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Inequitable Conduct as a Defense to Patent Infringement: What will the Effect of the Federal Circuit's Decision in Therasense, Inc. Have?

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I. Introduction

The doctrine of inequitable conduct was judicially created and derived from the doctrine of "unclean hands," over the lifetime of this doctrine it has evolved to being claimed in almost every case of patent infringement or patent litigation.[1] The equitable defense of "unclean hands" was created in order for the court to dismiss a claim of patent infringement for egregious misconduct on the part of the patentee. However, in three Supreme Court decisions, the Court derived the defense of inequitable conduct, in order to include a broader genus of conduct on behalf of the patentee, and to provide an adequate remedy that would not allow an individual to hold an exclusive right over their invention through misconduct.[2] In creating the defense of inequitable conduct, the Court sought to create a doctrine that would ensure that a patentee acted before the United States Patent & Trademark Office (PTO) with candor and in good faith.[3] In addition, to promoting the patentee's duty of good faith and candor, the inequitable conduct doctrine was created to foster disclosure during the application process before the PTO.[4]

In May 2011, the Court of Appeals for the Federal Circuit concluded that the threshold requirements of inequitable conduct were overly broad; thus, prompting the court in an *en banc* decision, to heighten the standards by which inequitable conduct must be pled.

[1] Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276, 1285 (Fed. Cir. 2011).
[2] *See, id* at 1287.
[3] 37 C.F.R. § 1.56 (1997). Duty of Disclosure, Candor, and Good Faith; Duty to disclose information material to patentability, a patent by its very nature is affected with a public interest. *Id.* The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. *Id.* However, 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. *Id.*
[4] *See, Therasense, Inc.*, 649 F.3d at 1275.

This paper addresses the *en banc* decision in Therasense, Inc. v. Becton, Dickinson and Company, 649 F.3d 1276 (Ct. App. Fed. Cir. 2011) in which, the Federal Circuit addressed the defense of inequitable conduct and the over application of the doctrine during patent litigation. The Federal Circuit, in their decision recognized that the over broad threshold requirements for inequitable conduct, altered the underlying principles and purpose of the doctrine. Since the Federal Circuit's decision, commentators have summarized and addressed the implications that the Federal Circuit's decision will have on the doctrine of inequitable conduct.[5] However, this paper, will address the impact the Federal Circuit's decision has had on the doctrine of inequitable conduct as a whole, where the doctrine will go in the future, and whether the Federal Circuit's decision was in fact correct.

Part II of this paper will address the origins of the inequitable conduct defense. In pleading inequitable conduct, the defendant or alleged infringer must establish by clear and convincing evidence that during the prosecution of the patent in question, the patentee failed to disclose material information with the intent to deceive the PTO.[6] If the defendant or alleged infringer establishes both elements, the court will then balance the equities and determine whether the patentee's misconduct is sufficient to allow the court to render the entire patent unenforceable.[7]

The Federal Circuit's *en banc* decision in Therasense, Inc. v. Becton, Dickinson and Company is discussed in Part III of this paper. In discussing the court's decision, this paper will

[5] *See,* Priscilla G. Taylor, *Bringing Equity Back to the Inequitable Conduct Doctrine*, 27 BERKLEY TECH. L.J. 349 (2012) (discussing the Federal Circuit's decision in Therasense, Inc. v. Becton, Dickinson and Company, and its practical implications); *see also,* John M. Golden, *Patent Law's Falstaff: Inequitable Conduct, the Federal Circuit, and Therasense*, 7 WASH. J.L. TECH. & ARTS 353 (2012) (discussing the Federal Circuit's decision); *see also,* Zhe (Amy) Peng, *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 Va. J.L. & Tech (2011) (discussing Federal Circuit's decision).
[6] *See,* Star Scientific Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008).
[7] *Id.*

look at the changes in the threshold requirements of proving each element of inequitable conduct, and the concerns the Federal Circuit addressed in heightening the standards of the defense. In heightening the standards by which a defendant or alleged infringer must establish both intent and materiality, the Federal Circuit affirmed their previous decision, requiring a specific intent to deceive the PTO in failing to disclose a material reference.[8] In addition, the court offered guidance on establishing a patentee's specific intent to deceive the PTO. Based on the Federal Circuit's previous decision, solely addressing the element of intent and citing that the defense was still being overly used, in Therasense, Inc., the court addressed the materiality element as well. The Federal Circuit articulated a "but-for" materiality standard, in which non-disclosure of information to the PTO will be considered material, if "but-for the disclosure the patent would not have been allowed."[9] In heightening the standards of both intent and materiality, the Federal Circuit reasoned that heightening both standards, will bring the doctrine of inequitable conduct back from being a litigation strategy, to one that promotes the patentee's duties of good faith, candor, and disclosure before the PTO.

Part IV of this paper, will address the implications and effects the Federal Circuit's decision will have on the defense of inequitable conduct. In addition, part IV will address the possible adverse effects of the Federal Circuit's decision, and the benefits of the heightened standard articulated by the court. Finally, Part V will conclude that the Federal Circuit overreached in heightening the standards of inequitable conduct, and rather than addressing the concerns cited in their decision, there will be an adverse impact on the doctrine of inequitable conduct. Therefore, the Federal Circuit's decision heightening the standards of inequitable

[8] *See, Therasense, Inc.*, 649 F.3d at 1290, *citing*, Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995).
[9] *See, Therasense, Inc.*, 649 F.3d at 1291.

conduct, must be overturned in order to preserve this defense, and promote the principles articulated by the United States Supreme Court in creating such a defense.

