The year 2011 proved to be a momentous year in patent law. The doctrine of inequitable conduct was particularly rocked by changes to the law. Both the Federal Circuit’s decision in Therasense, Inc. v. Becton, Dickinson and Co. and the America Invents Act effectively gutted the inequitable conduct cause of action. Therasense tightened the materiality and intent standards, thus lowering the duty of candor standard that will be enforced in the courts. The America Invents Act created an escape clause for those who fail to disclose adequately during initial examination through the supplemental examination process. Did Congress and the Federal Circuit overreact to the “plague” of inequitable conduct allegations? This article explores the unintended consequences that may follow from their actions.
“THERE’S A HOLE IN THE BUCKET:” THE EFFECTIVE ELIMINATION OF THE INEQUITABLE CONDUCT DOCTRINE

KATHERINE E. WHITE

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"THERE'S A HOLE IN THE BUCKET:" THE EFFECTIVE ELIMINATION OF THE INEQUITABLE CONDUCT DOCTRINE

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INTRODUCTION

In 2011, the combination of both Therasense, Inc. v. Becton, Dickinson & Co.¹ and the enactment of the America Invents Act (“AIA”)² effectively eliminated the judicial doctrine of inequitable conduct in patent cases. In order to obtain a patent, applicants have long had a duty of candor before the U.S. Patent and Trademark Office (“PTO”).³ Inventors are often the most knowledgeable about why their invention is new and nonobvious over the prior art, which are essential requirements for patentability.⁴ Candid correspondence with the PTO is essential to preserving integrity in the ex parte patenting process, where no other party participates to induce full disclosure.⁵ The doctrine of inequitable conduct, historically, has been the key gatekeeper policing the patent system’s integrity.⁶ Now, with its virtual elimination, is there still sufficient incentive to comply with the “duty of candor” principles that have traditionally served the patenting process? It is without question, the use of inequitable conduct to police the duty of candor has been abused over the years.⁸ But, perhaps this cure is worse than the disease. In making these changes, there was little discourse about the value of the inequitable conduct doctrine and its role in preserving the integrity of the patenting process. Instead, the focus was primarily on lessening the doctrine’s bite.

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⁶ Id.
⁷ See 37 C.F.R. § 1.56 (2011).
⁸ See Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988).
Therasense tightened the materiality and intent standards, thus lowering the duty of candor standard that will be enforced in the courts. At the same time, the AIA has instituted an escape clause for those who fail to disclose adequately during initial examination. Such applicants are now allowed to correct any deceptive conduct through the new supplemental examination process. Now, a patentee who was not originally candid with the PTO during initial examination may ask the PTO to “consider, reconsider, or correct information believed to be relevant to the patent.” This process has been coined a “patent amnesty program” because it tolerates all but the most egregious forms of fraud on the PTO. The question is whether such a profound change in policing the duty of candor will threaten the integrity of the patent system. The unintended consequences of these changes are yet to be known. Inequitable conduct was the traditional way to plug the hole in the proverbial bucket. But now, after these changes, whenever there is a hole in the bucket that needs plugging, the tools required to plug the hole need a bucket without one.

I. BACKGROUND

The Patent Clause explicitly grants Congress plenary power to write laws to “promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.” In fulfilling its duty, Congress, since the country’s founding, has passed laws to encourage inventors to disclose their inventions publicly. For the social contract to work, inventors are granted an exclusive monopoly over their inventions for a period of years in exchange for disclosing their inventions to the public. Publicly sharing innovation and ingenuity permits other skilled artisans to build on prior knowledge and advance their own unique ideas. Accordingly, disclosing patentable inventions, which are new and nonobvious advancements over what has come before, benefits society and future inventors.

To evaluate whether an invention is new and nonobvious over the prior art, the PTO must be aware of and evaluate the teachings of all information material to

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9 See Therasense, 649 F.3d at 1290.
11 Id.
13 Id.
14 U.S. CONST. art. I, § 8, cl. 8.
16 35 U.S.C. § 154 (a) (“[the patent] grant shall be a term beginning on the date the patent issues and ending 20 years from the date on which the application for patent was filed in the United States.”).
18 35 U.S.C. §§ 102–103 (authorizing new and nonobvious advances over the prior art to be patentable).
patentability. The inventor (or patent applicant) generally has the best information available to assist the patent examiner. As a consequence, to encourage the inventor to disclose what is known, the inventor, under section 1.56 of chapter 37 of the Code of Federal Regulations (“CFR”), has a “duty of candor and good faith” in dealing with the PTO. In other words, the inventor is required to disclose any known prior art to help the PTO establish whether the invention is patentable. Traditionally, patents obtained in bad faith, or through intentional misrepresentations or omissions are invalid or unenforceable. This legal concept has evolved into the judicial doctrine of inequitable conduct allowing challenges to patent enforceability for material misrepresentations or omissions made before the PTO. The remedy for an inequitable conduct finding makes a patent entirely and utterly unenforceable.

In addition, inequitable conduct charges damage a patent attorney’s reputation as a bad actor, discouraging settlement, and averting attention away from the alleged infringement. Tarnishing one patent with inequitable conduct could also spread to other related applications and patents, making them also unenforceable. Promoting candor before the PTO is a worthy goal because it assists patent examiners in performing their duties more effectively. But, because the remedy for inequitable conduct is so extreme, “the habit of charging inequitable conduct in almost every major patent case [despite it being difficult to prove subjective intent to

20 See 35 U.S.C. § 118 (allowing non-inventors to apply for patent applications where the inventor has assigned or is obligated to assign the invention).
21 See 37 C.F.R. § 1.56(a) (2011); see also Norton, 433 F.2d at 794 (“[The PTO] must rely on applicants for many of the facts upon which its decisions are based.”).
22 37 C.F.R. § 1.56(a).
23 Id.
24 Id.
26 Kingsdown, 863 F.2d at 877; J.P. Stevens & Co., Inc. v. Lex Tex Ltd., 747 F.2d 1553, 1559 (Fed. Cir. 1984) (“Conduct before the PTO that may render a patent unenforceable is broader than ‘common law fraud.’”); Norton, 433 F.2d at 793 ( “[T]he concept of ‘fraud’ on the Patent Office . . . encompasses . . . a wider range of ‘inequitable’ conduct found to justify holding a patent unenforceable.”); See also 35 U.S.C. § 282 (allowing patent unenforceability challenges generally).
27 See Kingsdown, 863 F.2d at 877; J.P. Stevens, 747 F.2d at 1559.
28 See Therasense, 649 F.3d at 1289.
30 See Norton, 433 F.2d at 794.
deceive] has become an absolute plague.”\(^{31}\) Such overkill in charging inequitable conduct, and its extreme remedy, make valuing a patent portfolio difficult and unpredictable. Plus, in an effort to avoid an inequitable conduct charge, patent applicants often submit marginally pertinent references to the PTO and fail to explain their relevance, as it may not be apparent.\(^{32}\)

To prove inequitable conduct, an alleged infringer must show, by clear and convincing evidence, “the patentee acted with the specific intent to deceive the PTO . . . [including] a deliberate decision to withhold a known material reference.”\(^{33}\)

