

Inequitable Conduct in Patent Cases

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The habit of charging inequitable conduct in almost every major patent case has been characterized by the Court of Appeals for the Federal Circuit as an "absolute plague." It has become standard practice for a patent infringement suit to proceed as follows. The patent owner files a complaint for infringement of the patent and the defendant, in nearly every case, files an answer that he does not infringe the patent, the patent is invalid under one or more provisions of the Patent Act, and the patent is unenforceable due to inequitable conduct during prosecution of the patent. A finding of inequitable conduct results in a powerful remedy – the patent is rendered unenforceable. More often, however, the charge of inequitable conduct is alleged to increase the cost of litigation for the patentee. Part of the reason this occurs is because the Federal Circuit's jurisprudence on inequitable conduct is confusing at best. Recently the court has been taking cases to clarify inequitable conduct and one underlying finding, breach of the duty of disclosure.

Duty of Disclosure

37 C.F.R. § 1.56 requires that a patent applicant fulfill a duty of candor and operate in good faith when dealing with the United States Patent and Trademark Office (PTO). This includes the duty to disclose information that is material to the patentability of any claim in a pending patent application. In general, the applicant must submit to the PTO any prior art, e.g., previous patents and publications, that may affect whether the invention claimed in his patent application is patentable. The duty also includes disclosing information of prior public use or sale of the invention that may constitute a bar to patentability.

The duty of disclosure extends not only to the inventor, but to his patent attorney and "every other person who is substantively involved in the preparation or prosecution of the application" or is associated with someone else that has the duty to disclose. While this seems to be a wide range of people subject to the duty, the Federal Circuit has held that the duty applies only to individuals and not to corporations.

One recent decision held that a person is substantively involved in a patent application if his "involvement relates to the content of the application or decisions related thereto, and that the involvement is not wholly administrative or secretarial in nature." In that particular case, the

court held that the founder and president of a closely held corporation, although not involved in invention nor in the preparation or prosecution of the patent application, nonetheless owed the duty of disclosure because he was involved in "all aspects" of the company, including the company's intellectual property.

Rule 56 does not specify the penalty for failing to comply with the duty of disclosure. Breach of this duty may result in a finding of inequitable conduct. If inequitable conduct is proven, the courts have instituted a penalty that renders the patent unenforceable. In fact, not only is that patent unenforceable, but any patent related to that patent is also held unenforceable. Thus, the penalty for failing to comply with the requirements of Rule 56 can be quite severe.

Inequitable Conduct

How does one prove that inequitable conduct has occurred during prosecution of a patent? Inequitable conduct has two elements. First, an individual associated with prosecution of the application must have made a misrepresentation, failed to disclose material information, or submitted false information to the PTO. Second, that the misrepresentation or failure was done with a specific intent to deceive the PTO. And, given that an issued patent is presumed valid, these elements must both be proven by clear and convincing evidence.

Rule 56 does provide some guidance as to the first element of the defense, the materiality element. The rule states that information is material to patentability if (1) by itself or combined with other information it establishes a prima facie case of unpatentability of any claim; or (2) it refutes or is inconsistent with an argument taken by the applicant regarding patentability of the claim. This is a fairly heavy burden, but not unduly so. Applicants generally err on the side of disclosing too much to the PTO rather than too little. While a patent owner can be accused of having "buried" a particularly material piece of information in a stack of less useful or non-material information, this is a more difficult case to make than that the patent owner withheld some information that was arguably material.

The real meat of the argument over inequitable conduct occurs on the second element of the claim: the intent element. It seems pretty straight forward—did the applicant intend to mislead the patent examiner into granting a patent that he would not otherwise have been entitled to if the examiner had had all of the material information available to the applicant? Either he did or he didn't, right? That's not how the Federal Circuit views it.

Instead, the Federal Circuit has developed a sliding scale test that blends the two elements of inequitable conduct. The more material a piece of information is, the less intent to deceive is required; conversely, the more the evidence shows that the patent owner intended to deceive the PTO, the less material the evidence need to be to prove inequitable conduct.

In fact, the "intent" element has been reduced to something less than gross negligence. The Federal Circuit has indicated that intent can be inferred when (1) highly material information is



withheld, (2) the patent applicant knew of the information and knew or should have known of its materiality, and (3) has not provided a credible explanation for its withholding. Thus, intent to deceive the PTO now sounds more akin to a negligence standard of proof that the patent applicant "should have known" that the information was material to the patentability of the claims.

There is a chance, however, that the Federal Circuit's jurisprudence on inequitable conduct will be clarified soon in an en banc opinion. On November 9, 2010, the Federal Circuit will hear oral argument in TheraSense v. Becton-Dickinson, where they will hopefully clarify the law of inequitable conduct.

TheraSense v. Becton-Dickinson

The plaintiffs have not had much luck in this case. They sued the defendants for infringement of a number of patents. The district court and the jury found the patents to be invalid for anticipation, obviousness, and violating the written description requirements. The court also held that U.S. Patent No. 5,820,551 was unenforceable due to inequitable conduct based on failure to disclose statements made to the European Patent Office in a revocation proceeding for a European patent. The court held that these statements were directly contradictory to statements made to the PTO in prosecution of the '551 patent. A Federal Circuit panel affirmed.

Judge Linn issued a lengthy dissent where he argued that the district court erred in its factual determinations in this case. The plaintiffs had an adequate explanation for how the statements were not contradictory and why they were not disclosed to the PTO. He also stated that he would find there was no intent to deceive on the part of the plaintiffs because they did not recognize that the statements were material. The trial court simply disagreed with the plaintiffs' interpretation and explanation of the facts.

According to Judge Linn, the Federal Circuit already has five different standards for materiality. And here, the majority seemed to want to add yet another standard that heightens the disclosure requirement for close cases.

For the en banc argument in November, the full Federal Circuit will entertain a number of questions regarding the inequitable conduct defense: (1) Should the materiality-intent balancing framework be modified or replaced? (2) Should it be tied more directly to fraud or unclean hands? (3) What is the proper standard for materiality? Should it be that a patent would not have issued if the material was not withheld? (4) Should intent ever be properly inferred from the circumstances? (5) Should the balancing inquiry be abandoned? (6) Should the court look to materiality and intent in the context of other agencies or at common law?



Hopefully the resulting opinion from this case will clarify the Federal Circuit's jurisprudence on inequitable conduct and alleviate the "plague" that is the allegation of inequitable conduct in every major patent case.

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