

INEQUITABLE CONDUCT AS REVIEWED

BY THE FEDERAL CIRCUIT

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Fraud on the Patent Office. Breach of the duty of candor. Bad faith. These are the battle cries of a litigation attorney trying to invalidate a patent. When inequitable conduct is successfully asserted in a patent infringement suit, patent rights are lost.

The most common example of inequitable conduct occurs when an intellectual property attorney fails to satisfy the Duty of Candor. If an attorney is aware of information (e.g. a publication) that is material to the patentability of the invention, the attorney is required to disclose that information to the Patent Office. Attorneys disclose that information by filing what is known as an Information Disclosure Statement, in which a publication that may be material to the patent rights is disclosed.

Because attorneys are concerned that they will be accused of inequitable conduct, attorneys tend to file Information Disclosure Statements with any publications that have even a remote possibility of being relevant. Information Disclosure Statements are thus filed frequently. In fact, before the Patent Office switched to an electronic filing system, the Patent Office struggled significantly with those documents, and often complained that they did not have the storage room with which to store all the Information Disclosure Statements that they had received. I recall being at a Bar Association meeting where the Patent Office proposed a ten reference Information Disclosure Statement limit and that fees would be charged for exceeding that limit. I also recall the Intellectual Property Bar complaining bitterly about the proposal and that the ensuing discussion was extremely heated. If a failure to disclose a relevant document to the Patent Office produced draconian results, then how could the Patent Office set an arbitrary limit on the number of references that practitioners could disclose?

The problem of how to deal with inequitable conduct, the challenges of applying the doctrine, and the consequences of a failure to disclose relevant reference were argued about, and fought over, for many years. Finally, the Federal Circuit issued a decision to try to deal with the difficult issues surrounding inequitable conduct. In my opinion, while the decision helps to clarify the law, I am not sure that the practical effect will be significant.

In Therasense v. Becton (Fed. Cir. 2011) the Court set a new standard for identifying whether inequitable conduct had occurred. The importance of the case is highlighted by the fact that the Federal Circuit received thirty-two *amicus curiae* briefs before they rendered their decision.

The case related to U.S. Patent No. 5,820,551, Disposable Blood Glucose Test Strips For Diabetes Management. Before being granted, the application was in prosecution for thirteen years. The patent included claims that are directed to a sensor that did not require a protective membrane for whole blood. During prosecution, the closest prior art patent (U.S. 4,545,382) was cited by the Examiner, but the Applicant responded that the '382 patent REQUIRED a protective membrane. A Declaration from an expert was presented to the Examiner to support that position:

One skilled in the art would not have read the disclosure of the
['382 patent] as teaching that the use of a protective
membrane with whole blood samples was optional.

Thus, the protective membrane was a major issue as to whether or not the patent in suit was granted. Again, to summarize, it was argued that the claims of the '551 patent were patentable because they did not require protective membrane. The Examiner argued that the prior art reference '382 patent also did not require protective membrane. The applicant disagreed and argued to the Examiner that the prior art '382 patent did require protective membrane and, thus, his claims were patentable.

At the time that the application for the '551 patent was being prosecuted in the United States, a related application was being prosecuted in the European Patent Office. In sharp contrast with the U.S. prosecution, the following statement was made during the EPO prosecution:

The protective membrane [in this application] is optional, however, it is preferred . . .

Two conflicting arguments were thus being presented in the U.S. prosecution and in the European prosecution. Again, to summarize:

U.S.: The U.S. claim should be allowed because of the lack of a protective membrane and because the protective membrane in the prior art was not optional.

Europe: The European claim should be allowed because the protective membrane is optional but preferred.

At the District Court level, the '551 patent was found to be unenforceable for inequitable conduct. The District Court explicitly stated that inequitable conduct had occurred because Abbott did not disclose to the USPTO its European briefs. The Federal Circuit affirmed the District Court's decision and was then petitioned for rehearing. Upon further review, the Federal Circuit vacated their previous decision and remanded for further consideration.

