

Striking a Balance on Inequitable Conduct in Patent Litigation

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In April, the U.S. Court of Appeals for the Federal Circuit took a major step towards clarifying the law of inequitable conduct when it granted a petition for en banc review of the *Therasense* case.¹ Inequitable conduct is a defense to patent infringement that is rooted in the law of "unclean hands" and permits a court to refuse to enforce a patent that was procured by fraud on the U.S. Patent & Trademark Office. The doctrine is intended to encourage candor during patent prosecution, which is an ex parte process, and thus protect the public interest. Overuse of the defense, however, led the Federal Circuit to describe it as "an absolute plague."² In the past few years, there have been many calls for the Federal Circuit to revisit the doctrine, and the court has now chosen to do so. The Federal Circuit's en banc order asks the parties to address six questions. The expansive scope of these questions suggests that the Federal Circuit is considering a thorough revision of the law. The Federal Circuit has been moving in the direction of toughening the legal standards for pleading and proving inequitable conduct for some time, but there have been individual decisions that seemed to relax the "elevated evidentiary burden"³ to prove the defense. It appears that the Federal Circuit now intends to make clear, once and for all, that this defense applies only to the rarest and most egregious set of facts.

Although the prophylactic intent of the inequitable conduct doctrine is well founded, its adverse impacts have been pointed out many times. Patent litigation is expensive and time-consuming, and often times the side show of litigating inequitable conduct claims morphs into the tail wagging the dog. Indeed, there are cases in which a court never even gets to the merits of the core infringement claim, because the patent case is dismissed on a finding of inequitable conduct. For the accused individuals, the impact can be life-altering. In *Therasense*, Mr. Pope, a former in-house attorney for Abbott, was responsible for the prosecution of the asserted patent. In the wake of the judicial finding that Mr. Pope committed inequitable conduct, Mr. Pope has been investigated by the disciplinary authorities in the USPTO and by the state bar of Illinois.⁴

As for the USPTO, the inequitable conduct doctrine threatens to cripple the examination process. Under USPTO rules, patent applicants "have a duty to prosecute patent applications in the Patent Office with candor, good faith, and honesty."⁵ That duty requires that persons involved in the prosecution of a patent disclose to the USPTO all known information "material" to patentability.⁶ Defendants'

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lawyers have tried to cobble together inequitable conduct charges based on any colorable claim of failure to disclose material prior art or information to the USPTO or any statement made to the USPTO that can be colorably characterized as a misstatement. As a result, patent practitioners now feel pressured to submit all art from their files, which can mean hundreds of references. At a time when the USPTO is severely overburdened, a deluge of prior art, much of it of marginal relevance, is not helpful. The goal during patent prosecution should be to identify and define an invention over the most important art. The mindless dumping of massive amounts of references on the USPTO does not aid the examination process. To the contrary, it is more likely than not to result in burying the key references and to create huge inefficiencies as the examiner tries to sort through the morass.

The Federal Circuit's 1988 en banc *Kingsdown* opinion was intended to curtail the use of inequitable conduct claims as a litigation tactic. *Kingsdown* involved a patent attorney's mistake that a district court deemed "gross negligence" that supported a finding of intent to deceive the USPTO,⁷ a necessary element of the defense. The Federal Circuit reversed, holding that gross negligence alone cannot justify an inference of intent to deceive the USPTO.⁸

In *Kingsdown*, the Federal Circuit affirmed that proof of inequitable conduct requires clear and convincing evidence of both materiality and intent.⁹ Both elements are questions of fact that must be proven by clear and convincing evidence.¹⁰ Under the *Kingsdown* test, the party urging inequitable conduct must make a threshold showing of both elements by clear and convincing evidence.¹¹ However, even after the threshold showings of materiality and intent have been made, a balancing is required: [T]he district court must still balance the equities to determine whether the applicant's conduct before the USPTO was *egregious* enough to warrant holding the entire patent unenforceable.¹²

The Federal Circuit has held that information is material to patentability when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.¹³ The materiality element may be established by clear and convincing evidence that the patent applicant made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information to the USPTO.¹⁴ In evaluating materiality, the Federal Circuit has often looked to the standard set forth in the USPTO rules, which currently defines information as material to patentability if, among other things, it is not cumulative and if it establishes unpatentability or is inconsistent with a position that the applicant is taking.¹⁵

The *Therasense* case will be the vehicle for revisiting the legal framework for inequitable conduct. *Therasense* involved patented disposable test strips for diabetic patients to measure blood sugar. The test strips contain an electrode and reactant system. For a sample consisting of whole blood, the presence of a membrane over the electrode may be important to prevent some of the constituents of the blood from reaching the electrode surface where they can interfere with measurement. The test strips of the invention are used to obtain measurements from samples of whole blood. A key issue is whether it was previously appreciated in the art that a membrane was not necessary when obtaining measurements from whole blood.

