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Priscilla G. Taylor

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UNIVERSITY OF CALIFORNIA, BERKELEY
SCHOOL OF LAW
BOALT HALL

BRINGING EQUITY BACK TO THE INEQUITABLE CONDUCT DOCTRINE?

Priscilla G. Taylor[†]

In hopes of recapturing the equitable spirit of the inequitable conduct doctrine, the Federal Circuit substantially reformed the doctrine in its en banc decision in *Therasense, Inc. v. Becton, Dickinson and Co.*¹ The inequitable conduct doctrine is based on a patent applicant's duty of candor before the PTO and, where this duty is breached, serves as an affirmative defense for an alleged infringer.² Prior to *Therasense*, the broad standards for the doctrine's application encouraged unsupported allegations in the courts and inundated patent examiners with duplicative and extraneous information.³ The court narrowed the inequitable conduct defense by significantly raising the standards for showing both intent and materiality and by eliminating the long-standing "sliding scale" step of the defense.⁴

Therasense addressed many of the perceived problems that the defense had created for both the courts and the Patent and Trademark Office ("PTO"). The *Therasense* decision was largely motivated by goals of efficiency for the courts and the PTO.⁵ The court also voiced concerns of fairness for

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[†] J.D. Candidate, 2013, University of California, Berkeley School of Law.

1. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011).

2. See, e.g., Benjamin Brown, *Inequitable Conduct: A Standard in Motion*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 593 (2009); Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J.L. & TECH. 37 (1993); Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147 (2005); J. Randall R. Rader, *Always at the Margin: Inequitable Conduct in Flux*, 59 AM. U. L. REV. 777 (2010).

3. *Therasense*, 649 F.3d at 1289. See generally, Lisa A. Dolak, *Beware the Inequitable Conduct Charge! (Why Practitioners Submit What They Submit)*, 91 J. PAT. & TRADEMARK OFF. SOC'Y 558 (2009) (discussing the broadening of the inequitable conduct doctrine and its relation to over-submission at the PTO); Christian E. Mammen, *Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct*, 24 BERKELEY TECH. L.J. 1329, 1330–44 (2009) (discussing the expansion of the inequitable conduct doctrine and the consequent encouragement of unwarranted inequitable conduct claims); Rader, *supra* note 2, at 783 (discussing how the "gradual evolution away from the roots of the inequitable conduct doctrine inspired litigants to use inequitable conduct as a strategic part of a defense against patent infringement").

4. *Therasense*, 649 F.3d at 1290–92.

5. *Id.* at 1290 (noting the "increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog,

patentees faced with inequitable conduct allegations, reiterating that the defense is an equitable one that “hinges on basic fairness.”⁶ Although the Federal Circuit may arguably have missed its mark when aiming to create efficiency and fairness within the inequitable conduct doctrine, the majority’s decision took, at minimum, a significant step in this direction and provided clarity to practitioners.

This Note first explores the development of the inequitable conduct doctrine from its inception, the problems it has created for the courts and the PTO in the ensuing years, and how the Federal Circuit addressed those problems in its en banc decision in *Therasense*. Part II then looks at the practical implications of the new law developed in *Therasense* in light of *Exergen Corp. v. Wal-Mart Stores, Inc.*,⁷ the PTO’s recent proposed revision to its Rule of Disclosure,⁸ and the Leahy-Smith America Invents Act (“Leahy-Smith AIA”).⁹ Part III explores the interpretation of the Federal Circuit’s decision by district courts in the months following *Therasense*. Finally, Part IV reviews academic and practitioner commentary, assessing the *Therasense* opinion as welcome but inadequate. Although the Federal Circuit may not have fixed the many problems of the inequitable conduct doctrine in one fell swoop, it did provide clarity and took a significant step in the right direction.

I. HISTORY OF THE INEQUITABLE CONDUCT DOCTRINE

The inequitable conduct doctrine is a judicially created, equitable defense to patent infringement.¹⁰ The defense requires that the accused infringer show that the patentee, “with intent to mislead or deceive the examiner, fail[ed] to disclose material information or submitted materially false information.”¹¹ If an accused infringer prevails in this defense, the entire patent, and possibly related patents, is deemed unenforceable.¹² This

and impaired patent quality” as primary reasons for redirecting the inequitable conduct doctrine).

6. *Id.*

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

8. 37 C.F.R. § 1.56(b) (1992).

9. Leahy-Smith America Invents Act, Pub. L. No. 112-29 (2011) (to be codified at 35 U.S.C. § 257).

10. *See, e.g.*, Goldman, *supra* note 2, at 45–51.

11. *Therasense*, 649 F.3d at 1287; *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006).

12. *Therasense*, 649 F.3d at 1288–89.

powerful remedy has been deemed the “atomic bomb” of patent law.¹³ The inequitable conduct doctrine has long been the subject of criticism and reform proposals.¹⁴ Although intended to encourage transparency and full disclosure in communications with the PTO,¹⁵ the intended benefits of the doctrine have arguably been far outweighed by the many detrimental consequences it has had on the patent system, both before the courts and at the PTO.¹⁶ This Part traces the evolution of the inequitable conduct doctrine, the significant broadening of the initial standards that led up to the narrowing in *Therasense*, and the problems these standards created for the courts and the PTO.

A. EVOLUTION OF THE INEQUITABLE CONDUCT DEFENSE

The inequitable conduct doctrine evolved from three Supreme Court decisions that applied the equitable doctrine of unclean hands to patent cases.¹⁷ Under this doctrine, a patentee seeking to enforce his patent rights must not come before the court with “unclean hands” from intentionally misleading the PTO to obtain the patent.¹⁸ Although each case in this trio involved particularly egregious behavior,¹⁹ the inequitable conduct doctrine has evolved to “embrace a broader scope of misconduct.”²⁰ At its broadest, the doctrine encompassed not only affirmative acts intended to deceive the PTO and the courts,²¹ “but also the mere nondisclosure of information to the PTO.”²² The inequitable conduct doctrine further evolved from the

13. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.* 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).

14. See generally Christopher A. Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723 (2009); Dolak, *supra* note 3; Mammen, *supra* note 3; Nolan-Stevaux, *supra* note 2.

15. *Therasense*, 649 F.3d at 1288.

16. See *infra* Section I.B.

17. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945) (finding unclean hands where the patentee had suppressed evidence of perjury at the PTO and attempted to enforce the perjury-tainted patent); *Hazel Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238 (1944) (finding unclean hands where a patentee manufactured a false article in support of its patent application and later suppressed the evidence), *overruled on other grounds by* *Standard Oil Co. v. United States*, 429 U.S. 17 (1976); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933) (finding unclean hands where the patentee submitted a false affidavit to the PTO to overcome a prior use).

18. See, e.g., J.V.B., *He Who Comes Into Equity Must Come With Clean Hands*, 4 A.L.R. 44 (originally published in 1919); Mammen, *supra* note 3, at 1334.

19. See *supra* note 17.

20. *Therasense*, 649 F.3d at 1287.

21. See *supra* note 17.

22. *Therasense*, 649 F.3d at 1287; see *Kingsdown Med. Consultants, Lt. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc) (citing *In re Jerabek*, 789 F.3d 866, 891 (Fed.

unclean hands doctrine by implementing a much stronger remedy—unenforceability of the entire patent rather than mere dismissal of the suit.²³

Before *Therasense*, three elements comprised a prima facie claim of inequitable conduct: (1) a specific intent to deceive the PTO, (2) a misrepresentation or omission of material information, and (3) a subsequent balancing of the findings of materiality and intent on a “sliding scale.”²⁴ The minimal requirements for showing both materiality and intent to deceive have fluctuated over time.²⁵

1. *Specific Intent To Deceive the PTO*

Prior to *Therasense*, the “intent prong” of the inequitable conduct inquiry required a showing of specific intent to deceive the PTO.²⁶ The inequitable conduct claim is essentially a fraud claim,²⁷ therefore a showing of deceptive intent is a key element. Because direct evidence of intent to deceive is very rarely available, the Federal Circuit has consistently allowed claimants to prove intent to deceive by indirect and circumstantial evidence.²⁸ However, the court has been clear that “materiality does not presume intent.”²⁹ Thus, the materiality of an action, standing alone, cannot prove deceptive intent.

Cir. 1986); *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984) (pointing to previous Federal Circuit opinions that held mere gross negligence could suffice for intent to deceive).

23. Compare *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945) (dismissing suit for a finding of unclean hands), with *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334 (Fed. Cir. 2008) (affirming a district court judgment holding a patent unenforceable for inequitable conduct where there was a finding of intent to deceive); *Therasense*, 649 F.3d at 1287.