Before recent changes were made to the inequitable conduct doctrine, its remedy rendered a patent utterly unenforceable as to every patent claim, regardless of whether or not such claim was otherwise a valid, new and nonobvious improvement over the prior art.\(^{34}\) Because of this, the remedy for inequitable conduct has been referred to as the “atomic bomb” of patent law.\(^{35}\)

With all of these aforementioned problems having existed for decades, it is no wonder both the Court of Appeals for the Federal Circuit (“Federal Circuit”) and Congress, virtually simultaneously, stepped in to rein in the standards for finding inequitable conduct as a defense to patent infringement. In \textit{Therasense},\(^{36}\) the Federal Circuit “tighten[ed] the standards for finding intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”\(^{37}\) In enacting the AIA in September 2011, Congress, for the first time, provides a way to purge or correct a misrepresentation or a failure to disclose material information in a supplemental examination process after the patent has issued.\(^{38}\) This process has been coined a “patent amnesty program.”\(^{39}\) Although these changes did fulfill the goal of tempering the use of an “atomic bomb” remedy available in inequitable conduct charges, governments do not normally grant amnesty in these situations. In amnesty programs, governments generally seek only to forgive past behavior because

\(^{31}\) \textit{Burlington}, 849 F.2d at 1422; \textit{see also} \textit{McKesson Info. Solutions, Inc. v. Bridge Medical, Inc.}, 487 F.3d 897, 926–27 (Fed. Cir. 2007) (Newman, J., dissenting) (“This court returns to the ‘plague’ of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent.”).

\(^{32}\) \textit{Therasense}, 649 F.3d at 1289.

\(^{33}\) Id. at 1289.

\(^{34}\) \textit{See} AIA Report, \textit{supra} note 19, at 28–29; \textit{see Therasense}, 649 F.3d at 1288.

\(^{35}\) \textit{Therasense}, 649 F.3d at 1288.

\(^{36}\) Id. at 1276.

\(^{37}\) Id. at 1290.

\(^{38}\) 35 U.S.C. § 257; AIA Report, \textit{supra} note 19, at 50.

The Act addresses the inequitable conduct doctrine by authorizing supplemental examination of a patent to correct errors or omissions in proceedings before the Office. Under this new procedure, information that was not considered or was inadequately considered or was incorrect can be presented to the Office. If the Office determines that the information does not present a substantial new question of patentability or that the patent is still valid, that information cannot later be used to hold the patent unenforceable or invalid on the basis for an inequitable-conduct attack in civil litigation.

\(^{39}\) \textit{See} Rantanen & Petherbridge, \textit{supra} note 12, at 24.

\(^{40}\) \textit{See Therasense}, 649 F.3d at 1288.
it is not tenable to police while seeking to protect the future. The forgiveness is what heals the past and reconciles it with moving forward peacefully. There is generally a cut-off date, and not blanket immunity for all time, for everyone going forward, which is what is available during supplemental examination. Instead of keeping the doctrine of inequitable conduct intact, and merely transforming the remedy and its disproportional result of forfeiting all patent rights in all cases, the combination of both Therasense and the AIA have effectively eliminated inequitable conduct as a defense in all but the most egregious and fraudulent situations. The doctrine of inequitable conduct was gutted by Therasense and then pierced through its core by the AIA.

In the debates surrounding the problems with inequitable conduct, lacking were affirmative discussions regarding the type of misconduct that should be policed in an inequitable conduct charge. Instead the focus was on ending the apparent litigation abuses by charging inequitable conduct in almost every case. In other words, instead of discourse on the value of the inequitable conduct doctrine and how it should be better implemented, the rhetoric fixated on stopping the doctrine because it was out of control. With unenforceability as inequitable conduct's remedy, the call for predictability in patent valuation won the day and drastic changes were made to cripple the doctrine by both the courts and Congress. Unfortunately, the changes weakened the doctrine so much it has lost all of its teeth. Such a drastic outcome may have serious unintended consequences that will probably need to be addressed either through case law or through regulation. It is unlikely, however, Congress will take up amending the patent laws within the decade.

This paper seeks to encourage the patent bar to have an affirmative debate about what type of misconduct or intent to deceive should continue to be policed and may now fall through the cracks and evade enforcement. In the past, courts have observed what type of disclosure is essential. This paper serves to motivate future

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42 Id. at 90.
43 Id.
45 AIA Report, supra note 19, at 50.
46 Id.
47 Id.
48 Larson Mfg. Co. of South Dakota v. Aluminart Prods. Ltd, 559 F.3d 1317, 1327 (Fed. Cir. 2009) ("[I]njectable conduct requires not intent to withhold, but rather intent to deceive."); M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., 439 F.3d 1335, 1340 (Fed. Cir. 2006) ("Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent."); LaBounty Mfg., Inc. v. U.S. Int'l. Trade Comm'n,
discussions that should have been part of the Patent Reform movement as it relates to the doctrine of inequitable conduct. Part II presents some of the dialogue and case law advocating restraining the inequitable conduct doctrine. Part III addresses what the combination of Therasense and the AIA have done to limit the application of the doctrine of inequitable conduct and other unintended consequences. Part IV reviews cases using the new inequitable conduct standard under Therasense after previously having used the prior standard. Finally, Part V concludes.

II. REASONS ARGUED FOR RESTRAINING THE INEQUITABLE CONDUCT DOCTRINE

The aforementioned criticism of how inequitable conduct is implemented is not new. The standard for the duty of candor before the PTO has been denounced as out of control for decades. In 1988, the American Intellectual Property Law Association (“AIPLA”) wrote a report detailing how inequitable conduct findings adversely affected the United States patent system. In a white paper, the Committee said the courts’ implementation of the duty to disclose before the PTO had the effect of denying “patent protection for some worthy inventions and to generate uncertainty and confusion as to the enforceability of many patents.” At that time, mere gross negligence in failing to disclose material information to the PTO was grounds for an inequitable conduct finding.

Further complicating matters, an inequitable conduct charge centers on the “moral turpitude of the inventor and the patent owner and the professional integrity of the patent attorney or agent.” This “makes settlement more difficult and tends to deflect attention away from the basic merits of whether the invention . . . is patentable . . . and . . . is being infringed.” In its paper, the Committee made suggestions to eliminate four undesirable aspects of the duty of candor standard before the PTO:

1. An ambiguous and inappropriate standard of materiality.

2. Disproportionality between the nature of the alleged inequitable conduct and the forfeiture of all patent rights.

3. An absence of clear opportunities to correct or “purge” prior inequitable conduct that may have occurred in the procurement of a patent.

958 F.2d 1066, 1076 (Fed. Cir. 1992) (“Close cases should be resolved by disclosure, not unilaterally by the applicant.”).

49 AIPLA Committee Paper, supra note 29, at 74–75.

50 Id. at 75.

51 Id. at 74; see also Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 1151 (Fed. Cir. 1983) (“Statements made with gross negligence as to their truth may establish intent [to prove fraud].”).

