

4-20-2012

Therasense-less: How the Federal Circuit Let Policy Overtake Precedent in *Therasense, Inc. v. Becton, Dickinson & Co.*

James J. Schneider
Boston College Law School, james.schneider@bc.edu

Follow this and additional works at: <http://lawdigitalcommons.bc.edu/bclr>



Part of the [Intellectual Property Commons](#)

Recommended Citation

James J. Schneider, *Therasense-less: How the Federal Circuit Let Policy Overtake Precedent in Therasense, Inc. v. Becton, Dickinson & Co.*, 53 B.C.L. Rev. E. Supp. 223 (2012), <http://lawdigitalcommons.bc.edu/bclr/vol53/iss6/19>

This Comments is brought to you for free and open access by the Law Journals at Digital Commons @ Boston College Law School. It has been accepted for inclusion in Boston College Law Review by an authorized administrator of Digital Commons @ Boston College Law School. For more information, please contact nick.szydowski@bc.edu.

THERASENSE-LESS: HOW THE FEDERAL CIRCUIT LET POLICY OVERTAKE PRECEDENT IN *THERASENSE, INC. v. BECTON, DICKINSON & CO.*

Abstract: On May 25, 2011, in *Therasense, Inc. v. Becton, Dickinson & Co.*, the en banc U.S. Court of Appeals for the Federal Circuit fundamentally restructured the patent law doctrine of inequitable conduct. The court did so by holding that both intent and materiality are required for successfully claiming the defense, and that materiality must be proven by a but-for test, thereby limiting the scope of conduct covered by the doctrine. Although in making this change the court may have helped to curb the over usage of inequitable conduct, it did so by contradicting Supreme Court precedent. Thus, this Comment argues that the *Therasense* court overstepped its bounds and, in its attempt to limit the doctrine, may have unduly narrowed this equitable defense.

INTRODUCTION

Inequitable conduct is a judge-made equitable defense to patent infringement.¹ Under this defense, if the defendant is able to show that the patent owner acted inequitably in dealing with the U.S. Patent and Trademark Office (PTO), then the patent in question is unenforceable.² Because the result of successfully claiming inequitable conduct is so powerful, this defense is a common litigation tactic.³ In fact, it is asserted so often that the Federal Circuit has referred to the doctrine as a “plague.”⁴

On May 25, 2011, in *Therasense, Inc. v. Becton, Dickinson & Co.*, the U.S. Court of Appeals for the Federal Circuit sitting en banc limited the scope of the inequitable conduct defense.⁵ The court held that *Therasense, Inc.* (now, Abbott Diabetes Care, Inc.) and Abbott Labora-

¹ *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense II)*, 649 F.3d 1276, 1285 (Fed. Cir. 2011).

² *Id.* at 1285, 1287.

³ *Id.* at 1289.

⁴ *E.g., Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1342 (Fed. Cir. 2009); *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).

⁵ *Therasense II*, 649 F.3d at 1296.

tories (collectively “Abbott”) committed inequitable conduct, and thus dismissed an infringement suit against Becton Dickinson and Co. (“Becton”).⁶ Although the court limited the doctrine in an attempt to curb its use, in doing so the court contradicted Supreme Court precedent and may have made the doctrine too narrow to serve its equitable purpose.⁷

Part I of this Comment outlines the history of the inequitable conduct doctrine.⁸ Further, it summarizes how the district court and the panel of the Federal Circuit applied the doctrine in *Therasense*.⁹ Part II examines how the Federal Circuit fundamentally altered the doctrine in an effort to cure what it viewed as a plague.¹⁰ Finally, Part III explores the origin of the inequitable conduct doctrine.¹¹ Then, it argues that the Federal Circuit’s ruling too narrowly restricts the inequitable conduct doctrine, thereby undermining the purposes of the doctrine and countering controlling Supreme Court precedent.¹²