24. See, e.g., *Mammen*, *supra* note 3, at 1332.

25. See Derek J. Brader, *Distilling a Rule for Inferring Intent to Deceive the Patent Office*, 83 TEMP. L. REV. 529 (2011); Brown, *supra* note 2; Elizabeth Peters, *Are We Living In A Material World?: An Analysis Of The Federal Circuit's Materiality Standard Under The Patent Doctrine Of Inequitable Conduct*, 93 IOWA L. REV. 1519 (2008); Rader, *supra* note 2.

26. See generally Thomas L. Irving, Lauren L. Stevens, Scott M.K. Lee & Alexis N. Simpson, *The Evolution of Intent: A Review of Patent Law Cases Invoking The Doctrine of Inequitable Conduct From Precision to Exergen*, 35 U. DAYTON L. REV. 303 (2010); see, e.g., *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008); *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363 (Fed. Cir. 2007). In *Therasense*, the Federal Circuit reiterated that “the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO.” *Therasense*, 649 F.3d at 1290.

27. See, e.g., *Goldman*, *supra* note 2, at 45–51; Rader, *supra* note 2.

28. See, e.g., *Larson Mfg. Co. of South Dakota*, 559 F.3d at 1340; *Star Scientific*, 537 F.3d at 1366; *Cargill*, 476 F.3d at 1364; *Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006).

29. *Larson Mfg. Co. of South Dakota*, 559 F.3d at 1340; *Star Scientific*, 537 F.3d at 1366.

Similarly, nondisclosure, by itself, does not satisfy the intent prong,³⁰ and evidence of good faith may dictate against a finding of deceptive intent.³¹

Before *Therasense*, Federal Circuit case law was varied and inconsistent on the *standard* for showing intent.³² In *Burlington Industries, Inc. v. Dayco Corp.*, the Federal Circuit stated that the “nondisclosure of facts of which the applicant should have known the materiality may justify an inference of intent to mislead in appropriate cases.”³³ However, six months later in *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.* the Federal Circuit concluded that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive.”³⁴ Although *Burlington* seemed to advocate a “should have known” intent standard,³⁵ *Kingsdown* went in the opposite direction, stating that “gross negligence” is not enough to show intent to deceive.³⁶ *Kingsdown* was the high water mark of the Federal Circuit’s intent cases up until *Therasense*.³⁷ From *Kingsdown*, a line of cases applying a somewhat lower standard began to develop.³⁸

Most recently, in *Ferring B.V. v. Barr Laboratories, Inc.*,³⁹ the Federal Circuit revitalized the “should have known” test from *Burlington*. The Federal Circuit held that in certain cases, summary judgment is appropriate if there has been a “failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.”⁴⁰ Thus, under *Ferring*, it seemed that a mere omission of material information could amount to a showing of deceptive intent if the actor should have known that the information was material.

30. *Larson Mfg. Co. of South Dakota*, 559 F.3d at 1340.

31. *Id.* at 1341.

32. See Brader, *supra* note 25, at 537; Mammen, *supra* note 3, at 1338–42.

33. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1421 (Fed. Cir. 1988) (decided June 14th).

34. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.* 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc) (decided Dec. 21st).

35. *Burlington*, 849 F.2d at 1421.

36. *Kingsdown*, 863 F.2d at 876.

37. Z. Peng, Stacy Lewis, Deborah Herzfeld, Jill MacAlpine & Tom Irving, *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*, 16 V.A. J.L. & TECH. 373, 388 (2011).

38. See, e.g., *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181 (Fed. Cir. 2006); *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.* 424 F.3d 1347 (Fed. Cir. 2005); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.* 120 F.3d 1253 (Fed. Cir. 1997).

39. *Ferring*, 437 F.3d 1181.

40. *Id.* at 1191.

2. *A Misrepresentation or Omission of Material Information*

The “materiality prong” of the inequitable conduct inquiry has long been guided by the PTO’s Rule 56 of the Rules of Practice in Patent Cases.⁴¹ Also known as the Rule of Disclosure, Rule 56 was first promulgated in 1949 and provided guidelines for prior art disclosure before an examiner.⁴² The 1949 rule stated that “any application fraudulently filed or in connection with which any fraud is practiced or attempted on the PTO, may be stricken.”⁴³ Rule 56 has undergone several revisions over the years. The 1977 version of Rule 56 defined information as material “where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”⁴⁴ The rule was amended again in 1992 in an attempt to provide a clearer and more objective standard.⁴⁵ The 1992 version of Rule 56 defines information as material when either “(1) [i]t establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) [i]t refutes, or is inconsistent with, a position applicant takes in: (i) [o]pposing an argument of unpatentability relied on by the Office, or (ii) [a]sserting an argument of patentability.”⁴⁶

Although the Federal Circuit has historically relied on the PTO’s Rule 56 to define the test for materiality, the court has vacillated on which version of Rule 56 should be used.⁴⁷ Up through the Federal Circuit’s 2006 *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.* decision, the court consistently held that the 1977 “reasonable examiner” test applied to patents prosecuted before March 16, 1992, the effective date of the PTO’s 1992 amendment, and the 1992 version of Rule 56 applied to all patents prosecuted following March 16, 1992.⁴⁸ *Purdue Pharma* was decided on February 1, 2006. One week later, on February 8, the Federal Circuit stated in *Digital Control Inc. v. Charles Machine Works* that the 1992 version of Rule 56 was “not intended to replace

41. 37 C.F.R. § 1.56(b) (1992); *see, e.g.*, Mammen, *supra* note 3, at 1334–38; Peters, *supra* note 25, at 1530–39.

42. 37 C.F.R. § 1.56 (1992).

43. 37 C.F.R. § 1.56 (1949).

44. 37 C.F.R. § 1.56(a) (1977).

45. Duty of Disclosure, 56 Fed. Reg. 37,321 (Aug. 6, 1991) (to be codified at 37 C.F.R. pt. 1 and 10).

46. 37 C.F.R. § 1.56(b) (1992).

47. *See generally* David Hricik & Seth Trimble, *Congratulations on Your Hallucinations: Why The PTO’s 1992 Amendment to § 1.56 Is Irrelevant to Inequitable Conduct*, 38 AIPLA Q.J. 1 (2010); Mammen, *supra* note 3, at 1334–38; Peters, *supra* note 25, at 1530–39.

48. *See, e.g.*, *Purdue Pharm. L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006); Mammen, *supra* note 3, at 1334–38.

or supplant the ‘reasonable examiner’ standard,” and that the “reasonable examiner” standard should continue to exist as one of the tests for materiality.⁴⁹ Thus, it seemed that the 1977 “reasonable examiner” standard could be used as a test for materiality generally and not only prior to March 16, 1992. However, the following week, on February 15, the Federal Circuit, in *Ferring*, reiterated that the 1977 “reasonable examiner” version of Rule 56 applied only to patents prosecuted prior to the 1992 revision.⁵⁰ The *Ferring* majority noted that the court’s previous decision in *Digital Control* was a departure from their precedent.⁵¹ Nevertheless, in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, the Federal Circuit’s most recent materiality decision before *Therasense*, the court again endorsed the 1977 “reasonable examiner” test as the controlling standard for defining materiality for patents prosecuted both before and after March 16, 1992.⁵²

3. *The Sliding Scale*

Once minimum thresholds of both materiality and intent to deceive were shown, a court then had to balance these elements to determine whether the misconduct was sufficiently culpable to hold the patent unenforceable.⁵³ This “sliding scale” of the inequitable conduct doctrine was introduced in *American Hoist & Derrick Co. v. Sowa & Sons, Inc.* in 1984.⁵⁴ The Federal Circuit later provided a detailed explanation of the balancing process in *Star*

49. *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006) (“That the new Rule 56 was not intended to replace or supplant the “reasonable examiner” standard is supported by the PTO’s comment during the passage of the new rule. The PTO noted that the rule ‘has been amended to present a clear and more objective definition of what information the Office considers material to patentability’ and further that ‘[t]he rules do not define fraud or inequitable conduct which have elements both of materiality and of intent.’”).

50. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1187 n.6 (Fed. Cir. 2006) (noting that “[a]lthough the PTO amended the language of 37 C.F.R. § 1.56 in 1992, we have continued to use the pre-1992 language regarding materiality for evaluating patents that were prosecuted before the amendment.”).

51. *Ferring*, 437 F.3d at 1202 n.3 (Newman, J., dissenting).

52. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008) (holding that “information is material when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent” (internal quotations omitted)).

53. *See, e.g., Star Scientific*, 537 F.3d at 1367.

54. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (1984) (“Questions of ‘materiality’ and ‘culpability’ are often interrelated and intertwined, so that a lesser showing of the materiality of the withheld information may suffice when an intentional scheme to defraud is established, whereas a greater showing of the materiality of withheld information would necessarily create an inference that its nondisclosure was ‘wrongful.’”).

Scientific.⁵⁵ Threshold levels of both intent to deceive and materiality had to be established by clear and convincing evidence before a district court could exercise any discretion.⁵⁶ Thus, a district court could not hold a patent unenforceable, regardless of the equities, unless the minimum thresholds were reached.⁵⁷ During the balancing stage, the district court balanced the substance of the facts proven by clear and convincing evidence, with the equities of the case.⁵⁸ The inquiry during the balancing stage was whether, given the proven facts and all the equities of the case, the penalty of unenforceability should be imposed.⁵⁹ “[T]he more material the omission or the misrepresentation, the lower the level of intent [was] required to establish inequitable conduct, and vice versa.”⁶⁰ The balancing of materiality and intent, in deciding whether to hold a patent unenforceable for inequitable conduct, was committed to the district court’s discretion.⁶¹ Significantly, the sliding scale has been used to find inequitable conduct where there is less than clear and convincing evidence of intent.⁶²

B. THE INEQUITABLE CONDUCT DOCTRINE BEFORE *THERASENSE*:
“THE PLAGUE”

Thus, prior to *Therasense*, the inequitable conduct doctrine had evolved from a narrow category of exceptional cases involving egregious misconduct⁶³ into a broad standard that encompassed even mere

55. *Star Scientific*, 537 F.3d at 1367.

56. *Id.* at 1367.

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.* (internal quotations omitted).

61. *Id.*; see also *supra* note 48.

62. See, e.g., *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008) (inferring intent to deceive where “(1) [] the RFO art was highly material to the prosecution of the #115 patent, (2) that the applicants knew of the RFO art and knew or should have known of its materiality, and (3) that the patentee has failed to come forward with any credible good faith explanation for the applicants’ failure to disclose prior art use of RFOs to the PTO”); *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337 (Fed. Cir. 2007) (finding that the “combination of action and omission permits an inference of the minimum, threshold level of intent required for inequitable conduct. The evidence to support a finding of intent may not be particularly strong here However, the district court was permitted to balance the relatively weak evidence of intent together with the strong evidence that DDI’s omission was highly material to the issuance of the #156 patent and to find that on balance, inequitable conduct had occurred); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003) (“Intent to mislead does not require direct evidence, and is typically inferred from the facts . . . where withheld information is material and the patentee knew or should have known of that materiality, he or she can expect to have great difficulty in establishing subjective good faith sufficient to overcome an inference of intent to mislead.”).

63. See *infra* note 17.

negligence.⁶⁴ This broad standard, paired with the doctrine's exceptional remedy of unenforceability, encouraged inequitable conduct allegations and ultimately caused countless problems for the courts and PTO.⁶⁵

The Federal Circuit has more than once described the inequitable conduct doctrine as an "absolute plague."⁶⁶ The court has stated that the defense "has been overplayed, is appearing in nearly every patent suit, and is cluttering up the patent system."⁶⁷ Judge Rader referred to the doctrine as an "ubiquitous weed that infects every prosecution and litigation involving patents."⁶⁸ Although intended to encourage honesty and sufficient disclosure at the PTO,⁶⁹ the doctrine has had many undesirable effects on the patent system.⁷⁰ The *Therasense* majority cited, among others, "increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality" as some of the unintended consequences of the inequitable conduct doctrine.⁷¹

The inequitable conduct doctrine has become a burden on the courts by encouraging litigation. The inequitable conduct defense has become a popular litigation tactic due to several strategic advantages the defense provides.⁷² One of these strategic advantages is the broad remedy that results if it is successfully raised.⁷³ The remedy has been called an "atomic bomb"⁷⁴

64. *See* *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984) ("Where they knew, or should have known, that the withheld reference would be material to the PTO's consideration, their failure to disclose the reference is sufficient proof of the existence of an intent to mislead the PTO.").

65. *See, e.g.*, *Mammen*, *supra* note 3, at 1332 ("One advantage is the possibility of a broad remedy With those advantages, together with an increasing murkiness in the elements and boundaries of the defense, it is little wonder that accused infringers look for any opportunity to inject the inequitable conduct defense into patent litigation"); Rader, *supra* note 2, at 783 ("This gradual evolution away from the roots of the inequitable conduct doctrine inspired litigants to use inequitable conduct as a strategic part of a defense against patent infringement. . . . The Federal Circuit, even early in its history, recognized this misuse of the fraud doctrine as a 'plague.'").

66. *See, e.g.*, *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.* 863 F.2d 867, 876 n.15 (Fed. Cir. 1988) (en banc); *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

67. *Kimberly Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1454 (Fed. Cir. 1984).

68. Rader, *supra* note 2, at 780.

69. *See, e.g.*, *Goldman*, *supra* note 2, at 45–51.

70. *Infra* note 3.

71. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011).

72. *See generally* *Mammen*, *supra* note 3, at 1345–47; Rader, *supra* note 2, at 783; Melissa F. Wasserman, *Limiting The Inequitable Conduct Defense*, 13 VA. J.L. & TECH 7 (2008).

73. *See, e.g.*, *Mammen*, *supra* note 3, at 1345–46; *Cotropia*, *supra* note 14, at 737.

because the entire patent is declared unenforceable, even if inequitable conduct is only shown for a single claim that is not at issue in the infringement action.⁷⁵ Another tactical litigation advantage the defense achieves is the opportunity to impugn the character of an inventor and cast a shadow over the patentee for the remainder of the trial.⁷⁶ Additionally, an accused infringer is able to gain access to privileged information during discovery by asserting the inequitable conduct defense.⁷⁷ A charge of inequitable conduct can expand discovery into corporate practices before patent filing, as well as disqualify the prosecuting attorney from the patentee's litigation team.⁷⁸

Due to the significant tactical advantages the inequitable conduct defense provides and the low substantive standards for the defense, inequitable conduct claims have become a standard pleading practice in patent cases.⁷⁹ In fact, the Federal Circuit has noted that “reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client’s interests adequately.”⁸⁰

The inequitable conduct defense has also been a burden on the PTO.⁸¹ Patent applicants are incentivized to submit “everything of even remote

74. *Aventis Pharm. S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).

75. Mammen, *supra* note 3, at 1345.

76. *See, e.g.*, Rader, *supra* note 2, at 783; Mammen, *supra* note 3, at 1346.

77. *See, e.g.*, Rader, *supra* note 2, at 783 (“[a]n allegation of inequitable conduct opened the door to vast discovery into the circumstances of the patent prosecution, leveled an embarrassing charge of fraud as a counterweight to the presumption of patent validity, and even disqualified the prosecuting attorney (who may be a witness) from the patentee’s litigation team”); *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334, 1349–50 (Fed. Cir. 2008) (noting that “[t]he allegation of inequitable conduct opens new avenues of discovery” in patent litigation).

78. *See* NAT’L RESEARCH COUNCIL OF THE NAT’L ACADS., *A PATENT SYSTEM FOR THE 21ST CENTURY* 122 (S.A. Merrill et. al. eds., 2004).

79. Rader, *supra* note 2, at 783.

80. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011).

81. *See, e.g.*, J.M. Kuhn, *Information Overload at the U.S. Patent and Trademark Office: Reframing the Duty of Disclosure in Patent Law as a Search and Filter Problem*, 13 *YALE J. L. & TECH.* 90 (2010–2011); E.S. Flores & S.E. Warren, Jr., *Inequitable Conduct, Fraud, and Your License to Practice Before the United States Patent & Trademark Office*, 8 *TEX. INTELL. PROP. L.J.* 299, 308 (2000) (“Many practitioners believe that under current inequitable conduct standards the safest course is to disclose information even if they believe ‘references . . . are cumulative or less material than [information] already before the Examiner’ for fear that an infringer will succeed in raising an inequitable conduct defense.”); Am. Bar. Ass’n Section of Intell. Prop. Law, *A Section White Paper: Agenda For 21st Century Patent Reform*, 18 (May 1, 2007), available at <http://www.americanbar.org/content/dam/aba/migrated/intelprop/home/PatentReformWP.authcheckdam.pdf> (“Applicants disclose too much prior art for the

relevance in one's possession to the PTO" due to the severe penalties that accompany a finding of inequitable conduct.⁸² The result is that patent examiners often have significantly more references to sort through than is necessary for prosecution of the patent.⁸³ Given the limited time that patent examiners may spend on an application, this inundation leads to impaired patent quality.⁸⁴ Other side effects include inefficiency, an increasing backlog of patent applications, and strain on already limited resources at the PTO.⁸⁵

Due to the significant burdens the inequitable conduct doctrine had produced for the courts and the PTO, the Federal Circuit stepped up and addressed these issues by tightening the standards for the defense in *Therasense*.

