

Microsoft, Therasense and Burdens of Proof

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The Court of Appeals for the Federal Circuit has complained that "the habit of charging inequitable conduct in almost every major patent case has [been] an absolute plague."^[1] In almost every case in which inequitable conduct is alleged, the assertion is predicated on a failure to disclose information in patent prosecution, often relevant prior art.

Since 1982, the Federal Circuit has repeatedly restated the elements and burden of proof in inequitable conduct cases, it has redefined the meaning and level of materiality, and it has re-described the relationship between intent and materiality.

On Nov. 15, 2010, *Therasense Inc. v. Becton Dickinson and Co.*, No. 2008-1511o (Jan. 25, 2010), was argued en banc. In *Therasense*, the nondisclosed information was not prior art. Instead, the litigated patent was initially declared "unenforceable for inequitable conduct based on a failure to disclose statements made to the European Patent Office (EPO) during a revocation proceeding."

The Federal Circuit ordered en banc review to consider whether "the materiality-intent-balancing framework for inequitable conduct [should] be modified or replaced?" and if so, how? The Federal Circuit also asked for briefs addressing whether the standards should "be tied directly to fraud or unclean hands," the "proper standard for materiality," and the circumstances in which it is proper to infer intent from materiality.

Prior to oral argument, it might have been anticipated that the Federal Circuit would again answer these questions by narrowing the range of cases in which inequitable conduct may be asserted, for example by reinvigorating a "but for" test of materiality or by enhancing the type of required proof of intent.^[2]

However, oral argument and the questions asked by the court left one guessing at the direction the Federal Circuit may take, or whether any change will occur at all.^[3] A critical moment occurred during questioning of Abbott's counsel (the patentee), in rebuttal.

The court asked whether the challenged conduct would "satisfy the but-for causation test?" Abbott's counsel replied it was necessary, but it could not meet that test.^[4] An opposite answer may have ensured affirmance. However, if the conduct challenged in *Therasense* did not satisfy the but-for causation test, almost no case would.

The Therasense Facts

The patent in *Therasense* covered disposable diabetes glucose test strips, which measure the level of glucose in a sample of blood, usually a single drop. A prior art patent, U.S. 4,545,382 (the '382 patent), issued to the same inventors, disclosed strips as follows: "Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules."

In the EPO, Abbott was faced with possible revocation of a European counterpart to Abbott's '382 patent, EP 0 078 636 (the '636 patent), a patent "with virtually identical specifications." The '636 patent was revoked as obvious over a German reference. In the EPO, Abbott argued that the '636 patent was distinguishable from the German reference because the "optionally, but preferably" language in the EU '636 patent, identical to the language in the US '382 patent, was "unequivocally clear" and that the "protective membrane [described in the EU '636 patent] is optional, however, it is preferred when used on live blood."

Abbott pursued the patent for 13 years in the USPTO through several continuation applications that were repeatedly rejected for anticipation and obviousness, including rejections over the prior art '382 patent. However, none of the EPO statements and proceedings were disclosed to the USPTO.

At some point, new claims were drafted including electrochemical sensors lacking a membrane. Abbott argued that they were novel because they taught a sensor that "did not require a protective membrane when testing whole blood." Abbott argued that "optionally, but preferably" would not have been read by a person having ordinary skill in the art (PHOSITA) to confirm that "a membrane is not necessary when testing live blood in vivo or whole blood in vitro."

In litigation over the U.S. patent, the trial court found that Abbott's EPO statements directly contradicted its representations to the USPTO. By describing the "[o]ptionally, but preferably" language as "unequivocally clear," in the EPO, Abbott contradicted representations to the USPTO that a PHOSITA would have understood the words as mere "patent phraseology" that "did not convey a clear meaning." Rejecting the prosecuting attorney's testimony, the trial court stated:

"This argument conveniently overlooks the fact that he consciously chose to withhold. Counsel who steer a course toward obtaining a strong patent should err on the side of disclosure, not nondisclosure. And, it must be said, after so many rejections over so many years, it seems clear that Abbott's primary goal was to eke out some claim, saving a fight over enforceability for a later day."^[5]

The inventor disclosed the inconsistent EPO information to the patent prosecutor, and "made direct representations to the USPTO — representations that were materially misleading by omission." Thus "he was obligated to avoid intentional deception," and was "duty-bound to avoid making an intentionally misleading submission, whether or not he told [the prosecuting attorney] about the inconsistency."^[6] The trial court found that the patentee's "explanations for withholding the EPO documents were so incredible that they suggested intent to deceive."^[7]

The Initial Therasense Appellate Opinion

As the initial Federal Circuit panel noted, these findings were based on assessments of credibility that are "virtually unreviewable" and were "amply supported." Even under the clear and convincing evidence standard, the Federal Circuit panel found no error in the trial court's finding of bad faith or intent to deceive the USPTO, by withholding the EPO documents.