I. ABBOTT’S PATENT AND THE HISTORY OF INEQUITABLE CONDUCT

A. *A New Patent, an Old Patent, and a Claim of Infringement*

On October 13, 1998, the PTO granted to Abbott U.S. Patent No. 5,820,551 (“the new patent”).¹³ The new patent covered a specific type of disposable blood glucose test strip, used by those with diabetes to measure their blood’s glucose level.¹⁴ The strip can test whole blood (blood that contains all of its components) without a membrane over the strip’s electrode.¹⁵ This feature differentiated the new patent from another patent, also held by Abbott—Patent No. 4,545,382 (“the old patent”)—which called for an “optional, but preferable” membrane over the electrode.¹⁶

⁶ *Therasense II*, 649 F.3d at 1282; *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense I)*, 565 F. Supp. 2d 1088, 1091, 1114–15 (N.D. Cal. 2008), *aff’d in part, rev’d in part*, 649 F.3d 1276 (Fed. Cir. 2011).

⁷ See *infra* notes 13–114 and accompanying text.

⁸ See *infra* notes 13–63 and accompanying text.

⁹ See *infra* notes 13–63 and accompanying text.

¹⁰ See *infra* notes 63–91 and accompanying text.

¹¹ See *infra* notes 92–114 and accompanying text.

¹² See *infra* notes 92–114 and accompanying text.

¹³ U.S. Patent No. 5,820,551 (issued Oct. 13, 1998), *ruled unenforceable by Therasense I*, 565 F. Supp. 2d 1088.

¹⁴ *Therasense II*, 649 F.3d at 1282.

¹⁵ *Id.* at 1282, 1283.

¹⁶ *Id.* at 1283; *Therasense I*, 565 F. Supp. 2d at 1094.

Abbott held both patents, and to obtain the new patent, it was Abbott's responsibility to identify previous similar patents and explain why the new patent was different.¹⁷ In doing so, Abbott had to prove to the PTO that, when looking at previous patents, the new patent would not have been an obvious next step to a practitioner having an ordinary level of familiarity with blood glucose test strips.¹⁸ To establish this level of non-obviousness, Abbott claimed that a practitioner would have read the old patent's claim of an optional but preferable membrane as mere patent phraseology, and that the membrane was, in fact, not optional.¹⁹ After Abbott made this declaration, the new patent was allowed.²⁰ Abbott did not, however, disclose to the PTO that it had made a contradictory statement about the European counterpart to the old patent (the "European patent").²¹ In discussing the European patent, Abbott had argued that the same optional but preferable language meant that the strip expressly did not require a membrane.²²

In March 2004, Becton brought suit against Abbott in the U.S. District Court for the District of Massachusetts, seeking a declaratory judgment of non-infringement of two other patents owned by Abbott.²³ Abbott responded by countersuing Becton in the U.S. District Court for the Northern District of California for infringement of these two patents and the new patent.²⁴ The case was transferred to the Northern District of California, and the court granted summary judgment for non-infringement on all asserted claims in the non-new patent actions.²⁵ A bench trial followed regarding the new patent.²⁶ It was during this trial that Abbott's contradictory statements regarding the "optional, but preferable" language—and its failure to disclose this conflict to the Patent Office—came to light.²⁷ Using these contradictory statements, Becton asserted a claim of inequitable conduct against Abbott as an affirmative defense.²⁸

¹⁷ See 35 U.S.C. § 112 (2006); *Therasense II*, 649 F.3d at 1283.

¹⁸ See 35 U.S.C. § 103(a).

¹⁹ *Therasense II*, 649 F.3d at 1283.

²⁰ *Therasense I*, 565 F. Supp. 2d at 1094.

²¹ *Id.* at 1110.

²² See *Therasense II*, 649 F.3d at 1284.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.* at 1285.

²⁷ *Therasense I*, 565 F. Supp. 2d at 1107–08.

²⁸ *Id.* at 1091.