II. THE FEDERAL CIRCUIT'S DECISION IN *THERASENSE*

Therasense involved a patent for disposable blood glucose test strips for diabetes management: U.S. Patent No. 5,820,551 ("the '551 patent").⁸⁶ The prior art for the '551 patent generally required either a diffusion-limiting or a protective membrane to cover the strip.⁸⁷ During filing, after repeated rejections the patentee submitted revised claims for a strip that did not require a membrane, in order to overcome the prior art.⁸⁸ However, one prior art reference describing blood glucose test strips, U.S. Patent No. 4,545,382 ("the '382 patent"), also belonging to the patentee, suggested "optionally, but preferably" using a protective membrane.⁸⁹ In order to overcome this prior art reference, the examiner requested an affidavit showing that a person of ordinary skill in the art for the '382 patent would understand the "optionally, but preferably" language to actually require a protective membrane.⁹⁰ The patentee submitted to the PTO a declaration to that effect.⁹¹

PTO to meaningfully consider, and do not explain its significance, all out of fear that to do otherwise risks a claim of inequitable conduct.").

82. *Cotropia*, *supra* note 14, at 768.

83. *Id.* at 770.

84. *See Therasense*, 649 F.3d at 1289–90; K. Mack, *Reforming Inequitable Conduct To Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147, 148 (2006).

85. *See Therasense*, 649 F.3d at 1290.

86. *Id.* at 1282.

87. *Id.* at 1283.

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

However, several years earlier in prosecuting the European counterpart to the '382 patent, the patentee declared to the European Patent Office ("EPO") that the "optional, but preferable" protective membrane was indeed optional.⁹² The patentee did not disclose this EPO declaration to the PTO years later during prosecution of the '551 patent, when the examiner requested the affidavit stating that the membrane was required.⁹³

In 2004, Becton, Dickinson and Co. ("Becton") sued Therasense, Inc. (now Abbot Diabetes Care, Inc.) and Abbott Laboratories (collectively "Abbott") for a declaratory judgment of noninfringement of Abbott's patents, U.S. Patent Nos. 6,143,164 ("the '164 patent") and 6,592,745 ("the '745 patent").⁹⁴ Abbott countersued Becton, alleging infringement of its '164, '745, and '551 patents.⁹⁵ Abbott also sued Becton's supplier and Bayer Healthcare LLC ("Bayer") for infringement.⁹⁶ These cases were consolidated in the Northern District of California.⁹⁷

The district court granted Becton summary judgment of noninfringement for the '164 and '745 Abbott patents.⁹⁸ Following a bench trial, the district court found four of the claims in the '551 patent invalid for obviousness.⁹⁹ The court also held the entire '551 patent unenforceable for inequitable conduct because Abbott had not disclosed to the PTO, in prosecuting the '551 patent, its declarations submitted to the EPO years earlier regarding its '382 patent.¹⁰⁰ Abbot appealed the judgments of noninfringement, invalidity, and unenforceability. The Federal Circuit affirmed the district court's judgments. Abbott petitioned for rehearing en banc and the Federal Circuit granted the petition.¹⁰¹

In the majority en banc opinion by Chief Judge Rader, the court discussed the many detrimental effects caused by the broad inequitable conduct defense.¹⁰² Judge Rader noted that in the past, the court had allowed the intent requirement to be met by low standards (gross negligence or negligence alone had been enough) and had adopted a broad view of

92. *Id.* at 1283–84.

93. *Id.* at 1285.

94. *Id.* at 1284.

95. *Id.*

96. *Id.*

97. *Id.*

98. The court found most of the claims in the '745 patent invalid due to anticipation. *Id.* at 1284–85.

99. *Id.* at 1285.

100. *Id.*

101. *Id.*

102. *Id.* at 1289–90.

materiality (using a “reasonable examiner” standard).¹⁰³ Also, intent and materiality were placed on a sliding scale.¹⁰⁴ The sliding scale further lowered the standard for showing inequitable conduct because a stronger showing of materiality could suffice with a weaker showing of intent, and vice versa.¹⁰⁵ Judge Rader noted that although the court originally implemented these low standards to foster honesty at the PTO, the low standards had encouraged the overuse of the inequitable conduct doctrine as a litigation strategy, discouraged settlement, and detracted attention from the merits of the case.¹⁰⁶ Moreover, the inequitable conduct doctrine had burdened the PTO by incentivizing applicants to “bury” examiners in prior art references.¹⁰⁷

In an effort to redirect the inequitable conduct defense, the court raised the standards for finding both intent and materiality.¹⁰⁸ First, to satisfy the intent prong of the inequitable conduct defense, an accused infringer must prove that the patentee acted with the “specific intent to deceive” the PTO.¹⁰⁹ Gross negligence or negligence under a “should have known” standard is no longer enough.¹¹⁰ In the case of nondisclosure of information, an accused infringer must prove by “clear and convincing evidence” that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.¹¹¹ Recognizing that direct evidence of deceptive intent is rare, the Federal Circuit held that intent may be inferred from indirect and circumstantial evidence.¹¹²

To meet the “clear and convincing evidence” standard, the specific intent to deceive must be the “single most reasonable inference” that can be drawn from the evidence, and the evidence must be sufficient to *require* a finding of “deceitful intent in light of the circumstances.”¹¹³ As a corollary, intent to deceive cannot be found where multiple reasonable inferences may be drawn from the evidence.¹¹⁴ The court also held that a “patentee need not offer any good faith explanation” until the alleging party has met its burden of proving the threshold level of intent by clear and convincing evidence.¹¹⁵ Moreover,

103. *Id.* at 1287–88.

104. *Id.* at 1288.

105. *Id.*

106. *Id.*

107. *Id.* at 1298–90.

108. *Id.* at 1290–93.

109. *Id.* at 1290.

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.* at 1290–91.

115. *Id.* at 1291 (internal quotations omitted).

intent cannot be inferred from materiality alone—intent and materiality are separate requirements.¹¹⁶

Second, with regard to the materiality prong of the inequitable conduct test, the court held that “the materiality required to establish inequitable conduct is but-for materiality.”¹¹⁷ That is, if the PTO would not have allowed a claim in light of the undisclosed prior art, then that prior art is “but-for material.”¹¹⁸ In determining the materiality of withheld information, “the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.”¹¹⁹ Thus to arrive at their decision, a court must apply the PTO’s “preponderance of the evidence standard and give claims their broadest reasonable construction.”¹²⁰ The Manual of Patent Examining Procedures indicates that the standard to be applied in all cases is the “preponderance of the evidence” test.¹²¹ “[A]n examiner should reject a claim if, in view of the prior art and evidence of record, it is more likely than not that the claim is unpatentable.”¹²² The majority opinion explained that equity dictates that a remedy “should be commensurate with the violation” and therefore a patent should only be deemed unenforceable on inequitable conduct grounds when “the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.”¹²³

The court added an exception to the but-for test in cases of affirmative egregious misconduct.¹²⁴ Conduct is material, regardless of the but-for requirement, if a patentee has “engaged in affirmative acts of egregious misconduct,” such as filing an intentionally false affidavit.¹²⁵ However, mere nondisclosure of prior art references to the PTO or failure to mention prior art references in an affidavit, without more, does not constitute affirmative egregious misconduct and does not fall under the exception to the but-for materiality standard.¹²⁶

116. *Id.* at 1290.

117. *Id.* at 1291.

118. *Id.*

119. *Id.*

120. *Id.* at 1291–92.

121. Manual of Patent Examining Procedure § 706.1 (2001).

122. *Id.*

123. *Therasense*, 649 F.3d at 1292.

124. *Id.* at 1292.

125. *Id.*

126. *Id.* at 1292–93.

The Federal Circuit also eliminated the long-standing sliding scale step of the inequitable conduct doctrine analysis.¹²⁷ The court stated that intent and materiality are separate requirements and therefore “a weak showing of intent may not be found sufficient based on a strong showing of materiality, and vice versa.”¹²⁸ The evidence of intent to deceive must be weighed separately from the evidence of materiality.¹²⁹ The court vacated and remanded for further proceedings consistent with the opinion.¹³⁰

Judge O’Malley filed a concurring-in-part and dissenting-in-part opinion.¹³¹ Judge O’Malley took issue with the majority’s “hard and fast rules” and pointed out that “flexibility rather than rigidity has distinguished equitable jurisdiction.”¹³² Furthermore, Judge O’Malley advocated that the proper remedy for a given instance of inequitable conduct should not be a singular penalty of unenforceability but should be left to the discretion of the courts.¹³³ For example, a court should have discretion to render fewer than all claims unenforceable, simply dismiss the action, or create a reasonable remedy commensurate with the violation.¹³⁴ These are penalties that a court might choose to impose in lieu of complete unenforceability.

