

A Panacea for Inequitable Conduct Problems or *Kingsdown* version 2.0? *The Therasense Decision and a Look into the Future of U.S. Patent Law Reform**

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ABSTRACT

For an alleged infringer, a judicial finding of inequitable conduct is the legal equivalent of a jackpot at the nickel slot machines in Las Vegas. The inequitable conduct defense was criticized in the recent Federal Circuit en banc decision of *Therasense, Inc. v. Becton, Dickinson & Co.*, and the

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majority explicitly directed a “tighten[ing] of the standards” for proving inequitable conduct. This Article analyzes the majority’s standards for materiality and intent, as well as the new “affirmative egregious misconduct” exception that may establish materiality per se. It also discusses the post-*Therasense* Federal Circuit and district court decisions to date; the interface of inequitable conduct and recently enacted U.S. patent law reform legislation; and the USPTO’s proposed Rule 56 regulations. In spite of the majority’s valiant efforts in *Therasense*, inequitable conduct allegations in patent infringement litigation will probably not decline, just as they did not the last time an en banc Federal Circuit “fixed” the inequitable conduct problem in the *Kingsdown* case. Simply put, it is unlikely that *Therasense* will be the panacea to the “plague” of inequitable conduct accusations, although it can be hoped that the house will win more often. The Article concludes with possible responses for practitioners going forward in a post-*Therasense* world.

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I. INTRODUCTION

Inequitable conduct has been increasingly used—and in the view of many, is now too frequently used—as a defense in U.S. patent infringement litigation. If an asserted patent was found by a U.S. court to have been procured through inequitable conduct

before the U.S. Patent and Trademark Office (USPTO or “the Office”), the court has refused to enforce the patent.¹ Inequitable conduct defenses have been criticized for increasing litigation costs, discouraging settlement, destroying reputations, reducing predictability, and being a veritable “atomic bomb,” rendering a U.S. patent totally unenforceable even if the perceived misconduct is related only to one of many patent claims.²

As a judge-made doctrine evolving from equitable principles in common law—much like unclean hands and fraud³—the rampant use of the inequitable conduct defense in patent infringement litigation has been referred to as a “plague” on the patent system.⁴ The en banc decision of the U.S. Court of Appeals for the Federal Circuit in *Therasense* recently provided a highly publicized example of a judicial response to the “plague.”⁵ The court noted statistics showing that the majority of patent litigation suits include allegations of inequitable conduct and that this has had a negative impact on both patent litigation and prosecution.⁶ The court identified low standards for intent and materiality as the cause of the overuse of the defense and responded by purportedly tightening the standards for proving inequitable conduct:

While honesty at the PTO is essential, low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality. *This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.*⁷

In an effort to raise the bar for finding inequitable conduct, the en banc court—with six of eleven judges joining the majority opinion written by Chief Judge Rader—in one fell swoop rejected a standard of materiality based on USPTO Rule 56. Instead, the Federal Circuit articulated standards for both materiality and intent that departed from

¹ JANICE MUELLER, *PATENT LAW* 433 (2009).

² *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595, 2011 WL 2028255, at *8 (Fed. Cir. May 25, 2011) (en banc).

³ *Id.* at *4.

⁴ *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

⁵ *Therasense*, 2011 WL 2028255, at *8.

⁶ *Id.* at *8–*9 (“One study estimated that eighty percent of patent infringement cases included allegations of inequitable conduct. Inequitable conduct ‘has been overplayed, is appearing in nearly every patent suit, and is cluttering up the patent system.’ . . . Left unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system. Because allegations of inequitable conduct are routinely brought on ‘the slenderest grounds,’ patent prosecutors constantly confront the specter of inequitable conduct charges. With inequitable conduct casting the shadow of a hangman’s noose, it is unsurprising that patent prosecutors regularly bury PTO examiners with a deluge of prior art references, most of which have marginal value.”) (citations omitted).

⁷ *Id.* at *9 (emphasis added). *See also* *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1350 (Fed. Cir. 2008) (Rader, J., dissenting) (“Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic.”).

many panel precedents.⁸ Additionally, the Federal Circuit abandoned the “sliding scale” for balancing intent and materiality,⁹ consequently requiring clear and convincing evidence of both materiality and specific intent.¹⁰

This Article observes that the standards articulated in *Therasense* are welcomed by the patent community, or at least by U.S. patentees and those who represent them, whether in patent prosecution or litigation. This Article further argues, however, that *Therasense* may not be the panacea many wish it to be and may not, contrary to the aspirations expressed by the *Therasense* majority, have a significant impact on the volume of litigation, inequitable conduct allegations, or materials presented by patent applicants for consideration by the USPTO.

Although the majority opinion in *Therasense* was not free from disagreement and included both a strong concurrence and a vigorous dissent, a petition for certiorari was not filed. Therefore, it is the law that the Federal Circuit and lower courts must follow, at least for now. But since nothing in *Therasense* is *absolutely* new, a review of some old case law will be informative for practitioners trying to predict how *Therasense* will be interpreted. The interface of inequitable conduct and U.S. patent law reform legislation¹¹ and the USPTO's proposed Rule 56 regulations¹² will also be discussed.

II. INEQUITABLE CONDUCT DOCTRINE BEFORE *THERASENSE*

The requirements for a finding of inequitable conduct before *Therasense* were (1) nondisclosure or misrepresentation of material information with (2) an intent to deceive the USPTO.¹³ The party alleging inequitable conduct (typically an alleged infringer) was

⁸*See, e.g.*, *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313–14 (Fed. Cir. 2008) (“An inference of intent to deceive is generally appropriate, however, when (1) highly material information is withheld; (2) ‘the applicant knew of the information [and] . . . knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.’” (quoting *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006)); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997) (“[A] patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead.”); *Aventis*, 525 F.3d at 1344 (“We have previously determined, however, that the dosage information was material to patentability. . . . Nevertheless, because materiality and intent to deceive are necessarily intertwined . . . we will consider the merits of *Aventis*'s argument with respect to deceptive intent.”).

⁹*Aventis*, 525 F.3d at 1344 (“The district court, upon finding materiality and intent, shall ‘balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable.’ . . . ‘The more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct.’”) (citations omitted).

¹⁰*Therasense*, 2011 WL 2028255, at *9 (“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.”) (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

¹¹ Leahy-Smith America Invents Act, Pub. L. No. 112-29 (2011) (to be codified in 35 U.S.C.).

¹² Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 Fed. Reg. 43,631 (proposed July 21, 2011) (to be codified at 37 C.F.R. pt. 1) [hereinafter *Proposed Revision*].

¹³*Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

supposedly required to establish both prongs of inequitable conduct by clear and convincing evidence.¹⁴

A. Intent: The Inconsistent Precedent

After a run of inequitable conduct cases in the 1970s and 1980s,¹⁵ the Federal Circuit sitting en banc purportedly tightened the standard of intent in 1988. In *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*,¹⁶ the Federal Circuit overturned prior precedent¹⁷ which held that a showing of “gross negligence” was sufficient to meet the “intent to deceive” prong of the inequitable conduct defense. Instead, *Kingsdown* held “the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate *sufficient culpability* to require a finding of intent to deceive.”¹⁸ Clearly, the “sufficient culpability” standard was intended to raise the bar for finding inequitable conduct higher than “gross negligence.”¹⁹ Such intention, however, ran aground in various subsequent Federal Circuit panel decisions, showing that although the lower courts and Federal Circuit “must” follow an en banc decision, “should” or “might” may more accurately reflect judicial reality.

In particular, through the 1990s panels of the Federal Circuit whittled away the “sufficient culpability” standard to a mere shadow of itself, finally resulting in panel decisions at least as early as 2003 reducing the standard to a “should have known” standard.²⁰ “Should have known” was a lower standard than “gross negligence,” even though *Kingsdown* was supposed to have raised, not lowered, the intent standard above “gross negligence.” That lower “should have known” standard, tantamount to mere negligence,²¹ made inequitable conduct allegations more attractive to parties trying to

¹⁴ 37 C.F.R. §1.56 (2011); *Star Scientific*, 537 F.3d at 1365.

¹⁵ See *Norton v. Curtiss*, 433 F.2d 779, 782 (C.C.P.A. 1970); *In re Jerabek*, 789 F.2d 886, 889 (Fed. Cir. 1986); *Jaskiewicz v. Mossinghoff*, 822 F.2d 1053, 1058 (Fed. Cir. 1987) (“Mere negligence is not sufficient to infer fraud or dishonesty though gross negligence may lead (in proper circumstances) to a finding of inequitable conduct.”) (citing *N.V. Akzo v. DuPont de Nemours & Co*, 810 F.2d 1148 (Fed. Cir. 1987)); *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984) (“Proof of deliberate scheming is not needed; gross negligence is sufficient.”); *Driscoll v. Cebalo*, 731 F.2d 878, 884 (Fed. Cir. 1984); *Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 714 (1st Cir. 1981); *True Temper Corp. v. CF&I Steel Corp.*, 601 F.2d 495, 499 (10th Cir. 1979).

