BARNES & THORNBURG LLP
btlaw.com

ALERT

INTELLECTUAL PROPERTY LAW

May 2011

Full Federal Circuit "Tightens the Standards" of the Inequitable Conduct Defense in Patent Cases

On May 25, 2011, the U.S. Court of Appeals for the Federal Circuit, sitting *en banc*, issued a landmark decision for the law of inequitable conduct in *Therasense, Inc., v. Becton, Dickinson & Co.*, Nos. 2008-1511, -1512, -1513, -1514, -1595. The court reaffirmed the basic principle that, "to prevail on the defense of inequitable conduct, the accused infringer must prove that the [patent] applicant misrepresented or omitted material information with the specific intent to deceive the PTO"—and must prove both of these elements by clear and convincing evidence. *Therasense*, slip op. at 19. Notably, the *en banc* court took the opportunity to "tighten[] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." *Id*. at 24.

The defendants accused Therasense (now known as Abbott Diabetes Care) of committing inequitable conduct by failing to disclose to the U.S. Patent & Trademark Office (USPTO) conflicting arguments it had made to the European Patent Office (EPO). *Id.* at 14. During prosecution, Abbott filed an affidavit taking a particular position on how the disclosure of an earlier Abbott patent would be read by one skilled in the art. *Id*. at 11. When prosecuting the earlier patent, however, Abbott had advanced a contrary position on what that disclosure taught. *Id.* at 12-13. Although Abbott's arguments to the EPO undercut its affidavit, the EPO briefs were not submitted to the USPTO. *Id.* at 14. The district court held that Abbott's actions constituted inequitable conduct that rendered its later patent unenforceable, and a panel of the Federal Circuit affirmed. *Id.* at 14-15.

The Federal Circuit's *en banc* opinion first sets out a high standard for proving intent to deceive the USPTO. The court emphasized that, in "a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference." *Id.* at 24 (emphasis original) (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995)). The court also clarified that "a district court should not use a 'sliding scale,' where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa." *Id.* at 25. Rather, a specific intent to deceive must be "the single most

reasonable inference able to be drawn from the evidence." *Id.* at 25 (quoting *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

The *Therasense* opinion also raises the standard for proving that an omitted disclosure was material. Specifically, the court held that, "as a general matter, the materiality required to establish inequitable conduct is but-for materiality," meaning that the USPTO "would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* at 27. In determining if the USPTO would have allowed a claim, "courts should apply the preponderance of the evidence standard, and give claims their broadest reasonable construction." *Id.* at 28. The court, however, provided for an exception to its new "but-for" materiality standard in cases of "affirmative egregious misconduct." *Id.* at 29. When a patentee has engaged in affirmative acts like those described in the earlier Supreme Court "unclean hands" cases, *see, e.g.*, *Keystone Drill Co. v. General Excavator Co.*, 290 U.S. 240 (1933), such misconduct is *per se* material. *Therasense*, slip op. at 29.

In light of the new standards announced in the *Therasense* decision, the Federal Circuit remanded the case to the district court for further consideration. Despite several dissenting opinions, the Federal Circuit judges unanimously supported the stricter intent standard, requiring a finding of specific intent to deceive the USPTO distinct from any materiality finding. Five of the eleven Federal Circuit judges, however, would not have adopted the "but-for" materiality test. Judge O'Malley's dissent-in-part favored the application of flexible, equitable rules, while Judges Bryson, Gajarsa, Dyk, and Prost would have tied the materiality standard to the USPTO's Rule 56.

The new standards for inequitable conduct are expected to make it more difficult for accused infringers to prevail on the defense. Further, when combined with the Federal Circuit's decision in *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009)—which tightened the standards for pleading the inequitable conduct defense—the *Therasense* decision could possibly have the effect in some cases, depending on the facts, of reducing costs relating to the inequitable conduct portion of the litigation. The possibility of reducing litigation costs and improving chances of prevailing could enhance the value of some patents.

Barnes & Thornburg LLP offers a full spectrum of intellectual property services, including patent prosecution and enforcement. For more information, please contact a member of the firm's Intellectual Property Department: Atlanta (404-846-1693), Chicago (312-357-1313), Columbus (614-628-0096), Elkhart (574-293-0681), Fort Wayne (260-423-9440), Grand Rapids (616-742-3930), Indianapolis (317-236-1313), Los Angeles (310-284-3880), Minneapolis (612-333-2111), South Bend (574-233-1171), Washington, D.C. (202-289-1313). You can also visit us online at www.btlaw.com.