Patent Law Update: Therasense v. Becton Dickinson

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Federal Circuit Inequitable Conduct Oral Argument Reverses Signals, and Now Portends Little Change Likely in the Law of Inequitable Conduct

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On November 9, 2010, the Federal Circuit Court of Appeals heard oral arguments in the potentially landmark inequitable conduct case *Therasense, Inc. v. Becton Dickinson & Co.*, No. 2008-1511. 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 little to no change may come to the law of inequitable conduct as a result of the case.

The oral argument was disappointing to those hoping for big changes for both its lack of range and lack of response to obvious questions of the Court. Remarkable, however, was the United States Patent and Trademark Office (USPTO) representative at argument freely admitting under questioning that the USPTO is experiencing a phenomenon so unusual that it was given a label during argument – "reference flooding" – *i.e.*, the overloading of the USPTO with prior art citations, "references," by applicants acting out of fear of inequitable conduct charges.

Argument began with the effort to narrow the materiality standard of inequitable conduct to a "but for" standard. The focus was a proposed standard under which inequitable conduct should be found only where bad conduct had resulted in the award of a patent that the applicant would not otherwise have gained. The argument asserted this standard was a correct reflection of United States Supreme Court decisions that established inequitable conduct as a doctrine, but the argument failed when a judge both read the Restatement of the law to the contrary, and asserted language that he was prepared to read from a Supreme Court case that was to the contrary. The advocate involved had no suitable response.

Questioning of all advocates speaking on materiality revealed that the judges are likely to invent a new standard for the law, a standard having a scope somewhere between "but for" materiality and section (b)(1) of the current Rule 56 of the USPTO, on the narrow side of materiality, and section (b)(2) of the current Rule 56, on the broad side. The judges were accepting of the part (b)(1) of the rule, that information is material if it "establishes, by itself or in combination with other information, a *prima facie* invalidity of a claim." This is broader than the narrow "but for" materiality." The judges were not accepting, however, 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."

More than one judge spoke 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 given was that if an

applicant argued for non-obviousness, inequitable conduct could be asserted in any failure to disclose any known information tending toward obviousness. 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.

On the intent aspect of inequitable conduct, consensus among the advocates 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.

Striking during argument – the only striking aspect of argument – was the freely made admission by the advocate for the USPTO that under current standards, including the Rule 56 standard for which he advocated, the USPTO 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. The advocate justified his position by asserting the Rule 56 standard was focused, definite and tailored. He also asserted the "reasonable examiner" standard still in use in the courts was the problem. The judges did not seem accepting of this argument.

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. Judges were focused solely on the potential for applicants to commit inequitable conduct under a significantly narrowed rule of law. Other judges were focused on the lack of precedents for a "but for" standard. No judge expressed the Court's willingness to replace older Federal Circuit law as expressed for example by *In re Seagate* as to willfulness of infringement. Indeed, willingness for significant change was absent from any aspect of the *Therasense* oral argument. The apparent disposition for only small changes is noteworthy in spite of more amicus briefs with more force toward change filed at the Federal Circuit in this case than possibly any other case in the history of the Court.

The decision of the Court is expected to issue in early March 2011.

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

Please click here to view the transcript of the argument.

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