52 See AIPLA Committee Paper, supra note 29, at 75.

53 Id.
4. Undue emphasis on the timing of a patent applicant’s disclosure of material information.\(^5\)

In 1988, the Federal Circuit began an attempt to fix the aforementioned problems by restoring the intent standard required to prove inequitable conduct.\(^5\) In *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*,\(^6\) the applicant was involved in a complicated patent prosecution with a continuation application and numerous claims. The applicant submitted a claim list to simplify which claims already were allowed and corresponded to the claims in the continuation application.\(^7\) But, the applicant incorrectly listed claim 43 as corresponding to allowed claim 50 in the parent application.\(^8\) Instead, claim 43 actually corresponded to the unamended claim 50, which was rejected for indefiniteness under section 112.\(^9\) The text of the unamended claim, however, was included in the patent unchanged.\(^10\)

The trial court found the applicant’s misrepresentation material, as it should have been allowed only after being amended.\(^11\) Furthermore, the trial court found the intent prong was met because the plaintiff’s “patent attorney was grossly negligent in not catching the misrepresentation because a mere ministerial review . . . would have uncovered the error.”\(^12\) Because the amended version of the claim might have given the defendant a possible defense to infringement, the court inferred motive to deceive the PTO.\(^13\) The trial court found the plaintiff’s patent attorney reviewed the allegedly infringing device before he amended claim 50 and before the continuation application was filed.\(^14\) The dispute arose as to whether the trial court’s finding of intent to deceive the PTO was clearly erroneous.

On appeal, the Federal Circuit held it was improper for the trial court to infer intent to deceive “based on what it perceived to be [patentee’s] gross negligence.”\(^15\) The Federal Circuit, savvy to the realities of patent practice, noted this case was merely one of copying the wrong claim during a ministerial act of transferring and renumbering allowed claims into the continuation.\(^16\) In any case, both claims contained allowable subject matter, the rejection of the unamended claim was not anticipated or obvious and thus “took nothing from the public domain.”\(^17\) To clarify conflicting precedent, the Federal Circuit held gross negligence, alone, does not infer an intent to deceive.\(^18\) To make a determination on whether the intent prong is met,

\(^{5}\) Id.

\(^{55}\) See *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

\(^{56}\) Id. at 867.

\(^{57}\) Id. at 871.

\(^{58}\) Id. at 870.

\(^{59}\) Id. at 871.

\(^{60}\) Id.

\(^{61}\) Id.

\(^{62}\) Id.

\(^{63}\) Id.

\(^{64}\) Id. at 872.

\(^{65}\) Id. at 873.

\(^{66}\) Id.

\(^{67}\) Id.

\(^{68}\) Id. at 876.
the conduct “viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.”

The court tried to raise the intent standard to rein in persistent and meritless charges of inequitable conduct. Nevertheless, the higher intent standard in Kingsdown did not “reduce the number of inequitable conduct cases before the courts and did not cure the problem of over-disclosure of marginally relevant prior art to the PTO.” Instead, courts began using the materiality standard as a way to expand the reach of the inequitable conduct doctrine. This led to the sliding scale test to determine whether inequitable conduct has occurred, where “balancing the levels of materiality and intent [was used] ‘with a greater showing of one factor allowing a lesser showing of the other.’” The sliding scale test began to be misapplied when courts found inequitable conduct without first finding clear and convincing evidence of both materiality and intent to deceive. The courts abused this standard going so far as to oft find inequitable conduct by summary judgment or to find it where absolutely no intent to deceive was found. In other words, materiality had swallowed up the intent analysis. But, materiality is really only relevant in direct relation as to how it informs intent, which is hard to prove.

To further complicate matters, the courts applied different versions of Rule 56 to determine materiality. As the sliding scale focused more on materiality than intent, five standards of materiality began to emerge:

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69 Id.
71 See id. (“In the past, this court has tried to address the proliferation of inequitable conduct charges by raising the intent standard alone.”).
73 See M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc., 439 F.3d 1335, 1343 (Fed. Cir. 2006) (rejecting the trial court’s grant of summary judgment for inequitable conduct where absolutely no findings of intent to deceive were made).
74 Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334, 1350 (Fed. Cir. 2008) (“More recently, however, the judicial process has too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct.”).
75 See Therasense, 649 F.3d at 1294 (stating Rule 56 has gone through several revisions from the 1949 standard, the 1977 standard, and the 1992 standard). The 1949 standard for Patent Office Rule 56, for improper applications, provides in pertinent part:
Any application signed or sworn to in blank, or without actual inspection by the applicant . . . and also any application fraudulently filed or in connection with which any fraud is practiced or attempted on the Patent Office, may be stricken from the files.
Id. The 1977 standard for section 1.56, for the duty of disclosure; fraud; striking or rejection of applications, provides in pertinent part:
A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood a reasonable examiner would consider it important in deciding whether to allow the
1. **Objective but for standard**: “misrepresentation was so material the patent should not have issued,”77

2. **Subjective but for standard**: “misrepresentation actually caused the examiner to approve the patent application when he would not have otherwise done so,”78

3. **But it may have standard**: “where the misrepresentation may have influenced the patent examiner in the course of prosecution,”79

4. **1977 Rule 56 standard**: duty to disclose material information, which is defined as “where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent;”80 and

5. **1992 Rule 56 standard**: including as material any information if it “refutes or is inconsistent with” any position the applicant took regarding patentability.81

In 2011, both the courts and Congress intervened to tackle the inequitable conduct debacle. But, these actions created a perfect storm, attacking the doctrine from both ends and causing its virtual destruction.

III. HOW Therasense AND THE AIA HAVE VIRTUALLY ELIMINATED THE DOCTRINE OF INEQUITABLE CONDUCT AND OTHER UNINTENDED CONSEQUENCES

A. Therasense, Inc. v. Becton, Dickinson and Co.

In Therasense, Inc. v. Becton, Dickinson and Co.,82 Chief Judge Rader, writing for the court, best described the ills inequitable conduct has thrust upon the patent bar:

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application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

*Id.* (emphasis added). It should be noted that in Therasense, the Federal Circuit specifically declines to adopt the current version of Rule 56 “because reliance on this standard has resulted in the very problems this court [seeks] to address.” *Id.* at 1294.

76 *Digital Control*, 437 F.3d at 1313–16.

77 *Id.* at 1315.