¹⁶ 863 F.2d 867, 876–77 (Fed. Cir. 1988) (en banc).

¹⁷ See, e.g., *Driscoll*, 731 F.2d at 884.

¹⁸ *Kingsdown*, 863 F.2d at 876 (emphasis added).

¹⁹ *Id.* (“We adopt the view that a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.”).

²⁰ *Bristol-Myers Squibb Co. v. Rhône-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239–40 (Fed. Cir. 2003) (stating that intent may be inferred when a patent applicant knew, or should have known, that withheld information could be material to the PTO’s consideration of the patent application) (citing *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1375–76 (Fed. Cir. 2001)).

²¹ *In re Bose Corp.*, 580 F.3d 1240, 1244 (Fed. Cir. 2009) (“By equating ‘should have known’ of the falsity with a subjective intent, the Board erroneously lowered the fraud standard to a simple negligence standard.” See *Ileto v. Glock, Inc.*, 565 F.3d 1126, 1155 (9th Cir. 2009) (“Knowing conduct thus stands in contrast to negligent conduct, which typically requires only that the defendant knew or *should have known* each of the facts that made his act or omission unlawful. . . .”); see also *Davis v. Monroe Ctny. Bd. of*

raise defenses in patent infringement litigation. After all, what was there to lose in making the allegation? Hindsight can be a glaring light that makes many decisions, perhaps innocuous when made, appear to result from malevolence on the part of the prosecuting attorney or scientific declarant. And if not enough malevolence was established to detonate the atomic bomb, there was no real legal penalty, such as attorney fees, that was applied against the party alleging inequitable conduct.²² In other words, just play the slots and if you lose, you simply walk away having lost the money fed into the machine.

While the standard for intent was being whittled back, another legal doctrine—which reared its head by at least 1984, early in the Federal Circuit’s history—further rendered allegations of inequitable conduct attractive to defendants. Specifically, the “sliding scale” doctrine, promulgated in *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, established a legal notion that as long as there was some clear and convincing evidence of both materiality and intent, one could then balance the intent and materiality evidence.²³ This “sliding scale” was interpreted by courts to mean that if omitted information was highly material, there need not be much—and perhaps only a scintilla—of “clear and convincing” evidence of intent to deceive.²⁴ Indeed, as the case law moved forward, the courts used the sliding scale doctrine to infer intent from sometimes seemingly flimsy evidence in cases where the materiality was high.²⁵

Consequently, the gold standard of an alleged infringer’s litigation strategy was to characterize the materiality as very high and then simply provide some circumstantial evidence of some small “clear and convincing” degree of intent to complete the equation and detonate the atomic bomb, rendering all claims unenforceable. That strategy was further aided by courts that began to justify reliance on scintillas of circumstantial evidence of intent by glibly noting that rarely is there a “smoking gun.”²⁶ Plainly, “clear and convincing” evidence of intent to deceive was greatly eroded in such circumstances, often being no more than winked at.

A fundamental natural law is that for every action, there is an equal and opposite reaction. By 2008, the Federal Circuit began looking for ways to counter the “sliding

Educ., 526 U.S. 629 (1999) (explaining that in *Gebser v. Lago Vista Indep. Sch. Dist.*, 524 U.S. 274 (1998), the Court ‘declined the invitation to impose liability under what amounted to a negligence standard—holding the district liable for its failure to react to teacher-student harassment of which it knew or *should have known.*”).

²² See 35 U.S.C.A. § 285 (West 2011) (“The court in exceptional cases may award reasonable attorney fees to the prevailing party.”); *Gardco Mfg., Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1215 (Fed.Cir.1987) (“[I]t has not been held that every case of proven inequitable conduct must result in an automatic attorney fee award.”).

²³ 725 F.2d 1350, 1364 (Fed. Cir. 1984).

²⁴ *Id.*

²⁵ See, e.g., *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1348 (Fed. Cir. 2007); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313 (Fed. Cir. 2008); *Cargill, Inc. v. Canbra Foods Ltd.*, 476 F.3d 1359, 1364 (Fed. Cir. 2007) (Under the balancing test, “[t]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa.”) (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997)).

²⁶ See, e.g., *Paragon Podiatry Lab. Inc. v. KLM Labs. Inc.*, 984 F.2d 1182, 1189–90 (Fed. Cir. 1993); *Bristol-Myers Squibb Co. v. Rhône-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003).

scale” and “no smoking gun” principles by emphasizing that the intent requirement was not collapsed into the materiality requirement.²⁷ To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with specific intent to deceive the PTO.²⁸ The fact that information later found material was not disclosed could not, by itself, satisfy the deceptive intent element of inequitable conduct.²⁹ The “patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence.”³⁰

In effect, the *Star Scientific* panel provided reasoning more in line with that of en banc *Kingsdown*. Not all panels at the Federal Circuit followed *Star Scientific*,³¹ but that case portended a return to a higher standard of intent such as that articulated in *Kingsdown*. For example, in *Scanner Technologies Corp. v. ICOS Vision Systems Corp.*, the Federal Circuit ruled that “whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”³² Panel decisions throughout 2010 echoed that principle.³³

B. Materiality: Multiple Standards

Pre-*Therasense*, confusion over intent was certainly no greater than the confusion surrounding materiality. The current version of USPTO Rule 56, promulgated in 1992, but ultimately rejected by the majority in *Therasense*,³⁴ provides that information is material if it is not cumulative and (1) “establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim,” or it (2) “refutes, or is inconsistent with” positions taken by the applicant during patent prosecution.³⁵ Prior to 1992, Rule 56, as established in 1976,³⁶ set forth a “reasonable examiner” standard: a reference was material if a “reasonable examiner” would have considered it important to determining the patentability of the claims.

In *American Hoist*, the Federal Circuit embraced the 1976 USPTO Rule 56 “reasonable examiner” standard as “the appropriate starting point,” but held “[t]here is no . . . reason to be bound by any single standard” as “a finding of inequitable conduct requires a balancing of materiality and intent.”³⁷ As discussed by Judge Rich, courts have

²⁷ See *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

²⁸ *Id.* at 1366 (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, F.2d 867, 876 (Fed. Cir. 1988)).

²⁹ *Id.*

³⁰ *Id.* at 1368.

³¹ See, e.g., *Larson Mfg. Co. v. Aluminart Prods. Ltd.*, 559 F.3d 1317 (Fed. Cir. 2009); *Ariad Pharms. Inc. v. Eli Lilly & Co. Inc.*, 598 F.3d 1336 (Fed. Cir. 2010).

³² 528 F.3d 1365, 1376 (Fed. Cir. 2008).

³³ See, e.g., *Lazare Kaplan Int'l, Inc. v. Photocrite Techs., Inc.*, 628 F.3d 1359 (Fed. Cir. 2010); *Ring Plus, Inc. v. Cingular Wireless Corp.*, 614 F.3d 1354 (Fed. Cir. 2010).

³⁴ *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595, 2011 WL 2028255, at *32–34 (Fed. Cir. May 25, 2011) (en banc).

³⁵ 37 C.F.R. § 1.56(b) (1992).

³⁶ 37 C.F.R. § 1.56(b) (1976).

³⁷ *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1364 (Fed. Cir. 1984).

utilized at least three other distinct measures of materiality: (1) an objective “but for” standard; (2) a subjective “but for” standard; and, (3) a “but it may have” standard.³⁸

Finally, the Federal Circuit has also used a nearly *per se* standard of materiality,³⁹ when the conduct consisted of false statements or affidavits submitted to the PTO. In the Federal Circuit’s view “[a]ffidavits are inherently material,” and “[t]he affirmative act of submitting an affidavit must be construed as being intended to be relied upon.”⁴⁰ The affirmative acts of submitting false affidavits are considered misleading in nature.⁴¹ That can particularly be so because the USPTO examiner often has no ability to investigate the facts recited in an affidavit.⁴²

III. *THERASENSE*: FEDERAL CIRCUIT EN BANC

A. Facts

The defendant in *Therasense* argued that Therasense’s U.S. Patent No. 5,820,551 (the ‘551 patent) should be found unenforceable due to inequitable conduct resulting from failure to disclose information to the USPTO from a European Patent Office (“EPO”) proceeding on a different prior art document (also owned by the patentee).⁴³

The undisclosed representations were made to the EPO several years prior to grant of Therasense’s U.S. patent. The alleged infringer averred that the undisclosed representations to the EPO were inconsistent with the representations made to the USPTO about that same prior art document.⁴⁴ The district court agreed, found inequitable conduct had occurred, and, applying the classic atomic bomb approach, held all claims of the ‘551 patent unenforceable.⁴⁵

On appeal, a panel of the Federal Circuit initially affirmed the finding of inequitable conduct.⁴⁶ That decision, however, was vacated and the appeal was reinstated when the Federal Circuit decided to hear the appeal en banc.⁴⁷ According to the Federal

³⁸ *Id.* at 1362 (referencing *Plastic Container Corp. v. Cont’l Plastics of Okla., Inc.*, 607 F.2d 885, 899 (10th Cir. 1979) and *Gemveto Jewelry Co. v. Lambert Bros., Inc.*, 542 F.Supp. 933, 939–40 (S.D.N.Y. 1982)).