B. *The Evolution of a Doctrine*

Although the inequitable conduct doctrine was originally used in patent litigation to curb egregious conduct, in recent years, it has been expanded considerably to cover a broad range of behavior.²⁹ In the Patent Act of 1790, the legislature recognized a private cause of action to repeal an improperly obtained patent.³⁰ Furthermore, until 1952, subsequent patent statutes contained provisions creating private remedies against such deceptive conduct.³¹ Yet, despite these remedies, before 1945, courts were reluctant to enforce these provisions.³² Initially, the Supreme Court applied the doctrine of unclean hands to dismiss patent cases in which there was extreme misconduct.³³ Under the unclean hands doctrine, a party cannot seek equitable relief if that party has itself violated an equitable principle, such as good faith.³⁴ Accordingly, the Court used this doctrine in patent cases in instances of perjury, the manufacture of false evidence, and the suppression of evidence.³⁵

Eventually, the unclean hands doctrine evolved into the patent-litigation doctrine of inequitable conduct.³⁶ Under inequitable conduct, a court may repeal the grant of a patent if the party accused of patent infringement can show that the party alleging infringement did not, while pursuing its patent application, present the PTO with all relevant facts concerning possible fraud or inequity, regardless of whether the conduct could constitute a violation of law.³⁷ The doctrine arose in the Supreme Court's 1945 case, *Precision Instrument Manufacturing, Co. v. Automotive Maintenance Machinery Co.*³⁸ In *Precision*, the Court held that a party seeking a patent had to submit all relevant facts to the PTO.³⁹ If the party did not submit all such facts, then it had engaged in inequitable conduct, which justified the dismissal of its patent in-

²⁹ *Therasense II*, 649 F.3d at 1287, 1288.

³⁰ Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J.L. & TECH. 37, 39 (1993).

³¹ *Id.* at 38.

³² *Id.*

³³ *Therasense II*, 649 F.3d at 1285.

³⁴ BLACK'S LAW DICTIONARY 286 (9th ed. 2009).

³⁵ See *Precision Instrument Mfg., Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 240 (1944); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 243 (1933).

³⁶ See *Precision*, 324 U.S. at 818; *Therasense II*, 649 F.3d at 1285.

³⁷ See *Precision*, 324 U.S. at 818.

³⁸ See *id.*; Goldman, *supra* note 30, at 51.

³⁹ *Precision*, 324 U.S. at 818.

fringement case.⁴⁰ Accordingly, in *Precision*, the Court dismissed the case after concluding that the party asserting patent infringement had committed inequitable conduct by failing to disclose information regarding another party's possible perjury, despite insufficient proof to make a case for the actual crime of perjury.⁴¹

Yet, the Court did not make clear, what conduct was sufficient to constitute "inequitable conduct."⁴² As a result, with no clear standard governing their decisions, lower courts tended to broaden the scope of the defense.⁴³ Thus, the doctrine came to cover a broad range of misconduct, including nondisclosure of information.⁴⁴ In addition, although a successful unclean hands defense resulted in the dismissal of the suit at hand, a successful inequitable conduct defense became much more powerful—it resulted in the patent's unenforceability.⁴⁵

In light of this stronger remedy, the inequitable conduct doctrine came to require first, that the patent holder had specific intent to deceive the PTO, and second, that the missing or fraudulent information was material to the granting of the patent.⁴⁶ Then, if both of those elements were proven by clear and convincing evidence, the court weighed the equities to determine whether the patent holder's conduct warranted the large penalty of rendering the patent unenforceable.⁴⁷

Yet, as the doctrine evolved, the Federal Circuit lowered the intent-to-deceive standard, no longer requiring a specific intent, and instead finding negligence sufficient.⁴⁸ In addition, the Federal Circuit loosened the definition of "material" to that which a reasonable examiner would be substantially likely to consider important.⁴⁹ Eventually, the Federal Circuit placed the intent and materiality elements together on

⁴⁰ *Id.* at 819.

⁴¹ *See id.* at 818–19.

⁴² Goldman, *supra* note 30, at 52.

⁴³ *Id.* at 55–67. For example, one court, as it expanded the conduct encompassed within inequitable conduct, noted that "[e]nforcing a patent in [sic] behalf of one who has made intentional misrepresentations to the Patent Office, irrespective of the merits of his patent application, might encourage an applicant to be dishonest . . ." *Corning Glass Works v. Anchor Hocking Glass Corp.*, 253 F. Supp. 461, 471 (D. Del. 1966), *rev'd on other grounds*, 374 F.2d 473 (3d Cir. 1966).

⁴⁴ *Therasense II*, 649 F.3d at 1287.

