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Intellectual Property
ALERT

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This is an urgent KLIP Alert from the Intellectual Property Department at Kramer Levin Naftalis & Frankel LLP.

INTENTIONALLY WITHHOLDING IMPORTANT INFORMATION FROM THE USPTO STILL HAS SERIOUS CONSQUENCES

In a case closely watched by patent litigators, the Federal Circuit Court of Appeals issued a decision last year that, on its face, seemed to impose tougher requirements for an accused patent infringer to establish that a patent is unenforceable because the patent applicant or the patent attorney intentionally withheld important information in obtaining the patent. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011). While commentators widely proclaimed that *Therasense* had raised the bar so high as to sound the death knell for the inequitable conduct defense, several recent decisions have proved otherwise, and further suggest that, in practice, the bar may have been at the same height all along.

Inequitable conduct is committed when a patent applicant or prosecuting patent attorney *intentionally* fails to disclose *material* information about the invention or the prior art to the U.S. Patent and Trademark Office (USPTO) during the patent application process. In the combined 88 page *Therasense* decision containing majority, concurring and dissenting opinions of the full court, the majority imposed tougher materiality and intent requirements. With respect to materiality, the accused infringer must establish that, had the withheld information been disclosed, the USPTO would not have issued the patent. The Federal Circuit also held that to find sufficient wrongdoing to prevent enforcement of the patent, the trial judge must be convinced that intentional deception by the applicant was the single most likely reason for the failure to disclose; wrongdoing cannot simply be inferred from the high materiality of the withheld information. Prior to *Therasense*, evidence that the prior art was very significant could ostensibly be used to make up for relatively weak evidence of intent to deceive the USPTO (or vice-versa), and it was not necessary to show that the withheld information would actually have prevented the patent from issuing.

Since the *Therasense* decision, several courts that have applied the heightened *Therasense* standard still confirmed their pre-*Therasense* findings that inequitable conduct barred enforcement of the patent. Indeed, in the remand of the *Therasense* case itself back to the trial court, Judge Alsup, after applying the new test, found that specific intent to deceive the USPTO had been proven by clear and convincing evidence and again held the patent unenforceable. *Therasense, Inc. v. Becton, Dickinson & Co.*, 2012 U.S. Dist. LEXIS 42100, at *39-41 (N.D. Cal. Mar. 27, 2012). In the judge's words, "[n]o judge takes any satisfaction in finding fault in the conduct of a professional, . . . however the district judge feels it is his duty to find . . . inequitable conduct, even under the new law to be applied on remand." *Id.* at *40-41.

In the recent *Aventis Pharma S.A. v. Hospira*, *Inc.* case, 2012 U.S. App. LEXIS 7095, at *25-29 (Fed. Cir. Apr. 9, 2012), the Federal Circuit affirmed Delaware district court Judge Sleet's finding of inequitable conduct by virtue of the inventor's failure to disclose two prior art references to the USPTO. The Federal Circuit concluded that Judge Sleet had applied a strict materiality standard of the type articulated in *Therasense*, even though *Therasense* had not yet been decided—evidence that courts were already applying a heightened standard driven by the serious nature of the defense. *Id.* at *19-22. In an even more recent decision, on remand from the Federal Circuit to reconsider under *Therasense*, Southern District of California Judge Sabraw in *Am. Calcar v. Am. Honda Motor Co.*, 2012 U.S. Dist. LEXIS 54059, at *31-32, (S.D. Cal. Apr. 17, 2012) confirmed that three asserted patents were unenforceable due to inequitable conduct by the patent owner company's founder. The court held that the founder was aware of material prior art; that he did not cite it to the USPTO; that had the prior art been cited, the patent application would have been rejected; and that circumstantial evidence overwhelmingly established that the founder acted with a specific intent to deceive the USPTO. *Id.* at *16-32.

In evaluating the extent to which *Therasense* actually raised the bar to establish an inequitable conduct defense, it is important to keep in mind that, even before *Therasense* was decided, courts were very reluctant to find wrongdoing absent both strong evidence of materiality and compelling evidence of intentional deception. In our view, before *Therasense*, trial court judges generally did not take lightly the serious nature of the defense and in practice applied essentially the same strict standard articulated by the Federal Circuit last year. Thus, as a practical matter, inequitable conduct remains a viable defense to protect against unscrupulous inventors, applicants and patent attorneys.
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If you have any questions or would like copies of the decisions referred to, please feel free to contact the authors below or any one of your Kramer Levin attorney contacts::

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