³⁹ *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1199 (Fed. Cir. 2006) (Newman, J., dissenting) (“The panel majority’s finding of ‘materiality’ is not substantive scientific materiality, but materiality *per se* of the relationship of the affiant to the applicant.”).

⁴⁰ *Refac Int’l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1583 (Fed. Cir. 1996).

⁴¹ *Paragon Podiatry Labs. Inc. v. KLM Labs. Inc.*, 984 F.2d 1182, 1191 (Fed. Cir. 1993) (“The inference [of intent to mislead] arises not simply from the materiality of the affidavits, but from the affirmative acts of submitting them, their misleading character, and the inability of the examiner to investigate the facts.”).

⁴² *Id.*

⁴³ *Therasense, Inc. v. Becton, Dickinson & Co.*, 565 F.Supp.2d 1088, 1127 (N.D. Cal. 2008)

⁴⁴ *Id.*

⁴⁵ *Id.* at 1191–92.

⁴⁶ *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1292 (Fed. Cir. 2010) (Linn, J., dissenting).

⁴⁷ *Therasense, Inc. v. Becton, Dickinson & Co.*, 374 Fed.App’x. 35 (Fed. Cir. April 26, 2010) (*per curiam*).

Circuit, en banc rehearing was required in recognition of “the problems created by the expansion and overuse of the inequitable conduct doctrine.”⁴⁸ Upon rehearing en banc, the Federal Circuit vacated the district court’s finding of inequitable conduct and remanded the case.⁴⁹

Based on the questions the parties were asked to brief in the appeal,⁵⁰ there was some expectation in the patent community that the Federal Circuit would primarily weigh in en banc on the “intent to deceive” prong of the inequitable conduct inquiry, for the first time since *Kingsdown* in 1988. Interestingly, the en banc decision,⁵¹ rendered May 25, 2011, focused on the standard for materiality, as well as on intent. The Federal Circuit noted:

In the past, this court has tried to address the proliferation of inequitable conduct charges by raising the intent standard alone [This] did not reduce the number of inequitable conduct cases before the courts and did not cure the problem of overdisclosure of marginally relevant prior art to the PTO. To address these concerns, this court adjusts as well the standard for materiality.⁵²

With a majority of six judges, the Federal Circuit vacated the district court’s finding of inequitable conduct and remanded the case for reconsideration of both materiality and intent under the standards set forth in the Federal Circuit’s en banc decision. The court stated that it was, “tighten[ing] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”⁵³

B. Abandoning the Rule 56 Materiality Standard

As noted above, current Rule 56 provides that the undisclosed information is material if it is not cumulative to known information and:

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:

⁴⁸ *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595, 2011 WL 2028255, at *4 (Fed. Cir. May 25, 2011) (en banc).

⁴⁹ *Id.*

⁵⁰ *See Therasense*, 2010 WL 1655391 at *1 (“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 unclean hands? If so, what is the appropriate standard for fraud or unclean hands? 3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office’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.”) (citations omitted).

⁵¹ *Therasense*, 2011 WL 2028255, at *11.

⁵² *Id.*

⁵³ *Id.* at *9.

- (i) Opposing an argument of unpatentability relied on by the Office, or
- (ii) Asserting an argument of patentability.⁵⁴

In the view of the Federal Circuit, the standard set forth in current Rule 56 is too broad.⁵⁵ The first prong of Rule 56 considers information to be material even if the information would be found irrelevant after a patent examiner considers it and is persuaded by any subsequent argument made by the applicant.⁵⁶ The second prong of Rule 56, interpreted literally, encompasses all the information which is inconsistent with applicant's arguments of patentability or opposition to the Office's positions on unpatentability. That means that any information which is in at least some degree—however small—contrary to the applicant's arguments for patentability could be found material under Rule 56, including information contrary to arguments made in the specification.⁵⁷ According to the *Therasense* majority, both the “prima facie case” and “inconsistent” standards in Rule 56 resulted in too much disclosure of marginally relevant prior art and overuse of the defense of inequitable conduct in litigation.⁵⁸

In addition, the *Therasense* majority lamented the unpredictability of case law applying changing USPTO rules,⁵⁹ and reviewed the history of Rule 56 revisions: “[F]rom the ‘fraud’ standard in its original promulgation in 1949 to the ‘reasonable examiner’ standard in 1977 to the current version of Rule 56, which includes any information that ‘refutes or is inconsistent with’ any position the applicant took regarding patentability.”⁶⁰

To select the “but-for” test of materiality, the *Therasense* majority was forced to cast aside the definition of materiality in the USPTO's current Rule 56. Dismissing PTO Rule 56 as not binding on the Federal Circuit,⁶¹ the court proceeded to usher in the “but-for” materiality test.⁶² The Federal Circuit emphasized that in applying that test in

⁵⁴ 37 C.F.R. § 1.56 (2000).

⁵⁵ *Therasense*, 2011 WL 2028255, at *14 (“If an applicant were to assert that his invention would have been non-obvious, for example, anything bearing any relation to obviousness could be found material under the second prong of Rule 56.”).

⁵⁶ *Id.*

⁵⁷ *See, e.g.*, *Golden Hour Data Sys., Inc., v. EMSCharts, Inc.*, 614 F.3d 1367, 1375–76 (Fed. Cir. 2010).

⁵⁸ *Therasense*, 2011 WL 2028255, at *14 (“Because Rule 56 sets such a low bar for materiality, adopting this standard would inevitably result in patent prosecutors continuing the existing practice of disclosing too much prior art of marginal relevance and patent litigators continuing to charge inequitable conduct in nearly every case as a litigation strategy.”).

⁵⁹ *Id.* (“Tying the materiality standard for inequitable conduct to PTO rules, which understandably change from time to time, has led to uncertainty and inconsistency in the development of the inequitable conduct doctrine.”).

⁶⁰ *Id.*

⁶¹ *Id.* (“This court does not adopt the definition of materiality in PTO Rule 56. As an initial matter, this court is not bound by the definition of materiality in PTO rules.”).

⁶² *Id.* at *11 (“This court holds that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality.”). Curiously, the USPTO in its recent Federal Register notice proposing to amend Rule 56, refers to the *Therasense* but-for materiality standard as “but-for-plus.” *Proposed Revision*, 76 Fed. Reg. 43,632 (July 21, 2011). The USPTO explains that term as follows: “The Office notes that, under the ‘but-for-plus’ standard of *Therasense*, information is not material if the pending claim is allowable, applying the preponderance of the evidence standard and giving the claim its broadest

litigation, the judge has to recreate the conditions applicable to USPTO examination and consider the preponderance of the evidence on patentability in light of the broadest reasonable construction of the claim. Indeed, those are the standards that would have been applied had the USPTO in fact been given a chance to consider that evidence during prosecution.⁶³

The en banc majority defined “but-for” materiality as follows:

[P]rior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. . . . [E]ven if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO's different evidentiary standards.⁶⁴

If the conclusion is that the examiner would have allowed the claim(s) anyway, then the undisclosed information is not material.

Four judges in dissent vigorously disagreed with the majority's adoption of the “but-for” materiality standard, arguing instead for deference to the USPTO's current Rule 56 standard.⁶⁵ Judge O'Malley, concurring with the decision to vacate and remand, rejected the standards of materiality set forth by both the majority and the dissent.⁶⁶ Judge O'Malley preferred a flexible approach that provides a “guideline” test for district courts to use in the exercise of their discretion:

[C]onduct should be deemed material where: (1) but for the conduct (whether it be in the form of an affirmative act or intentional non-disclosure), the patent would not have issued . . . ; (2) the conduct

reasonable construction, and the applicant does not engage in affirmative egregious misconduct before the Office as to the information.”

⁶³ *Therasense*, 2011 WL 2028255, at *11 (“Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.”).