The panel concluded that the withheld EPO information was “highly material” and that to “deprive an examiner of the EPO statements — statements directly contrary to Abbott’s representations to the USPTO — on the grounds that they were not material would be to eviscerate the duty of disclosure.” It found that the district court did not abuse its discretion in holding the Abbott patent unenforceable due to inequitable conduct.[8]

If intentional nondisclosure of “highly material” information does not “satisfy the but-for causation test,” what does? In *Therasense*, the inventor admitted “that he affirmatively participated in the group discussion not to disclose the EPO submission, i.e., that he knew all along that no one was going to disclose the EPO submissions.” *Id.*, 565 F.Supp. at 1115.

What more should be required?

For those, like the trial court and the initial Federal Circuit panel, who may have found the challenged nondisclosure to be the type that should invalidate a patent for “unclean hands” or “fraud,”[9] the compulsion to adopt a lesser standard, or at least a standard other than the “but-for causation test,” may have been increased by a response that the challenged conduct would not “satisfy the but-for causation test.”

To ensure that candid disclosures are made to the USPTO, a lower evidentiary standard may be required, so that the type of conduct challenged in *Therasense* is condemned and the appropriate incentive to candor is created.

Microsoft: An Intervening Event

Intervening action by the U.S. Supreme Court may well have changed the outcome of *Therasense* or, at least, the framework in which a decision will be rendered. On Nov. 29, the Supreme Court granted Microsoft’s petition in *i4i LP, et al. v. Microsoft Corp.*,[10] patent litigation resulting in a \$290 million damages award and a permanent injunction restraining Microsoft from selling certain versions of its best-selling Microsoft Word product.

The Supreme Court granted certiorari to consider whether, in determining patent validity, the courts must require proof by clear and convincing evidence, rather than a preponderance of the evidence, especially where invalidity is based on prior art unreviewed during patent prosecution.

The Microsoft Facts

In *Microsoft*, the patent related to a “metacode map” that allows a computer “to understand the meaning behind certain text that a user placed in document,” without reference to the content of the text.[11] XML is a markup language that uses such “metacodes.”

In 2003, Microsoft introduced a version of Word with XML editing capabilities. The plaintiff, *i4i*, accused Microsoft of willful infringement. Microsoft claimed that its products did not infringe and that the patent was invalid for inequitable conduct.

The inequitable conduct allegation centered on the plaintiff's sale of the "S4" product prior to filing of the first patent application. Microsoft asserted that the S4 product embodied the patented invention, and that the patent was invalid because "the inventor failed to disclose the S4 system to the USPTO."

The trial court found no dispute that "the S4 system was not specifically disclosed," that it is prior art, and that the S4 product employed a markup language, marketed and put to use more than a year before the first patent application was filed.[12] The parties dispute was "whether S4 was material to patentability because it taught the 'metacode map' limitation and whether [the inventor] had deceptive intent in failing to disclose the prior art."

The "source code of S4 certainly would have been an ideal and key piece of evidence." By the time of trial, however, the source code was discarded and could not be found. Moreover, the inventors testified that they "could not remember the internal operation of S4." [13]

While facts relating to the S4 source code may not have provided "clear and convincing evidence" of "unclean hands" or "fraud," they may well have undermined the basis for the USPTO's judgment that the patent should be issued. Nevertheless, Microsoft's other invalidity arguments were determined at trial under the same clear and convincing evidence standard. Unlike the parties in *Therasense*, however, Microsoft argued that a different standard should apply.

The Microsoft Trial Court Opinion

The trial court found testimony about materiality and deceptive intent to be insufficient when considered under the "clear and convincing evidence" standard, and refused to invalidate the i4i patent for inequitable conduct.[14] The trial court also rejected Microsoft's other invalidity arguments, holding that the "burden remained on Microsoft to prove invalidity by clear and convincing evidence." [15]

Microsoft sought a new trial, quoting the Supreme Court's statement in *KSR International Co. v. Teleflex Inc.* that "the rationale behind the clear and convincing evidence standard seems 'much diminished' when defendants present evidence of prior art not considered by the USPTO." [16] The trial court rejected these arguments as well. [17]

Microsoft in the Federal Circuit

Microsoft's similar arguments were rejected by the Federal Circuit, which affirmed the judgment and injunction issued against Microsoft:

"We conclude that the jury instructions were correct in light of this court's precedent, which requires the challenger to prove invalidity by clear and convincing evidence. This court's decisions make clear that the Supreme Court's decision in *KSR* ... did not change the burden of proving invalidity by clear and convincing evidence. Thus, based on our precedent, we cannot discern any error in the jury instructions." [18]

Microsoft petitioned the Supreme Court for review, focusing solely on the question “Whether the Court of Appeals erred in holding that Microsoft’s invalidity defense must be proved by clear and convincing evidence.”