II. The Origins of Inequitable Conduct as a Defense of Patent Infringement

The origins of the inequitable conduct defense to patent infringement lie with the equitable defense of "unclean hands," the doctrine was judicially created to address a broader scope of misconduct on behalf of the patentee during the patent prosecution stage before the PTO. [10] In a trio of Supreme Court cases creating the doctrine of inequitable conduct, the Supreme Court outlined the boundaries and the remedy for an inventor securing the exclusive right over their invention through misconduct. In creating the doctrine of inequitable conduct, the Supreme Court addressed the patentee's duty of good faith and candor before the PTO, requiring the patentee to disclose all material information to the patentability or unpatentability of their invention.[11] The party alleging inequitable conduct must prove by clear and convincing evidence, the patentee failed to disclose a material reference with the specific intent to deceive the PTO, in order to obtain an exclusive right to their invention.[12] After, properly pleading the requisite elements of intent and materiality, the court will balance the equities as to the plaintiff's conduct and the effect allowing the plaintiff to retain their exclusive right over their invention, and apply the appropriate remedy.[13]

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[10] *See*, *id* at 1285-89; *citing*, Keystone Driller Co. v. General Excavator Co., 290 U.S. 240 (1933) (holding that where a party does not come to court with clean hands because the patentee was aware of a possible prior use prior to filing a patent application but did not inform the patent office of such, dismissal of the case is appropriate); Hazel Atlas Glass Co. v. Hartford Empire Co., 322 U.S. 238 (1944) (holding that a patentee's deception before the PTO, dismissal of the patentee's action was proper because they had not come to court with clean hands); Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806 (1945) (holding that dismissal of a patentee's claim was appropriate where the patentee suppressed evidence of perjury before the PTO and attempted to enforce the patent it obtained against a third party).

[11] 37 C.F.R. § 1.56 (1997).

[12] *See*, *Star Scientific, Inc.*, 537 F.3d at 1365, *citing*, Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp., 351 F.3d 1139, 1146 (Fed. Cir. 2003); Cargill, Inc. v. Canbra Foods, Ltd. 476 F.3d 1359, 1363 (Fed. Cir. 2007).

[13] *Star Scientific, Inc.*, 537 F.3d at 1365-66.

Moreover, a defendant or party alleging inequitable conduct, must establish that the information or reference withheld by the patentee was material to the patentability or unpatentability of the invention at issue.[14] In creating the doctrine of inequitable conduct, the Supreme Court began addressing the materiality of either, the information withheld from the PTO or the patentee's representations to the court during a claim of patent infringement. The Supreme Court held, in Keystone Driller Co. v. General Excavator Co, the dismissal of a patentee's claim of infringement was appropriate, where the patentee failed to disclose a prior use that would have affected the patentability of their invention.[15] The Federal Circuit, prior to their decision in Therasense, Inc., interpreted the materiality of a non-disclosed reference under a "reasonable examiner" definition of materiality.[16] In utilizing a "reasonable examiner" definition of materiality, the Federal Circuit, held that a non-disclosed reference is material if there was a substantial likelihood that a reasonable examiner would find the information important as to the patentability of the invention.[17] If such a determination was made, the reference or withheld information was considered material.

Furthermore, the doctrine of inequitable conduct requires that the patentee withheld material information or a material reference, with the intent to deceive the PTO. The Supreme Court addressed the element of intent in, Hazel Atlas Glass Co. v. Hartford Empire Co.[18] In which, the Supreme Court held, that the inventor had deceived the PTO in obtaining their patent; thus, dismissal of a claim for infringement was appropriate.[19] Since the creation of the inequitable conduct defense, the Federal Circuit has addressed what the correct standard, under

[14] Am. Hoist & Derrick Co. v. Sona & Sons, Inc., 725 F.2d 1350, 1362 (Fed. Cir. 1984) (discussing the materiality of a withheld reference, as it applies to the doctrine of inequitable conduct).
[15] *See, Keystone Driller Co.*, 290 U.S. 240.
[16] *See, Am. Hoist & Derrick Co.*, 725 F.2d at 1362.
[17] *Id.*
[18] *See, Hazel Atlas Glass Co.*, 322 U.S. 238.
[19] *Id* at 243.

which a party must establish a patentee's intent to deceive the PTO.[20] The Federal Circuit has held, that the patentee's intent to deceive the PTO is not satisfied, when a misrepresentation or failure to disclose a reference was a result of either negligence or gross negligence.[21] Rather the Federal Circuit has held, there must be clear and convincing evidence that the patentee acted with a specific intent to deceive the PTO, either by failing to disclose a material reference or making an affirmative misrepresentation to the PTO.[22] In proving a patentee's specific intent to deceive the PTO, the Federal Circuit noted in a subsequent decision, there must have been a "deliberate decision to withhold a reference," on behalf of the patentee.[23] Thus, the Federal Circuit interpreted the Supreme Court's decision in Hazel Atlas Glass Co., to require a specific intent on behalf of the inventor and/or their representative to deceive the PTO.

Prior to Therasense, Inc. and Kingsdown Med. Consultants, LTD, certain district and circuit courts allowed for intent and materiality to be inferred from one another. This allowed a "sliding scale" to be created for proving intent and materiality for a claim of inequitable conduct.[24] Applying a "sliding scale" to the elements of materiality and intent, parties alleging inequitable conduct were required to meet a lower standard as to each element then originally contemplated during the creation of the doctrine. Therefore, as a result of the "sliding scale" employed by several district and circuits courts, a broader range of conduct was considered inequitable.

[20] *See, Therasense, Inc.*, 649 F.3d at 1289.
[21] *See,* Kingsdown Med. Consultants, LTD v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988).
[22] *Id.*
[23] *See, Molins PLC,* 48 F.3d at 1172; *see also,* Driscoll v. Cebalo, 731 F.2d 878, 885 (Fed. Cir. 1984).
[24] *See,* Digital Equipment Corp. v. Diamond, 653 F.2d 701 (1st Cir. 1981) (holding that materiality and intent are often "related and intertwined" with one another, allowing a lesser showing of materiality as to the withheld reference or information where an intentional scheme to defraud or deceive the Patent Office is established, and where the greater the materiality of the information withheld, the greater the inference of an intent to deceive or defraud the Patent Office).

After, a party establishes a prima facie showing by clear and convincing evidence that the patentee withheld material information with the specific intent to deceive the PTO in obtaining a patent, the court hearing the case must apply the necessary remedy.[25] In fashioning the appropriate remedy, the Supreme Court in Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., articulated the first remedy and the one consistently held as appropriate in cases of inequitable conduct.[26] Following a prima facie showing of inequitable conduct, the court hearing the case, must balance the equities to determine whether the applicant's conduct before the PTO, was egregious enough to warrant holding the entire patent unenforceable.[27] By allowing the court to balance the equities, prior to rendering a patent unenforceable, the court has the discretion to decline to conclude that a patent claim is unenforceable against a third party.[28] Thus, a finding of inequitable conduct has the possibility of forcing an inventor to surrender their exclusive rights to an invention.