⁴⁵ *Id.*; Michael J. Meurer, *Controlling Opportunistic and Anti-Competitive Intellectual Property Litigation*, 44 B.C. L. Rev. 509, 541 (2003).

⁴⁶ *Therasense II*, 649 F.3d at 1287 (citing *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008)).

⁴⁷ *Id.*

⁴⁸ *Id.* at 1287–88 (citing *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984)).

⁴⁹ *Id.* at 1288 (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984)).

a sliding scale, allowing a finding of inequitable conduct even if there was a weak showing of one element so long as there was a strong showing of the other.⁵⁰ This materiality-intent-balancing framework essentially conflated and diluted the standards, which were intended to be two distinct requirements.⁵¹

Although the Federal Circuit hoped these changes would encourage full disclosure to the PTO, unforeseen consequences emerged.⁵² Inequitable conduct became an important litigation strategy, with one study estimating that eighty percent of patent infringement cases included allegations of inequitable conduct.⁵³ Because of the threat of future inequitable conduct claims, those seeking patents consistently submitted all possibly relevant pieces of prior art, often overwhelming the PTO with unnecessary documents.⁵⁴ Thus, inequitable conduct's powerful remedy of rendering the entire patent unenforceable incentivized not only an excess of allegations of inequitable conduct, but also the over-disclosure of information to the PTO.⁵⁵ It is no wonder, therefore, that the Federal Circuit referred to the doctrine as a "plague."⁵⁶

C. *Becton's Claim of Inequitable Conduct*

Against this legal backdrop, Becton asserted inequitable conduct in Abbott's infringement suit offering, as evidence, Abbott's failure to disclose the contradictory statements regarding the European patent to the PTO.⁵⁷ The district court found for Becton, holding the new patent unenforceable due to inequitable conduct.⁵⁸ Abbott appealed the decision.⁵⁹ By a split-panel decision, the Federal Circuit upheld the district court's finding of invalidity.⁶⁰

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Therasense II*, 649 F.3d at 1288.

⁵³ Ad Hoc Comm. on Rule 56 and Inequitable Conduct, Am. Intellectual Prop. Law Ass'n, *The Doctrine of Inequitable Conduct and the Duty of Candor in Patent Prosecution: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 75 (1988).

⁵⁴ *Therasense II*, 649 F.3d at 1289.

⁵⁵ *Id.*

⁵⁶ *Burlington Indus.*, 849 F.2d at 1422.

⁵⁷ See *Therasense I*, 565 F. Supp. 2d at 1091, 1107–08.

⁵⁸ *Therasense II*, 649 F.3d at 1285.

⁵⁹ *Id.*

⁶⁰ *Id.*

Three months later, however, the court granted Abbott's petition for a rehearing en banc.⁶¹ The order suggested that the Court was ready to reconsider the doctrine of inequitable conduct; parties were asked to address how the materiality-intent-balancing framework should be modified or replaced.⁶² Further supporting this inference, Chief Judge Randall R. Rader of the Federal Circuit had recently stated that the doctrine was "constantly overflowing its banks."⁶³

II. RESTRUCTURING THE INEQUITABLE CONDUCT DOCTRINE

Writing for the majority, Chief Judge Rader authored a decision he openly hoped would change the doctrine of inequitable conduct.⁶⁴ The decision affirmed that a claim of inequitable conduct requires specific intent to deceive the PTO.⁶⁵ Yet, it also held that intent and materiality are separate elements, and that they should not be put on a sliding scale with one another.⁶⁶ Furthermore, the court held that for undisclosed information to meet the materiality requirement, it must meet a "but-for" test.⁶⁷ Under this test, non-disclosed information is material only if the PTO would not have allowed the claim had it been aware of that information.⁶⁸

The en banc court unanimously supported two of the three changes to the doctrine.⁶⁹ All eleven judges agreed that the two elements—intent and materiality—are separate elements and should not be put together on a sliding scale.⁷⁰ In addition, all eleven judges agreed that the infringer must prove that the patentee acted with specific intent to deceive and that negligence, even gross negligence, was insufficient to meet this standard.⁷¹ Nonetheless, because direct evidence of intent to deceive is rare, the court held that intent to deceive

⁶¹ *Therasense, Inc. v. Becton, Dickinson & Co.*, 374 F. App'x 35 (Fed. Cir. 2010) (granting rehearing en banc).

