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The Federal Circuit Says

Inequitable conduct may be found where a patentee knowingly failed to disclose to a USPTO examiner contradictory representations made in another forum with respect to prior art. In *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 08-1511, -1512, -1513, -1514, -1595 (Fed. Cir. Jan. 25, 2010), the Federal Circuit found U.S. Patent No. 5,820,551 ("the '551 patent"), owned by Abbott Diabetes Care, Inc. (Abbott), Therasense, Inc.'s (Therasense) successor, to be unenforceable due to inequitable conduct during prosecution. The '551 patent related to disposable glucose test strips utilizing electrochemical sensors, and its claims were particularly directed to electrochemical sensors lacking a protective membrane.

During examination, the USPTO rejected the claims of the '551 patent over U.S. Patent No. 4,545,382 ("the '382 patent"), which was also owned by Abbott. In response, Abbott represented to the USPTO that the claims of the '551 patent were specifically directed to a new glucose sensor that did not require a protective membrane when testing blood samples. In particular, Abbott argued that the teachings of the '382 patent relating to sensors for use with blood samples required a protective membrane over the sensors. Slip op. at 20. Moreover, Abbott submitted a declaration to the USPTO stating that, at the time of the '382 patent's invention, such protective membranes were considered to be

essential when testing blood samples, and that one skilled in the art would read the ’382 patent’s “optionally, but preferably” language relating to protective membranes not as a technical teaching but rather as “patent phraseology” that did not have a clear meaning. *Id*. at 20-22. Shortly thereafter, the USPTO allowed the claims of the ’551 patent.

During a revocation proceeding before the EPO of EP Patent No. 0 078 636 (“the ’636 patent”), a counterpart to the ’382 patent with a virtually identical specification, an Abbott predecessor represented to the EPO that the ’636 patent “is unequivocally clear. The protective member is optional, however, it is preferred when used [with samples of] blood.” *Id*. at 22 (emphasis omitted). The Federal Circuit therefore agreed with the district court’s conclusions that the representations made to the EPO contradicted the representations made to the USPTO because the EPO documents clearly explained that a protective membrane was not necessary when testing blood samples. *Id*. at 22-23.

Further, the Court found that the district court’s holdings that the representations made to the EPO were material to the prosecution of the ’551 patent, that Abbott was aware of those representations, and that Abbott intentionally withheld them from the USPTO, were supported by the record and were either not clearly erroneous or undisputed. Based on these findings, the Court concluded that to deprive a USPTO examiner of the EPO statements—statements directly contrary to the representations made to the USPTO—on the grounds that they were not material would be to eviscerate the duty of disclosure. Moreover, if this could be regarded as a close case, which the Court found it was not, the Court reminded the bar that “the duty of disclosure requires that the material in question be submitted to the examiner rather than withheld by the applicant.” *Id*. at 26. The Federal Circuit ultimately affirmed the district court’s decision finding the ’551 patent unenforceable due to inequitable conduct.

The *Therasense* decision highlights the importance of coordinating the prosecution of cases within a family or related families. In addition to minimizing

the risk of taking inconsistent positions, a single counsel overseeing the prosecution of related cases in multiple forums may be also able to better comply with the duties of disclosure, if any, required by those forums.