In rendering a single patent unenforceable, the defense of inequitable conduct has far more severe consequences depending on the extent of the patentee and/or their representative's misconduct, and the nature of the patent found to be unenforceable. A single finding of inequitable conduct is not claim or patent specific, allowing the court to conclude, the taint from a single patent or act of misconduct renders any related patent or claim unenforceable.[29] This permits the court within their discretion, to render all related patents and claims unenforceable, allowing a single act of inequitable conduct to render a substantial portion of an inventor or

[25] *See, Star Scientific, Inc.*, 537 F.3d at 1365.
[26] *See, Precision Instrument Manufacturing Co.,* 324 U.S. at 808 (holding a patent unenforceable against third party where the patent was obtained through misconduct on behalf of the inventor).
[27] *Star Scientific, Inc.* 537 F.3d at 1365 (holding that where a patentee has deceived the Patent Office and obtained the exclusive benefits of such on the basis of their misconduct, the patent will be held unenforceable against subsequent third parties) .
[28] *Id.*
[29] Consol. Aluminum Corp. v. Foseco Int'l Ltd, 910 F.2d 804, 808 (Fed. Cir. 1990) (discussing the unenforceability of one patent, as to related patents and claims possessed by the same inventor or corporation).

company's patent portfolio to be unenforceable.[30] This concept has allowed the doctrine of inequitable conduct, to become known as the "atomic bomb" of patent law, due to the far-reaching nature of its remedy.[31]

The creation of the inequitable conduct defense was for ensuring that inventors and/or corporations disclosed all material information as to the patentability or unpatentability of their inventions. In addition, the doctrine prevents inventors from securing the exclusive rights to an invention, through misconduct in obtaining a patent. Due to the serious nature of the defense, the Federal Circuit, prior to Therasense, Inc. had become concerned that the defense was being overused, and no longer promoting the underlying principles of the doctrine. Therefore, in May 2011, the Federal Circuit in Therasense, Inc. v. Becton, Dickinson and Company, addressed their concerns surrounding the defense of inequitable conduct. In attempt to realign, the defense with its underlying principles the Federal Circuit heightened the standards used in evaluating a claim of inequitable conduct.

III. Federal Circuit's *en banc* decision in Therasense, Inc. v. Becton, Dickinson and Company

In May of 2011, the Court of Appeals for the Federal Circuit, granted Therasense, Inc.'s, petition for rehearing by an *en banc* panel, vacating the Federal Circuit's decision affirming a finding of inequitable conduct on behalf of Therasense, Inc. The Federal Circuit granted Therasense, Inc.'s petition, in order to address the elements of inequitable conduct and the proper standard that should be applied to each element. In making their decision, the Federal Circuit concluded, that solely requiring a specific intent to deceive the PTO in obtaining a patent did not address the overuse of the doctrine. Thus, the Federal Circuit articulated, a heightened standard

[30] *See*, Aventis Pharma S.A. v. Amphastar Pharma. Inc., 525 F.3d 1334, 1349 (Fed. Cir. 2008) (discussing the reach of the inequitable conduct remedy).
[31] *Id.*

under which materiality must be proven. In heightening the standards of materiality and intent, the Federal Circuit believed, their decision realigned the doctrine of inequitable conduct with the principles and purpose cited by the Supreme Court in the creation of the defense.

A. Background of Therasense, Inc. v. Becton, Dickinson and Company

Therasense, Inc. now doing business as Abbott Diabetes Care, Inc., initiated an action against several competitors for a claim of patent infringement based on a patent, for disposable blood glucose testing strips utilizing electrochemical sensors for measuring the level of glucose in a sample of blood, held by the plaintiff.[32] At trial, the defendants collectively plead the defense of inequitable conduct.[33] The trial court found in favor of the defendants, finding that the plaintiff had obtained their exclusive patent rights through egregious misconduct rising to the level of inequitable; thus, rendering their claim unenforceable.[34] On direct appeal, the Federal Circuit affirmed the district court's finding of inequitable conduct; however, the plaintiff petitioned for rehearing, and the Federal Circuit granted their petition in order to address the defense of inequitable conduct.[35]

During the trial phase, the defendants claimed, the plaintiff had obtained the benefit of exclusive rights to their patented invention, through misconduct rising to the level of inequitable.[36] Specifically, the defendants cited two declarations submitted by the plaintiff, one submitted during the prosecution phase of their American patent application, and the second made several years prior during the prosecution phase of the European equivalent to their American patent.[37] In both patent prosecutions, the attorney representing the plaintiff made an

[32] *Therasense, Inc.*, 649 F.3d at 1282.
[33] *Id* at 1283.
[34] *Id* at 1285.
[35] *Id.*
[36] *See, id* at 1283.
[37] *Id.*

evidentiary disclosure explaining the phrase "optionally, but preferably."[38] In the American disclosure, the plaintiff took the phrase "optionally, but preferably," as one making a specific membrane "necessary," whereas, in the European disclosure, the plaintiff took the phrase to merely mean "optional," and not necessary.[39] Based on these disclosures, the District Court concluded that the European disclosure was material to the patentability of the invention, and that the plaintiff deliberately failed to disclose the reference in order to deceive the Patent Office.[40]

Following, the District Court finding inequitable conduct on the part of the plaintiff, the patent was held unenforceable against the defendants. The plaintiff appealed the District Court's decision, and the Federal Circuit affirmed a finding of inequitable conduct; however, the Federal Circuit on petition by the plaintiff, vacated their decision granting the plaintiff's petition for rehearing by an *en banc* panel.

B. The Federal Circuit's Decision to Heighten the Standards of Inequitable Conduct

In granting the plaintiff's petition for an *en banc* panel review, the Federal Circuit cited, the long-standing issue of overuse surrounding the doctrine of inequitable conduct. The Federal Circuit began their opinion, citing several concerns surrounding the doctrine and the consequences of overly broad and low standards as applied to the elements of intent and materiality. In addressing their concerns, the Federal Circuit, affirmed the need for a specific intent to deceive the PTO standard, and articulated a narrow "but-for" definition of materiality. Thus, the Federal Circuit altered the landscape of the inequitable conduct doctrine, and sought to curtail the overuse of the defense.