⁶² *See id.*

⁶³ *See* Randall R. Rader, *Foreword—Always at the Margin: Inequitable Conduct in Flux*, 59 AM. U. L. REV. 777, 780 (2010).

⁶⁴ *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense II)*, 649 F.3d 1276, 1290 (Fed. Cir. 2011).

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.* at 1291.

⁶⁸ *Id.*

⁶⁹ *See id.* at 1302 (Bryson, J., dissenting).

⁷⁰ *See Therasense II*, 649 F.3d at 1290; *id.* at 1297 (O'Malley, J., concurring in part, dissenting in part); *id.* at 1302 (Bryson, J., dissenting).

⁷¹ *See id.* at 1290 (majority opinion); *id.* at 1297 (O'Malley, J., concurring in part, dissenting in part); *id.* at 1302 (Bryson, J., dissenting).

may be inferred from indirect and circumstantial evidence, but only if the inference is the single most reasonable inference from the evidence.⁷² Thus, if multiple reasonable inferences can be drawn, a court cannot find an intent to deceive.⁷³

In making these holdings, the *Therasense* court reaffirmed the Federal Circuit's 1988 en banc decision, *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*⁷⁴ In *Kingsdown*, the court established that inequitable conduct required an intent to deceive.⁷⁵ Yet, *Kingsdown* addressed only the intent prong of the doctrine; the materiality prong had been addressed four years earlier, in 1984, by the Federal Circuit in *J.P. Stevens & Co. v. Lex Tex Ltd.*⁷⁶ The *J.P. Stevens & Co* formulation governed the materiality standard until the court's decision in *Therasense*.⁷⁷

It was the change to the materiality standard that sharply divided the court.⁷⁸ By adopting a but-for standard, the Federal Circuit acted contrary to its own previous decisions, which had expressly rejected such a test.⁷⁹ Furthermore, such a standard contradicted both the PTO's Rule 56, which governs what information is deemed material by the patent office, and the position taken by the PTO in its amicus brief.⁸⁰ Nonetheless, the *Therasense* majority supported its but-for stan-

⁷² *Id.* at 1290.

⁷³ *Id.* at 1290–91 (citing *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008)); see *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988).

⁷⁴ See *Therasense II*, 649 F.3d at 1304 (Bryson, J., dissenting).

⁷⁵ See *id.* at 1291 (majority opinion) (citing *Kingsdown*, 863 F.2d at 867).

⁷⁶ *Id.* at 1303 (Bryson, J., dissenting); *J.P. Stevens & Co. v. Lex Tex Inc.*, 747 F.2d 1553, 1559 (Fed. Cir. 1984).

⁷⁷ *Therasense II*, 649 F.3d at 1291; *id.* at 1303–04 (Bryson, J., dissenting) (citing *J.P. Stevens & Co.*, 747 F.2d at 1559).

⁷⁸ *Id.* at 1291 (majority opinion); *id.* at 1297 (O'Malley, J., concurring in part, dissenting in part); *id.* at 1302–03 (Bryson, J., dissenting).

⁷⁹ See *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1132 (Fed. Cir. 2006); *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1421 (Fed. Cir. 1989).

⁸⁰ Compare *Therasense II*, 649 F.3d at 1293 (“This court does not adopt the definition of materiality in PTO Rule 56.”), with Brief for the United States as Amicus Curiae on Rehearing En Banc in Support of Neither Party at 8–9, *Therasense II*, 649 F.3d 1276 (Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1514, and 2008-1595), 2010 WL 3390234 at *8–9 (“The single proper standard for materiality should be Rule 56.”). Rule 56 states that information is material when it establishes a prima facie case of un-patentability or refutes, or is inconsistent with, a position the applicant takes in seeking a patent. 37 C.F.R. § 1.56 (2010). The *Therasense* majority acknowledged that its standard for materiality was counter to that advocated by the PTO. *Therasense II*, 649 F.3d at 1293. Yet, as the court observed, the PTO is not the only body affected by the inequitable conduct doctrine. *Id.* at 1294. The majority cited both the American Bar Association and the American Intellectual Property Law Association as supporters for the but-for standard, stating that it is not bound by the definition of materiality in the PTO's rules. *Id.*

dard with the 1928 Supreme Court case, *Corona Cord Tire Co. v. Dovan Chemical Corp.*⁸¹ In *Corona Cord*, the Court declined to extinguish a patent's validity because the patentee's misrepresentation to the patent office was not the but-for cause of the patent's issuance.⁸²

