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Therasense Inequitable Conduct Guidelines Explained

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Applying the inequitable conduct guidelines it announced in its *en banc* ***Therasense*** **decision (**see *IP Update*, Vol. 14, No. 6), the U.S. Court of Appeals for the Federal Circuit vacated a district court's holding of **inequitable conduct** in a 2008 decision that preceded *Therasense*. ***American Calcar, Inc. v. American Honda Motor Co.*****,** Case Nos. 09-1503, -1567 (Fed. Cir., June 27, 2011) (Lourie, J.).

Following a jury trial, the district court held a number of Calcar's patents unenforceable due to inequitable conduct, among its other rulings. As a preliminary matter, the Federal Circuit confirmed that the jury's advisory verdict of no inequitable conduct was not binding on the district court because there is no Seventh Amendment right to a jury trial on inequitable conduct.

Although the jury rejected Honda's invalidity arguments based on certain prior art, the district court held that inequitable conduct was committed for failure to disclose this prior art to the U.S. Patent and Trademark Office (USPTO). American Calcar appealed.

The Federal Circuit vacated the district court's materiality finding because the district court applied the **"reasonable examiner" standard, rather than the *Therasense* "but-for" materiality standard.** The Federal Circuit instructed the district court to determine whether the USPTO would have granted the Calcar's patents but for Calcar's failure to disclose the prior art. The Federal Circuit also vacated the district court's intent finding because it "made no holding that any of the inventors knew that the withheld information was in fact material and made a deliberate decision to withhold it" and instead applied the sliding scale standard of intent based on materiality rejected in *Therasense*. Noting that the district court found Calcar's testimony lacking in credibility, the Federal Circuit instructed the district court to "make a specific finding on whether any of the three inventors knew that withheld information was material and whether they made a deliberate decision to withhold it."

Practice Note: The USPTO has now published a notice in the Federal Register that it proposes to modify the duty of disclosure rules by limiting the scope of materiality in a manner consistent with the "but for" standard announced in the *Therasense* decision. As stated in the notice:

> Specifically, the Office is proposing to revise the materiality standard for the duty to disclose to match the materiality standard, as defined in *Therasense*, for the inequitable conduct

doctrine. While *Therasense* does not require the Office to harmonize the materiality standards underlying the duty of disclosure and the inequitable conduct doctrine, the Office believes that there are important reasons to do so. The materiality standard set forth in *Therasense* should reduce the frequency with which applicants and practitioners are being charged with inequitable conduct, consequently reducing the incentive to submit information disclosure statements containing marginally relevant information and enabling applicants to be more forthcoming and helpful to the Office. At the same time, it should also continue to prevent fraud on the Office and other egregious forms of misconduct. Additionally, harmonization of the materiality standards is simpler for the patent system as a whole.

The newly proposed Rule 56(b) (37 C.F.R. 1.56(b)) would read as follows:

Sec. 1.56 Duty to disclose information material to patentability.

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(b) Information is material to patentability if it is material under the standard set forth in *Therasense, Inc. v. Becton, Dickinson & Co*., --- F.3d --- (Fed. Cir. 2011). Information is material to patentability under *Therasense* if:

(1) The Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or

(2) The applicant engages in affirmative egregious misconduct before the Office as to the information.

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Written comments regarding the proposed rule change should be submitted by September 19, 2011.

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