[38] *Therasense, Inc.*, 649 F.3d at 1283-84.
[39] *Id.*
[40] *Id* at 1285.

Furthermore, the Federal Circuit began their opinion, citing the issues surrounding the doctrine of inequitable conduct and the overuse of the defense, as a direct result of overly broad and low standards required for the elements of intent and materiality. Writing for the Majority, Chief Judge Rader noted, that the reduced and over broad standards applied to the elements of inequitable conduct has altered the purpose of the defense, and has, "plagued not only the courts but also the entire patent system."[41] The Federal Circuit has previously cited the overuse of the inequitable conduct doctrine, and the effect the defense has on subsequent court proceedings.[42] Specifically, the Federal Circuit noted, the following consequences of the low and over broad definitions of intent and materiality: (1) charges of inequitable conduct "cast a dark cloud" over the character of both the inventor and their representatives; (2) increases the cost, complexity, and duration of a patent infringement claims; (3) allows other causes of action to stem from a single claim; and (4) has forced applicants to flood the Patent Office with non-material disclosures in anticipation of a claim of inequitable conduct.[43] Due to the numerous concerns surrounding the doctrine of inequitable conduct, the Federal Circuit concluded, the standards of intent and materiality must be altered in order to realign the use of the doctrine with its underlying purpose and principles.

Moreover, the Federal Circuit addressing the element of intent affirmed their previous decision in Kingsdown Med. Consultants, LTD v. Hollister, Inc, requiring the patentee have a

[41] *Id* at 1289. Reasoning that the defense of inequitable conduct has been charged in nearly 80 percent of all cases of patent infringement or related patent litigation, altering the defense from one that was created to foster disclosure and good faith before the Patent Office to becoming a "litigation strategy" used as a discovery tool and forcing parties to settle. *Id.*
[42] Kevin Mack, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands,* 21 BERKLEY TECH. L.J. 147, 155-60 (2006). The defense of inequitable conduct is pled so often that the Federal Circuit has denounced its overuse. *Id* at 156. "The Federal Circuit's ostensible hostility towards the inequitable conduct doctrine stems from its perceived effects: defendants employ inequitable conduct as magic incantation against patentees, diverting the court's attention away from the statutory requirements of patent protection." *Id* at 158.
[43] *See, Therasense, Inc.*, 649 F.3d at 1288-90.

specific intent to deceive the Patent Office in failing to disclose material information.[44] In addition, the Federal Circuit citing their decision required, in order to establish a patentee's specific intent to deceive the PTO the party pleading the defense of inequitable conduct must establish by clear and convincing evidence, the patentee and/or their representative "made a deliberate decision to withhold a known material reference."[45] Although, the Federal Circuit affirmed their previous holding requiring a specific intent to deceive the PTO, the Federal Circuit offered guidance in establishing this element at trial. [46] Previously, the Federal Circuit believed requiring a specific intent to deceive the PTO would address the overuse of inequitable conduct; however, the Federal Circuit concluded in Therasense, Inc. that such a belief was incorrect.[47] Hence, the Federal Circuit's decision to heighten the standard applied to the element of materiality.

The Federal Circuit, altered the definition of materiality as used in the defense of inequitable conduct, moving away from a low "reasonable examiner" definition to a "but-for" materiality standard.[48] The court held, a reference is "but-for" material, if the PTO would not have granted a patent for the given claim had it been aware of the undisclosed reference.[49] In articulating a "but-for" materiality standard, the Federal Circuit held, the trial court must determine whether a reference is "but-for" material, finding that by a preponderance of the evidence the reference was material to the patentability or unpatentability of the invention at

[44] *See, id* at 1290.
[45] *See, id* at 1291, *citing, Molins, PLC,* 48 F.3d at 1181.
[46] *See, Therasense, Inc.*, 649 F.3d at 1290, (holding that a defendant must establish each of the following to show intent to deceive: (1) the applicant knew of the reference; (2) knew that it was material; and (3) made a deliberate decision to withhold it).
[47] *See, id* at 1291.
[48] *See, id, citing*, Corona Cord Tire Co. v. Dovan Chemical Corp., 276 U.S. 358, 373 (1928) (noting that although the Supreme Court's decision in Corona Cord did not speak to unclean hands, which is the underlying doctrine of inequitable conduct, it demonstrated the Court's unwillingness to render a patent unenforceable although a misrepresentation that was immaterial to the issuance of the patent was made).
[49] *See, Therasense, Inc.*, 649 F.3d at 1291 (discussing the application of "but-for" materiality).

issue.[50] The Federal Circuit further held, when determining the scope of a claim, the trial court is to give all claims their broadest reasonable construction.[51] Thus, the Federal Circuit concluded, coupling a narrow and stringent "but-for" materiality standard and the already strict specific intent to deceive the PTO standard previously articulated, the overuse of the inequitable conduct doctrine would be adequately curtailed.

Moreover, the Federal Circuit carved a very narrow and limited exception to the newly crafted "but-for" materiality standard.[52] In creating this exception, the court noted that it incorporated the doctrine of "unclean hands," in that it would prohibit acts of egregious misconduct, regardless of whether or not the withheld references were material to the patentability or unpatentability of the claim and/or invention at issue. [53] In constructing the boundaries of this exception, the court distinctly stated, neither the mere non-disclosure of prior art references to the PTO or failure to mention prior art references in a patent application rises to the level of egregious misconduct.[54] Thus, the court reasoned the need for this exception, was to strike a balance between encouraging disclosure and honesty before the PTO and preventing unfounded accusations of inequitable conduct.[55]

Additionally, the court further addressed the elements of materiality and intent, directly stating that materiality and intent are separate and distinct elements of inequitable conduct, and that neither element may be inferred from the other. No longer permitting intent and materiality to be inferred from one another, the Federal Circuit abrogated previous decisions implementing a

[50] *See, id.*
[51] *Id* at 1291.
[52] *Id* at 1292, (holding "but-for" materiality standard does not apply, "when the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit," the misconduct is considered material).
[53] *See, id*, *citing*, *Hazel Atlas*, 322 U.S. at 245, (reasoning the exception to the "but-for" materiality standard, allows for inequitable conduct to be found when there is a "deliberately planned and carefully executed scheme to defraud the PTO and the courts).
[54] *See, Therasense, Inc.*, 649 F.3d at 1292.
[55] *Id* at 1293.