78 *Id.*

79 *Id.*

80 *Id.*

81 Therasense, 649 F.3d at 1294 (citing 37 C.F.R. § 1.56 (1992)).

82 *Id.* at 1276.
While honesty at the PTO is essential, low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality.\(^{83}\)

In response to these aforementioned problems, an en banc Federal Circuit, tightened “the standards for finding both intent and materiality.”\(^{84}\) Although no new intent standards were added, the court reinforced principles articulated in earlier cases requiring deliberate action and knowledge of the materiality of an undisclosed reference:\(^{85}\)

1. To prove a claim of inequitable conduct, the accuser must show “the infringer acted with specific intent to deceive the PTO.”\(^{86}\)

2. A finding that a “misrepresentation or omission amounts to gross negligence or negligence under a ‘should have known standard’ does not satisfy this intent requirement.”\(^{87}\)

3. A “deliberate decision to withhold a known material reference” is required. In other words, it must be proven applicant knew of the reference, knew it was material, and made a deliberate decision to withhold it.\(^{88}\)

The court emphasized that the intent and materiality standards are separate and independent requirements.\(^{89}\) Consequently, the court rejected the sliding scale analysis, “where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.”\(^{90}\) However, the court did allow a trial court to infer intent to deceive from indirect evidence, as direct evidence of deceptive intent is uncommon.\(^{91}\) But the court clarified, “to meet the clear and convincing evidence standard, the specific intent to deceive must be, in light of the totality of the circumstances, ‘the single most reasonable inference able to be drawn from the

\(^{83}\) Id. at 1290.
\(^{84}\) Id.
\(^{85}\) Id.
\(^{86}\) Id. See also Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 (Fed. Cir. 2009) (“[A] pleading of inequitable conduct under Rule 9(b) must include sufficient allegations . . . from which a court may reasonably infer . . . a specific intent to deceive . . .”).
\(^{87}\) Therasense, 649 F.3d at 1290.
\(^{88}\) Id. (emphasis added).
\(^{89}\) Id.
\(^{90}\) Id.
\(^{91}\) Id.
The court emphasized that where “multiple inferences may be drawn, intent to deceive cannot be found.”

As was discussed in Part II, the court has tried, without success, to stem the tide of unwarranted inequitable conduct charges by raising the intent standard alone. Because that strategy has failed, the court took the most logical step and made a significant change to the materiality standard in *Therasense*. Taking a monumental leap, the court held the required materiality standard for establishing inequitable conduct is but-for materiality. Undisclosed prior art is “but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” In evaluating but-for materiality, the court applies the same standard the PTO would to determine whether the claim would have been allowed if the reference had been disclosed. In other words, the court is to “apply the preponderance of the evidence standard and give claims their broadest reasonable construction.” If there is a corresponding invalidity finding for a claim, the higher clear and convincing burden of persuasion required by the district court ensures that the undisclosed reference is material. Even if the claim is not invalidated, the court may determine the undisclosed reference is material if it would have prevented the PTO from issuing the claim.

In *Therasense*, the court posits that adding the but-for requirement will add some proportionality to the remedy for inequitable conduct. So, instead of any minor misconduct creating unenforceability for the entire patent, this would only occur where a claim is unwarranted. Concerned, however, the but-for materiality requirement may not effectively incorporate the conduct the Supreme Court maligned in the unclean hands cases from which the doctrine of inequitable conduct sprung, the court also creates an exception to the but-for requirement in cases of affirmative egregious misconduct.

Before the modern inequitable conduct doctrine was coined, the courts initially policed fraudulent behavior before the PTO and the courts using the equitable

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92 Id.
93 Id. at 1290–91 (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”).
94 Id. at 1291 (requiring an intent to deceive beyond gross negligence).
95 Id. See AIPLA Committee Paper, supra note 29, at 79–81. In that report, the Committee argued it was a mistake to apply the materiality standard found in proxy statement disclosures to inequitable conduct cases. In its view, disclosing information to shareholders was not analogous to submitting patent applications to a skilled government officer like a patent examiner. See *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 444–49 (1976) (holding a material fact is one “a reasonable shareholder would consider . . . important in deciding how to vote”, without having a decisive effect on voting).
96 *Therasense*, 649 F.3d at 1291.
97 Id.
98 Id. at 1291–92.
99 Id. at 1292.
100 Id.
101 Id.
102 Id. at 1292 (“It is inequitable to strike down an entire patent where the patentee committed only minor missteps or acted with minimal culpability.”).
103 Id. (“there is no room to argue that submission of false affidavits is not material.”).
doctrine of unclean hands. There were three important Supreme Court unclean hands cases where the patentee had deliberately and carefully planned to deceive not only the PTO, but also the courts. In *Keystone Driller Co. v. Gen. Excavator Co.*, the patentee bribed a prior inventor to say he abandoned the invention when he had not. The patentee conspired with the prior inventor to suppress evidence of prior use to lessen the chance the patent would be invalidated. In *Hazel-Atlas Glass Co. v. Hartford-Empire*, to overcome prior art rejections in the PTO, patentee paid an alleged disinterested well-known expert to lie about writing an article touting the advantages of the invention over the prior art, when in fact, patentee’s lawyers wrote the article. After submitting this article to the PTO, the patent was granted. Patentee later sued Hazel-Atlas for patent infringement. At trial, the patent was found not infringed. On appeal, patentee drew attention to the ill-gotten article and the court overturned the trial court, finding infringement. In *Precision Instrument Mfg. v. Automotive Maintenance Machinery*, the patentee failed to disclose fraudulent testimony, before both the PTO and in court, regarding inventor’s alleged dates of “conception, disclosure, drawings, description and reduction to practice . . .” Instead of disclosing the perjury, patentee entered into a settlement agreement with the prior inventor and suppressed the evidence of perjury. Then, patentee enforced its patent against alleged infringers, knowing it was ill-gotten.

In these aforementioned seminal unclean hands cases, the remedy in each differed from the modern version of inequitable conduct. Instead of rendering the entire patented invention unenforceable, the Court denied relief for any claimed infringement of the patent procured in the pertinent action. In other words, the

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104 Id.
106 *Keystone*, 290 U.S. at 240.
107 Id. at 243.
108 Id.
110 Id. at 240–42.
111 Id. at 240–41.
112 Id. at 241.
113 Id.
114 Id.
116 Id. at 809–10.
117 Id. at 812–14.
118 Id. at 814.
119 Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988) (“When a court has finally determined that inequitable conduct has occurred . . . the entire patent is rendered unenforceable.”).
patent claims were found unenforceable in the present action, but not found to be entirely unenforceable against all future actions against any party.

Although the court in *Therasense* does not define affirmative egregious misconduct, the court makes clear “the exception to the general rule requiring but-for proof . . . [includes the] ‘deliberately planned and carefully executed scheme[s]’ to defraud the PTO and the courts.”121 Another example falling within the exception is the “filing of an unmistakably false affidavit.”122 Such misconduct is regarded as material.123

*Therasense*, however, did not address all of the concerns complained about regarding inequitable conduct. But, where *Therasense* left off, the AIA took over. One of the most groundbreaking changes the AIA added to U.S. patent law is the supplemental examination process in section 257, which will be effective September 16, 2012.124 This new process “authoriz[es] supplemental examination of a patent to correct errors or omissions in proceedings before the [PTO].”125 Thus, any omission or misrepresentation that was not previously considered, was inadequate, or was incorrect can be put forth in the PTO, allowing misconduct to be purged after the patent has issued.126 A patent owner may request supplemental examination of its patent “to consider, reconsider, or correct information believed to be relevant to the patent.”127 In effect, this is a type of immunity from patent unenforceability claims.