Microsoft and Therasense Intersect

One of the amicus briefs filed in support of Microsoft’s petition noted the direct connection between the issue raised in the petition and the issues pending in Therasense.[19] After noting the conflict between the Federal Circuit’s unwavering application of the clear and convincing standard, and the more flexible standard applied by all of the regional circuit courts after enactment of the modern Patent Act in 1952, the Teva and Cisco amicus brief described an “additional reason” supporting Microsoft’s request for Supreme Court review.

In words evocative of the trial court’s comments in Therasense,[20] the brief argued that the Federal Circuit rule “encourages patent applicants to forgo 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.”

Because litigants bear the burden of proving invalidity by clear and convincing evidence, it argued, it is to the patentee’s advantage “if problematic information is considered for the first time in patent litigation and not by the examiner during patent prosecution,” because “such evidence will carry less weight than it would have carried with the patent examiner.”

On the other hand, the brief asserted, if patent applicants know that the “preponderance of the evidence standard will apply in case involving previously undisclosed information — the incentives to willful ignorance and active deception created by the Federal Circuit’s rule would be significantly reduced.”[21] The “incentive to suppress material information,” the brief argued, “is not significantly counterbalanced by the inequitable conduct defense,” which is “even more difficult to establish than invalidity.”

This is particularly true because, in inequitable conduct cases, the inference of deceptive intent in non-disclosure of even highly material information must be “the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing evidence standard.”[22]

Implications

The “absolute plague” of inequitable conduct allegations is a by-product of the Federal Circuit’s inflexible application of the clear and convincing evidence to overcome the statutory presumption of patent validity.[23] Alteration of this inflexible requirement may provide a vaccine against the “plague.”

If Microsoft has the better argument, the Supreme Court might well again reverse Federal Circuit precedent and rule that patent invalidity may be established by a preponderance of evidence, at least where the defense is based on previously unreviewed information. Application of the clear and

convincing evidence standard supposedly “rests on the ‘basic proposition that a government agency such as the then Patent Office was presumed to do its job.’”[24]

However, “the strength of the presumption should logically depend on the depth and quality of the review the USPTO actually gave to an application.”[25] Whatever the implications of the “basic proposition as a matter of administrative law, the USPTO cannot remotely be “presumed to do its job” when the relevant evidence was never before it.”[26] As other courts have said:

“Where the validity of a patent is challenged for failure to consider prior art, the bases for the presumption of validity, the acknowledged experience and expertise of the Patent Office personnel and the recognition that patent approval is a species of administrative determination supported by evidence, no longer exist.”

In such cases, “there is no factual determination with respect to patentability that warrants deference in the form of a clear-and-convincing-evidence standard.”[27]

In many cases the fact of nondisclosure is undisputed. In such cases, if invalidity may be proven by a preponderance of the evidence, a patent challenger might well choose to refrain from asserting a defense of inequitable conduct to avoid the impact of the clear and convincing evidence burden. While this may change the nature of the “plague” and, in some cases, make it easier to prove a patent’s invalidity, the change may well be warranted, both by law and policy.

Invalid patents “stifle, rather than promote, the progress of useful arts.”[28] As the Supreme Court noted in *KSR*, “Invalid patents confer market power ‘without consumer benefit,’ encourage litigation, raise ‘transaction costs,’ and create uncertainty that ‘may deter investment in innovation and/or distort its direction.’”[29]

While patent litigation has been “an important tool for ‘weeding out ... those patents that should not have been granted,’” it is also an expensive and inefficient tool when a heightened burden of proof allows patents to survive that would never have been issued if they had been examined, in light of all relevant evidence and without benefit of the protection of a “presumption of validity” enforced through application of the clear and convincing evidence standard.[30]

The more “important tool” for “weeding out” bad patents is examination in the USPTO with an enhanced incentive for full disclosure by patent applicants, even of evidence that may undermine a pending application. Full disclosure, of course, will also serve to diminish the “absolute plague” of inequitable conduct allegations, especially those based upon nondisclosure of important information, like the allegations in both *Therasense* and *Microsoft*. When “highly material” information is disclosed, an element of both inequitable conduct and other invalidity arguments will be missing.