Finally, Judge O’Malley proposed her own materiality standard: conduct should be deemed material where “(1) but for the conduct . . . the patent would not have issued . . . ; (2) the conduct 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 . . . was wholly undermined.”¹³⁵ Judge O’Malley’s materiality standard follows the majority’s except for the addition of conduct that “constitutes a false or misleading representation of fact.”¹³⁶

Judge O’Malley also noted that the majority could have addressed their concern with unsupported allegations of inequitable conduct in the courts in other ways, such as careful application of the pleading requirements set forth in *Exergen*,¹³⁷ “early case management techniques designed to identify and test

127. *Id.* at 1290.

128. *Id.*

129. *Id.*

130. *Id.* at 1296.

131. *Id.*

132. *Id.* at 1297 (internal quotations omitted).

133. *Id.* at 1299.

134. *Id.*

135. *Id.* at 1300.

136. *Id.*

137. In *Exergen*, the Federal Circuit stated that Federal Rule of Civil Procedure 9(b) applies to allegations of inequitable conduct. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009). To satisfy Rule 9(b), an allegation must identify the “who,

unsupported inequitable conduct claims, orders to stay discovery or consideration of such [inequitable conduct] claims pending all other determinations in the case,” and sanctions.¹³⁸

Judge Bryson filed a dissenting opinion, which Judges Gajarsa, Dyk, and Prost joined.¹³⁹ J. Bryson noted that there was substantial agreement with the majority’s holdings regarding intent and the sliding scale.¹⁴⁰ However, the dissent strongly disagreed with the majority opinion on the issue of the proper test to apply in determining whether conduct is sufficiently material to render a patent unenforceable.¹⁴¹ The dissent noted that the Federal Circuit had long “looked to the PTO’s disclosure rule, Rule 56,¹⁴² as the standard for defining materiality in inequitable conduct cases involving a failure to disclose material information,” and advocated adherence to that standard.¹⁴³ To support his position, Judge Bryson argued that “the PTO is in the best position to know what information examiners need to conduct effective and efficient examinations.”¹⁴⁴ Moreover, the dissent claimed that the majority’s new “but for” materiality test was too restrictive to serve the purposes of disclosure to the PTO that the doctrine of inequitable conduct was designed to promote.¹⁴⁵ The dissent also noted that the majority’s opinion had no support in Federal Circuit precedent.¹⁴⁶

The dissent expressed the belief that the current problems with the inequitable conduct doctrine could be addressed by reaffirming the principles from “the early years” of the Federal Circuit, “in light of the provisions of

what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Id.* at 1328. Additionally, the complainant must provide sufficient allegations of the underlying facts from which a court could reasonably infer that “a specific individual (1) knew of the withheld information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Id.* at 1326–29.

138. *Therasense*, 649 F.3d at 1302.

139. *Id.*

140. *Id.* (“First, the parties to this case and most of the amici agree that proof of inequitable conduct should require a showing of specific intent to deceive the PTO; negligence or even gross negligence should not be enough. Second, the parties and most of the amici agree that a party invoking the defense of inequitable conduct should be required to prove both specific intent and materiality by clear and convincing evidence; there should be no ‘sliding scale’ whereby a strong showing as to one element can make up for weaker proof as to the other.”).

141. *Id.* at 1302–03.

142. 37 C.F.R. § 1.56 (1992).

143. *Therasense*, 649 F.3d at 1303.

144. *Id.*

145. *Id.*

146. *Id.* at 1304.

the current PTO disclosure rule.”¹⁴⁷ The dissent advocated strict adherence to the pleading requirements of Federal Rule of Civil Procedure 9(b), which requires detailed factual averments.¹⁴⁸ The dissent also noted that sanctions provided by Federal Rule of Civil Procedure 11 are available to provide additional safeguards against the problems recognized by the majority.¹⁴⁹ Finally, the dissent noted that the majority’s new materiality standard is at odds with materiality standards in analogous contexts: securities law, criminal proceedings, and common law actions for fraud do not rely on a but-for materiality test.¹⁵⁰

III. THE INEQUITABLE CONDUCT DOCTRINE AFTER *THERASENSE*

The Federal Circuit attempted to strike a delicate balance in the *Therasense* decision. The original goal of encouraging full disclosure and honesty before the PTO is still an important one, both for the sake of efficiency at the PTO and for the sake of integrity in our patent system. However, equally important are the fairness and efficiency goals of preventing unsupported inequitable conduct allegations and preventing applicants from inundating patent examiners with extraneous and duplicative information during prosecution.

In order to evaluate whether the *Therasense* majority struck the appropriate balance, the decision—like all court opinions—cannot be read in isolation. Several adjacent legal developments have direct bearing on the application of *Therasense*. First, the pleading standards for a claim of inequitable conduct, not addressed in *Therasense*, were discussed in the 2009 *Exergen* case.¹⁵¹ Additionally, in the months following the Federal Circuit’s *Therasense* decision, the PTO proposed a revision of their Rule 56, which expressly adopted the majority’s but-for materiality test.¹⁵² Finally, the recently enacted Leahy-Smith America Invents Act (“Leahy-Smith AIA”), also addresses inequitable conduct.

A. THE NEW STANDARD

Under the new materiality test, announced in *Therasense* and adopted by the PTO in its proposed revision to Rule 56, prior art is but-for material if

147. *Id.*

148. *Id.* at 1304–05.

149. *Id.* at 1305.

150. *Id.* at 1314–17.

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

152. Proposed Revision, 76 Fed. Reg. 43,631 (July 21, 2011).

the PTO would not have allowed a claim had it been aware of the undisclosed prior art.¹⁵³ Thus in applying the Federal Circuit's new materiality test, a judge must recreate the conditions of a PTO examination to determine the materiality of a withheld reference. The inquiry is whether, by a preponderance of the evidence, given the broadest reasonable construction of the claim, the claim would not have issued if the PTO examiner had seen the withheld information. It has been suggested that, similar to the way many courts now hold *Markman* hearings, courts may begin to hold "*Therasense* hearings" in which the court will find the broadest reasonable construction for a particular claim and then determine whether under a preponderance of the evidence standard that the claim would not have been allowed by the PTO had it been aware of the undisclosed information.¹⁵⁴

The Federal Circuit previously raised the intent standard *Kingsdown* in an attempt to reduce the flood of inequitable conduct allegations.¹⁵⁵ However, the high standard quickly eroded, and inequitable conduct allegations continued.¹⁵⁶ A significant amount of time has passed since the Federal Circuit's *Kingsdown* decision in 1988 and the inequitable conduct doctrine continues to be a problem for the courts and PTO.¹⁵⁷ Although *Kingsdown* failed, *Therasense* may have a significantly better chance for success as it comprehensively reformed the doctrine. Rather than just raising the intent standard or the materiality standard, the Federal Circuit in *Therasense* clearly dictated standards for both of these key elements of the inequitable conduct defense, as well as specifically pointed to standards that were henceforth abolished. The Federal Circuit created a set of coherent standards in *Therasense* that provide substantial direction in comparison to the continuously vacillating inequitable conduct standards prior to *Therasense*.¹⁵⁸ The court's holistic approach may well prove more effective and enduring than its predecessor, *Kingsdown*.

B. *THERASENSE* AND *EXERGEN*

Despite the comprehensive approach the *Therasense* court took, they did not discuss the interaction of their heightened standards for finding

153. *Id.* at 1292.

154. Peng, *supra* note 37, at 397 (emphasis omitted).

155. *Kingsdown Med. Consultants, Lt. v. Hollister, Inc.*, 863 F. 2d 867, 876 (Fed. Cir. 1988).

156. Peng, *supra* note 37, at 387 ("[t]he last en banc inequitable conduct decision in *Kingsdown* did not prove successful in choking off garden-variety allegations of inequitable conduct.").

157. See *supra* Section I.B.

158. *Id.*

inequitable conduct with the Federal Circuit's *Exergen* standards for pleading inequitable conduct. Although these two sets of standards are applied at different stages in a trial, *Therasense* must be understood within the context of *Exergen*.