After a supplemental examination is completed, the Director of the United States Patent and Trademark Office (“Director”), issues a certificate indicating whether the information put forth during the supplemental examination “raises a substantial new question of patentability.”128 If so, a reexamination is ordered.129 But, unlike traditional reexamination proceedings, those in a supplemental examination process are not limited in review by looking to prior art consisting of only patents and printed publications.130 If the reexamination does not raise a substantial new question of patentability, or if the patent is still valid despite the information disclosures, any information submitted is collaterally estopped from

122 Id. at 1292.
124 AIA Report, supra note 19, at 28.
125 Id. at 31.
126 Id.
127 AIA, § 12 (to be codified 35 U.S.C. § 257(a)).
128 Id.
129 Id. See 35 U.S.C. § 305. Conduct of reexamination proceedings, in pertinent part:

In any reexamination proceeding under this chapter [35 USC §§ 301 et seq.], the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art . . . . No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding . . . .

Id.
130 AIA, § 12 (to be codified 35 U.S.C. § 257(b)) (“During the reexamination, the Director shall address each substantial new question of patentability identified during the supplemental examination, notwithstanding the limitations in chapter 30 [35 U.S.C. §§ 301, 303 relating to patents and printed publications.”) (emphasis added).
being used later, in civil litigation, to “hold the patent unenforceable or invalid on the
basis for an inequitable-conduct attack.”\textsuperscript{131} Specifically, “[a] patent shall not be held
unenforceable . . . if the information [although not considered before supplemental
examination] was considered, reconsidered, or corrected during a supplemental
examination . . . .”\textsuperscript{132} This is what has been called in effect a “patent amnesty
program.”\textsuperscript{133}

There are exceptions to this estoppel provision, however.\textsuperscript{134} For example,
estoppel would not apply where an allegation, plead with particularity challenging
the patent in a civil litigation, was made prior to the supplemental examination
request; or in a defense in a patent enforcement action brought under section 281 or
under the Tariff Act of 1940, regarding information dealt with in the supplemental
examination, unless the supplemental examination and subsequent reexamination
concludes before the date the patent enforcement action was brought.\textsuperscript{135} But for both
exceptions, it is worth noting the patentee has great control over whether these
exceptions would apply.\textsuperscript{136} Because challenging patent liability, validity or
unenforceability are affirmative defenses and not causes of action, would be
infringers cannot challenge patents in federal court unless declaratory judgment
jurisdiction is triggered.\textsuperscript{137} The Declaratory Judgment Act\textsuperscript{138} does not provide an
independent basis for jurisdiction in federal court; it only provides a remedy.\textsuperscript{139} Only
the patentee’s actions can trigger declaratory judgment jurisdiction.\textsuperscript{140} To thwart
jurisdiction, a patentee can make a covenant not to sue the alleged infringer, and this
will eliminate any real and substantial conflict between the parties.\textsuperscript{141}

To combat “material fraud”\textsuperscript{142} before the PTO, section 257(e) addresses means to
police fraud, beyond the remedies otherwise available through the reexamination
process (e.g. cancelling invalid patent claims).\textsuperscript{143} If during the supplemental
examination process, the Director becomes aware of facts amounting to “material
fraud” committed regarding the entire patenting process, the Director shall

\textsuperscript{131} AIA Report, \textit{supra} note 19, at 31.
\textsuperscript{132} AIA, \S 12 (to be codified 35 U.S.C. \S 257(c)(1)).
\textsuperscript{133} Rantanen & Petherbridge, \textit{supra} note 12 at 25.
\textsuperscript{134} AIA, \S 12 (to be codified 35 U.S.C. \S 257(c)(2)).
\textsuperscript{135} Id.
\textsuperscript{136} See Rantanen & Petherbridge, \textit{supra} note 12, at 25.
\textsuperscript{137} 35 U.S.C. \S 282 (2006) (listing noninfringement, invalidity and unenforceability as
affirmative defenses).
\textsuperscript{138} 28 U.S.C. \S 2201 (2006)
\textsuperscript{139} Cat Tech L.L.C. v. TubeMaster, Inc., 528 F.3d 871, 879 (Fed. Cir. 2008).
\textsuperscript{140} MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 128 (2007) (requiring the dispute to be
definite and concrete between parties with real and substantial adverse legal interests in order to
trigger declaratory judgment jurisdiction).
\textsuperscript{141} See Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999) (finding
an actual case or controversy must be in existence at all times during the action, not merely on the
filing date).
\textsuperscript{142} But see 77 Fed. Reg. 3666, 3667 (Jan. 25, 2012) (to be codified at 37 C.F.R. \S 1) (“The Office
regards the term ‘material fraud’ in 35 U.S.C. 257(e) to be narrower in scope than inequitable
conduct as defined by . . . \textit{Therasense} . . . ”).
\textsuperscript{143} AIA, \S 12 (to be codified 35 U.S.C. \S 257(e)).
confidentially “refer to the Attorney General” the matter,144 leaving it to the Attorney General’s discretion to take further appropriate action.

In response, the Attorney General might pursue an action under 18 U.S.C. section 1001(a)(1),145 making it a crime to falsify facts before federal agencies.146 This crime, however, only has a five-year statute of limitations.147 It is measured from the time the crime is complete, meaning when each element of the crime has occurred.148

For patent cases, this is likely to be measured from the date the false document is submitted.149 Consequently, the statute of limitations will likely render the teeth to this provision dull, because five years from the date of filing is too short of a time to have much effect. For example, in fiscal year 2011 it took, on average, 33.7 months for a patent application to issue as a patent.150 Similarly, the patent average total pendency was 35.3 months in fiscal year 2010.151 If it takes, on average, almost three years to get a patent, then it will generally take longer than five years for a patentee to request supplemental examination. Any fraudulent information submitted, no matter how egregious, could be corrected in a supplemental examination process because the statute of limitations will have run out by the time the PTO is informed as to the fraud. Unfortunately, the supplemental examination process could be used as a way to cure even the most egregious misconduct before the PTO, giving the patentee another bite at the apple despite engaging in bad behavior.

Congress, however, did leave open, some other avenues to punish deceptive practices. Setting forth a “[r]ule of construction,” Congress specifically permits other causes of action to address misconduct.152 For example, the supplemental examination process is not meant to preclude imposing sanctions based on criminal,

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144 Id.
145 18 U.S.C. § 1001(a) (2006) provides, in pertinent part:
Except as otherwise provide in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—
(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact . . . shall be fined under this title, imprisoned not more than 5 years . . .

Id.
146 Generally, those prosecuted under 18 U.S.C. § 1001(a) commit an underlying crime in addition to the false statement before a federal agency. For example, when a person brings firearms to the United States border trying to enter the country, that itself is a crime. Making a false statement to the customs agent about having the weapons is an additional crime under 18 U.S.C. § 1001(a). In the patent prosecution context, having knowledge about a material prior art reference is not an underlying crime, even if lying about that knowledge might be under 18 U.S.C. § 1001(a). Without the underlying crime, it is unclear if the Attorney General will use discretion to take further action.