The alleged inequitable conduct in *Therasense* turns on whether arguments made to the European Patent Office ("EPO") were inconsistent with those made by Therasense to the USPTO and, if so, whether the patentee engaged in inequitable conduct by failing to disclose the fact of the inconsistent arguments to the USPTO. In the EPO, an argument was made that "optionally, but preferably" meant that a membrane was not absolutely required for whole blood testing. At the USPTO, however, the patent owner argued that a person of ordinary skill in the art would have believed that a membrane was required, and not optional, and the artisan of ordinary skill would recognize that the language "optionally, but preferably" was mere patentese. The district court found inequitable conduct, finding the testimony of the two individuals most involved in the patent prosecution, the patent attorney, Mr. Pope, and Dr. Sanghera, who submitted an affidavit to the USPTO regarding the meaning of the "optionally, but preferably" language, to be "not credible."

Therasense appealed to the Federal Circuit and the appeal was heard by a panel of three judges. On January 25, 2010, a written opinion issued from the panel.¹⁶ Two of the three judges (Judges Dyk and Friedman) agreed with the district court's finding of inequitable conduct. The third judge, Judge Linn, dissented. He found the language in the EPO papers to be ambiguous. Judge Linn proposed a reading of the statement to the EPO in context that reconciled the arguments made in the EPO and USPTO, and thus would support a conclusion of no intent to deceive the USPTO by failing to disclose inconsistent arguments.

Based largely on Judge Linn's dissent, Becton, Dickinson sought en banc review of the panel decision. The Federal Circuit has now granted that petition and ordered the *Therasense* appeal to be reviewed by the whole court. The April 26, 2010 en banc order directs the parties to address six questions:

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
2. If so, how? In particular, should the standard be tied directly to fraud or unclear hands? The Federal Circuit order cites to three U.S. Supreme Court cases, indicating that the Federal Circuit intends to look closely at Supreme Court precedent in resolving this appeal.
3. What is the proper standard for materiality? What role should the USPTO's rules play in defining materiality? Should a finding of materiality require that "but for" the alleged misconduct, one or more claims would not have issued?
4. Under what circumstances is it proper to infer intent from materiality?
5. Should the balancing inquiry (balancing materiality and intent) be abandoned?
6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

Oral argument in the en banc proceeding is scheduled for November 9, 2010. This case will represent a major event in the recently initiated reign of Chief Judge Rader, who replaced retiring Chief Judge Michel in June. The Court's en banc order invited the submission of amicus briefs, and, given the interest in this issue (there were several amici who filed briefs in support of the en banc petition), it is likely that a considerable number of such briefs will be submitted. Regardless of the fate of the parties in the *Therasense* case, it is likely that the en banc opinion (expected in the

Spring of 2011) will rewrite the book on inequitable conduct and, going forward, limit inequitable conduct to a tool that will only be used sparingly and reserved for egregious cases.

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¹ *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 08-01511, -01512, -01513, -01514, -01595, 2010 BL 92007 (Fed. Cir. Apr. 26, 2010) (per curiam) (nonprecedential). Therasense is now Abbott Diabetes Care, Inc., a division of Abbott Laboratories, the other named plaintiff. The defendants are Becton Dickinson and Bayer Healthcare, LLC.

² *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("the habit of making a claim for inequitable conduct in almost every major patent case has become an absolute plague.").

³ *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

⁴ Mr. Pope sought to intervene in the *Therasense* appeal but the Federal Circuit denied his motion. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 08-01511 (Fed. Cir. Oct. 23, 2008).

⁵ *Honeywell Int'l Inc. v. Universal Avionics Systems Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007).

⁶ See 37 C.F.R. § 1.56(a). The defense is usually predicated on misrepresentations during patent prosecution, but has not been confined to instances of misrepresentation that bear on the patentability of claims. One example is the payment of a small entity fee by an entity that is not entitled to small entity status. See, e.g., *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed. Cir. 2007); *Ulead Systems, Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1144 (Fed. Cir. 2003).

⁷ See *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc to overrule precedent governing inequitable conduct standards).

⁸ See *id.*

⁹ See *id.*

¹⁰ See *Young v. Lumenis, Inc.*, 492 F.3d 1336 (Fed. Cir. 2007).

¹¹ See *Star Scientific*, 537 F.3d at 1365.

¹² See *id.*

¹³ *Id.* at 1367 (referencing *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1297 (Fed. Cir. 2008); *Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309, 1314 (Fed. Cir. 2006)).

¹⁴ See *id.* at 1365 (referencing *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363 (Fed. Cir. 2007)).

¹⁵ 37 C.F.R. § 1.56(b).

¹⁶ *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 08-01511, -01512, -01513, -01514, -01595, 593 F.3d 1289 (Fed. Cir. 2010) (Dyk, J., writing for himself and J. Friedman; Linn, J., concurring-in-part and dissenting as to the affirmance of inequitable conduct) (panel opinion vacated by Apr. 26, 2010 order).