In 2009, the Federal Circuit substantially raised the pleading standards for inequitable conduct claims in *Exergen*.¹⁵⁹ In *Exergen*, the defendant sought leave under Federal Rule of Civil Procedure 15(a) to allege inequitable conduct as an affirmative defense and counterclaim.¹⁶⁰ The district court denied the motion, "stating that the proposed pleading failed to allege inequitable conduct with particularity under Rule 9(b)."¹⁶¹ On appeal, the Federal Circuit held that the materiality prong of inequitable conduct must be pled with "particularity" under Rule 9(b).¹⁶² This standard is satisfied by identifying the specific "who, what, when, where and how" of the material misrepresentation or omission committed before the PTO.¹⁶³ The standard for pleading intent is somewhat lower—knowledge and intent may be averred generally under 9(b).¹⁶⁴ This standard is satisfied by "providing sufficient underlying facts from which a court could reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO."¹⁶⁵ The Federal Circuit agreed with the district court that the defendant's pleading was deficient under this new standard, "with respect to both the particularity of the facts alleged and the reasonableness of the inference of scienter."¹⁶⁶

C. REVISION OF RULE 56

The *Therasense* opinion included a strong dissent, joined by four of the Federal Circuit justices.¹⁶⁷ The key issue that separated the majority opinion and the dissent was the departure of the majority from the PTO's Rule 56 as the materiality standard in the inequitable conduct inquiry. The dissent

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

160. *Exergen*, 575 F.3d at 1317.

161. *Id.* Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." FED. R. CIV. P. 9(b).

162. *Exergen*, 575 F.3d at 1317.

163. *Id.* at 1327.

164. *Id.* at 1328–29.

165. *Id.*

166. *Id.* at 1329.

167. The dissent was filed by Circuit Judge Bryson, joined by Circuit Judges Gajarsa, Dyk and Prost; Circuit Judge O'Malley filed a concurrence. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1302 (Fed. Cir. 2011).

argued that the PTO was “in the best position to know what information examiners need to conduct effective and efficient examinations.”¹⁶⁸ The dissent also argued that the majority’s new but-for materiality standard was a clear departure from Federal Circuit precedent.¹⁶⁹ However in the months following the decision, the PTO proposed to amend Rule 56 to expressly adopt the but-for materiality standard as set forth by the majority in *Therasense*.¹⁷⁰ In light of this proposed revision, the key issue that separated the majority and the dissent may have become moot.

Less than two months after *Therasense*, the PTO expressed approval and acceptance of the new standard.¹⁷¹ The PTO recognized that the new standard is less inclusive than the pre-*Therasense* Rule 56, but wrote that “the ‘but-for-plus’ standard from *Therasense* will result in patent applicants providing the most relevant information and reduce the incentive for applicants to submit information disclosure statements containing only marginally relevant information out of an abundance of caution.”¹⁷² The new standard, the PTO continued, “will continue to prevent applicants from . . . breaching their duty of candor and good faith.”¹⁷³ The PTO noted that although they had previously considered and rejected a pure “but-for” materiality standard, the exception the majority created for affirmative egregious misconduct “addresse[d] the Office’s long-standing concern” with the possibility of “unscrupulous conduct.”¹⁷⁴

Due to its approval and a desire for uniformity within the patent system, the PTO proposed to amend Rules 56(b) and 55(b) to adopt the standard of materiality set forth by the majority opinion.¹⁷⁵ The PTO specifically cited to, and adopted, the standard set forth in *Therasense*:

168. *See supra* Part II.

169. *Id.*

170. Proposed Revision, 76 Fed. Reg. 43,631 (July 21, 2011).

171. *Id.*

172. *Id.* at 43,632.

173. *Id.* The PTO’s Rule 56(a) describes the duty of candor:

Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section . . . no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.

37 C.F.R. § 1.56(a) (1992).

174. Proposed Revision, 76 Fed. Reg. 43,631, 43,632 (July 21, 2011).

175. *Id.* at 43,632.

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 possible 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 misconduct.¹⁷⁶

The PTO agreed with the dissent that the *Therasense* decision was a clear severance of the “historical connection” between the materiality standards of the inequitable conduct doctrine and the PTO’s rule of disclosure.¹⁷⁷ Although it was not under any obligation to adopt the *Therasense* standard, the PTO cited harmony and simplicity within the patent system as primary motivation for their proposed revision.¹⁷⁸ It also mentioned concern about patent applicants having to meet one standard for materiality in defending inequitable conduct allegations and another standard for fulfilling the duty to disclose before the PTO.¹⁷⁹

In light of the PTO’s recent proposed revision to Rule 56, the arguments that the dissent articulated against a but-for materiality standard appear to have fallen by the wayside. The dissent primarily argued that (1) the decision of what information examiners need to conduct effective and efficient examinations should be left to the PTO, and (2) that the materiality standard has historically been tied to the PTO’s Rule 56.¹⁸⁰ By proposing this revision, the PTO has articulated that the information they need to conduct effective and efficient examinations *is* provided by the standard set forth in *Therasense*. Furthermore, by revising Rule 56 to replicate the *Therasense* standard, the new but-for materiality standard is once again tied to Rule 56, as the dissent advocated for.

This development is significant for the reason that the *Therasense* decision came from a bare majority, a 6–5 decision, and that the departure from the PTO’s Rule 56 as a materiality standard was the critical disagreement

176. *Id.* at 43,633.

177. *Id.*

178. *Id.*

179. *Id.*

180. *See supra* Part II.

between the majority of six justices, and the dissent of four.¹⁸¹ With the dissent's principal arguments now moot, it stands to reason that *Therasense* now may stand on substantially stronger ground. Given the Federal Circuit's tendency to vacillate on inequitable conduct standards,¹⁸² with at least ten justices now in agreement on what the standards should be, it may be that *Therasense* is here to stay.

D. LEAHY-SMITH AMERICA INVENTS ACT

The recent enactment of the Leahy-Smith AIA significantly revised the patent statute.¹⁸³ The Leahy-Smith AIA is the culmination of many years of patent reform proposals, and it is the first comprehensive revision to the patent laws in nearly sixty years—since the Patent Act of 1952. Although provisions in the Act only indirectly affect the inequitable conduct doctrine, the presence of these provisions may directly affect a court's assessment of an inequitable conduct defense and may significantly affect a patentee's disclosure strategy at the PTO.

The new act includes a provision for supplemental examinations, under which a patentee may request the PTO to consider, reconsider, or correct information.¹⁸⁴ Thus, if a patentee becomes aware of new information or discovers old information relevant to his patent or even suspects impending litigation and wishes to clear the record, the patentee may request a supplemental examination. In a supplemental examination, the Director of the PTO will conduct an examination and determine whether a new question of patentability is raised.¹⁸⁵

Leahy-Smith AIA amends 35 U.S.C § 287 to state:

[A] patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent, in accordance with such requirements as the Director may establish. Within 3 months after the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conduct the supplemental examination and shall conclude such supplemental examination by issuing a certificate indicating

181. Six justices joined the *Therasense* majority; one justice filed a concurrence, and four justices dissented. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011).

182. *See supra* Section I.A.

183. *See Leahy-Smith America Invents Act*, Pub. L. No. 112-29 (2011) (to be codified at 35 U.S.C. § 257).

184. *Id.* at § 12(a).

185. *Id.*

whether the information presented in the request raises a substantial new question of patentability.¹⁸⁶

If a substantial new question of patentability is raised, then the Director must order the re-examination of the patent.¹⁸⁷ The amendment to § 287 also states:

[A] patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent. The making of a request under subsection (a), or in the absence thereof, shall not be relevant to enforceability of the patent under section 282.¹⁸⁸

This provision also includes a limitation such that a patentee cannot request a supplemental examination if an adequate allegation of inequitable conduct has already been asserted against the patentee.¹⁸⁹ A patentee cannot wait until an inequitable conduct allegation has been asserted against him, to request a supplemental examination in order to clear his name.

Although the new act doesn't specifically address inequitable conduct doctrine reform, it does seem to offer some protection to well-meaning patentees. Patentees who make honest presentations to the PTO and later discover relevant information that could be used by an opponent as grounds for an inequitable conduct allegation are provided with a path to rectify any mistakes or oversights. However, it may be that the provision is also useful to a patentee who intentionally withholds information from the PTO and later, under threat of impending litigation, redeems the patent through a supplemental examination proceeding. The supplemental examination provision essentially gives a patentee a second chance to come clean before the PTO. A court could take the presence of this additional safeguard as a factor weighing against the patentee in an inequitable conduct claim, reasoning that the patentee has already had an opportunity to redeem himself.