147 18 U.S.C. § 3282. Offenses not capital, provides in pertinent part “[e]xcept as otherwise expressly provided by law, no person shall be prosecuted, tried, or punished for any offense, not capital, unless the indictment is found or the information is instituted within five years next after such offense shall have been committed.” Id. at § 3282(a).
148 See United States v. Smith, 740 F.2d 734, 736 (9th Cir. 1984).
149 Id. (triggering the statute of limitations from the date of submission as opposed to the date received); see United States v. Roshko, 969 F.2d 9, 12 (2d Cir. 1992).
151 Id. at 14.
152 AIA, § 12 (to be codified 35 U.S.C. § 257(f)).
antitrust or unfair trade practices, or limit the authority of the Director to investigate misconduct and impose sanctions, or restrain the Director from issuing regulations to sanction misconduct by those authorized to practice before the PTO.

Although Congress has opened the door to punish egregious misconduct more broadly, Congress did not mandate the PTO to investigate or sanction misconduct under any specific circumstances. The question is, should misconduct, not quite amounting to the fraud undertaken in the early Supreme Court cases, be policed? In *Therasense*, the court specifically authorized policing “egregious misconduct” without requiring but-for causation of invalidity. Clearly included in “egregious misconduct” is the behavior in the traditional unclean hands cases that led to the development of the inequitable conduct doctrine. But, in *Therasense*, the court also mentioned filing unmistakably false affidavits amounted to material misconduct. It is clear from the proposed regulations governing supplemental examination, the PTO regards the term “material fraud” in section 257(e) to be narrower in scope than the inequitable conduct the Federal Circuit defined in *Therasense*. The one deterrent for requesting supplemental examination and follow-on ex parte reexamination may be the fee. The proposed fee for filing a request for supplemental examination is $5180. If ex parte reexamination is ordered, the fee is an additional $16,120. This compares to the cost of ex parte reexamination, before the proposed changes, of $2520. If enacted, these fees will increase the cost by tenfold. But, in exchange, a patentee can maintain the enforceability of its patent.

Further, the AIA, in order to weaken the reach of inequitable conduct defense, has removed the deceptive intent language in several of the sections of Title 35: 116(c), 251(a), and 256. The Savings Clause found in section 115(h)(3) makes

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153 Id. (to be codified 35 U.S.C. § 257(f)(1)).
154 Id. (to be codified 35 U.S.C. § 257(f)(2)).
155 Id. (to be codified 35 U.S.C. § 257(f)(2)).
157 Id.
159 Id. at 3668.
160 Id.
161 Id.
163 35 U.S.C. § 116(c) (2006). Correction of Errors in Application says: “Whenever through error a person is named in an application for patent as the inventor, or through error an inventor is not named in an application, the Director may permit the application to be amended accordingly . . .” Id. Removing the language “and such error arose without any deceptive intention of his part.” Id.
164 Id.
165 35 U.S.C. § 251. Reissue of defective patents (a) removed “without any deceptive intention” language and allows patents to be reissuessed “[w]henever any patent is, through error, deemed wholly or partially inoperative or invalid . . . by reason of patentee claiming more or less than he had a right to claim . . .” Id.
it so patents cannot be held invalid or unenforceable for failure to comply with naming an inventor, provided such error is remedied. 167 The intent to withhold an inventor is no longer policed specifically. All fraud appears to be policed through 18 U.S.C. section 1001, with its five-year statute of limitations. 168

It may be necessary for members of the patent bar to have an open dialogue about the practices that should be penalized even when the misconduct would not have prevented a patent from issuing. As was mentioned in Part II, these types of discussions were lacking even back when the AIPLA wrote its white paper in 1988, because the focus centered on how draconian the application of the doctrine had been. 169 Now is the time to have this conversation to encourage thoughtful PTO regulations to police any significant misconduct not specifically addressed either in Therasense or in the AIA. Possibilities include defining “material fraud” more broadly than what is currently stated in the proposed rules. 170 Also, there may be an opportunity to have discussions with the PTO on the requirement under section 26 that the PTO report to Congress on the implementation of the AIA. Perhaps, over time, the concerns expressed above will take hold and there can be another opportunity for Congress to address some of these shortcomings.

IV. CASES USING THE NEW INEQUITABLE CONDUCT STANDARD UNDER THERASENSE


In Powell v. Home Depot U.S.A., Inc., 171 the patentee, Powell, sued Home Depot for infringing his patent on radial arm guard safety technology. 172 For customer convenience, Home Depot has radial arm saws to cut lumber on site at its stores. 173 Because employees were getting injured using these saws, Home Depot either had to remove them or make them safer. 174 Powell installed and repaired radial arm saws for Home Depot. 175 He invented a safety guard mechanism, patented it, and was supposed to be the contractor to install them. During patent prosecution, Powell submitted a petition to make special 176 because he thought he was going to be “obligated to manufacture and supply devices embodying the claims sought.” 177

166 35 U.S.C. § 256. Correction of named inventor, where correct could be made provided the error arose without deceptive intent. Removes "and such error arose without any deceptive intent on his part," so that all errors can be changed at any time.
169 AIPLA Committee Paper, supra note 29, at 74–75.
170 Contra Supplemental Examination Provisions, supra note 158, at 3667.
172 Id. at 1226–27.
173 Id. at 1227.
174 Id.
175 Id.
176 See 37 C.F.R. § 1.102. Generally patent applications are examined in turn. Id. An applicant may petition to make an application special so that it is advanced out of turn. Id.
177 Powell, 663 F.3d at 1235.
Before the Petition to Make Special was granted, however, Home Depot contracted with Powell’s competitor to install the safety devices.\footnote{\textit{Id.}} Powell’s petition was granted after he knew he was no longer obligated to build and supply devices embodying the claims, but failed to update the petition stating so.\footnote{\textit{Id.}} After the patent issued, Powell sued Home Depot for patent infringement.\footnote{\textit{Id.} at 1228.} Home Depot alleged Powell committed inequitable conduct when he failed to update his petition.\footnote{\textit{Id.} at 1234.}

The trial court found Powell, with intent to deceive, failed to disclose to the PTO he no longer had an obligation to manufacture.\footnote{\textit{Id.}} Such an omission was found material, but the court, after balancing the equities, determined Home Depot failed to prove inequitable conduct by clear and convincing evidence.\footnote{\textit{Id.} at 1235.} On appeal, the Federal Circuit affirms the trial court applying the new standards in \textit{Therasense}.\footnote{\textit{Id.}}

The court held a failure to “update the record to inform the PTO that the circumstances which support a Petition to Make Special no longer exist—[] does not constitute inequitable conduct.”\footnote{\textit{Id.}.} The court reached this conclusion because Powell’s conduct did not meet the but-for materiality standard and was not “the type of unequivocal act, ‘such as the filing of an unmistakably false affidavit,’ that would rise to the level of ‘affirmative egregious misconduct.’”\footnote{\textit{Id.}.}

Here, it is possible Powell intended to deceive the PTO, but it is equally plausible that he merely forgot or was negligent in failing to update. Thus, the facts may not support a finding of affirmative egregious misconduct to invoke an exception to the \textit{Therasense} but-for materiality standard. But, closing the door on any false statements made in a petition to make special from meeting the but-for materiality standard seems extreme and could open the door for abuse. Without some flexibility in interpreting materiality regarding failure to update petitions at the PTO, the court may be opening Pandora’s Box. It may be difficult to prove affirmative egregious misconduct, but allowing applicants who submit false petitions to go unpunished is likely imprudent. For example, after reading this case, applicants might think it is acceptable to intentionally fail to update pertinent facts when submitting petitions to make special or petitions for small or micro entity status, because such a misrepresentation “does not constitute inequitable conduct.”\footnote{\textit{Id.}} Instead of categorically finding a failure to update does not constitute the type of behavior amounting to inequitable conduct, the focus should really be on whether the failure to update was intentional or not. In \textit{Powell}, the trial court did find an intent to deceive.\footnote{\textit{Id.}}

An alternative to the Federal Circuit’s ruling might be to interpret the but-for materiality standard differently. In the past, false statements in a petition to make
special were considered material when the petition would not have been granted, but-for the misstatement. In this situation, the court evaluates whether the statement made was false. If it is not, then materiality is lacking. If it is false, then the court should determine whether the petition would have been granted without the false statement.

