June 2, 2011

The Federal Circuit Redefines Inequitable Conduct

In *Therasense, Inc. (now Abbott Diabetes Care) v. Becton, Dickinson and Company* (Fed. Cir., May 25, 2011) (en banc), the Federal Circuit recalibrated the test for rendering a patent unenforceable based on inequitable conduct by the patentee. *Therasense* held one must now show that the patentee specifically intended to deceive the patent office and that the deception materially affected the outcome of the patent process. Intent and materiality are now separate requirements. For allegations that a reference was withheld from the patent office, one must now show by clear and convincing evidence that the patentee "knew of the reference, knew that it was material, and made a deliberate decision to withhold it" *and* that, "but for" this misconduct, the patent would not have been issued. The "but-for" test of materiality raises the hurdle for the party trying to show inequitable conduct based on omitted prior art. In addition, this decision does away with the "sliding scale" formulation, whereby a strong showing of materiality, coupled with weak evidence of intent (or vice versa), could establish inequitable conduct. The intent and materiality prongs of the inequitable conduct doctrine have been decoupled, which further tightens the standard for inequitable conduct. The *Therasense* court did create an exception to the new materiality standard for "affirmative egregious misconduct." The Court vacated the district court's finding of inequitable conduct and remanded for further findings in light of the revised standards.

I. Background Facts

Abbott asserted infringement of U.S. Patent No. 5,820,551 for a Strip Electrode with Screen Printing, used as a disposable blood test strip for diabetes management that employs electrochemical sensors to measure blood glucose. During prosecution of the '551 patent, Abbott had submitted an affidavit stating that prior art patent 4,545,382, owned by Abbott, disclosed a device which "required" a protective diffusion-limiting membrane to control the flow of blood to the electrode. However, when prosecuting a foreign counterpart application to the '382 patent, Abbott had submitted a brief arguing that the device disclosed in the '382 patent did not require a membrane, and never submitted a copy of the brief to the USPTO when prosecuting the '551 patent. The District Court held the '551 patent unenforceable due to inequitable conduct.

II. The Doctrine of Inequitable Conduct before *Therasense*

The doctrine of inequitable conduct arose from a trio of Supreme Court cases that applied the doctrine of unclean hands, based on egregious misconduct, to dismiss patent cases: *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), and *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945). As it had developed, the doctrine had embraced both egregious affirmative acts of misconduct intended to deceive the USPTO (or the courts) and the nondisclosure of information to the USPTO. The remedy for such misconduct was not dismissal of the lawsuit, however, but a declaration that the entire patent at issue - and possibly "related patents and applications in the same technology family" as well - were unenforceable.

Although the Federal Circuit's previous tests for inequitable conduct had required a showing of intent (as opposed to negligence or even gross negligence), the *Therasense* court decided that previous tests were not sufficient to deter inequitable conduct allegations "plaguing" almost every major patent case and causing ripple effects through the entire patent system. It found that allegations of inequitable conduct "conveniently expand discovery into corporate practices before patent filing," "cast a dark cloud over the patent's validity," "discourage settlement and deflect attention from the merits of validity and infringement issues," and "increase the complexity, duration and cost of patent infringement litigation that is already notorious for its complexity and high cost." The Court called the doctrine of inequitable conduct "the 'atomic bomb' of patent law."

III. How *Therasense* Changes the Playing Field

i. The Standard for Intent, Decoupled from Materiality

The Federal Circuit emphasized the need for specific proof of the intent prong of the inequitable conduct doctrine, and, in decoupling that prong from the materiality prong, reinforced that such proof of intent is required for every case. The Court reaffirmed that specific intent to deceive the patent office must be proven by clear and convincing evidence. In the case of a withheld reference, this means that the patentee "knew of the reference, knew that it was material, and made a deliberate decision to withhold it." If proven by circumstantial evidence, this specific intent must be "the single most reasonable inference able to be drawn from the evidence...requir[ing] a finding of deceitful intent in the light of all the circumstances." When multiple reasonable inferences are available, "intent to deceive cannot be found." In addition, the patentee need not provide a good-faith explanation of its acts unless the infringer first proves a threshold level of intent to deceive by clear and convincing evidence.

Notwithstanding the high bar for proving intent to deceive, litigants have sometimes in the past hurdled this bar by arguing that omitted information was so material that an intent to deceive must be inferred. In the past, courts were permitted to consider materiality and intent together on a sliding scale- the more material the omission, the more reasonable the inference that its omission was intentional. *Therasense* breaks the link between intent and materiality. An accused infringer must now prove the intent element separately, irrespective of the materiality of an omitted reference.

ii. The Standard for Materiality

The Court raised the bar for showing materiality, in most cases requiring "but-for" causation. Previously, an omitted reference could be material even if not critical to the outcome of examination merely if a "reasonable examiner would consider [the information] important in deciding whether to allow the application." The *Therasense* case forecloses that argument. Now, omitted prior art is "but-for material" when, giving the claims their broadest reasonable construction, the patent office would not have allowed a patent claim in light of the omitted reference. If an omission is not the "but-for" cause of the issuance of a claim, the omission is immaterial. Because the new standard turns on action in the patent office, which uses a preponderance of the evidence standard for patentability, an omitted reference may be material for purposes of the inequitable conduct defense even if insufficient to render a claim invalid in the district court, where the higher clear-and-convincing burden of proof applies.

The Court noted an exception to its new "but-for" standard. Egregious affirmative acts by the patentee, such as "deliberately planned and carefully executed scheme[s] to defraud the PTO and the courts," are material, without the need to also show "but-for" causation. The reason for this exception, the Court explained, is that a patentee will not go to such "great lengths to deceive the PTO with a falsehood unless it believes that the falsehood would affect issuance of the patent." The Court cited the filing of an "unmistakably false affidavit" as an example of an affirmative act falling under this exception, but made clear that this exception is intended to be flexible enough to capture other egregious affirmative misconduct.

Notably, the Court did not adopt the patent office's administrative definition of materiality under 37 C.F.R. 1.56 ("Duty to disclose information material to patentability") ("Rule 56") for inequitable conduct allegations in litigation, although that definition continues to apply to the administrative process before the patent office. Responding to a criticism in the dissent, the *Therasense* majority concluded that tethering the litigation defense to Rule 56 had led to "uncertainty and inconsistencies in the development of the inequitable conduct doctrine."

IV. What This Means to You

In this decision, the Court expressly hopes to limit application of the inequitable conduct defense to "instances where the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim." Such a result would certainly be welcomed by patent prosecutors, whose reputations have often been put at issue. The Commissioner of Patents and Trademarks has announced that the patent office is reviewing the decision and will issue future guidance to patent practitioners. For the time being, however, those seeking patents and involved with patent prosecution must continue to take care, as the duty of candor under Rule 56 continues to apply throughout the pendency of a patent application and is unaffected by *Therasense*.

Therasense does not spell the end to all inequitable conduct claims. However, the bar has certainly been raised, especially for misconduct by omission. Becton, Dickinson and Company has moved to stay issuance of the Federal Circuit's mandate in order to seek review by the Supreme Court.

If you have questions concerning the future implications of *Therasense*, give us a call.