In adopting the but-for standard, the *Therasense* majority recognized that a pure but-for test for materiality would be too rigid for an equitable doctrine.⁸³ Thus, the court carved out an exception: cases of affirmative egregious misconduct would satisfy the materiality prong.⁸⁴ Yet, the court provided little guidance to define the affirmative egregious misconduct exception.⁸⁵ It did, however, provide one example of conduct which would meet the standard—the filing of an unmistakably false affidavit—and two examples which would not—nondisclosure of prior art references and failure to mention prior art references in an affidavit.⁸⁶

In contrast, the dissent argued that a but-for standard was unnecessarily severe and would provide little incentive for applicants to be candid with the PTO.⁸⁷ The dissent agreed with the PTO that strictly adhering to a tightened intent standard would largely solve the problems of the inequitable conduct doctrine.⁸⁸ According to the dissent, a but-for standard of materiality was an unnecessary step, and one that would eliminate incentives to meet disclosure obligations to the PTO.⁸⁹ Because under a but-for standard only patents that would not have been issued would be invalidated, an applicant with information that could prevent the patent from being issued will simply withhold it.⁹⁰ Thus, under such a standard, the applicant loses nothing by withholding the information, although under the previous materiality standard, this failure to disclose would result in the unenforceability of the patent.⁹¹

⁸¹ *Therasense II*, 649 F.3d at 1291 (citing *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 373–74 (1928)); see *Precision Instrument Mfg., Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 818–19 (1945).

⁸² *Corona Cord*, 276 U.S. at 373–74.

⁸³ *Therasense II*, 649 F.3d at 1292–93.

⁸⁴ *Id.* at 1292.

⁸⁵ See *id.* at 1292–93.

⁸⁶ *Id.*

⁸⁷ *Id.* at 1305–06 (Bryson, J., dissenting).

⁸⁸ *Id.* at 1305; see also Christina Bohannan & Herbert Hovenkamp, *IP and Antitrust: Reform and Harm*, 51 B.C. L. REV. 905, 944 (2010) (discussing how “patent law is clearly seeing the beginning of reform” and how several judicial decisions have “limit[ed] the scope of injunctive relief”).

⁸⁹ *Therasense II*, 649 F.3d at 1305 (Bryson, J., dissenting).

⁹⁰ *Id.* at 1305–06.

⁹¹ *Id.*

III. A PRECEDENT PROBLEM: DID THE FEDERAL CIRCUIT CONTRADICT THE SUPREME COURT?

The *Therasense* court, by establishing a but-for standard of materiality, not only contravened Supreme Court precedent, but in its attempt to limit the doctrine, may have also unduly narrowed this equitable defense.⁹² Despite the fact that the *Therasense* court's establishment of a but-for standard and the dissent's argument against it are policy-driven, such a standard implicitly rejects Supreme Court precedent.⁹³ The standard contradicts the Supreme Court's 1945 decision, *Precision Instrument Manufacturing, Co. v. Automotive Maintenance Machinery Co.*, in which the Court formulated the skeletal guidelines for the inequitable conduct doctrine.⁹⁴

Although the majority and dissent both recognized the trio of Supreme Court cases from which the inequitable conduct doctrine arose, neither examined the guidelines for the doctrine established in *Precision*.⁹⁵ The *Precision* court first used the term "inequitable conduct" in a patent litigation setting, giving rise to the doctrine.⁹⁶ Specifically, in *Precision*, the Court recognized the need for a flexible approach in an equitable claim.⁹⁷ Thus, in establishing a rigid, but-for standard, the *Therasense* court contravened the Supreme Court's articulation of the doctrine set out in *Precision*.⁹⁸ In addition, in formulating the but-for standard, the *Therasense* court concluded that *Corona Cord Tire Co. v. Donovan Chemical Corp.*, a 1923 Supreme Court case, supported the estab-

⁹² See *infra* notes 93–114 and accompanying text.