⁶⁴ *Id.* at *11.

⁶⁵ *Id.* at *33 (“Because inequitable conduct is an equitable doctrine applied by courts, and not simply a mechanism for judicial enforcement of PTO rules, the scope of the court-made doctrine is not inseparably tied to the breadth of the PTO's disclosure rules. However, the basic purposes of both the inequitable conduct doctrine and Rule 56 are the same, and the disclosure duties that the PTO imposes on applicants, which are defined by Rule 56, are reasonably calculated to produce the disclosure necessary to promote efficient conduct of examinations and to discourage the types of omissions and misrepresentations that (if made intentionally) raise equitable concerns. In these circumstances, considerations of efficiency and economy encourage us to embrace the PTO's approach. So long as it reasonably aligns with our own equitable calculus, we should defer to the PTO's assessment of its needs and treat intentional breaches of the PTO's disclosure rules as providing a basis for a finding of inequitable conduct.”).

⁶⁶ *Id.* at *18 (“The majority defines materiality under a but-for test, with an exception for intentionally false affidavits filed with the PTO. The dissent, on the other hand, defines materiality according to Rule 56. Both tests fail to provide district courts with flexibility to find inequitable conduct in an extraordinary case where the conduct in question would not be defined as such under either test. This result is contrary to the very nature of equity and centuries of Supreme Court precedent. I cannot, accordingly, lend support to either of the immutable tests proposed by my colleagues.”) (citations omitted).

constitutes a false or misleading representation of fact . . . ; or (3) the district court finds that the behavior is so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application at issue was wholly undermined.⁶⁷

Significantly, therefore, the “but-for” materiality standard was approved by only six of the eleven judges. However, in our common law system, since a petition for certiorari was not filed, the majority’s decision is the precedent by which the Federal Circuit and lower courts “must” abide, subject to the type of judicial backsliding explained above that occurred post-*Kingsdown*. The majority also enunciated an “affirmative egregious misconduct” exception to the “but-for” materiality standard to apply to situations where, although the “but-for” materiality test had not been satisfied, it would be unjust to allow the patentee to enforce the patent because of “affirmative egregious misconduct.” This exception to the general rule requiring but-for proof incorporates elements of the early unclean hands cases before the Supreme Court, which dealt with “deliberately planned and carefully executed scheme[s]” to defraud the PTO and the courts. When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.⁶⁸

The *Therasense* majority clarified, albeit in dicta, that neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct. Furthermore, the majority felt compelled to explain—in what may represent nothing more than wishful thinking—that its articulated standard for intent balances patent application dishonesty against unfounded accusations of inequitable conduct

By creating an exception to punish affirmative egregious acts without penalizing the failure to disclose information that would not have changed the issuance decision, this court strikes a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct.⁶⁹

C. Abandoning the “Should Have Known” Negligence Standard

Pre-*Therasense*, as noted, the *Kingsdown* standard of intent could be met even by a misrepresentation or omission amounting to gross or even simple negligence, under a “should have known” standard considered sufficient to satisfy the intent prong of

⁶⁷ *Id.* at *20.

⁶⁸ *Id.* at *12 (citation omitted).

⁶⁹ *Id.*

inequitable conduct.⁷⁰ The *Therasense* majority was clear in its intent to eradicate the “should have known” standard.⁷¹

In particular, the en banc court expressly required specific intent to deceive the USPTO⁷² and adopted a “single most reasonable inference from all of the evidence” standard for proving the intent prong of inequitable conduct.⁷³ In other words, for there to be intent to deceive in terms of inequitable conduct, the *Therasense* majority emphasized that the single most reasonable inference from all of the evidence must be that one with a Rule 56 duty “knew of the reference, knew that it was material, and made a deliberate decision to withhold it.”⁷⁴

Indeed, the majority explained that if multiple reasonable inferences could be drawn from the evidence, intent to deceive cannot be found.⁷⁵ The absence of a good faith explanation for a failure to disclose a material reference, as in *Therasense*, does not, by itself, constitute intent to deceive.⁷⁶ The four dissenting judges⁷⁷ and Judge O’Malley, concurring,⁷⁸ agreed with the majority’s view that specific intent to deceive is required. Moreover, all eleven judges in *Therasense* seem to have a similar view of what is required to prove intent to deceive.⁷⁹

D. Abandoning the “Sliding Scale” Standard

Star Scientific, as noted, served as a reminder that “at least a threshold level of each element—i.e., both materiality and intent to deceive—must be proven by clear and convincing evidence.”⁸⁰ Running with that concept, the *Therasense* en banc majority explicitly forbade inferring intent solely from materiality and abandoned the “sliding scale.”⁸¹ There was no disagreement in the dissenting or concurring opinions on that point.⁸²

⁷⁰ See *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984); *Orthopedic Equip. Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1383 (Fed. Cir. 1983).

⁷¹ *Therasense*, 2011 WL 2028255, at *9 (“To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO. A finding that the misrepresentation or omission amounts to gross negligence or negligence under a ‘should have known’ standard does not satisfy this intent requirement.”) (citations omitted).

⁷² *Id.*

⁷³ *Id.* at *10.

⁷⁴ *Id.* That of course raises the question of whether the only way to find the intent is if one with a Rule 56 duty “knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” Such black letter law might prove difficult to apply in the context of an equitable doctrine, such as inequitable conduct.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.* at *22 (O’Malley, J., concurring in part).

⁷⁸ *Id.* at *17 (Bryson, J., dissenting).

⁷⁹ *Id.* at *10, *17, *22.

⁸⁰ *Id.*

⁸¹ *Therasense*, 2011 WL 2028255, at *10.

⁸² *Id.* at *24 (“There is no ‘sliding scale’ under which the degree of intent that must be proved depends on the strength of the showing as to the materiality of the information at issue.”); *Id.* at *17 (“In making this

The sliding scale rule was established at least as early as 1984 in *American Hoist*.⁸³ Notwithstanding the fact that the *Kingsdown* court later emphasized that the clear and convincing evidentiary requirement applied to both intent and materiality, the sliding scale was broadly interpreted by panels in some cases, resulting essentially in a weakly supported—if not unsupported altogether—assumption of intent if there was high materiality and even if there was realistically less than “clear and convincing” evidence.⁸⁴ Such panel decisions significantly weakened the evidentiary requirement for intent.⁸⁵

The *Therasense* majority commented that the “sliding scale” resulted in inequitable conduct findings based on a reduced showing of intent or materiality, and thus “conflated, and diluted, the standard for both intent and materiality.”⁸⁶ As a result, the Court issued the following instruction:

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. Moreover, a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality.⁸⁷

E. More on the "Affirmative Egregious Misconduct" Exception

Although the Federal Circuit rejected the “sliding scale,” and explicitly stated that “[i]ntent and materiality are separate requirements,”⁸⁸ does the “affirmative egregious misconduct” exception to materiality, in the presence of such conduct, collapse the inquiry into one exclusively looking at intent to deceive? Does that exception, when it applies, read out the “materiality” prong for establishing inequitable conduct?

In other words, it appears that if certain acts qualify as “affirmative egregious misconduct,” such as unmistakably false affidavits, then materiality is assumed per se and the inquiry would then only focus on intent. One might thus think that if an infringer proves affidavits to be unmistakably false, the infringer has also proven that the single most reasonable inference was intent to deceive, and the infringer thus wins on inequitable conduct, even in the total absence of proof of materiality. Only time—and additional case law—will tell if this exception will be considered a fundamental flaw in *Therasense*.⁸⁹

determination, intent to deceive and materiality must be found separately. District courts may not employ a ‘sliding scale,’ nor may they infer intent from materiality alone.”).

⁸³ *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1364 (Fed. Cir. 1984)

⁸⁴ *See, e.g., Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008); *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337 (Fed. Cir. 2007); *Bristol-Myers Squibb Co. v. Rhône-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003).

⁸⁵ *See Erik R. Puknys & Jared D. Schuettenhelm, Application of the Inequitable Conduct Doctrine after Kingsdown*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 839, 870 (2009).

⁸⁶ *Therasense*, 2011 WL 2028255, at *7.

⁸⁷ *Id.* at *10.