In *Therasense* the court discusses the but-for materiality standard as it applies to prior art: “[w]hen an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed art.” The court does not discuss what the disclosure standards are for evaluating petitions. The court states, however, affirmative acts of egregious misconduct are material irrespective of whether or not they meet the but-for materiality standard. Such an example, the court offers, is an unmistakably false affidavit. But, the court does not necessarily preclude applying the but-for materiality standard for petitions the way it had in the past—whether but-for the false statement the PTO would have granted the petition. If this modified but-for materiality standard is used, to prevent abuse, it is important the intent to deceive prong is also met.

In *Powell*, it is disturbing that Home Depot, by infringing and contracting with someone else, actually caused Powell’s statement to be false. If Home Depot had not breached the contract with Powell, his statement would have been true. This is something that should have been part of the discussion in the case, and it was not. The focus on materiality has swallowed up the intent discussion, just like it did before *Therasense*.

Clearly, the proposed regulations for supplemental examination would not include this type of conduct as a “material fraud,” as it is defined more narrowly than that in *Therasense*.

**B. District Court Cases Since Therasense**


The two patents comprising the inventions use scanning technology to create accurate three-dimensional digital models of physical objects. Patentee sued

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189 Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V., 528 F.3d 1365, 1375 (Fed. Cir. 2008) (holding “a false statement that succeeds in expediting the application is, as a matter of law, material for purposes of assessing the issue of inequitable conduct”). Gen. Electro Music Corp. v. Samick Music Corp., 19 F.3d 1405 (Fed. Cir. 1994) (holding “as a matter of law that a false statement in a petition to make special is material if . . . it succeeds in prompting expedited consideration”).

190 *Therasense*, 649 F.3d at 1291.

191 Id. at 1292.


193 See Supplemental Examination Provisions, supra note 158, at 3667.

competitor for patent infringement. After a bench trial, but before *Therasense* was issued, the court found the patents unenforceable due to inequitable conduct. Subsequently, the trial court ordered further briefing to address the consequences of the *Therasense* decision. After applying the new standards, the trial court found the inequitable conduct challenges could no longer be proven by clear and convincing evidence. The previous decision was vacated.196

Originally, the court found the named inventor, Crampton, intended to deceive the patent office by withholding information about the collaboration between the patentee, and the defendant.197 In developing the patented invention, Crampton worked together, in depth, with the defendant, Faro Technologies, Inc. (“Faro”), to perfect synch and trigger scanning technology to operate using articulated arms to improve three-dimensional scanning accuracy. Additionally, Crampton denied Faro played any role in interfacing its arm with patentee’s scanner technology.198 Crampton also described an “excessively narrow understanding of prior art,”199 despite having previously drafted patent applications.200 The trial court found inventor intended to deceive the PTO because he withheld information that he collaborated with and used Faro’s articulated arms together with patentee’s scanners.201 As a consequence, the court cast doubt on the accuracy of patentee’s claims of sole inventorship and found the relationship with Faro should have been disclosed.202

But, after *Therasense*, the court was required to apply the but-for materiality standard. The court said defendant did not establish “that the undisclosed information would have altered the patent examiner’s finding of inventorship.”203 The question of joint inventorship may be a more likely conclusion, but, under the but-for materiality standard in *Therasense*, “Faro has not met its burden of proving that the patent would not have been issued to Crampton alone if information about Faro’s collaboration had been disclosed.”204

Further, Faro was unsuccessful in convincing the court Crampton’s lying amounted to affirmative egregious misconduct, an exception to the but-for

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195 *Id.* at *1.
196 *Id.*
198 *Id.* at 352.
199 *Id.*
200 *Id.* at 349 (Faro drafted both the British and the Patent Cooperation Treaty (PCT) application because he could not afford to hiring an attorney).
202 *Metris*, 768 F. Supp. 2d at 357.

Where a putative joint inventor has not played a role in the conception of the entire invention, he or she can still be a joint inventor as long as he or she ‘(1) contribute[s] in some significant manner to the conception or reduction to practice of the invention[,] (2) makes[s] a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention[;] and (3) do[es] more than merely explain to the real inventors well-known concepts and/or the current state of the art.’

*Id.*

204 *Id.*
materiality standard.\textsuperscript{205} Although the court found Crampton’s sworn testimony in litigation was “purposefully evasive,”\textsuperscript{206} since it did not occur during patent prosecution, it did not constitute affirmative egregious misconduct as described by the Federal Circuit in \textit{Therasense}, where the “focus of the inequitable conduct inquiry is the inventor’s conduct before the patent examiner.”\textsuperscript{207} In any case, the court noted the concern in \textit{Therasense} that inequitable conduct “only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.”\textsuperscript{208} Thus, it would be inappropriate to find inequitable conduct here.

In addition to the changes made by \textit{Therasense}, the AIA amends the provisions regarding inventorship and correction of inventorship.\textsuperscript{209} Under the old rule, a patent applicant was not allowed to correct inventorship to add a named inventor who was intentionally left off when filing a patent application.\textsuperscript{210} If an inventor were omitted, with deceptive intent, the error could not be cured and the patent was void.\textsuperscript{211} Under the AIA, the language “without any deceptive intent” has been removed.\textsuperscript{212} Now, any error in identifying inventors may not be the basis of invalidating a patent\textsuperscript{213} or make the patent unenforceable.\textsuperscript{214}