⁹³ See *Precision Instrument Mfg., Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 818 (1945); *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense II)*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) ("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."); *id.* at 1305–06 (Bryson, J., dissenting) (discussing the negative repercussions of a but-for standard for three paragraphs); see also *Williams v. United States*, 240 F.3d 1019, 1030 (Fed. Cir. 2001) (stating that the Federal Circuit is "strictly bound" to follow applicable Supreme Court precedent); *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1421 (Fed. Cir. 1989) (rejecting but-for materiality).

⁹⁴ See 324 U.S. at 818.

⁹⁵ See *Precision*, 324 U.S. at 818–19; *Therasense II*, 649 F.3d at 1285–87; *id.* at 1306–08 (Bryson, J., dissenting).

⁹⁶ See *Precision*, 324 U.S. at 819; Holly S. Hawkins & Labriah Lee, Exergen: A Clarification to Pleading Inequitable Conduct, INTELL. PROP. LITIG., Summer 2010, available at http://apps.americanbar.org/litigation/litigationnews/practice_areas/062210-intellectual-property-exergen-inequitable-conduct.html; D. Christopher Ohly, *Therasense: Another Case for Rejection of Rigid Rules*, INTELL. PROP. & TECH. L.J., Aug. 2011, at 14, 14.

⁹⁷ Ohly, *supra* note 96, at 15.

⁹⁸ See *Williams*, 240 F.3d at 1030; Kevin Mack, Note, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147, 152 (2006).

lishment of a but-for materiality test, because *Corona Cord* illustrated the Court's unwillingness to extinguish a patent's presumption of validity because of a misrepresentation that did not affect the patent's issuance.⁹⁹ Yet, the Supreme Court's 1945 decision in *Precision*, in which the Court formulated the standard of the inequitable conduct doctrine, was a "striking departure" from *Corona Cord*.¹⁰⁰

Furthermore, a but-for standard of materiality narrows the doctrine of inequitable conduct beyond the guidelines established in *Precision*—that one must disclose to the PTO *all* facts concerning possible fraud and inequitableness.¹⁰¹ Although *Precision* provides specific guidance as to what information must be disclosed to the PTO to avoid a finding of inequitable conduct, this guidance is contradicted by the holding in *Therasense*.¹⁰² According to the *Precision* court, a patent applicant has an "uncompromising duty to report to [the PTO] all facts concerning possible fraud or inequitableness."¹⁰³ In contrast, a but-for standard requires a patent applicant to disclose only that information which would prevent the applicant from receiving the patent, rather than all facts concerning fraud or inequitableness.¹⁰⁴ Thus, the *Therasense* court tightens the doctrine beyond the language of *Precision*.¹⁰⁵ Although the *Therasense* court recognizes an exception for affirmative acts of egregious misconduct, the new standard still appears too narrow; it explicitly does not cover a failure to mention prior art references, conduct seemingly encompassed in a duty to report all facts concerning possible fraud or inequitableness.¹⁰⁶

Although this language from *Precision* may be classified as dicta, the Federal Circuit should still have considered it binding.¹⁰⁷ As the Federal Circuit has previously acknowledged, it must follow the Su-

⁹⁹ *Therasense II*, 649 F.3d at 1291.

¹⁰⁰ Goldman, *supra* note 30, at 51; see 6 DONALD S. CHISUM, CHISUM ON PATENTS § 19.03[1][c] (Matthew Bender 2011) ("[The Court] articulated a duty of disclosure of applicants and assignees.").

¹⁰¹ See *Precision*, 324 U.S. at 818; *Therasense II*, 649 F.3d at 1292.

¹⁰² See *Precision*, 324 U.S. at 818; *Therasense II*, 649 F.3d at 1291; Matthew M. Peters, Legislative Update, *The Equitable Inequitable: Adding Proportionality and Predictability to Inequitable Conduct in the Patent Reform Act of 2008*, 19 DEPAUL J. ART, TECH. & INTELL. PROP. L. 77, 83 (2008).