⁸⁸ *Id.*

⁸⁹ Unmistakably false affidavits as an example of affirmative egregious misconduct would appear to make the per se rule an exception rarely to be called upon. But what of the “sin of omission?” It is not hard

The majority explained its creation of the “affirmative egregious misconduct” exception in the following terms: “By creating an exception to punish affirmative egregious acts without penalizing the failure to disclose information that would not have changed the issuance decision, this court strikes a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct.”⁹⁰ While this language indicates the majority is comfortable with creating a *per se* exception, it seems to also create opportunities for time-consuming arguments in litigation over whether an act or series of acts constitutes “affirmative egregious misconduct” and therefore qualifies for *per se* inequitable conduct treatment. This seems contrary to the majority’s concern, expressed earlier in its opinion, that inequitable conduct disputes “increas[e] the complexity, duration and cost of patent infringement litigation that is already notorious for its complexity and high cost.”⁹¹ One is left to wonder whether the *Therasense* majority would have been better off reverting to the old “unclean hands” exception—with the attendant remedy of dismissing the complaint—that was applied in the Supreme Court trilogy of pre-1950 cases⁹² cited in the *Therasense* majority.

IV. INEQUITABLE CONDUCT ALLEGATIONS WILL PROBABLY NOT DECLINE

In spite of clear and noble intentions from the Federal Circuit, inequitable conduct allegations in patent infringement litigation will probably not decline. *Therasense* is not the panacea to the “plague.” As recognized by the majority in *Therasense*, past judicial attempts to reduce the volume of inequitable conduct allegations have not been successful:

In the past, this court has tried to address the proliferation of inequitable conduct charges by raising the intent standard alone. . . . This higher intent standard, standing alone, did not reduce the number of inequitable conduct cases before the courts and did not cure the problem of overdisclosure of marginally relevant prior art to the PTO.⁹³

As discussed above, the last *en banc* inequitable conduct decision in *Kingsdown* did not prove successful in choking off garden-variety allegations of inequitable conduct. In the last few years, moreover, a panel of the Federal Circuit tried to impose more stringent pleading standards in *Exergen Corp. v. Wal-Mart Stores, Inc.*⁹⁴ Yet as seen in the charts below, *Exergen* has not yet noticeably reduced inequitable conduct allegations. With the

to imagine arguments that will swirl around in litigation as to whether the omission was affirmative egregious misconduct or merely negligent. If the alleged infringer can get the omission characterized as affirmative egregious misconduct, then the omission is apparently *per se* material and may lead to intentional deception as the only reasonable inference.

⁹⁰ *Id.* at *12.

⁹¹ *Id.* at *9 (quoting Brief for Am. Bar Ass’n as Amici Curae, *Therasense*, 379 F. App’x 979 (2010) (Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595)).

⁹² *Precision Instruments Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds by* *Standard Oil Co. v. United States*, 429 U.S. 17 (1976); and *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933).

⁹³ *Id.* at *11.

⁹⁴ *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009).

erosion of the intent standard from a high water mark in *Kingsdown* in 1988 came a steady increase in the volume of inequitable conduct allegations made in patent litigation, as demonstrated in Figures 1 and 2.

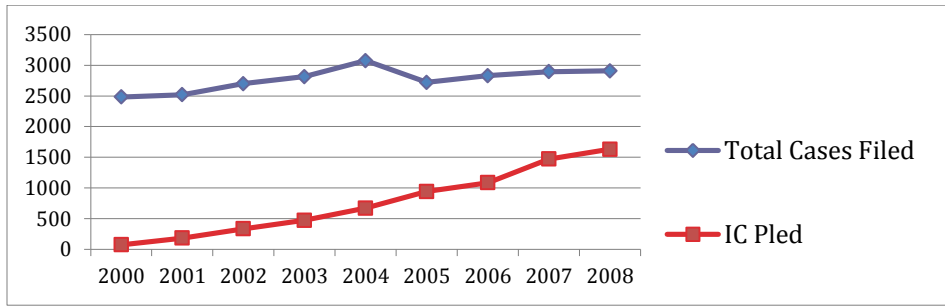


Fig. 1. District Court Patent Cases Filed and Inequitable Conduct Pled. Source: Christian E. Mammen, *Controlling the ‘Plague’: Reforming the Doctrine of Inequitable Conduct,* 24 Berkley Tech. L.J. 1329, 1351 (2009).

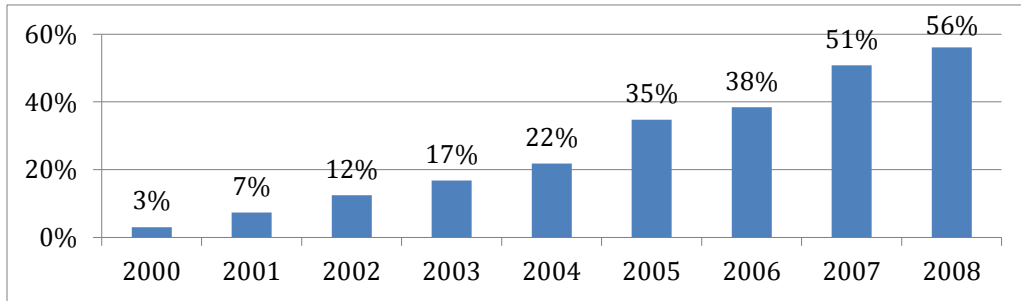


Fig. 2. Percentage of District Court Patent Filings in Which Inequitable Conduct Pled. Source: Christian E. Mammen, *Controlling the ‘Plague’: Reforming the Doctrine of Inequitable Conduct,* 24 Berkeley Tech. L.J. 1329, 1351 (2009).

The absolute number of inequitable conduct cases finding their way to the Federal Circuit has also increased, as seen in Figure 3.

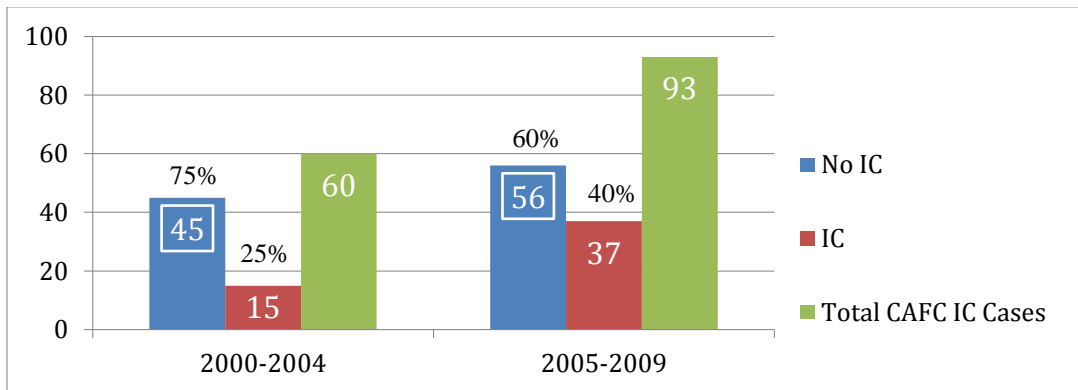


Fig. 3. Federal Circuit Cases with Inequitable Conduct Results, 2000–09. Source: patstats.org (<http://www.patstats.org/2000-04.htm>) and (http://www.patstats.org/2005-2009_composite.htm).

While there is no proof of causality, with the increased number of inequitable conduct decisions came a drop in the success rate of the patentees from seventy-five percent in 2000 through 2004 to sixty percent in 2005 through 2009. Looking at the data a little differently, one sees that twenty-five percent of the patentees lost in 2000 through 2004 and forty percent lost in 2005 through 2009. Numerous losses were due to the “atomic bomb” of inequitable conduct, with the attendant dire possibilities of exceptional case, attorney fees, and antitrust violations.

For 2010 through July 31, 2011, patentees, as shown in Figure 4., appear to be having more success fending off inequitable conduct allegations:

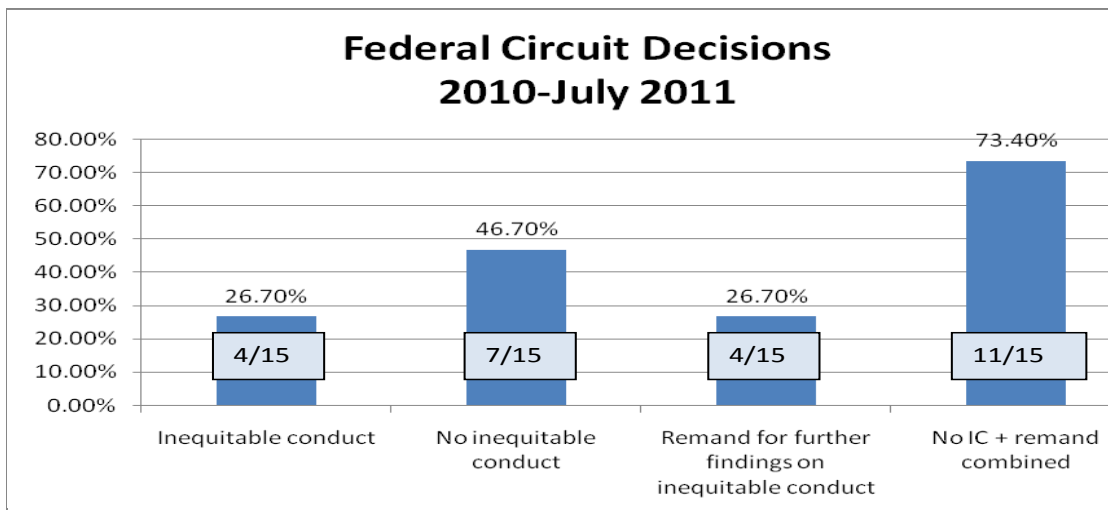


Fig. 4. Federal Circuit Cases with Inequitable Conduct Results, 2010-11. Source: Westlaw, CTAF database, query da(aft 12/31/2009 & bef 07/31/2011) & "inequitable conduct" % "not selected for publication".

