What Recent Changes in the Inequitable Conduct Doctrine Mean for Patent Applicants

In an important decision, the Federal Circuit has limited the doctrine of inequitable conduct, potentially affecting the process of obtaining US patents. *Therasense, Inc. v. Becton, Dickinson and Company* (Fed. Cir. 2011). If the decision is not overturned by the US Supreme Court, it will likely lead to fewer references being disclosed to the United States Patent and Trademark Office (USPTO) by a patent applicant.

The doctrine of inequitable conduct means that a patent may be found unenforceable if a patent applicant, or his attorney, was not fully candid during the process of obtaining a patent in the USPTO. Some examples can include concealing a relevant prior art reference, misrepresenting relevant facts or information, and other similar misconduct. The goal of this doctrine, therefore, is to encourage full disclosure of all relevant information to the USPTO.

To prove inequitable conduct, two key elements must be shown: 1) an intent to deceive and 2) materiality of the withheld reference or other information. In Therasense, the Federal Circuit has considerably raised the standards for finding both of these elements, thus limiting the application of the doctrine.

Most importantly, the Federal Circuit has adopted a “but-for” test for finding materiality, holding that a reference is only material if a patent claim would not have been allowed had the USPTO been aware of the reference. The “but-for” test is subject to an exception in cases of “affirmative egregious misconduct.” Such misconduct can, for example, encompass the filing of an unmistakably false affidavit with the USPTO. Future opinions from the Federal Circuit will help to define the contours of additional conduct which is considered egregious and subject to this exception.

Regarding the second element of inequitable conduct, the Federal Circuit has emphasized that the alleged infringer must prove a specific intent to deceive the USPTO. Gross negligence or a “should have known standard” used by courts in the past, do not satisfy the intent requirement.

Given the importance and implications of Therasense, it is possible that the US Supreme Court will review this decision. In addition, the USPTO has indicated it is reviewing the decision and will issue guidance regarding an applicant’s duty of disclosure in light of the decision. If the
decision stands and the USPTO changes the duty of disclosure rules accordingly, it is likely that fewer prior art references will have to be disclosed to the USPTO. However, until and, unless the USPTO changes its duty of disclosure rules, it remains prudent for patent applicants to disclose all potentially relevant references. Wood Phillips will continue to monitor developments in this evolving area.

To ensure validity of its patents, it is important for a company to have an effective and reliable internal system to comply with the duty of disclosure rules. There are a number of often overlooked tasks which, if timely performed, may help save a significant amount of money in the long run and minimize the risk of a patent being held unenforceable. For example, when a patent application is considered for filing, an in-house counsel or outside patent attorney needs to speak with the inventor to learn how that person came up with the invention, what information was considered by the inventor, whether there were any public disclosures, whether sales or other commercial activities took place, etc. Second, while it is important to ensure that an inventor does not hide any information, it is equally important to ensure the inventor does not independently conduct a broad prior art search which may potentially turn up hundreds of references which would then need to be evaluated by a patent attorney and possibly disclosed to the USPTO. Any prior art search is best done in coordination with a patent attorney.

To summarize, a large amount of money and time can be spent in litigation over inequitable conduct accusations. By doing its homework upfront and having a reliable process of dealing with prior art, a company can help minimize these issues from arising during litigation – potentially saving a lot of money. Wood Phillips stands ready to assist you in developing and/or optimizing this process. If you have any questions or need further assistance with complying with the duty of disclosure rules, please contact a Wood Phillips attorney.