¹⁰³ *Precision*, 324 U.S. at 818.

¹⁰⁴ See *Therasense II*, 649 F.3d at 1291.

¹⁰⁵ See *Precision*, 324 U.S. at 818; *Therasense II*, 649 F.3d at 1291; Ohly, *supra* note 96, at 14.

¹⁰⁶ See *Precision*, 324 U.S. at 818; *Therasense II*, 649 F.3d at 1292–93.

¹⁰⁷ See *Precision*, 324 U.S. at 818; Daimlerchrysler Corp. v. United States, 361 F.3d 1378, 1385 n.3 (Fed. Cir. 2004); Stone Container Corp. v. United States, 229 F.3d 1345, 1350 (Fed. Cir. 2000).

preme Court's "explicit and carefully considered" language, even if it is dicta.¹⁰⁸ The *Precision* Court's detailed discussion of a patentee's "uncompromising duty" to report to the PTO all facts concerning possible fraud or inequity appears to meet this "explicit and carefully considered" threshold.¹⁰⁹ The Court dedicated a paragraph to the public policy behind its standard for inequitable conduct, stating that one must submit all information regarding inequity to the PTO in order to best serve the public interest by preventing the public from becoming victims of deception and fraud.¹¹⁰

Thus, the Federal Circuit in *Therasense* overstepped its bounds in establishing a but-for test of materiality.¹¹¹ As the language from *Precision* appears to be explicit and carefully considered, the *Therasense* court should have considered itself bound by it.¹¹² If it had, the court could not have ruled in favor of a but-for standard, a rigid test that contradicts the uncompromising duty by patent-seekers to report all facts concerning possible fraud or inequity stated by *Precision*.¹¹³ Although the doctrine of inequitable conduct has evolved since *Precision*, never before has the range of conduct policed by the doctrine shrunk beyond the Supreme Court's framework—by not requiring disclosure of possible inequity—until now.¹¹⁴

CONCLUSION

Facing what it considered to be a growing "plague," the Federal Circuit in *Therasense* fundamentally altered the doctrine of inequitable conduct. It did so by holding that intent and materiality are separate elements and cannot be placed on a sliding scale, that intent can only be shown by proving a specific intent to deceive the PTO, and that the correct test for materiality is a but-for test, in which only information that would have prevented the issuance of the patent in question can

¹⁰⁸ See *Daimlerchrysler*, 361 F.3d at 1385 n.3; *Stone Container*, 229 F.3d at 1350.

¹⁰⁹ See *Precision*, 324 U.S. at 818; *Daimlerchrysler*, 361 F.3d at 1385 n.3; *Stone Container*, 229 F.3d at 1350.

¹¹⁰ *Precision*, 324 U.S. at 818.

¹¹¹ See *id.* at 818; *Therasense II*, 649 F.3d at 1291; Ohly, *supra* note 96, at 14.

¹¹² See *Precision*, 324 U.S. at 818; *Daimlerchrysler*, 361 F.3d at 1385 n.3; *Stone Container*, 229 F.3d at 1350; Thomas L. Irving et al., *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, 311 (2010) ("Precision Instrument, as arguably the only case where the Supreme Court expressly applied the doctrine of inequitable conduct, remains the definitive pronouncement of the law of inequitable conduct.").

¹¹³ See *Precision*, 324 U.S. at 818.

¹¹⁴ See *Therasense II*, 649 F.3d at 1291; *Precision*, 324 U.S. at 818.

meet the materiality requirement. Although the state of the inequitable conduct doctrine may have been in desperate need of change, the Federal Circuit does not have unfettered discretion to amend the doctrine as it sees fit. Furthermore, although there are undoubtedly strong policy reasons for such a standard, the Federal Circuit cannot limit a patentee's duty to disclose beyond the framework established by the Supreme Court.

JAMES J. SCHNEIDER

Preferred citation: James J. Schneider, Comment, *Therasense-less: How the Federal Circuit Let Policy Overtake Precedent in Therasense, Inc. v. Becton, Dickinson & Co.*, 53 B.C. L. REV. E. SUPP. 223 (2012), http://bclawreview.org/e-suppl/2012/18_schneider.pdf.