The certainty provided to the patent community in terms of clarifying the standards for materiality and intent is unquestionably a welcome development. At least theoretically, more stringent pleading standards from *Exergen* and more stringent proof standards from *Therasense* should have a positive impact for patentees by making inequitable conduct allegations tougher to prove, thus lowering the success rate in litigation against patentees based on inequitable conduct allegations.

However, none of the other factors motivating alleged infringers has changed, such as a disproportionate discovery burden on the patentee or the possibility of a huge gain for the alleged infringer if the “atomic bomb” detonates and wipes out the entire patent. Merely changing the standard for finding inequitable conduct may be insufficient to reverse the trend of an ever-increasing volume of inequitable conduct pleadings, even if those changed standards are heightened and apply to both intent and materiality.

Furthermore, as mentioned in Part III.E, *infra*, the "affirmative egregious misconduct" exception may serve as a secret passage back into the world of time-consuming and expensive inequitable conduct allegations in patent litigation.

In addition, another goal of the Federal Circuit in *Therasense*—to eliminate voluminous submissions of prior art, at least some of which may be marginally relevant—may go unrealized. Rather, the Federal Circuit's "but-for" materiality may in fact encourage applicants to continue to submit significant amounts of prior art during prosecution. The *Therasense* "but-for" test is "objective" according to the USPTO standards of examination. But at least generally, the standard applies only to information not before the USPTO during patent prosecution. If the information was before the USPTO and the claims were allowed, the patentee might merely argue that the information was considered by the USPTO and nonetheless, the claims were allowed. That would generally seem to short circuit the need for the patentee to defend against inequitable conduct on any information previously considered by the USPTO, absent affirmative egregious misconduct. In such case, a patent applicant would be motivated to submit as much information during prosecution as possible, essentially defusing the atomic bomb that otherwise could be detonated in subsequent litigation based on non-disclosure of information found, for example, in the inventors' and attorneys' files.

If that rationale proves sound, the USPTO and Federal Circuit may find that post-*Therasense*, patentees submit even more information to the USPTO to have that information cleansed from inequitable conduct allegations in the holy water of allowance in view of that information. If the amount of disclosure continues to rise, alleged infringers might try to establish that the sheer volume of information causes material information to be buried.⁹⁵ But does that go to materiality or merely intent to deceive? And if the latter, can an alleged infringer establish that the submission of voluminous prior art is "affirmative egregious misconduct," particularly where a USPTO examiner avers in writing that she considered all art submitted?

As an aside, the en banc court, as noted, in *Therasense* included a vigorous dissent of four judges on materiality. It is possible that a given case could be assigned a panel of judges who all participated in the *Therasense* dissent. Since panels have previously and routinely ignored the en banc *Kingsdown*, would such panels, also including in the future newly appointed judges, also ignore *Therasense*?

V. NOT ABSOLUTELY "NEW"

As is evident at least in part from points made above, the fate of the inequitable conduct doctrine depends significantly on how *Therasense* is interpreted, applied, and developed by able trial and appellate judges—and skillful counsel on both sides—in the case law going forward. No one knows exactly how this will unfold. This uncertainty is

⁹⁵ See *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) ("Moreover, 'burying' a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith."). See also *id.* (discussing *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp. 948 (S.D. Fla. 1972), *aff'd*, 479 F.2d 1328 (5th Cir. 1973), *cert. denied*, 414 U.S. 874 (1973)).

compounded by the general rule that all facts for a specific allegation of inequitable conduct are unique to that particular situation and that inequitable conduct boils down to a decision in equity. That last point may in fact have been what caused the *Kingsdown* “intent erosion.” Judges intent on doing both justice and equity simply needed different words and standards than those propounded in *Kingsdown*.

The *Therasense* majority did its best to prop up its opinion by invoking Supreme Court precedent and attempting to resolve conflicting Federal Circuit precedent, in an effort to decelerate the recent trend of increased inequitable conduct allegations.⁹⁶ In that sense, *Therasense* did not create something absolutely new.

The majority opinion identified the Supreme Court trilogy of cases which it deemed to be the origins of the modern law of inequitable conduct,⁹⁷ and pointed out that in all those cases, the patentee acted knowingly and deliberately with the purpose of defrauding the USPTO and the courts.⁹⁸ The majority expected this precedent to serve as a limit on the judge's discretion that accompanies any equitable consideration.⁹⁹

The *Therasense* decision leaves many gray areas to be worked out by future judicial decisions, particularly since each inequitable conduct assessment depends on its own specific facts. For example, if the accused infringer is not able to provide clear and convincing evidence to prove a threshold level of intent to deceive, the patentee is not required to provide any good faith explanation in order to survive an inequitable conduct pleading.¹⁰⁰ The court ruled that the patentee need not offer any good faith explanation, unless “the accused infringer first . . . prove[s] a threshold level of intent to deceive by

⁹⁶ *Therasense*, 2011 WL 2028255, at *10 (“This requirement of knowledge and deliberate action has origins in the trio of Supreme Court cases that set in motion the development of the inequitable conduct doctrine.”); *id.* at *13 (“[T]he general rule requiring but-for materiality provides clear guidance to patent practitioners and courts, while the egregious misconduct exception gives the test sufficient flexibility to capture extraordinary circumstances. Thus, not only is this court's approach sensitive to varied facts and equitable considerations, it is also consistent with the early unclean hands cases—all of which dealt with egregious misconduct.”).

⁹⁷ *Id.* at *10 (citing *Precision Instruments*, 324 U.S. at 815-16 (discussing patent known to be tainted by perjury); *Hazel-Atlas Glass*, 322 U.S. at 245 (discussing a “deliberately planned and carefully executed scheme to defraud” the PTO involving both bribery and perjury); *Keystone Driller*, 290 U.S. at 246 (discussing bribery and suppression of evidence)).

⁹⁸ *Id.*

⁹⁹ *Id.* at *13 (“[N]ot only is this court's approach sensitive to varied facts and equitable considerations, it is also consistent with the early unclean hands cases—all of which dealt with egregious misconduct . . . Although equitable doctrines require some measure of flexibility, abandoning the use of tests entirely is contrary to both longstanding practice and Supreme Court precedent. Courts have long applied rules and tests in determining whether a particular factual situation falls within the scope of an equitable doctrine. . . . Moreover, the Supreme Court has made clear that such tests serve an important purpose in limiting the discretion of district courts.”) (citations omitted). Notably, the Federal Circuit highlighted that the trilogy of cases dealt with “egregious affirmative conduct” and as explained *supra*, can be viewed as pure intent cases in which materiality does not matter a whit.

¹⁰⁰ *Id.* at *10 (“Because the party alleging inequitable conduct bears the burden of proof, the ‘patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence.’”) (quoting *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1368 (Fed. Cir. 2008)). One can ask, how low will that threshold level be? *See infra*.

clear and convincing evidence.”¹⁰¹ However, the *Therasense* majority opinion did not define what a “threshold level” is. What is and is not “affirmative egregious misconduct” is another concept that will be worked out in future case law based on specific facts presented and developed during discovery and depositions of key witnesses, whose demeanor will often be evaluated by the judge.

Taking cues from the *Therasense* majority opinion, practitioners can look to old common law fraud and unclean hands case law to try to prepare for how *Therasense* will be interpreted. Plenty of room remains, however, for judicial discretion; for development of the outlines of the standards for materiality and intent; for highly skilled counsel to build a story of intent to deceive; or, alternatively, for painting an innocuous picture of what specifically was done or not done.

VI. POST-THERASENSE: CONGRESS AND THE USPTO

The *Therasense* majority’s “tightening” of inequitable conduct law must also be considered along with the America Invents Act,¹⁰² which was enacted on September 16, 2011, less than four months after the *Therasense* decision. It will be interesting to watch how the Federal Circuit will reconcile the ruling in *Therasense* with the new patent reform legislation. In addition, the USPTO has already begun to act in response to *Therasense*.

