In a landmark decision in Therasense, Inc. v. Becton, Dickinson & Co. (Fed. Cir. No. 2008-1511), the U.S. Court of Appeals for the Federal Circuit redefined the legal standards for proving inequitable conduct as a defense to a charge of patent infringement.

By way of background, a Court may hold a patent unenforceable if the patent was obtained through inequitable conduct (formerly known as “fraud on the Patent Office”). A Court may find inequitable conduct when, for example, an individual associated with the prosecution of a patent (such as the inventor, the prosecuting attorney, or an assignee of the patent) withheld a prior art reference from, or misrepresented some facts to, the U.S. Patent and Trademark Office (USPTO) during prosecution of the patent. Such conduct may violate the duty of disclosure required by federal regulations, such as USPTO Rule 56.

Courts had initially set a high standard for proving inequitable conduct. For example, to find inequitable conduct, Courts have required proof that (1) the reference is material to patentability of the invention; and (2) the reference was withheld with intent to deceive the USPTO. Later decisions, however, blurred these two discrete prongs, holding that intent can be inferred when the materiality of the withheld reference is sufficiently high. As a result, defendants frequently raise the inequitable conduct defense in U.S. patent litigation even though such intent, on its own, is difficult to prove.

In yesterday’s decision, the Federal Circuit significantly raised the bar for proving inequitable conduct. Notably, the Court stated that it “now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.” According to the new standard, an accused infringer must now prove by clear and convincing evidence that “the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” (emphasis added) Further, with respect to the materiality prong, the Court held that when “an applicant fails to disclose prior art to the USPTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” (emphasis added) Thus, at least for purposes of the inequitable conduct defense, a reference is no longer material merely because it establishes a prima facie case of unpatentability, or because it refutes or is inconsistent with a position taken by the applicant during prosecution of a patent (the standard for materiality currently defined in PTO Rule 56). It remains to be seen whether (and how) the USPTO will address the new standard set forth in the Court’s decision.

This seemingly “pro-patent” decision may have long-lasting effects in U.S. patent litigation because it significantly restricts the popular defense of inequitable conduct. Indeed, one dissenting judge stated that the new standard “does not merely reform the doctrine of inequitable conduct, but comes close to abolishing it altogether.” Whether or not this prediction comes true, the Therasense case will have far-reaching implications for current and future patent litigants in the United States.


During prosecution of a patent application, it is sometimes helpful to conduct an interview with the USPTO examiner assigned to the application. (An interview is simply a phone call or in-person meeting with the examiner in which the legal merits of the claimed invention are discussed.) Interviews can be conducted telephonically or in person at the USPTO. Traditionally, examiner interviews are conducted after an office action has been issued. The USPTO, however, recently announced an extension of a pilot program that will allow applicants to conduct an interview with an examiner prior to the issuance of an Office Action.

According to the USPTO’s “Full First Action Interview Pilot Program,” the examiner will conduct a prior art search and provide an applicant with a “Pre-Interview Communication” that cites relevant prior art and identifies rejections or objections. Within 30 days of receipt of this communication, an applicant can schedule an interview and submit proposed amendments and/or arguments. At the interview, the relevant prior art, proposed rejections, and proposed amendments and arguments can be discussed. If agreement is not reached with the examiner, the applicant will then receive a “First Action Interview Office Action” which includes an interview summary that
constitutes a first Office Action on the merits under 35 U.S.C. 132. The initial version of the pilot program only applied to applications assigned to specific art units of the USPTO, but the proposed extended program will not be limited in this manner. In order to participate in the pilot program, a request must be filed with the USPTO before **May 16, 2012**, and at least one day prior to a first Office Action on the merits. There are additional requirements in order to be eligible to participate in the program, such as limits on the number of claims in an application and other requirements.

According to the USPTO, benefits of participating in the program include: (1) the ability to advance prosecution of an application; (2) enhanced interaction between the applicant and the examiner; (3) the opportunity to resolve patentability issues one-on-one with the examiner at the beginning of the prosecution process; and (4) the opportunity to facilitate possible early allowance. Also, according to PTO statistics, approximately 34 percent of applications in the initial version of the pilot program were allowed on the first action on the merits, as compared to approximately 11 percent on average across all technologies for new non-continuing applications.

If you are interested in participating in this program, or if you have any questions or would like more information about it, please contact any of the patent partners of the McCarter & English IP/IT practice group.