

## REPORT

**DISTRICT COURT AGAIN FINDS INEQUITABLE CONDUCT IN THE  
*THERASENSE* CASE**

April 6, 2012

Further to our June 6, 2011 Special Report, entitled "The Federal Circuit Announces a More Stringent Standard for Proving Inequitable Conduct," the patent at issue in the *Therasense* case has again been held unenforceable for inequitable conduct.<sup>1</sup>

In summary, even though the Federal Circuit raised the standard for proving inequitable conduct, the District Court on remand maintained that Abbott's U.S. patent attorney and its R&D director committed inequitable conduct, and held the entire patent unenforceable due to inequitable conduct. The present District Court decision is not binding on other courts or the U.S. Patent and Trademark Office (USPTO), and almost certainly will be appealed to the Federal Circuit for review. However, in accordance with our previous information disclosure recommendations, this decision emphasizes the need to disclose potentially material information from related applications to the USPTO.

**I. Background Facts**

Abbott Diabetes Care, Inc. (formerly Therasense, Inc.) and Abbott Laboratories

(collectively "Abbott") own the patent at issue. To rebut the USPTO examiner's unpatentability position and obtain allowance, Abbott argued and submitted a supporting affidavit that those skilled in the art would not have understood specific language in a prior art Abbott patent according to its plain and ordinary meaning. However, several years earlier, Abbott had submitted EPO briefs during prosecution of the European counterpart application for that prior art patent. Those briefs contradicted Abbott's position by calling the subject language "unequivocally clear." The EPO briefs were not submitted to the USPTO examiner for consideration. Please see our June 6, 2011 Special Report for a more detailed discussion of the facts of the Therasense case.

**II. The *En Banc* Therasense Federal Circuit Decision**

The Federal Circuit raised the standard for establishing that a U.S. patent is unenforceable due to inequitable conduct. Specifically regarding nondisclosure of information, an accused infringer must prove that (1) the patent would not have issued "but for" the nondisclosure, and (2) the patentee acted with specific intent to deceive the USPTO by making a deliberate decision to withhold known material information. Thus, an accused infringer must prove both "but for" materiality and deceptive intent to establish unenforceability due to inequitable conduct. The

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<sup>1</sup> *Therasense, Inc. v. Becton, Dickinson & Co.* Order on Remand Regarding Inequitable Conduct (N.D. Calif. March 27, 2012), on remand from *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (*en banc*).

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Federal Circuit remanded the case to the District Court to apply this heightened standard to the facts.

### III. The District Court Decision

On remand, the issue before the District Court was whether, under the heightened standard, Abbott's U.S. patent attorney and its R&D director committed inequitable conduct in failing to disclose the EPO briefs. Specifically, the Federal Circuit ordered the District Court to determine (1) whether the USPTO would not have granted the patent but for Abbott's failure to disclose the EPO briefs, and (2) whether Abbott's attorney and its R&D director knew of the EPO briefs, knew of their materiality, and made the conscious decision not to disclose them in order to deceive the USPTO. As discussed below, the District Court held the EPO briefs "but for" material to patentability, and held that Abbott's attorney and R&D director withheld the EPO briefs with specific intent to deceive the USPTO.

#### A. "But For" Materiality

The District Court held that the EPO briefs were "but for" material on the grounds that the prior art language at issue that was addressed in the EPO briefs was the "roadblock" against patentability. Over thirteen years after the original application was filed and rejected on multiple occasions, Abbott's attorney first advanced the argument that the language in the prior art patent would not have been understood according to its plain and ordinary meaning. The examiner was willing to accept Abbott's argument if, and only if, corroborated by a sworn affidavit of a qualified scientist. Abbott's R&D director signed an affidavit to this effect, and Abbott's attorney submitted the affidavit, along with arguments based on statements made in the affidavit, to the USPTO.

Based on these facts, the District Court found that, if the examiner had read the EPO

briefs, the examiner would not have allowed the patent to issue. In particular, the examiner had indicated that the specific language at issue was of concern, and the EPO briefs would have reinforced the examiner's expressed concern regarding the prior art language and what it would have been understood to teach those skilled in the art. Accordingly, the District Court concluded that the examiner relied on and was misled by Abbott's misrepresentations.

The District Court rejected as "wholly unpersuasive" Abbott's argument that, even if the EPO briefs were disclosed, the examiner would still have allowed the patent. Claims of the patent were held invalid at trial and on appeal as having been obvious over the prior art patent based on the subject language in it. Accordingly, the District Court reasoned that the examiner would have come to the same conclusion as the courts if the EPO briefs were before the examiner.

#### B. Deceptive Intent

Abbott conceded, and overwhelming evidence confirmed, that Abbott's attorney and its R&D director knew of the EPO briefs and made a conscious decision not to disclose them. Thus, the District Court centered its analysis on whether they (1) knew that the EPO briefs were "but for" material, and (2) intended to deceive the USPTO.

The District Court held that Abbott's attorney and its R&D director "knew the EPO briefs, standing alone, would so seriously undermine their submission that the examiner would have reverted to unpatentability," because they knew that the language they were characterizing as not being a technical teaching was earlier argued by Abbott to be an "unequivocally clear" teaching. Thus, the District Court found that Abbott's attorney and its R&D director had actual knowledge that the EPO briefs were "but for" material to patentability.

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The District Court further considered the facts and circumstances established at trial in order to determine whether the record, as a whole, supported finding specific intent to deceive the USPTO. The District Court held that the single most reasonable inference that can be drawn is that Abbott's attorney and its R&D director intended to deceive the USPTO by withholding the EPO briefs. It based this holding on the facts that they knew that (1) the language at issue was the last "roadblock" to allowance, (2) the examiner permitted them to submit an affidavit to support their position on the subject language, and (3) the meaning of the subject language alleged in the affidavit was directly contradicted by the EPO briefs. The District Court also pointed out that Abbott was interested in obtaining the patent to attack its competition, as evidenced by the fact that Abbott asserted the patent against a competitor on the same day that the patent issued.

The District Court further responded to the Federal Circuit's admonishment that the absence of a good faith explanation by Abbott should not be used against it. The District Court pointed out that the testimony of Abbott's attorney lacked credibility, and the demeanor of Abbott's attorney, when testifying, as unfavorable. The District Court found that the explanation for withholding the EPO briefs lacked sufficient coherency and consistency compared to the rest of the record, as well as not being corroborated by any evidence.

#### **IV. Recommendations**

We reiterate the recommendations set forth in our June 6, 2011 Special Report. The present decision highlights the fact that, in spite of the heightened legal standard for establishing inequitable conduct, undisclosed activities in related patent applications may still form the basis for a holding of inequitable conduct.

We will keep you informed of significant developments affecting the U.S. duty of disclosure as they occur. We welcome your questions and comments.

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*For further information, please contact us by telephone at (703) 836-6400, facsimile at (703) 836-2787, email at [email@oliff.com](mailto:email@oliff.com) or mail at 277 South Washington Street, Suite 500, Alexandria, Virginia 22314. Information about our firm can also be found on our web site, [www.oliff.com](http://www.oliff.com).*

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