

Keywords: inequitable conduct

General: To avoid potentially causing a patent to be unenforceable due to inequitable conduct, care should be taken to review submissions to foreign patent offices to determine if statements contained therein are contrary to arguments made before the PTO.

Therasense Inc. v. Becton, Dickinson and Co.
93 U.S.P.Q.2d 1489 (Fed. Cir. 2010)
Decided January 25, 2010

I. Facts

The patents-in-suit (the '164, '745, and '551 patents) are in the area of disposable blood glucose test strips for measuring glucose levels in blood. Abbott Diabetes Care, Inc. ("Abbott"), a subsidiary of Abbott Laboratories, is the successor to Therasense, Inc. and the owner of the patents-in-suit. Becton, Dickinson and Co. ("BD") sued Abbott seeking a declaratory judgment of non-infringement of the '164 and '745 patents. Abbott countersued BD alleging infringement of the '164, '745, and '551 patents. Abbott also sued Nova Biomedical Corp. ("Nova"), BD's supplier, alleging infringement of the '164, '745, and '551 patents, and Bayer Healthcare LLC ("Bayer"), alleging infringement of the '745 and '551 patents.

The district court issued a summary judgment order finding that BD/Nova's products did not infringe any of the asserted claims of the '164 or '745 patents. It also found claims 1–5, 8, 21–23, 28, 31, and 34 in the '745 patent anticipated. The district court also determined after a bench trial that claims 1–4 of the '551 patent were invalid due to obviousness and that the entire '551 patent was unenforceable due to inequitable conduct. Abbott appealed the rulings of the district court.

II. Issues

- A. Did the district court err in holding claims 1-4 of the '551 patent to be obvious?
- B. Did the district court err in holding the '551 patent unenforceable for inequitable conduct?

III. Discussion

A. No. The Federal Circuit agreed with the district court that claims 1-4 of the '551 patent were obvious in view of Abbott's own '382 patent. The claims of the '551 patent describe a test strip with an electrochemical sensor for testing whole blood without any membrane over the electrode. The court found that the central question in determining obviousness was whether the prior art disclosed a glucose sensor without a membrane for use in whole blood. The court focused on language in the specification of the '382 patent that stated:

Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.

The Federal Circuit found that the use of the term "preferably" implies that such a membrane is not necessary. Abbott disagreed and argued that the conventional wisdom of those skilled in the art was that a membrane was necessary when testing with blood, and that skilled artisans would not have read the patent's disclosure literally when it said that a membrane was not necessary with blood. However, the Federal Circuit was not persuaded by Abbott's argument and held that the district court did not err in finding that '382 patent disclosed a membraneless sensor for whole blood testing.

B. No. The Federal Circuit noted that inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive. Additionally, the party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence, and the court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, with a greater showing of one factor allowing a lesser showing of the other. The Federal Circuit noted that while the penalty for inequitable conduct is severe (unenforceability of the patent), “[T]his is one of those rare cases in which a finding of inequitable conduct is appropriate.”

With respect to the materiality prong of the test for inequitable conduct, the court reviewed 37 C.F.R. § 1.56 and the representations made by Abbott to the PTO during prosecution of the ‘551 patent. The court found that after thirteen years of unsuccessful prosecution of the ‘551 application at the PTO, Abbott’s attorney and its director of research and development (Dr. Sanghera) amended the claims to recite sensors lacking a membrane. During an interview with the Examiner, the “optionally, but preferably” language in the cited art of record (the ‘382 patent) was discussed and the attorney argued that the ‘382 sensor required a membrane when used with blood. It was agreed that this argument would be presented in the form of an affidavit, which was signed by Dr. Sanghera. The affidavit specifically stated that the “optionally, but preferably” language in the ‘382 patent was not a technical teaching, but rather mere patent phraseology. Subsequently, the ‘551 patent issued.

