The petition for a writ of certiorari should be granted.

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September 29, 2010