

'Therasense': Vaccine for a plague

The Federal Circuit issued a much needed ruling, tightening requisite proofs to render a patent unenforceable for inequitable conduct.

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Finally, a vaccine for the plague. In *Therasense Inc. v. Becton, Dickinson & Co.*, the U.S. Court of Appeals for the Federal Circuit rendered a much needed decision tightening the analytical framework and requisite proofs to render a patent unenforceable for inequitable conduct in patent litigation. No. 2008-1511 (Fed. Cir. May 25, 2011). Inequitable conduct is a judicial doctrine that was created to address fraud or unclean hands by patent applicants in dealing with the U.S. Patent and Trademark Office (PTO). It theoretically required proof of two elements: First, there must be an intent to deceive the PTO by some act or omission; and second, the act or omission must be material to patentability, such as withholding a material prior-art reference from the PTO or making a material false statement. In the past, however, courts would "balance" the evidence for these elements on a sliding scale in a manner that too often led to holdings of inequitable conduct with little or no independent support for a finding of intent.

Inequitable conduct became a common defense in part because this threshold of proof was low relative to the severe consequences of an adverse determination. It has been called the "atomic bomb" of patent litigation because such determination not only renders the patent unenforceable but may also render related patents unenforceable while also spawning antitrust and unfair competition claims. The combination of low burden with such drastic consequences caused inequitable conduct allegations against even reputable lawyers to become so commonplace as to be famously characterized as an "absolute plague."

This plague affected not only the courts but the entire patent system. In the patent-application process (also called patent prosecution), lawyers came to labor under a constant specter that charges might someday be leveled against them for any misstep in prosecution. They would understandably act out of an abundance of caution by tending to overdisclose. An unfortunate byproduct was that

PTO examiners would become buried in numerous prior-art references of marginal value and piles of other tangential information, obscuring the most relevant prior art and information, thereby undermining the quality of the examination process.

These developments set the stage for the Federal Circuit's announcement that it would be revisiting the framework and proofs required for inequitable conduct in the *Therasense* rehearing. In its decision, the court cited a number of cases and amicus submissions in acknowledging the detrimental effect of the prior balancing test and the low threshold required to prove inequitable conduct. Abandoning that framework, the Federal Circuit held that a court must evaluate the evidence of specific intent to deceive independent of its analysis of materiality. And although such intent may be inferred from indirect and circumstantial evidence, it must be "the single most reasonable inference able to be drawn from the evidence."

For the materiality prong, the court generally adopted a standard that requires proof that, "but for" the improper conduct, at least one claim would have been found unpatentable. The court also incorporated an egregious-conduct exception that allows extraordinary affirmative acts, such as false affidavits, to be considered material without but-for proof.

Therasense should be heralded by patent holders and prosecutors as a good decision. The increased burden to prove inequitable conduct is appropriate given the powerful remedy, and should provide some inoculation against the plague of inequitable conduct allegations. It also provides substantial guidance in identifying circumstances in which an inequitable conduct allegation lacks merit, which should help to avoid unsubstantiated accusations.

Therasense is also likely to streamline patent litigation. Because the standard for materiality is now primarily but-for unpatentability, the scope of references used to allege inequitable conduct may be narrowed in many cases to those capable of proving invalidity. Along similar lines, more inequitable conduct allegations may be resolved on summary judgment because



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courts may now more efficiently address prior art relating to invalidity together with materiality.

In addition, *Therasense* provides important guidance for inventors and patent prosecutors, who may treat the but-for rule as a safe harbor from future inequitable conduct allegations. Past concerns about disclosing every possible reference and every event during prosecution of related U.S. and foreign patent applications should be much diminished. As the routine practice of overdisclosure subsides, patent examiners may also come to appreciate the *Therasense* decision.

Therasense also represents one of the most significant pro-patent pronouncements in recent memory. Although the sharply divided Federal Circuit suggests that U.S. Supreme Court review is a real possibility, if the decision stands, *Therasense* is at least one departure from recent decisions that have worn away at certain aspects of patent rights.

Therasense should therefore help treat, if not eradicate, the inequitable conduct plague, streamline litigation and prosecution, and provide clear and helpful guidance to patent litigators and prosecutors.

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