

WIGGIN AND DANA
Counsellors at Law

If you have any questions about this Advisory, please contact:

JOSEPH V. SAPHIA
212.551.2631
jsaphia@wiggin.com

JAY H. ANDERSON
212.551.2625
janderson@wiggin.com

ERIKA V. SELLI
212.551.2616
eselli@wiggin.com

Avoiding the Plague: The Federal Circuit Re-defines the “Intent” and “Materiality” Standards of Inequitable Conduct

In an *en banc* decision dated May 25, 2011, the United States Court of Appeals for the Federal Circuit addressed the problem of proliferating allegations of inequitable conduct in patent litigation. (*Therasense, Inc. and Abbott Laboratories v. Becton, Dickinson & Co.*, (Fed. Cir. May 25, 2011) (*en banc*)). The Federal Circuit raised the standards for finding both “intent” and “materiality” regarding nondisclosure of information to the U.S. Patent and Trademark Office (PTO), discarded the prior “sliding scale” analysis, and held that “intent” and “materiality” are separate and distinct requirements. The court stated that the purpose of its ruling was “to redirect a doctrine that has been overused to the detriment of the public.”

BACKGROUND

Abbott Laboratories filed a patent application in the PTO claiming disposable blood glucose test strips that utilized electrochemical sensors to measure the amount of glucose in a blood sample. The patent examiner focused on whether the prior art taught that glucose sensors could be used to test without a protective membrane, and required Abbott to submit declarations on that issue. Abbott declared to the PTO that one skilled in the prior art would *not* have read that the use of a protective membrane was optional. However, Abbott omitted the fact that during earlier prosecution of a European patent application for the same subject matter, it represented that the same prior art language taught that a protective membrane *was* optional. Abbott’s patent application issued as U.S. Pat. No. 5,820,551 (the “’551 patent”). Litigation ensued, and after a series of decisions including: a trial court judgment

that the ’551 patent was unenforceable due to inequitable conduct, and a Federal Circuit panel affirmation of the trial court, the case was heard by the Federal Circuit sitting *en banc*.

A NEW LEGAL STANDARD

Inequitable conduct is a judicially-created defense to patent infringement which, if proved, can render the patent or family of patents unenforceable. The scope of inequitable conduct has broadened to include affirmative acts of deceit and the non-disclosure of information by a patent applicant to the PTO during patent prosecution.

To prevail on this defense, the accused infringer must prove by clear and convincing evidence that the applicant misrepresented or omitted *material* information with the *specific intent* to deceive the PTO. If the alleged infringer proves this, the court must then “weigh the equities” to determine whether the conduct warrants such a drastic remedy of unenforceability.

Previously, the “intent” requirement was met by negligence, *i.e.*, the applicant knew or should have known that the withheld prior art reference would have been material to the examiner’s consideration, whereas the “materiality” requirement was based on the “reasonable examiner” standard, *i.e.*, “a substantial likelihood that a reasonable examiner would consider it important in deciding whether the application should issue as a patent” (37 C.F.R. § 1.56). Moreover, intent and materiality were analyzed together on a “sliding scale”; for example, a strong showing of intent could offset a weak showing of materiality.

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Although these reduced thresholds were intended “to foster full disclosure to the PTO,” the court noted that the inequitable conduct defense has plagued both the courts and the patent system by bombarding the PTO’s patent examiners with prior art references of marginal value—thus straining resources, increasing prosecution time, and impairing the quality of the patent system—while later increasing the costs, complexities, and scope of patent litigation.

In an opinion written by Chief Judge Rader, the court rejected the “sliding scale” analysis and held that “intent” and “materiality” are two distinct requirements, which still must be proved by clear and convincing evidence. Intent may now be inferred from indirect and circumstantial evidence, but the evidence presented must be “the single most reasonable inference able to be drawn from the evidence.” Moreover, an applicant’s failure to provide a “good faith” explanation for withholding a material reference will not prove intent to deceive by itself. Materiality should now be analyzed under a “but for” test—that is, the failure to disclose prior art will be material if the PTO would not have allowed the claim if it was aware of the undisclosed prior art. Furthermore, if the applicant engages in affirmative acts

of egregious misconduct, such as filing a false affidavit, then the misconduct will be material. Applying this new standard, the Federal Circuit vacated the earlier panel’s finding of inequitable conduct and remanded the decision to the district court for further proceedings.

CONCLUSION

The Federal Circuit’s new standard for inequitable conduct attempts to strike “a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations.” This new standard should significantly decrease the number of inequitable conduct claims asserted by accused infringers, and allow litigants to “weed out” frivolous allegations of inequitable conduct before trial.

Patent attorneys prosecuting applications should note that the duty of disclosure has not changed. The best practice is still to disclose *all* information relating to the application, without trying to assess the materiality of each item. However, as a result of this new standard, a prosecutor should be freer to point out to the examiner which items are believed to be most relevant; this will reduce the burden on the examiner and lead to quicker issuance of the patent.

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