Upon rehearing, it was explained that inequitable conduct evolved from the doctrine of unclean hands to dismiss patent cases involving egregious misconduct. As inequitable conduct has emerged from unclean hands, the standards for intent to deceive and materiality have fluctuated over time. Now, however, the remedy for inequitable conduct is the "atomic bomb" of patent law. The Court explained why the consequences of an inequitable conduct decision were so dire:

- 1) A finding of inequitable conduct renders the entire patent unenforceable.
- 2) A finding of inequitable conduct can spread to other patents in a patent portfolio.
- 3) A finding of inequitable conduct spawns anti-trust and unfair competition claims.
- 4) An accusation of inequitable conduct is a common litigation tactic.
- 5) Inequitable conduct "has become an absolute plague."

Against that backdrop, the Court took the following positions:

With inequitable conduct casting a shadow of hangman's noose, it is unsurprising that patent prosecutors regularly bury PTO Examiners with a deluge of prior art references, most of which have marginal value.

Applicants disclose too much prior art for the PTO to meaningfully consider and do not explain the significance, a lot fear that to do otherwise risks claims of inequitable conduct.

This Court 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.

To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO.

Thus, arguing that a practitioner "should have known" that a withheld reference is material does not satisfy the intent requirement. Furthermore, it was explained that intent and materiality are separate requirements and that a Court should not use a "sliding scale" where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. Thus, a District Court can infer intent from indirect and circumstantial evidence. To meet the clear and convincing evidence standard, however, the specific intent to deceive needs to be "the single most reasonable inference able to be drawn from the evidence." Thus, the Federal Circuit explained that because the party alleging inequitable conduct bears the burden of proof, the "patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence."

In the past, the Federal Circuit tried to address the flood of inequitable conduct charges by simply raising the intent standard. It was explained, however, that by simply raising the intent standard, the number of inequitable conduct cases was not reduced. Furthermore, the problem of "over disclosure of marginally relevant prior art" to the Patent Office was not addressed.

To try to deal with all of these problems, the Federal Circuit adjusted the standard of materiality:

This Court holds that, the materiality required to establish inequitable conduct is but-for materiality. When an Applicant fails to disclose prior art to the PTO, 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.

The Court was also clear that the doctrine should only be applied when the patentees misconduct resulted in the benefit of an unwanted claim.

To put it another way, if the patent would have issued WHETHER OR NOT the misconduct occurred, then materiality does not exist, inequitable conduct has not occurred, and the patent remains valid. To prove inequitable conduct, it needs to be shown that if the withheld reference had been submitted, then the patent would not have issued.

The Court also recognized an exception in cases of affirmative egregious misconduct. The Court thus provided flexibility with their new standard for inequitable conduct:

Accordingly, the general rule requiring but-for materiality provides clear guidance to patent practitioners and courts, while the egregious misconduct exception gives the test sufficient flexibility to capture extraordinary circumstances.

It is interesting to note that the Federal Circuit specifically stated that they were not adopting the definition of materiality which appears in Patent Office Rule 56. The first prong of that rule considers information material even if the information would be rendered irrelevant in light of subsequent argument. The second prong of Rule 56 encompasses anything that could be considered marginally relevant to patentability. The Federal Circuit argued that the standards of Rule 56 were too broad and adopting those standards by the Federal Circuits would continue to motivate litigators to charge inequitable conduct in nearly every case as a litigation strategy.

The Federal Circuit thus vacated the District Court's decision. The District Court was now charged with determining whether the failure to disclose the statements made to the EPO ultimately determined whether or not the patent should have issued.

To summarize, here are the take aways from the decision:

- 1) Evidence of being a "deliberate decision" to deceive is required to conclude that inequitable conduct had occurred.
- 2) Materiality must satisfy the but-for test.
- 3) But-for does not need to be found and inequitable conduct will be determined if the misconduct was egregious.
- 4) A patent should be rendered unenforceable "when the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim."

Because of the ease with which Information Disclosure Statements can be filed, patent procurement practitioners will probably continue to file Information Disclosure Statements in abundance. It is hoped, however, that the revised materiality standards will result in fewer charges of inequitable conduct during litigation.