A. The Interface with Patent Reform

Historically, once a patent issues, it is not possible to purge the taint of inequitable conduct that was practiced in the procurement of the original patent grant.¹⁰³ The *Therasense* decision also followed the precedents that inequitable conduct cannot be cured by reissue or reexamination.¹⁰⁴ Yet, in *Therasense*, the Federal Circuit seemed to allow a back door “purge” by a patentee of what might have previously been considered to be inequitable conduct by establishing no “but-for” materiality. In other words, according to the *Therasense* standard, the court will not find inequitable conduct if the alleged infringer fails to establish that the information not disclosed would not have rendered the claim unpatentable under the PTO standards. Failure to cite the reference is in effect “purged,” even though in the past, under different standards of materiality and intent, the seeds for a finding of inequitable conduct might have been planted by such non-disclosure.

That concept is not inconsistent with the treatment of inequitable conduct in the America Invents Act. The new law allows a procedure called “supplemental examination.”¹⁰⁵ Supplemental examination attempts to reduce inequitable conduct

¹⁰¹ *Id.*

¹⁰² Leahy-Smith America Invents Act, PUB. L. NO. 112-29 (2011) (to be codified in 35 U.S.C.).

¹⁰³ Compare this to the doctrine of patent misuse, which allows the patent to “reinstate” temporarily suspended enforceability by purging the misuse. *See* *Kearney & Trecker v. Cincinnati Milacron*, 403 F.Supp. 1040, 1066 (S.D. Ohio 1975), *aff’d*, 562 F.2d 365 (6th Cir. 1977).

¹⁰⁴ *Therasense*, 2011 WL 2028255.

¹⁰⁵ America Invents Act § 12.

pleadings from patent litigation, at least to some extent, by allowing the USPTO to make an adjudication both post-issuance and pre-litigation, while leaving issues of antitrust liability and criminal exposure to the courts and patent attorney sanctions to the USPTO.

Specifically, under certain circumstances, a patentee can avail itself of supplemental examination to provide the USPTO with information that was not submitted during the procurement of the patent.¹⁰⁶ If the USPTO reviews that information and finds no substantial new question (SNQ) of patentability, inequitable conduct cannot in general be asserted against the patentee in litigation based on the information reviewed during the supplemental examination.¹⁰⁷ And even if in the supplemental examination the USPTO finds an SNQ regarding a patent claim, the patentee can then proceed to reexamination. Assuming the patentee establishes patentability of the claim in the reexamination over the SNQ raised by the information reviewed, the patentee is insulated in subsequent litigation from a charge of inequitable conduct based on that information.¹⁰⁸

It appears, therefore, that if supplemental examination is utilized, inequitable conduct cannot be asserted in a subsequent litigation against patent claims surviving the supplemental examination based on the information considered during that process. But, what if there was “affirmative egregious conduct” in the nondisclosure/misrepresentation that occurred during the original patent procurement? The *Therasense* majority would, under such circumstances, carve out an exception to but-for materiality and, as explained above, apparently collapse the whole inequitable conduct analysis solely into a consideration of intent.

Similarly, but using different language, the patent law reform bill includes a “fraud exception” allowing that:

[i]f the Director becomes aware, during the course of a supplemental examination or reexamination proceeding ordered under this section, that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination, then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under section 307 as a result of a reexamination ordered under this section, the Director shall also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate.¹⁰⁹

In other words, the Director can vacate any supplemental examination or reexamination proceeding that is pending if fraud is found during the original procurement. While fraud is not defined by the bill, one could argue that “affirmative egregious conduct” is at least part of fraud. And what if the Director does not become aware of such fraud or “affirmative egregious conduct” while supplemental examination

¹⁰⁶ *Id.* at § 12(a).

¹⁰⁷ *Id.* at § 12(c).

¹⁰⁸ *Id.* at § 12(b).

¹⁰⁹ *See id.* at § 12(e).

or reexamination is pending? Perhaps under such circumstances, a court sufficiently offended by the misconduct revealed during litigation would revert to the original Supreme Court trilogy of *Keystone Driller*, *Hazel-Atlas Glass*, and *Precision Instrument*¹¹⁰ to find unclean hands and dismiss the complaint. That is, there may end up being an affirmative egregious misconduct exception to the enforceability of even those patent claims cleansed through Supplemental Examination. That would read back the element of “intent” regarding such patent claims.

Reissue patent law reform in the America Invents Act raises other interesting possibilities. The Act removes “deceptive intent” from the reissue statute, leaving the implication that a reissue is proper even if there was deceptive intent during the original prosecution. But that sounds analogous to the analysis above regarding supplemental examination, leaving one to wonder if there will be a resurgence of “unclean hands” defenses in cases where there was no but-for materiality but a finding of affirmative egregious misconduct.

B. *Therasense* and 37 C.F.R. §1.56 (“Rule 56”)

Since inequitable conduct allegations relate to actions taken during patent prosecution, it stands to reason that the new materiality standard in *Therasense* should have an impact on prosecution practice before the USPTO. The but-for materiality—set forth in *Therasense* as a general prerequisite for a finding of inequitable conduct—is a stricter requirement than the current Rule 56 definition of materiality. On July 21, 2011, the USPTO issued proposed rules that would amend Rules 56(b) and 555(b) in light of *Therasense*.¹¹¹ The proposed change explicitly cites *Therasense* and adopts the standard of materiality set forth by the majority:

Section 1.56(b) as proposed to be amended would provide that information is material to patentability if it is material under the standard set forth in *Therasense*, and that information is material to patentability under *Therasense* if:

- (1) The Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or
- (2) the applicant engages in affirmative egregious misconduct before the Office as to the information.

As stated in *Therasense*, neither mere nondisclosure of information to the Office nor failure to mention information in an affidavit, declaration, or other statement to the Office constitutes affirmative egregious

¹¹⁰ *Precision Instruments Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds by* *Standard Oil Co. v. United States*, 429 U.S. 17 (1976); and *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933).

¹¹¹ *Proposed Revision*, 76 Fed. Reg. 43,631 (July 21, 2011) (“Specifically, the Office is proposing to revise the materiality standard for the duty to disclose to match the materiality standard, as defined in *Therasense*, for the inequitable conduct doctrine.”).

misconduct.¹¹² The Office notes that, under the “but-for-plus” standard of *Therasense*, information is not material if the pending claim is allowable, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction, and the applicant does not engage in affirmative egregious misconduct before the Office as to the information. The Office recognizes the tension inherent in a disclosure standard based on unpatentability, but appreciates and expects that patent applicants are inclined to be forthcoming and submit information beyond that required by proposed Rule 56, in an effort to assist examiners in performing their duties. The Office wishes to facilitate and encourage such efforts by applicants.¹¹³

Although the USPTO commented that practitioners would disclose information “beyond that required,”¹¹⁴ elsewhere in the announcement it stated that the ““but-for-plus” standard from *Therasense* will . . . reduce the incentive for applicants to submit information disclosure statements containing only marginally relevant information out of an abundance of caution.”¹¹⁵ These seemingly contradictory positions are further blurred by the reality of patent prosecution that it might be unduly burdensome to analyze prior art for “marginal relevance” rather than simply submit “everything” that might be relevant. And there remains the possibility, discussed in Part IV, *supra* that practitioners will hope to eliminate any future “but-for” references by submitting as much prior art as can be found, so that art is clearly considered by the USPTO under the preponderance of evidence standard against the claim, as most broadly reasonably construed.

The USPTO's proactive efforts in July, 2011 appear to have paid off, since a petition for certiorari was not filed in *Therasense*. There will thus be no need to delay finalizing the rule change waiting for a Supreme Court decision.¹¹⁶ Regardless of any changes to Rules 56 and 555, the USPTO can always still rely on 37 C.F.R. § 1.105 to request any information it deems necessary to undertake examination of the patent application.¹¹⁷ Whether that will be done, and to what extent, is unknown at present, and there was no reference to Rule 105 in the July 21, 2011 Proposed Rules.

¹¹² *Therasense*, 2011 WL 2028255, at *12. Of course, in litigation, there will undoubtedly be much evidence produced on both sides as to whether there was “mere” nondisclosure.

¹¹³ *Id.* at 43,633. Also, the invitation to submit more than is required will not be a positive factor in stemming the tidal wave of information that caused the *Therasense* majority to complain.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 43,632.