Arguments will be made, as they were in *Therasense*, that patent examiners are already overloaded and that a reduced burden in litigation will provoke pernicious “data dumping” by patent prosecutors, who may choose to inundate overburdened examiners with marginally relevant information, in order to avoid later charges of nondisclosure in an environment governed by proof by a preponderance of evidence. These arguments miss two points.

First, alteration of the evidentiary standard, in cases in which an assertion of invalidity is based on nondisclosure of “highly material” information that a patent examiner did not review during patent prosecution, does not eliminate the statutory presumption of patent validity.

The burden will remain with a patent challenger to adduce evidence that demonstrates prima facie invalidity. Hence, it will not be a patentee’s nondisclosure of any evidence that will result in enhanced risk. Only nondisclosure of important or “highly material” information will persuade a fact finder that the initial burden has been met. That burden, of course, can be rebutted in a number of ways, whatever the burden of proof on the accused infringer.

Second, because invalidity will be established by nondisclosure of important information, “data dumping” is unnecessary and even counterproductive. Such “data dumping” may even yield charges that a patentee endeavored to conceal important information as a needle in a “data dumped” haystack.

Instead, what will be required is real candor: in order to secure a strong patent a patentee will be required not only to disclose, but also to point out, what is important, and not simply to provide an examiner with everything or nothing.

The beneficial effects on patent prosecution and on the patent system are self-evident. In an environment in which candid and full disclosure is encouraged, examiners will be better able to do their job, with the assistance of a patentee’s counsel, and the presumption of validity will be more meaningful, because it will be applied to well-examined patents that embody real, novel invention, and that have earned the monopoly that patents confer.

[1] *Burlington Indus. Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

[2] See, e.g., *Exergen Corp. v. Wal-Mart Stores Inc.*, 573 F.3d 1312 (2009).

[3] See Transcript of Argument, <http://www.patentlyo.com/files/therasense-v-becton---transcription.pdf>.

[4] Tr. 55, lines 14-16.

[5] *Therasense, Inc. v. Becton-Dickinson and Company*, 565 F.Supp. 108, 1113-15 (N.D. Cal. 2008).

[6] *Id.*, at 1115.

[7] *Therasense, Inc. v. Becton-Dickinson and Company*, 593 F.3d 1289, 1306 (Fed. Cir. 2010).

[8] *Id.*, at 1305 - 08.

[9] See *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944); *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945).

[10] 670 F. Supp. 2d 568 (E.D. Tex. 2009), *aff'd* 598 F.3d 831 (Fed. Cir. 2010)(hereinafter *Microsoft*).

[11] *Microsoft*, 670 F.Supp.2d at 573.

[12] *Id.*, at 606.

[13] *Id.*, at 605.

[14] *Id.*, at 607.

[15] *Id.*, at 585.

[16] *Id.*, citing *KSR*, 550 U.S. 398, 426, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007).

[17] *Id.*, at 588.

[18] *Id.*, 598 F.3d at 864, 898.

[19] See Teva and Cisco Amicus Brief, at <http://www.i4ilp.com/court/i4i%20--20Teva%20Amicus%20Br.pdf> (last visited Dec. 3, 2010).

[20] Therasense, 565 F.Supp. at 1113-15.

[21] Teva and Cisco Amicus Brief, *supra*, at 4-5.

[22] *Id.*, at 17, quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008).

[23] See *Connell v. Sears, Roebuck & Co.*, 772 F.2d 1542 (Fed. Cir. 1983); *Kahn v. General Motors Corp.*, 135 F.3d 1472, 1480 (Fed. Cir. 1998). Compare *American Hoist & Derrick Co. v. Sowa & Sons Inc.*, 725 F.2d 1350 (Fed. Cir. 1984). See also Law Professor' Amicus Brief, *supra*, at 7.

[24] Petition for Certiorari, at 16, <http://www.i4ilp.com/court/Petition%20for%20a%20Writ%20of%20Certiorari.pdf> (last visited Dec. 2, 2010).

[25] Law Professor' Amicus Brief, at 3, <http://www.i4ilp.com/court/i4i%20--%20Law%20Professors'%20Amicus%20Br.pdf> (last visited Dec. 2, 2010).

[26] Petition for Certiorari, *supra*, at 16.

[27] *Id.*, quoting *Baumstimler v. Rankin*, 677 F.2d 1061, 1066 (5th Cir. 1982).

[28] KSR, 550 U.S. at 427; Petition for Certiorari, at 19.

[29] *Id.*, citing Nat'l Research Council, *A Patent System for the 21st Century* 95 (2004), available at <http://www.nap.edu/html/patentsystem/0309089107.pdf>.

[30] *Id.*, at 21.

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