Another theory is that the supplemental examination provision of the Leahy-Smith may act as a "patent amnesty program."¹⁹⁰ Rantanen and

186. *Id.*

187. *Id.*

188. *Id.*

189. *Id.*

190. See Jason Rantanen & Lee Petherbridge, Commentary, *Toward a System of Invention Registration: The Leahy-Smith America Invents Act*, 110 MICH. L. REV. FIRST IMPRESSIONS 24

Petherbridge argue that the Act encourages patent applicants to employ unscrupulous strategies to obtain a patent and then “cure” the tainted patent through a supplemental examination request when litigation appears imminent.¹⁹¹ The supplemental examination, they write, is little more than a mechanism to provide amnesty to issued patents that were obtained inequitably.¹⁹² The authors believe that this “patent amnesty” jeopardizes American innovation, job creation, and economic competitiveness.¹⁹³

It seems that, at best, the Leahy-Smith AIA supplemental examination provision could become a double-edged sword for patentees. On the one hand, they are provided with a route to absolve any unintentional breaches of their duty of candor at the PTO. On the other hand, a judge might take this “second chance” into account when assessing an inequitable conduct claim against the patentee. At worst, it is possible that the supplemental examination provision could actually increase instances of inequitable conduct before the PTO. In this scenario, the tightened *Therasense* standards for finding inequitable conduct may prove to be too high.

E. IN THE DISTRICT COURT

In the few months that have followed the *Therasense* decision, district courts have been quick to apply the new standard laid out by the Federal

(2011), available at <http://www.michiganlawreview.org/articles/toward-a-system-of-invention-registration-the-leahy-smith-america-invents-act>.

191. *Id.* (“For example, potential descriptions of a claimed invention in a prior art printed publication, or possible instances of prior patenting of the claimed invention by another, that are known to a patent applicant, and that might have a high probability of barring a patent or limiting claim scope, may not be disclosed during the initial examination. Similarly, sales and public uses that are known to a patent applicant and that may have a high probability of barring the patentability of a claimed invention may be withheld at least until supplemental examination if the applicant likes (and perhaps longer depending on an applicant’s risk tolerance). Even the use of false data to obtain the patent in the initial examination can be exonerated by filing a supplemental examination request.”).

192. *Id.* (“Under the AIA, therefore, a patent owner may now obtain a patent through the ex parte examination process despite conduct that would be abhorrent under traditional understandings of a patent applicant’s obligation to be equitable in dealing with the public. The owner may then immunize the conduct using supplemental examination should litigation appear on the horizon.”).

193. *Id.* (“[I]t does so by potentially increasing the cost of competition, making research and development more expensive, and making market entry more difficult and risky. At the same time, and somewhat perversely, it creates an environment in which organizing capital around a patent or modestly sized patent portfolio might make less sense than it did before the AIA.”).

Circuit. Courts have taken note of the heightened intent and materiality standards and overturned prior findings of inequitable conduct.¹⁹⁴

For example, in *Metris U.S.A., Inc. v. Faro Technologies, Inc.*, a Massachusetts district court held that a patentee's failure to disclose information was not material under the new *Therasense* standard and thus the patentee did not engage in inequitable conduct.¹⁹⁵ Prior to *Therasense*, the patentee had alleged infringement against a competitor for devices used in an apparatus for scanning and modeling three-dimensional objects.¹⁹⁶ The accused infringer subsequently brought forth an inequitable conduct defense.¹⁹⁷ The court initially found, under pre-*Therasense* standards, that the inventor intended to deceive the PTO by withholding information and, furthermore, that the withheld information was material and thus the patent was unenforceable due to inequitable conduct.¹⁹⁸ However, following *Therasense*, the district court ordered further briefing on the patent claims and reexamined its prior holding of unenforceability. The court reiterated the Federal Circuit's holding that "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."¹⁹⁹ The court reversed its earlier decision and found that the inequitable conduct defense could not succeed under the "stringent standard" of *Therasense*.²⁰⁰ Although the prior finding of intent to deceive withstood *Therasense*, the information withheld by the inventor did not rise to the new "but-for" standard of materiality.²⁰¹ The court further held that the patentee's conduct did not amount to affirmative egregious misconduct so as to fall within the exception carved out by the Federal Circuit.²⁰²

In *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, a Virginia district court held that an attorney's failure to produce a Statement of Claim to the PTO did not constitute inequitable conduct under the new *Therasense* standard.²⁰³ The patentee alleged imminent infringement of a certain pharmaceutical

194. See, e.g., *Metris U.S.A., Inc. v. Faro Tech., Inc.*, No. 08-CV-11187-PBS, 2011 WL 4346852 (D. Mass. 2011); *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, No. 2:10CV128, 2011 WL 3563112 (E.D. Va. 2011).

195. *Metris U.S.A.*, 2011 WL 4346852, at *4.

196. *Id.* at *1.

197. *Id.*

198. *Id.* at *2.

199. *Id.* at *1 (quoting *Therasense*).

200. *Id.*

201. *Id.* at *2.

202. *Id.* at *4.

203. *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, No. 2:10CV128, 2011 WL 3563112, *33 (E.D. Va. 2011).

compound patent (the '012 patent), by its competitor.²⁰⁴ The competitor defended the allegation by claiming that the patent was invalid because of inequitable conduct committed by the patentee during prosecution.²⁰⁵ During prosecution of the patent, the patentee's attorney received a Statement of Claim from another competitor, suing under the patentee's Canadian version of the U.S. application and alleging invalidity.²⁰⁶ The patentee's attorney withheld this Statement of Claim from the PTO during prosecution.²⁰⁷

In coming to a decision regarding the inequitable conduct allegation, the court looked to the Federal Circuit's *Therasense* decision.²⁰⁸ The court noted that under *Therasense*, "in order to substantiate a claim of inequitable conduct, 'the accused infringer must prove by clear and convincing evidence that the applicant knew of the references, knew that it was material, and made a deliberate decision to withhold it.'"²⁰⁹ Looking to the facts of the case, the court determined that the information withheld, "hardly approaches" the *Therasense* but-for materiality.²¹⁰ Similarly, the court found that there was no evidence to suggest that the patentee's attorney had any intent to deceive the PTO in failing to disclose the statement of claim because (1) he had no such duty in the first place and (2) such intent is hardly the single most likely inference from his actions.²¹¹ Consequently, the court held that the

204. *Id.* at *1.

205. *Id.* at *33.

206. *Id.* at *35.

207. *Id.*

208. *Id.*

209. *Id.* at *37 (quoting *Therasense*).

210. *Id.* at *38 ("First, the Bayer Statement of Claim concerned a patent under Canadian law, law which has not been shown to have anything in common with or any bearing on the law of the United States as regards validity of patents. . . . Second, the Bayer Statement of Claim related to the Canadian patent, a patent which was issued under different standards than the '012 patent in the United States. Third, the Bayer Statement of Claim appears to be merely a rote recitation of causes of action and does not contain any factual contentions or references which could have informed the patent examiner in the United States. Fourth, and finally, it is emblematic of how little relevance the Bayer Statement of Claim has to the prosecution of the '012 patent in the United States that the patent examiner specifically requested not to receive any other foreign references similar to those already submitted.").

211. *Id.* at *38–39 ("*Therasense* commands the court to determine whether the party challenging the patent has made a showing by clear and convincing evidence that the intent to deceive the PTO is 'the single most reasonable inference able to be drawn from the evidence.' The only inference the court can draw from the evidence presented at trial was that Mr. O'Rourke was a busy young law partner who devised a somewhat 'sloppy' system for sorting foreign litigation material. Teva unendingly repeats the incantation that Mr. O'Rourke engaged in [a] 'scheme of willful blindness.' It is as if Teva hopes to conjure up the flame of inequitable conduct from thin air. Instead the court sees this claim of inequitable conduct for what it is: an attempt to induce the court to believe that if enough smoke is created, there must be a fire. The court sees through this smokescreen and finds

competitor had failed to make a showing of inequitable conduct by clear and convincing evidence.²¹² The district court noted that the present case was the “archetype of the action” the Federal Circuit was targeting with its *Therasense* decision.²¹³ The court described *Therasense* as a “bulwark against the waste of resources by both the judiciary and litigants.”²¹⁴

It is still unclear what district courts’ reception of *Therasense* will be in the long term. However, in the few inequitable conduct cases that have been decided post-*Therasense*, the Federal Circuit’s decision appears to be welcome, which may be an indication of its future reception.

IV. WILL *THERASENSE* BRING EQUITY BACK TO THE INEQUITABLE CONDUCT DOCTRINE?

It is too soon to determine whether the *Therasense* decision will radically reform the doctrine as hoped, or if its effect will be more attenuated. Members of the legal community—both academics and practitioners—have already weighed in on the decision.²¹⁵ The clear consensus is that although the clarity the Federal Circuit provided in *Therasense* is welcome, the decision falls far short of creating the ultimate solution that the court aimed for.²¹⁶ Nevertheless, the Federal Circuit has taken a significant step in the right direction.