"sliding scale," as to the elements of intent and materiality.[56] However, the Federal Circuit, citing the difficulty in providing direct evidence of an individual's specific intent to deceive the PTO, permitted a party claiming inequitable conduct to utilize indirect or circumstantial evidence to establish the intent element.[57] In addition, the court held a party's failure to offer a good faith explanation for withholding a reference, would not in and of itself, establishes a party's specific intent to deceive the PTO, due to the burden of proof being placed solely on the party pleading inequitable conduct.[58] Thus, the Federal Circuit, no longer permit's intent and materiality to be inferred from one another, and no longer allows a court to employ a "sliding scale" as to each element.

Following, the Federal Circuit's decision in Therasense, Inc., the court altered the way in which a defendant or adverse party during patent litigation pleads inequitable conduct. First, the court affirmed and strengthened its previous rulings in Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.; Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.; and Molins PLC v. Textron, Inc. However, the Federal Circuit abrogated its decision, in Am. Hoist & Derrick Co. v. Sona & Sons, Inc., which strengthened and tightened the standard applied to a patentee's intent to deceive the PTO. Next, the Federal Circuit relying on Corona Cord Tire Co. v. Dovan Chemical Corp., articulated a new narrow and stringent standard for establishing the materiality of a withheld reference or piece of prior art. Citing several justifications for the newly articulated

[56] *Id* at 1290; *citing*, Hoffman La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1359 (Fed. Cir. 2003).
[57] *See, Therasense, Inc.*, 649 F.3d at 1290 (holding, that in order to meet the clear and convincing evidence standard, a party claiming inequitable conduct on behalf of the patentee must establish that "the single most reasonable inference able to be drawn from the evidence," was that a party intended to deceive the Patent Office and obtain the exclusive benefit of holding a patent).
[58] *Id* at 1291.

standards, the Federal Circuit reasoned, the new standards would address the overuse of the inequitable conduct doctrine, allowing for its use in only a limited number of circumstances.[59]

Thus, the Federal Circuit concluded that their newly articulated standards would, "redirect a doctrine that has been overused to the detriment of the public."[60]

C. Remand Decision in Therasense, Inc. v. Becton, Dickinson and Company

Following their decision, the Federal Circuit remanded the case to the U.S. District Court for the District of Northern California, for a determination on the defendant's claim of inequitable conduct, consistent with their opinion.

On remand, the District Court for the District of Northern California, affirmed their previous decision finding inequitable conduct on behalf of Therasense, Inc.[61] Writing the opinion of the Court, District Judge William Alsup, commented that the Federal Circuit's decision altering the definition of materiality was a, "seismic shift in the law of inequitable conduct."[62] The District Court held, the disclosure made by the plaintiff's representatives to the PTO regarding the inventor's interpretation of the phrase "optional, but preferably," was "but-for" material, in that the patent would not have issued if not for that definition.[63] Additionally, the court held, the plaintiff withheld such a reference with the specific intent to deceive the PTO due to the previous rejections by the PTO for issues of anticipation and obviousness.[64]

Therefore, the plaintiff's patent was held unenforceable, in turn no longer subjecting the defendants to liability for patent infringement.

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[59] *See, Therasense, Inc.* 649 F.3d at 1292, (reasoning that because inequitable conduct renders an entire patent and possibly related patents as unenforceable, it should only be used in cases where the patentee's misconduct has resulted in an unfair benefit in receiving a patent for the litigated claim).
[60] *Id at* 1290.
[61] *See*, Therasense, Inc. v. Becton, Dickinson and Company, 864 F.Supp.2d 856, 860 (N.D.Cal. 2012), (holding clear and convincing evidence established that the withheld EPO specification disclosure was "but-for material, and was withheld by the plaintiff and/or their representative attorney with the specific intent to deceive the PTO).
[62] *Id* at 859.
[63] *Id* at 860.
[64] *Id.*

IV. Implications of Heightened Standards of Inequitable Conduct

The Federal Circuit's *6-4-1 en banc* decision in Therasense, Inc. v. Becton, Dickinson and Company, resulted in a substantial change in the defense of inequitable conduct, as it is applied to patent infringement. The long-term impact of the Federal Circuit's decision, implementing a newly crafted standard for materiality and affirming an already heightened standard for intent, are unknown. Based on the Federal Circuit's decision, there are clearly beneficial consequences of their decision; however, it is unclear whether those beneficial consequences, will adequately address the Federal Circuit's concerns cited in their opinion. In addition, some consequences indicate, the Federal Circuit in their decision went too far and the heightened standard articulated by the court will not address their concerns, adversely affecting the defense of inequitable conduct. Following the Federal Circuit's decision, there is still a question as to whether there decision will benefit the defense of inequitable conduct, or adversely impact the doctrine of inequitable conduct.

A. *Adverse Effects of a Heightened Standard of Inequitable Conduct*

In constructing a new standard of materiality coupled with the specific intent standard previously articulated, the Federal Circuit addressing the overuse of the inequitable conduct doctrine, failed to take into account the adverse implications of such a high standard. The Federal Circuit, in articulating their new standard for materiality believed it would promote the underlying goals of the defense; however, there is a highly likely possibility the court's decision went too far, and will likely foster the specific type of conduct that the defense was created to prevent. Therefore, the extent of the impact that the adverse effects will have is yet to be known; however, such effects are predictable.

In articulating a "but-for" materiality standard, the Federal Circuit went against its own precedent. The Federal Circuit has previously rejected the idea of using "but-for" materiality as a standard for inequitable conduct.[65] In addition, the court has continuously held, deference must be given to the PTO in defining the materiality of a reference or non-disclosed reference, as it pertains to the patentability or unpatentability of a claimed invention.[66] The Federal Circuit explicitly rejected the USPTO's own definition of materiality, citing that the PTO's definition of materiality was too lax of a standard.[67] The standard articulated in Therasense, Inc. is clearly a more stringent standard than that articulated by Rule 56 of the Patent & Trademark Office.[68] As cited by the PTO in their *amicus curiae* brief submitted to the court, such a stringent standard is likely too restrictive to serve the purpose surrounding the creation of the inequitable conduct doctrine.[69] Thus, the Federal Circuit, in their decision heightening the standard of materiality, went against its previous rejection of such a stringent and narrow standard, and no longer gave deference to the PTO in defining materiality.

