

Patent Alert

Federal Circuit's *Therasense* Decision Toughens Standards for Establishing Inequitable Conduct

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Responding to views from the United States Patent and Trademark Office (“PTO”) and elsewhere about the unintended consequences of the inequitable conduct doctrine in its current form, the Federal Circuit issued a divided *en banc* ruling yesterday that will make it harder to establish the requisite showings of materiality and intent to prevail on this defense. Writing for the majority in *Therasense, Inc. v. Becton, Dickinson and Co.*, Chief Judge Rader emphasized the impact of a finding inequitable conduct (unenforceability of the entire patent) and lamented that the doctrine has been overused to the detriment of the courts and “the entire patent system.”

BACKGROUND OF THE CASE

Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. This judge-made doctrine evolved from a trio of Supreme Court cases applying the equitable doctrine of unclean hands.

The inequitable conduct issue in *Therasense* concerned the district court’s finding that the patentee made representations to the PTO about the meaning of a statement in one of its prior art patents that were inconsistent with arguments made to the European Patent Office (“EPO”) about the same statement.

The invention at issue is directed to test strips for measuring the level of glucose in a sample of blood; when blood contacts the test strip, glucose in the blood reacts with an enzyme, resulting in the transfer of electrons to an electrode on the strip and then to a glucose meter. During prosecution of the patent with the PTO, the original application was repeatedly rejected for anticipation and obviousness based on a prior art patent (also owned by the patentee) which disclosed a similar test strip, but referred to the use of a protective membrane “optionally, but preferably when being used on live blood.” In an attempt to distinguish this prior art, the patentee told the PTO, in both a declaration and amendment, that a person of ordinary skill in the art would understand the statement in the prior art as requiring a membrane for use with whole blood. Prior to this representation to the PTO, when trying to obtain the prior art patent from the EPO, the patentee had argued that the same statement was “unequivocally clear” that the membrane is optional, and merely preferred for live blood.

Following a bench trial, the district court held the patent unenforceable for inequitable conduct because the patentee did not disclose to the PTO the previous statements it had made to the EPO. On appeal, a panel of the Federal Circuit affirmed the finding of unenforceability, with one of the judges dissenting. The panel’s decision was vacated when the Federal Circuit agreed to grant the patentee’s petition for rehearing *en banc*.

HEIGHTENED STANDARD FOR ESTABLISHING INEQUITABLE CONDUCT

To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO. In its split decision (6-1-4) in *Therasense*, the Federal Circuit explicitly “tightens the standards” for finding both intent and materiality.

Materiality

A significant aspect of the *Therasense* ruling is the Court’s adoption of a heightened “but-for” standard for establishing materiality. Under this standard, prior art that an applicant fails to disclose to the PTO is only considered material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Notably, the “but-for” standard adopted in this ruling sets an even higher bar for establishing materiality than the PTO’s own regulations set forth under 37 C.F.R. §1.56 (“Rule 56”). In explicitly declining to adopt the Rule 56 standard, the majority reasoned that it would not be sufficiently stringent to address two problems it stated resulted from a more relaxed standard of proof for materiality: applicants’ prophylactic tendency to flood the PTO with only marginally-relevant information during the prosecution phase, and patent litigators’ over-assertion of the inequitable conduct defense.

The Court did carve out an exception to this heightened “but-for” standard for the materiality prong of inequitable conduct. If an accused infringer can demonstrate that the patentee has engaged in *affirmative acts* of egregious misconduct, as opposed to mere omissions, then the misconduct will be considered material absent any further showing. As to what type of acts may come within this exception, the court noted that “the filing of an

unmistakably false affidavit” would qualify, but it did not attempt to define its boundaries except to note that it was incorporating elements of early Supreme Court unclean hands cases, which dealt with “deliberately planned and carefully executed scheme[s]” to defraud the PTO and the courts.

Intent

With respect to the intent prong, the Federal Circuit reiterated its prior holdings that a finding that a patent applicant’s misrepresentation or omission amounted to negligence or recklessness under a “should have known” standard will not be sufficient to prevail on a claim of inequitable conduct. Rather, the accused infringer must show that the applicant knew of the prior art reference, knew that it was material, and made a deliberate decision to withhold it. And while acknowledging that it may be necessary to infer specific intent from indirect and circumstantial evidence, the court emphasized that in order to prove inequitable conduct, that an intent to deceive the PTO must be the *only* reasonable inference that can be drawn from the totality of available evidence. In other words, if there are multiple reasonable inferences that may be drawn, only one of which constitutes a specific intent to deceive, this will not satisfy the intent requirement for inequitable conduct.

No Sliding Scale

Lastly, the Court affirmatively rejected the use of a “sliding scale” approach to the materiality and intent requirements for establishing inequitable conduct. Under this previously applied approach, a particularly strong showing of materiality might be enough to make up for a weak showing of intent to deceive—and vice versa. Emphasizing that these are two separate and unrelated requirements, the court also reiterated that no matter how strong the evidence of materiality may be, a district court may not infer intent solely from materiality.

IMPLICATIONS

This highly anticipated revisiting of the legal doctrine on inequitable conduct will make it harder for accused infringers to establish unenforceability on these grounds in litigation. Application of the materiality rule which will require a district court to determine whether the PTO would have allowed claim(s) to issue had it been aware of the withheld information (applying the same standard the PTO would have, namely a preponderance of evidence standard and giving the claims the broadest reasonable interpretation) will be important to watch as it evolves. Other recent Federal Circuit decisions placed greater emphasis at the pleading stage to weed out unmeritorious claims of inequitable conduct. The materiality standard

in *Therasense* often may require a substantive analysis of the patent-in-suit, prosecution context, and understanding of the teachings of the prior art information at issue. Patentees presumably will continue to seek early dismissal of inequitable conduct defenses and, when based on the heightened materiality standard, may require significant work on the part of the district court to make the determination. One aspect of this determination to watch at the pleading stage, is what, if anything, district courts will require beyond just the allegation that “but for” information being withheld, the patent would not have issued. In the merits stage another aspect to watch is the weight that district courts will give to expert opinion on the “but for” behavior of the PTO.

Those prosecuting patent applications and managing prosecution of portfolios should revisit their guidelines and practices on disclosing information. One of the articulated concerns of the *Therasense* court was reducing the cautionary incentive of prosecutors to “over disclose” information to the PTO, often without context or explication of its possible relevance. With an eye to achieving this, information which, in recent years, often would be disclosed during prosecution as a matter of course now can be seen as not material. In revisiting prosecution guidelines, one check to consider is reviewing prosecution at or near the time of closing, to determine if events may have made some information “material” in the but-for sense which earlier had not been. Additionally, the Federal Circuit’s exception of certain affirmative acts from the heightened “but-for” standard will continue to warrant close review of declarations under 37 C.F.R. §§ 1.131 and 1.132 (Rules 131 and 132) arguing for patentability for compliance with the duty of candor. In addition, since the determination of which type of acts fall under this different standard will likely be hard fought between litigants, it will be an important issue for prosecutors to monitor as it evolves in the courts.

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