## THERASENSE—WILL IT MAKE SENSE? WILL THE LAW OF INEQUITABLE CONDUCT FINALLY BE FIXED? AND WHEN?



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Readers of past editions of this
newsletter may recall that last
year, the newsletter predicted
that by year end 2010 the

Federal Circuit would work big changes in the patent law doctrine of inequitable conduct.<sup>1</sup> Did it happen? No. Was there a reason? Yes, a simple one. The case is taking longer than expected. Any day now, however, the decision in *Therasense*,<sup>2</sup> the case to potentially make the changes, will issue. Will it make sense? Will it work big changes? And will it finally fix the law of inequitable conduct? The answer to each of these questions, now after oral argument, is: don't bet the farm.

The Federal Circuit heard the oral arguments in *Therasense* in November. Instead of continuing the potential for big change to the law that was signaled by the Federal Circuit's initial listing of the questions for which it wanted argument, the oral argument signaled that the change to the law could range from big change to some change to little change at all.

The only striking aspect of argument was that the advocate for the United States Patent and Trademark Office (USPTO) admitted that under current standards, which include the current Rule 56 standard for which he advocated, the Patent Office was experiencing the disclosure of so many prior art references by so many applicants that it had labeled the practice as "reference flooding." The advocate also volunteered that the USPTO knew applicants

were acting in fear and did not know what to disclose.

In spite of this admission, however, and in spite of setting the case up as if the whole of the framework of law for inequitable conduct was in question, the Federal Circuit at oral argument revealed it may only change inequitable conduct law in nuanced and minor ways. In spite of reference flooding as a compelling reason to narrow the law, some judges were focused solely on

the potential for applicants to commit inequitable conduct under a significantly narrowed rule of law. Other judges were focused solely on a companion issue, the lack of precedents for a narrow "but for" standard of a narrowed rule.

Questioning by the judges of all advocates speaking on materiality at the oral argument revealed that, perhaps to get to a unifying decision of the Court, the judges may invent a new, "midrange" standard of materiality: a standard having a scope somewhere between the "but for" materiality and the section (b)(1) materiality of the current Rule 56 of the Patent Office<sup>3</sup>—the narrow side of materiality—and section (b)(2) of the current Rule 56—the broad side of materiality.

The judges were accepting of the part (b)(1) of the rule, which states that information is material if it "establishes, by itself or in combination with other information, MORE.



- See "Federal Circuit Signals Big Changes On Inequitable Conduct Likely By Year End 2010."
- Therasense, Inc. v. Becton Dickinson & Co., No. 2008-1511.
- 3 (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
- (i) Opposing an argument of unpatentability relied on by the Office; or
- (ii) Asserting an argument of patentability.

## [THERASENSE, FROM PAGE 17]

a *prima facie* case of invalidity of a claim." This is somewhat broader than the narrow "but for" materiality," but not truly broad.

The judges were not accepting of part (b)(2) of the rule, that information is material if it "refutes, or is inconsistent with, a position an applicant takes in opposing an argument of unpatentability relied on by the Office," or a position the applicant takes in "asserting an argument of unpatentability." This standard is truly broad. More than one judge spoke out against the (b)(2) standard, the most notable assertion being that it was broad and amorphous, and would swallow up any other definitional aspect of "materiality." An example

was that the Court should state that intent could not be inferred from materiality alone, and that wrongful intent had to be the single most reasonable inference from the evidence. This, however, is essentially no change from recent Federal Circuit case law. Uniformity of suggestion to reinforce the intent standard of the *Kingsdown* case would also cause no change in the law, as that case articulated only a language variation that wrongful intent must be the single most reasonable inference from the evidence.

In the author's opinion, and his alone, with no change to the (b)(1) standard of materiality, and no change to the standard

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given was that if an applicant argued for nonobviousness, inequitable conduct under the (b) (2) standard could be asserted in any failure to disclose any known information tending toward obviousness.

The potential change of the case is not as predictable in part because the oral argument lacked for responses to obvious questions of the Court. In a golden opportunity, an advocate was invited to suggest the articulation of a standard that would lie between the (b)(1) standard and the (b)(2) standard, and overcome the problem of the stated example. The advocate involved failed to respond meaningfully.

The potential of the case for drama was also reduced because on the intent aspect of inequitable conduct, there was an apparent consensus among the advocates, rather than a vigorous dispute that could lead to significant analysis and change. The apparent consensus

of intent, patent prosecutors will not enjoy inequitable conduct law gaining the sense it now lacks. There will be no fix of the law. Prosecutors will continue to be concerned that they cannot know what they can refrain from disclosing, and cannot assure that their good intentions will be assessed so as to prevent conclusions of inequitable conduct. They will worry that the one or two references they do not disclose will be considered to make out a prima facie case of invalidity of one or more claims, and that inability to remember later why references were not disclosed, will subject them to decisions against them and their licenses to practice. And with no change to prosecutor worries, the USPTO will continue to get flooded.

Banner & Witcoff will continue to monitor and report the case as more information becomes available.