Prior to the submission of the affidavit, Abbott made statements to the European Patent Office (“EPO”) during a revocation proceeding of the European counterpart to the ‘382 patent. These arguments contrasted an applied reference with a semi-permeable membrane with the protective membrane optionally utilized with the sensor in the ‘382 patent. Abbott further discussed the “optionally, but preferably” language in the ‘382 patent in a brief filed to the EPO, stating:

It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor. Furthermore it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is “permeable” to glucose molecules.

Abbott attempted to argue that an argument made by an attorney regarding prior art is not information material to patentability and that since both the EPO and the PTO representations were merely attorney argument, any inconsistency between the two could not be material. The court found that under 37 C.F.R. § 1.56(b)(2), an applicant’s earlier statements about prior art, especially one’s own prior art, are material to the PTO when those statements directly contradict the applicant’s position regarding that prior art in the PTO. Additionally, the court noted that the representations to the PTO were not merely attorney arguments, they were factual assertions as to the views of those skilled in the art, provided in affidavit form. Accordingly, the court found the district court did not err in finding that the EPO statements were highly material because they contradicted the position taken before the PTO.

With respect to the intent prong of the test for inequitable conduct, the court recited the test for determining whether a failure to disclose material information was intentional, was whether the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, indicates sufficient culpability to require a finding of intent to deceive. The court further noted that because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence.

The court focused on two of the district courts findings regarding intent to deceive the PTO by withholding the EPO documents: that neither Abbott’s attorney nor Dr. Sanghera provided a credible explanation for failing to submit the EPO documents to the PTO and that the attorney’s and Dr.

Sanghera's explanations for withholding the EPO documents were so incredible that they suggested intent to deceive. The court noted that the district court judge had observed both the attorney's and Dr. Sanghera's testimony during the bench trial and found their explanations neither plausible nor credible, noting that the attorney "did not prove to be a convincing trial witness" and that Dr. Sanghera's demeanor was unconvincing. The court referred to the testimony by Abbott's attorney that he made "a judgment call" that the EPO documents were not attempting to convey anything about the "optionally, but preferably" language in the '382 patent. Similarly, the court noted that while Dr. Sanghera admitted that he would not generally use the terms "optional" or "preferable" to describe something that was required, and that he had not used the terms "optional" or "preferable" to describe something that was required during his scientific career, Dr. Sanghera testified that representations to the EPO confirming that the language in the specification of the '382 was "unequivocally clear" could be withheld from the PTO.

Upon reviewing the record, the court found that the district court was clearly correct in concluding that the explanations offered by Abbott's attorney and Dr. Sanghera were not plausible. Accordingly, the court held that the district court did not abuse its discretion in holding the '551 patent unenforceable due to inequitable conduct, since the district court did not abuse its discretion in finding that the EPO submissions were highly material to the prosecution of the '551 patent and that Abbott's attorney and Dr. Sanghera intended to deceive the PTO by withholding those submissions.

IV. Conclusion

To avoid potentially causing a patent to be unenforceable, care should be taken to review submissions to foreign patent offices. Additionally, practitioners should take great care in reviewing statements made in the form of an affidavit, as they may be found to not fall under the scope of attorney arguments, and, thus, inconsistencies between statements made in an affidavit and in an attorney argument may be found to be material if the patent is challenged for inequitable conduct.

V. Dissent

Judge Linn dissented from the majority opinion. With respect to the materiality prong of the test for inequitable conduct, Judge Linn found that the submissions made by Abbott to the EPO were susceptible of multiple reasonable inferences, including inferences that rendered the submissions immaterial. With respect to the intent prong of the test for inequitable conduct, Judge Linn reminded the majority that that requisite level of intent was not simple negligence or even gross negligence, but specific intent, which requires a subjective rather than objective standard and is generally associated with actions deliberately and consciously taken to achieve a specific result. That is, intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible. Judge Linn found that it was plausible that Abbott's attorney could read the "optionally, but preferably" language in the '382 patent in context as meaning that a membrane was required for use with whole blood. Accordingly, Judge Linn argued that both the materiality and intent prongs of the inequitable conduct test were not met.