[65] *See, Therasense, Inc.*, 649 F.3d at 1313, *citing*, Golden Hour Data Sys. v. emsCharts, Inc., 614 F.3d 1367, 1374 (Fed. Cir. 2010) (stating that "but-for" materiality is the inappropriate standard for determining the materiality of a reference before the PTO).
[66] *See, Therasense, Inc.*, 649 F.3d at 1312, *citing*, Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd., 394 F.3d 1348 (Fed. Cir. 2005) (holding that the court is to give deference to the PTO's definition of materiality as it applies to failure to disclose material information, and that deference is to be given to the PTO as to the definition of materiality).
[67] *See, Therasense, Inc.*, 649 F.3d at 1293-94. The Court refused to rely on the PTO's Rule 56 definition of materiality because the current version of the Rule has resulted in the concerns cited by the Federal Circuit in making their decision to articulate a new standard for materiality and the defense of inequitable conduct. *Id* at 1293.
[68] *Id* at 1291. The Federal Circuit defined withheld information or reference as "but-for" material if having the reference or information, PTO would not have granted the patent for the claimed invention had it been aware of the undisclosed prior art or reference. *Id. Comparing*, 37 C.F.R. 1.56 (1997). Defining materiality under this section as: information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or(ii) Asserting an argument of patentability).
[69] Brief for the United States as Amicus Curiae Supporting Neither Party, Rehearing En Banc, Therasense, Inc. v. Becton, Dickinson and Company, 649 F.3d 1276 (2011) (No. 2008-1511), 2010 WL 3390234, (reasoning that "but-for" materiality is to narrow of standard, and it would not allow the Patent Office to obtain information it needs to evaluate patentability so that when its decision are reviewed by the courts they may be presumed as correct).

Moreover, the heightened standard articulated by the Federal Circuit, has tightened the boundaries of inequitable conduct previously constructed by the Supreme Court's decisions creating the doctrine. In creating the defense of inequitable conduct, the Supreme Court in Precision Instrument Manufacturing, Co. v. Automotive Maintenance Machinery Co., cited the need "for a flexible approach in an equitable claim."[70] However, by the articulating such a narrow standard for materiality, the Federal Circuit in essence has taken away the flexibility originally contemplated by the Supreme Court. Thus, the Federal Circuit has departed from the case law that is credited for creating the defense of inequitable conduct, and in doing so, they are likely to have destroyed the boundaries set by the Supreme Court in creating the defense.

Furthermore, the policy reasons surrounding the creation of the inequitable conduct doctrine, are no longer promoted due to the Federal Circuit's decision, drastically narrowing the defense by articulating a "but-for" materiality standard. The defense of inequitable conduct was created in order to promote disclosure to the PTO, by either the patentee or their representative during the application phase, and to ensure the patentee's duty of good faith and candor before the PTO.[71] In addition, the dissenting opinion, written by Circuit Judge William C. Bryson, cited the policy reasons the Supreme Court articulated in the creation of the inequitable conduct doctrine, and the need not to allow individuals to benefit from their misconduct.[72] In addition, the dissent in Therasense, Inc., noted in the application of the "but-for" materiality standard there

[70] 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) (discussing the Federal Circuit's decision, to go against the Supreme Court's previous holdings and the Federal Circuit's own previous decisions giving deference to the PTO).
[71] *See, Am. Hoist*, 725 F.2d at 1363.
[72] *See, Therasense, Inc.*, 649 F.3d at 1308-09 (discussing the principles surrounding the creation of inequitable conduct are: (1) protect the public's interest in seeing monopolies established though fraud other inequitable conduct; (2) the patentee's have an affirmative duty to report all facts surrounding fraud or inequitableness surrounding applications; (3) all facts relevant to a patent application must be submitted to USPTO; (4) the intentional failure to do so may lead to unenforcement of the subsequent patent; and (5) the misconduct in question need not be fraud only a willful act violating standards of equitable conduct before the patent office).

is little incentive for applicants to be candid with the PTO, and disclose references possibly leading to the unpatentability of their invention.[73] In requiring such a heightened standard of materiality, the promotion of the patentee's duties of disclosure, candor, and good faith will likely no longer be promoted through this doctrine.

The newly constructed standard of materiality coupled with the already stringent specific intent standard, will likely allow for the protection of the particular conduct the inequitable conduct doctrine was traditionally created to prevent. Writing in the dissent, Circuit Judge Bryson, cited that the newly articulated definition of materiality, would likely promote lying and other misconduct not only before the PTO, but also before the courts.[74] For example, if an applicant remained silent about a prior use, the patent issues, and the prior use was never discovered, the applicant would benefit from the non-disclosure. However, if the non-disclosed reference were later discovered, the patentee's conduct would only be inequitable if the prior use would have rendered the claims invalid.[75] In an *amicus curiae* submission to the court, the Association for Patent Protecting the Public Interest, argued the narrow "but-for" materiality standard would promote misconduct before the court and the PTO because the traditional incentives for disclosure are no longer present.[76] In addition, the heightened "but-for" materiality standard coupled with the specific intent element, has created too a high burden that

[73] *Id* at 1305, (stating the incentives to act in good faith and candor before the Patent Office, while promoting disclosure of all information leading to the patentability of an invention will no longer exist because "in most instances the sanction of inequitable conduct will apply only if the claims that issue are invalid anyway.").
[74] *See; id* at 1305.
[75] *Id* at 1306 (reasoning the heightened standard of materiality allows for this type of misconduct to go unremedied because the patentee would not have had a valid claim had they disclosed the reference, but if the reference is never discovered the patentee obtains an exclusive benefit based on their misconduct.).
[76] Brief for the Association of Citizens for Patent Protection in the Public Interest as Amicus Curiae Supporting Defendants-Appellees, Therasense, Inc. v. Becton, Dickinson and Company, 649 F.3d 1276 (2011) (No. 2008-1511) 2010 WL 4622533 (discussing the correct standard of materiality and the conduct likely to result from an overly stringent standard applied to inequitable conduct).

such conduct cited by the dissent and *amicus curiae* will likely go undetected.[77] Therefore, the standard articulated by the Federal Circuit, is overly narrow and likely to promote the specific conduct the doctrine was created to prevent.