A. *THERASENSE* MAY NOT BE AN ADEQUATE CURE FOR “THE PLAGUE”

Scholars seem to think that *Therasense* will have some positive effects, but that these effects are overstated by the court majority. Although there is

that Teva has failed to bring any evidence to the court’s attention which shows that Mr. O’Rourke acted with the specific intent to deceive the PTO.”).

212. *Id.* at *37–39.

213. *Id.* at *39. (“In sum, this court finds that this case is the archetype of the action the Federal Circuit was aiming to curtail with the tightening of the standards in *Therasense*.”).

214. *Id.*

215. See, e.g., Thomas F. Cotter, *An Economic Analysis of Patent Law’s Inequitable Conduct Doctrine*, 53 ARIZ. L. REV. 735 (2011); Lee F. Johnston, *The Therasense Decision: Just What the Doctor Ordered or Will the Inequitable Conduct Plague Mutate and Survive?*, 23 NO. 9 INTELL. PROP. & TECH. L.J. 14 (2011); Joseph A. Micallef, *Therasense and the New Order*, 1063 PLI/Pat 731 (2011); Peng, *supra* note 37, at 373.

216. Cotter, *supra* note 215, at 735 (“[p]ost-*Therasense*, the doctrine poorly defines many of the variables affecting a rational applicant’s decisionmaking process and thus potentially encourages risk-averse agents to overdisclose”); Johnston, *supra* note 215, at 14 (“[t]he new rules could lead to problems of their own and ultimately result in Supreme Court intervention”); Micallef, *supra* note 215, at 733 (“*Therasense* may have settled very little”); Peng, *supra* note 37, at 376 (“[t]he standards articulated in *Therasense* are welcomed by the patent community . . . however . . . *Therasense* may not be the panacea many wish it to be”).

disagreement over the utility of the specific holdings of *Therasense*, the heightened standards for the defense have generally been welcomed by the patent community.²¹⁷ Practitioners also appreciate the clarity that the Federal Circuit offered.²¹⁸ Some authors believe that the combination of heightened pleading standards²¹⁹ and the stringent proof standards found in *Therasense* together will reduce assertions of inequitable conduct.²²⁰ Another author predicted a wave of summary judgment motions in pending inequitable conduct cases following the *Therasense* decision.²²¹ Although what the decision actually accomplishes remains to be seen, it has at least put the patent community on notice that the current status quo is unacceptable and that the courts are determined to effect change in the application of inequitable conduct.²²²

For scholars, the list of what *Therasense* did *not* accomplish is substantially longer. Although one of the Federal Circuit's primary goals was to decrease the frequency of inequitable conduct allegations, one author predicts that allegations will not decline.²²³ None of the *Therasense* holdings affect an accused infringer's ability to *plead* the defense. Simply raising the standards for *finding* inequitable conduct may be insufficient to decrease the number of inequitable conduct *pleadings*.²²⁴ Additionally, but-for materiality may be easier to allege than the court majority would like to believe.²²⁵ In inequitable conduct allegations, materiality is often asserted based on anticipation or obviousness, which are inherently flexible notions.²²⁶ Also, the but-for materiality standard is reviewed under a preponderance of the evidence standard, and the broadest reasonable interpretation of the claims.²²⁷ The "preponderance of the evidence" standard is significantly lower than "clear and convincing evidence."

In the *Therasense* opinion, the Federal Circuit operated on the underlying assumption that raising the standards for finding inequitable conduct would concurrently optimize disclosure practices at the PTO. However, one author contradicts this assumption, arguing that the conditions that trigger a finding

217. Peng, *supra* note 37, at 376.

218. *Id.* at 389.

219. See *Ashcroft v. Iqbal*, 129 U.S. 1937, 1949–50 (2009); *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009).

220. Micallef, *supra* note 215, at 750; Peng, *supra* note 37, at 389.

221. Johnston, *supra* note 215, at 16.

222. *Id.*

223. Peng, *supra* note 37, at 387.

224. *Id.* at 389.

225. Micallef, *supra* note 215, at 750.

226. *Id.*

227. *Id.*

of inequitable conduct post-*Therasense* are at best “only a rough proxy for the conditions defining optimal disclosure.”²²⁸ After a thorough economic analysis of the inequitable conduct doctrine, this author concludes that the variables affecting a rational applicant’s decision-making process are ill-defined in the doctrine and therefore the new standards may actually encourage applicants to over-disclose at the PTO.²²⁹

Therasense may have other unintended effects as well. The *Therasense* dissent predicted that the majority’s “affirmative acts of egregious misconduct” exception to their but-for materiality standard would “become fertile ground for litigation in the future.”²³⁰ The dissent’s concern was over the difficulty in drawing a line between “egregious misconduct” and less-than-egregious misconduct.²³¹ The lack of a clear distinction here could, in itself, encourage additional litigation in this area.²³² Others have agreed, stating that the decision may have “spawned more litigation tactics than it laid to rest.”²³³

In light of the significant criticism the *Therasense* decision has received, it is not surprising that some scholars have predicted that the Federal Circuit’s recent decision is “unlikely to be the last word on the subject.”²³⁴ In the end, the *Therasense* decision seems that it “may not be the panacea many wish it to be.”²³⁵

B. *THERASENSE* PROVIDED VISIBILITY AND CLARITY

Despite scholars’ predictions, it is still too early to determine the effects of the *Therasense* decision in actual practice. The inequitable conduct doctrine is complex and intricate, as it attempts to construct rational incentives for actors who do not always act rationally. Many different thoughtful and insightful opinions have been written discussing what redemptive path the inequitable doctrine must take, not the least of which are the concurrence

228. Cotter, *supra* note 215, at 735.

229. *Id.*; see also Peng, *supra* note 37, at 390 (“[t]he Federal Circuit’s ‘but-for’ materiality may in fact encourage applicants to continue to submit significant amounts of prior art during prosecution”).

230. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, n.3 (Fed. Cir. 2011).

231. *Id.*

232. *Id.*

233. Johnston, *supra* note 215, at 16; see also Peng, *supra* note 37, at 396 (“*Therasense* may in fact have the unintended consequence of making litigation more complicated.”).

234. Micallef, *supra* note 215, at 757, see also Peng, *supra* note 37, at 389 (“[s]ince 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”).

235. Peng, *supra* note 37, at 376.

and dissent in *Therasense*. The en banc decision garnered only a bare majority.²³⁶ There are many different views on the subject precisely because the answer to the problem is not straightforward. The probability that the *Therasense* opinion struck the perfect chord—if there is one to be struck—is necessarily low.

However, the *Therasense* decision is still a valuable one. The inequitable conduct doctrine before *Therasense* was a vacillating mess, where a patentee could face the grave charge of inequitable conduct without even knowing under which set of standards he would be judged.²³⁷ The *Therasense* court has provided a comprehensive set of guidelines under which practitioners and patentees alike can readily identify the standards they are held to.

The second valuable element that the *Therasense* decision provides is visibility. The Federal Circuit took the case en banc and plainly and thoroughly criticized the entire inequitable conduct doctrine. Although academics and practitioners have long been calling for reform, in *Therasense* the Federal Circuit has stepped up and comprehensively addressed the issues in this highly anticipated decision. Even the concurrence and dissent in *Therasense* agreed with the majority that the inequitable conduct doctrine must be reined in. Fine-tuning the rules to finally achieve the right balance may take time, but the Federal Circuit has made its end goal clear. Although the decision may not have provided the cure to the “plague,” by bringing the problems to light, the court took a notable step in that direction.

V. CONCLUSION

The Federal Circuit has significantly restructured the inequitable conduct defense through its en banc decision in *Therasense*. In an effort to rein in rampant inequitable conduct allegations in the courts and stem the tide of prior art references flowing into the PTO, the Federal Circuit raised the standards for both intent and materiality. The court abolished the “should have known” intent standard and held that a specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence. The court implemented a but-for materiality standard, and eliminated the long-standing sliding-scale step of the inequitable conduct inquiry. The Federal Circuit’s revision of the inequitable conduct doctrine was comprehensive, however this new standard must be appreciated within the

236. *Therasense* had a 6–5 majority. See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011).

237. See *supra* Section I.A.

context of the *Exergen* pleading standards, the PTO's proposed revision of Rule 56, and the recently enacted Leahy-Smith AIA.

Although the Federal Circuit attempted to provide a cure to the inequitable conduct "plague" in its *Therasense* opinion, it probably fell short. However, what *Therasense* has done is to provide a set of clear, workable guidelines to practitioners. And perhaps more importantly, it has provided visibility for the problems in the inequitable conduct doctrine and the goals of the Federal Circuit with respect to them.