¹¹⁶ *Id.*

¹¹⁷ 37 C.F.R. § 1.105 (2009). “Requirements for information. (a)(1) In the course of examining or treating a matter in a pending or abandoned application filed under 35 U.S.C. 111 or 371 (including a reissue application), in a patent, or in a reexamination proceeding, the examiner or other Office employee may require the submission, from individuals identified under § 1.56(c), or any assignee, of such information as may be reasonably necessary to properly examine or treat the matter[.]”

VII. IMPACT OF *THERASENSE*

A. The Tightened Standard in Litigation: Intent and Materiality

It seems fair to conclude that the *Therasense* majority intended its decision to discourage use of inequitable conduct as a routine defense, or at least to diminish the chances that inequitable conduct will be found.¹¹⁸ One might also look to the Federal Circuit's 2009 decision in *Exergen* to further assist in achieving this objective.¹¹⁹ For example, *Exergen*'s "who, why, where, when, and how" pleading requirements in conjunction with the *Therasense* elimination of the sliding scale might make it more difficult to prove inequitable conduct based solely on unsupported assertions of high materiality of undisclosed/misrepresented information.

The elimination of the Rule 56 standard that "inconsistent" information is material could be helpful in avoiding charges of inequitable conduct. As the majority points out, application of "inconsistent information" under the Rule 56 standards can greatly expand the universe of relevant information to be considered in the materiality calculus.¹²⁰

However, although *Therasense* stands, at least for now,¹²¹ inequitable conduct charges will not magically disappear. As long as the cost of such an allegation is minimal, the burden on the patentee to respond to such an allegation is large, and the payoff is complete elimination of the patent and attorney fees if successful, alleged infringers will continue to see the benefit of such an allegation. More stringent pleading requirements may not change that. *Exergen* was decided in 2009 and has not appeared to stem the tide of inequitable conduct allegations.¹²²

Therasense may in fact have the unintended consequence of making litigation more complicated. Practitioners may continue to flood the USPTO with prior art at least marginally relevant, with the expectation that if the claim is allowed, they will not have to address whether any of those references, if not disclosed, could have been but-for

¹¹⁸ *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595, 2011 WL 2028255, at *9 (Fed. Cir. May 25, 2011) (en banc) ("This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.").

¹¹⁹ *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009); *see also Therasense*, 2011 WL 2028255, at *21 (O'Malley, J., concurring) ("To the extent there are concerns with litigation abuses surrounding the improper use of this otherwise important doctrine, there are vehicles available to the district court to address those concerns. Careful application of the pleading requirements set forth in *Exergen* . . . , early case management techniques designed to ferret out and test unsupported inequitable conduct claims, orders to stay discovery or consideration of such claims pending all other determinations in the case, or even sanctions, are all tools district courts can employ where appropriate.").

¹²⁰ *Therasense*, 2011 WL 2028255, at *14.

¹²¹ To be sure, even though Becton Dickinson did not file a petition for certiorari in *Therasense*, another defendant, displeased with the application of *Therasense* in finding no inequitable conduct, might indeed petition the Supreme Court for review.

¹²² *See* Figures 1–3, *supra*.

material. The lack of “but-for” materiality will have been established by prosecution leading to the allowance of claimed subject-matter over those references.

The possibility also arises that patent claims will now have to be construed two ways. Under a *Markman*¹²³ hearing, the court will construe them one way for invalidity and infringement based on the specification, the language of the claims, and the prosecution history.¹²⁴ But then the court, to assess an inequitable conduct charge, will conduct a “*Therasense*” hearing in which, the court will decide what the broadest reasonable construction is for a particular claim. And once the *Therasense* construction is achieved, the court can then decide, whether, under a preponderance of evidence standard, the claim would have been held unpatentable over information *not* considered by the USPTO. In other words, perhaps there will be two routine pretrial hearings: a *Markman* hearing to assess claim construction for infringement and validity and a *Therasense* hearing to assess claim construction for inequitable conduct.

The tightened *Therasense* majority intent standard, moreover, if applied as expressed, should shift the “intent” battleground to determine whether the “single most reasonable inference from all of the evidence” is that there was no intent to deceive. The “threshold level of intent to deceive” sufficient to shift the burden to the patentee to provide a good faith explanation will no doubt be vigorously contested, with alleged infringers asserting they have satisfied it.¹²⁵ Many litigated battles no doubt lie ahead to determine the exact contours of the concepts expressed in *Therasense*.

B. The Federal Circuit: Will *Therasense* Go the Way of *Kingsdown*?

Kingsdown, as noted above, cast out gross negligence and established “sufficient culpability to require an intent to deceive” as a higher bar. Notwithstanding that pronouncement, over the years Federal Circuit panels diluted the standard for inequitable conduct until, in some circumstances, “should have known” or simple negligence appeared to be all that was required to establish intent. Furthermore, just a scintilla of evidence of such negligence sufficed to undermine patents and ruin reputations. So too, since inequitable conduct charges are unique to specific facts and circumstances, case law may wobble in the future as judges look for words to brand as inequitable conduct what they see as bad conduct. Hence, even if the bar is raised, *Therasense*—just like *Kingsdown* before it—may be yet another en banc decision that slows, but does not substantially curtail, inequitable conduct allegations and findings.

¹²³ *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970–71 (Fed. Cir. 1995) (en banc) (holding that claim construction “is a matter of law exclusively for the court”). In a unanimous opinion, the Supreme Court agreed with the Federal Circuit, holding that patent construction “is a special occupation, requiring, like all others special training and practice.” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996) (quoting *Parker v. Hulme*, 18 F. Cas. 1138, 1140 (E.D. Pa. 1849)).

¹²⁴ See *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

¹²⁵ *Therasense*, 2011 WL 2028255, at *10.

C. How Will Practitioners Respond in Prosecution?

How will *Therasense*'s impact spread to patent prosecution? As the *Therasense* majority admits and the dissent attacks, the tightened standard of materiality could lead to a concern, in particular cases, as to whether there will be enough pressure to compel full disclosure from the patent applicant so that the USPTO can properly do its job. How should the patent applicant proceed?

Patentees face at least two approaches for submitting prior art and information to the USPTO. One approach would be to review the art carefully, make a determination that certain art is not but-for material, conclude that there is no obligation to submit the art, and—by a more focused approach to disclosure—increase the chances that the USPTO will provide an even more thorough examination over the closest prior art.

Another approach, alluded to above, would be to continue to flood the USPTO with all of the at least marginally relevant information available, on the theory that if the USPTO allows claims over that art, that allowance will prove that none of the information submitted was but-for material and will hamstring allegations of inequitable conduct that otherwise could have been made in the case of nondisclosure. But what would be the effect, if any, of that flood of marginally relevant information in view of *Therasense*'s “affirmative egregious acts” exception to materiality that purportedly strikes the balance between encouraging honesty before the PTO and preventing overuse of inequitable conduct?¹²⁶ In other words, even if there is no materiality but there is affirmative egregious misconduct, i.e. “but-for-plus” is not satisfied, one can argue that materiality is met per se, and the entire analysis reduces to an examination of intent. And if the “affirmative egregious acts” exception is proven, will it not be a very rare case that intent to deceive the USPTO is not found? So, when all is said and done, increased disclosure may not end up precluding an inequitable conduct finding.

As all the contours of the *Therasense* decision are worked out in the forthcoming case law, practitioners may want to proceed slowly and read carefully all relevant judicial precedent before radically changing any pre-*Therasense* prosecution practices.

VIII. CONCLUSION

In the late 1970s and early 1980s, there was a concern that the creation of the Federal Circuit would result in patent law departing from the common law tradition. *Therasense* seems to be an effort to reconcile patent law inequitable conduct with common law fraud and the equitable defense of unclean hands.¹²⁷

The *Therasense* en banc opinion was driven by a genuine desire to change current practices with respect to inequitable conduct. To that end, the Federal Circuit frankly criticized its own precedents and expressly overturned old standards, painstakingly trying to construct a new paradigm in their place. But an attempt to clarify an equitable doctrine

¹²⁶ *Id.* at *12.

¹²⁷ *Id.*

is anything but an exact science. Time will tell how much *Therasense* changes the law of inequitable conduct and whether the goals expressed by the *Therasense* majority will be achieved or whether *Therasense* will be a failure of *Kingsdown*-like proportions.

The tightened standards of *Therasense* will be welcomed by the patent community, but, as this paper observes, are unlikely to be a panacea. *Therasense* may be unsuccessful in significantly impacting the volume of inequitable conduct allegations. In the meantime, since nothing in *Therasense* is *absolutely* new, old case law may be instructive to practitioners and litigators trying to predict how *Therasense* will be interpreted. Finally, the USPTO's proposed change to Rule 56 to make it consistent with *Therasense* at least indicates that the USPTO is trying to address the "plague" of inequitable conduct and would like to take positions consistent with those of the *Therasense* majority.