Thus, the heightened standards articulated by the Federal Circuit, in Therasense, Inc. v. Becton, Dickinson and Company, are likely to cause substantial adverse effects to the defense of inequitable conduct, such as protecting the type of misconduct the doctrine was created to prevent.

B. *Beneficial Effect of Heightened Inequitable Conduct Standards*

The decision by the Federal Circuit, in Therasense, Inc., can be found to have beneficial effects on the defense of inequitable conduct. The Federal Circuit reasoned their newly constructed standards for both elements of inequitable conduct, would directly address the overuse of the defense during patent litigation. In addition, the court cited the need to protect patent attorneys, inventors, and corporations from frivolous claims against their character. The new standard will likely protect an inventor's exclusive rights over his invention, no longer permitting such rights to be challenged on the "slenderest of grounds." Thus, the Federal Circuit's decision will likely address the overuse of the doctrine, and protect the interests of the individuals involved in the patent system, along with the public's interest.

The main reason cited by the Federal Circuit in their decision, was the need to address the overuse of the inequitable conduct doctrine. [78] The Federal Circuit noted, low and broad

[77] Tony Dutra, *Patent Inequitable Conduct Charge Requires 'Deliberate Decision" to Withhold Prior Art, discussing the implementation of Therasense, Inc. v. Becton, Dickinson and Company as applied in 1st Media LLC v. Electronic Arts Inc.*, Fed. Cir., No. 2010-1435, (9/13/12). The court cited the difficulty in proving the standard handed down in Therasense, Inc., because there must be a deliberate decision to withhold a reference *known to be material*. *Id.*

[78] *See*, *Therasense, Inc.*, 649 F.3d at 1288 – 89 (reasoning that the need for a heightened standard of materiality and intent is to address the overuse of the inequitable conduct doctrine, which has turned the defense into a litigation strategy).

standards were previously employed in order to promote disclosure to the PTO; however, the over broad standards have allowed the doctrine to depart from its original purpose.[79] There is evidence that the defense of inequitable conduct is pleaded in almost every case of patent litigation, which has resulted in patentees disclosing almost every possible reference whether it is material or not.[80] Although, the use of the defense has promoted disclosure, as it was intended do, the reason for the disclosure is not attributed the patentee's duty of good faith or candor, but rather one of fear. Through, the Federal Circuit increasing the standards by which a defendant or alleged infringer must plead inequitable conduct, it is possible that it will no longer be seen as a litigation strategy, and promote disclosure in the way it was traditionally intended.

Furthermore, the Federal Circuit cited the effects a claim of inequitable conduct may have not only on rendering a patent unenforceable, but the effect a claim of inequitable conduct has on all parties involved in the litigation.[81] A claim of inequitable conduct is one that goes directly to the morals and character of those subject to the alleged misconduct, simply by the very nature of the doctrine. Unsupported claims of inequitable conduct have been described as "offensive" and "unprofessional."[82] In requiring a higher standard, the Federal Circuit, has taken the necessary steps to protect inventors, corporations, and most importantly attorneys from being characterized as individuals of low moral character. Although, a patentee can rebut a claim of

[79] *Therasense, Inc.*, 649 F.3d at 1288 – 89 (stating that the over broad and low standards although, initially employed to promote disclosure to the Patent Office has moved to being an overused and overplayed litigation strategy utilized to obtain additional discovery and force settlement, and being pleaded over 80 percent of cases of patent litigation.).
[80] Kevin Mack, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKLEY TECH. L.J. 147, 155-56 (2006) (discussing the over disclosure by patent applicants, in order to protect themselves and their inventions from claims of inequitable conduct).
[81] *See, Therasense, Inc*., 649 F.3d at 1299 (discussing how a claim of inequitable conduct impacts the individuals involved, regardless of the cases disposition).
[82] Committee No. 403 – Inequitable Conduct, American Bar Association. Section of Intellectual Property Law. Annual Report, Vol. 1997-1998, pp. 254-258 ("Unjustified accusation … have been called a 'plague' on the patent system. Unjustified accusation may deprive patentees of their earned property rights and impugn fellow professionals. They should be condemned.")

inequitable conduct, it is hard to un-ring a bell that has already been rung, leaving a question in most people's mind as to that inventor or attorney's moral character. Thus, the new standards articulated by the Federal Circuit, will likely prevent unsupported charges that an individual is of low moral character.

Moreover, the remedy following a finding of inequitable conduct on behalf of the patentee supports the need for a stringent and narrow standard, preventing the possibility of false positives. A single claim of inequitable conduct has the potential of rendering not only the patent at issue unenforceable, but also all related claims or patents flowing from the unenforceable patent.[83] In addition, the Federal Circuit cited the various causes of action that can stem from a single claim of inequitable conduct, on behalf of the inventor or corporation involved.[84] Due to the extensive consequences of a claim of inequitable conduct, the overuse of the defense must be curtailed and the standards altered, in order to justify its severe remedy. In requiring a heightened standard of materiality as to the withheld information or reference, the Federal Circuit is providing trial courts with the necessary information to evaluate claims of inequitable, and truly determine whether the conduct of the patentee truly deserves the remedy of unenforceability. Therefore, the seriousness of the remedy attached to a supported claim of inequitable conduct, justifies the stringent and heightened standard articulated by the Federal Circuit in Therasense, Inc.

Thus, the Federal Circuit's decision, heightening the standards of intent and materiality, will likely curtail the overuse of the doctrine, further justify the reach and seriousness of the

[83] *See, Aventis Pharma S.A.*, 525 F.3d at 1449 (discussing the extent of the unenforceability of multiple patent claims, flowing from a single claim of inequitable conduct).
[84] *See, Therasense, Inc.*, 649 F.3d at 1289 (citing the possibility of antirust, unfair competition, or fraud claims following a claim of inequitable conduct on behalf of an inventor or competition).

doctrine's remedy, and prevent unsupported attacks on the character of the parties involved in patent litigation.

C. Where Does Inequitable Conduct Stand Following the Federal Circuit's Decision

In Therasense, Inc., the Federal Circuit clearly outlined the need for reform of the inequitable conduct doctrine; however, there is reason to conclude that the Federal Circuit went too far and in essence abolished the doctrine. In addition, although there was a need for reform, the adverse implications of the Federal Circuit's decision, point to a need for the Federal Circuit's decision to be reversed.

Through, increasing the standards of intent and materiality, the Federal Circuit, departed from the traditional policy reasons and concerns cited as the need for such a doctrine. The Federal Circuit cited the overuse of the defense, as its main reason for altering the doctrine; however, in addressing their concern of overuse, the court went against precedent and policy. In creating the doctrine of inequitable conduct, the Supreme Court reasoned, it went against the public's interest to permit an individual to benefit from exclusive patent rights when such rights are secured through misconduct.[85] In addition, the doctrine was created to promote the patentee's duties of good faith, candor, and disclosure before the PTO; although, applying the Federal Circuit's newly articulated standard, these duties are no longer promoted. [86] Applying a stringent and narrow definition of materiality, the Federal Circuit, has in essence allowed a patentee to benefit from their misconduct.[87] Thus, the Federal Circuit's decision goes against the policy and principles cited as the need for such a doctrine.

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[85] *See, Therasense, Inc.*, 649 F.3d at 1291 (discussing the creation of the inequitable conduct doctrine).
[86] Jason Rantanen, Lee Petherbridge, *Therasense v. Becton Dickinson: A First Impression*, 14 YALE J. L. & TECH 226 (2011-2012), (discussing the impact of the Federal Circuit's new standard, and the difficulty of promoting disclosure, where non-disclosed references must fit into a narrow category).
[87] *See, Therasense, Inc.*, 649 F.3d at 1304. Writing for the dissent, Circuit Judge Bryson, stated that the majority has taken a "radical approach" to addressing their policy concerns of inequitable conduct; however, case law precedent

Furthermore, the newly enacted American Invents Act will have a substantial and lasting effect on the doctrine of inequitable conduct. In addition, combining the newly enacted AIA with the standards articulated by the Federal Circuit, the doctrine has all but dissolved. Under the AIA, a patent applicant is permitted to submit non-disclosed references to the PTO during a process called, a "supplemental examination."[88] Supplemental examinations by the PTO following the issuance of a patent, permits a patentee to withhold a material reference and disclose such a reference only when needed. Due to the patentee disclosing the reference, their conduct cannot be found to be inequitable; however, they previously withheld a material reference with the specific intent to deceive the PTO.[89] Therefore, combining the AIA, "supplemental examination" and the Federal Circuit's new standards, the inequitable conduct doctrine is in essence no longer needed.[90]

Although, there is a possibility the Federal Circuit's newly articulated standard will curtail the overuse of the inequitable conduct doctrine, the new standards are likely to make the doctrine of inequitable conduct no longer effective in promoting the patentee's duty of disclosure.[91] The standards articulated by the Federal Circuit, created doubt as to whether an

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and principles of the doctrine do not support the majority's test for materiality. *Id.* "The effect of the majority's new test, moreover, does not merely reform the doctrine of inequitable conduct, but comes close to abolishing it." *Id.*

[88] 35 U.S.C. § 257, (2011), (Permits a patentee to have their patent reexamined in a procedure called "supplemental examination" permitting a patentee an opportunity to protect their patents against unenforceability arising out of claims of inequitable conduct.).

[89] Katherine E. White, *There's a Hole in the Bucket: The Effective Elimination of the Inequitable Conduct Doctrine,* 11 J. MARSHALL REV. INTELL. PROP. L. 716 (2012), ("With Therasense tightening the standards to prove inequitable conduct and the AIA limiting the enforcement remedies for misconduct before the PTO, the doctrine's effectiveness has essentially been eliminated.).

[90] Peter E. Strand, *Disarming an "Atomic Bomb": The Federal Circuit Clips Wires for Inequitable Conduct*, 24 No. 8 INTELL. PROP. & TECH. L.J. 20 (August, 2012) (concluding that, "that supplemental examination provision of the American Invents Act allowing disclosure of prior art after issuance may make this defense a dinosaur").

[91] Stijepko Tokic, *Enforcing the Duty of Disclosure After Therasense: Antitrust Implications*, 40 AIPLA QUARTERLY JOURNAL 221 (Spring 2012) (discussing the ineffectiveness of the inequitable conduct doctrine following the Federal Circuit's decision).

individual submitting a patent application, is likely to disclose a reference.[92] As cited by the dissent in Therasense, Inc., there is a likelihood that a non-disclosed reference will never be discovered, and even if such a reference is discovered it must fit into such a narrow category, there is only a limited possibility the non-disclosure would rise to the level of inequitable conduct.[93] Therefore, the stringent and narrow standards articulated by the majority in Therasense, Inc., would likely lead to the doctrine of inequitable conduct no longer being an effective method of promoting the patentee's duty of disclosure.

Thus, the adverse implications of the Federal Circuit's decision are at the forefront of the inequitable doctrine as it moves forward. The Federal Circuit, sought to realign the doctrine with its traditional purpose; however, in attempting to do so the Federal Circuit effectively abolished the doctrine. In addition, the Federal Circuit's decision and the newly enacted AIA "supplemental examination" proceeding, has effectively removed the remedy of the inequitable conduct doctrine. Lastly, the patentee's duties of good faith, candor, and disclosure are likely no longer promoted.

V. Conclusion

Although, the Federal Circuit believed it was correcting the course of the inequitable conduct doctrine, their decision will likely lead to the effective disappearance of the defense. The standard articulated by the Federal Circuit, is overly stringent and narrow, leaving no flexibility in the application of the doctrine. In addition, the Federal Circuit overstepped and went too far in an attempt to correct the inequitable conduct doctrine. Therefore, the Federal

[92] Zhe (Amy) Peng, *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 Va. J.L. & Tech. 373, 398 (Fall 2011) (discussing the manner in which a patent applicant will disclose references during the patent prosecution following Therasense, Inc.).
[93] *See, Therasense, Inc.*, 649 F.3d at 1305.

Circuit's decision in Therasense, Inc. v. Becton, Dickinson and Company, should be reversed and a broader standard should be articulated.