\begin{footnotesize}
\begin{itemize}
\item\textsuperscript{205} \textit{Id.} at *4.
\item\textsuperscript{206} \textit{Id.}
\item\textsuperscript{207} \textit{Id.} (stating the affirmative egregious exception is available because it is unlikely a patentee would go to such lengths unless it believes the deceit will affect patent issuance).
\item\textsuperscript{208} \textit{Id.}
\item\textsuperscript{210} 35 U.S.C. § 256.
\item Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent \textit{and such error arose without any deceptive intention on his part}, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.
\item\textsuperscript{211} \textit{Id.} (emphasis added).
\item\textsuperscript{212} See, e.g., Kennedy v. Hazelton, 128 U.S. 667, 672 (1888) (“The patent law makes it essential to the validity of a patent that it shall be granted on the application . . . of the original and first inventor . . . ”).
\item\textsuperscript{213} AIA, \textit{supra} note 2, § 20(f)(1–2) (to be codified 35 U.S.C. § 256).
\item\textsuperscript{214} \textit{Id.} at § 4(a)(1) (to be codified 35 U.S.C. § 115 (h)(3)).
\end{itemize}
\end{footnotesize}
The AIA amendments regarding inventorship were made primarily to recognize the realities of patent practice “[where] it has become increasingly common for patent applications to be assigned to corporate entities, most commonly the employer of the invention.”215 The purpose for changing the statute was to correct the antiquated way in which the law had catered to the idea that inventors were primarily the ones filing patent applications, and not the company-assignee.216 Although modernizing the law to meet current patent practice has merit, the change may have had some unintentional effects. Namely, correcting inventorship is no longer grounds for making a patent invalid or unenforceable, even if it were intentionally misrepresented.217 The punishment no longer follows the patent where attacking the property right made it unenforceable or invalid. Instead, when filing an inventor’s oath or declaration, the statement must contain a clause stating that a “willful false statement” regarding inventorship is punishable under 18 U.S.C. section 1001 by fine, not more than five years imprisonment, or both.218 The question is whether any deceptive behavior regarding inventorship should be policed besides that amounting to proving fraud under 18 U.S.C. section 1001, with its five-year statute of limitations.

Because the AIA was enacted after the patent application in Metris was filed, the new provisions would not apply.220 Nonetheless, Metris foreshadows future

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(3) **Savings Clause:** A patent shall not be invalid or unenforceable based upon the failure to comply with a requirement under this section if the failure is remedied.

*Id.*


216 See generally AIA Report, *supra* note 19.


(a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—

(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

(2) makes any materially false, fictitious, or fraudulent statement or representation; or

(3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry; shall be fined under this title, imprisoned not more than 5 years.

*Id.*


(i) **Acknowledgement of Penalties.** Any declaration or statement filed pursuant to this section shall contain an acknowledgement that any willful false statement made in such declaration or statement is punishable under section 1001 of the title 18 by fine or imprisonment of not more than 5 years, or both.

*Id.*

220 See AIA, *supra* note 2, § 3(a)(1) (giving the date and subject matter as to when the act becomes effective as 18 months from the date of enactment (September 16, 2011)); Metris U.S.A.,
problems that might arise when both the standards in Therasense and the AIA are applied to a similar fact pattern.

A solution to this situation may be to characterize lying about inventorship as affirmatively egregious so that the behavior becomes an exception to the but-for materiality test for Therasense. A drawback is that sometimes the egregious behavior occurs in litigation and not just before PTO. Perhaps, this misconduct should be policed as well.221


In Jersey Asparagus Farms, Inc. v. Rutgers Univ.,222 the licensee, Jersey Asparagus Farms, Inc. (“JAFI”), sued Rutgers University (“Rutgers”) for, inter alia, antitrust monopolization and sought a declaratory judgment that the pertinent patents on asparagus varieties were obtained fraudulently. Specifically, JAFI called into question the legitimacy of the exclusive license agreements and the royalties Rutgers desired. Defendant filed a motion to dismiss. The court dismissed plaintiff’s claim for failing to allege the requisite scienter for antitrust monopolization under a Walker Process223 theory.224

JAFI, exclusive licensee for over twenty years, terminated the license agreement between the parties sometime after realizing the underlying patents were either invalid or had expired. The license had granted JAFI authorization to cross-breed defendant’s patented asparagus, harvest all-male hybrid seed from those plants, and sell such with a license prohibiting both JAFI and farmers from propagating new hybrids through asexual reproduction.225 After JAFI discovered some of the patents had expired, it stopped paying Rutgers.226 Then, Rutgers demanded the plants be returned.227

JAFI contends almost all of defendants’ patents on asparagus are fraudulently obtained because the inventors, all of whom work for Rutgers University, falsely swore in signed affidavits they had no knowledge the subject asparagus varieties had been previously described in any printed publication or in public use or on sale in the United States more than one year before filing the application.228 JAFI sets forth

221 A remedy for this behavior may be to seek to find the case exceptional under 35 U.S.C. 285, leading to the possibility of an award of attorney fees. See MarcTec, L.L.C. v. Johnson & Johnson, 664 F.3d 907, 916 (Fed. Cir. 2012); Aptix Corp. v. Quickturn Design Sys., Inc., 269 F.3d 1369, 1379 (Fed. Cir. 2001) (Mayer, C.J., dissenting); Therasense, Inc. v. Becton Dickinson & Co., 649 F.3d 1276, 1296 (O’Malley, J., concurring).


223 Walker Process Equip., Inc. v. Food Mach., 382 U.S. 172, 179 (1965) (Harlan, J., concurring) (holding fraud on the patent office may violate the Sherman Act if all other elements to prove antitrust are present, including treble damages under the Clayton Act).

224 Jersey Asparagus Farms, 803 F. Supp. 2d at 312.

225 Id. at 298.

226 Id.

227 Id. at 302.

228 Id. at 298–99; See 35 U.S.C. § 102(b) (2006). A person is entitled to a patent unless:
specific examples of sales and/or public uses of patented varieties that took place before the critical date. The misrepresentations are material because but-for these statements, the patents would not have issued, as the technology would have been dedicated to the public. But, the court finds plaintiff was unable to satisfy the intent prong because it failed to allege defendant “intentionally omitted reference to these uses/sales in order to defraud the PTO.”

The court agreed with defendants, that the patents themselves indicate prior uses were disclosed to the PTO. The court identifies some of those references, but fails to acknowledge that those disclosures appear to be related to experimental uses of the claimed inventions, which would not preclude patentability. Because this action was a motion to dismiss, the court was required to accept the plaintiff’s allegations as true and did not need to evaluate whether the use was experimental. It should, however, be suspicious that the uses disclosed appeared, on their face, to be experimental while all the other alleged uses, which were not disclosed, would have invalidated the patent claims.

It is more plausible to thwart a charge of intent to deceive where Rutgers submits its license agreements during patent prosecution indicating it is engaged in experimental research with the patented invention.

The court focuses on the language attacking a finding of inequitable conduct as an atomic bomb remedy:

Because inequitable conduct renders an entire patent (or even a patent family unenforceable, as a general rule, this doctrine should only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.

But, here, if those public uses and sales took place before the critical date, the only claim for each patent would be invalidated.

The court said to prove antitrust, negligent misrepresentations are not enough. “[A] plaintiff must not only allege that the inventor knew of the prior sale but also that he knew the relevance of that prior sale.” But this analysis may be somewhat flawed because the charge of antitrust can be sustained where patentee knows the patents are ill-gotten and is enforcing them anyway. If there is a sale or

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229 Jersey Asparagus Farms, 803 F. Supp. 2d at 299 (stating that the critical date is defined as one year before the date of filing a patent application in the United States).
230 Id.
231 Id. at 310.
232 Id. at 307.
233 Id.
234 Id.
235 Id. at 312.
236 Id. at 310.
237 Id. at 311.
238 See e.g. Walker Process Equip., Inc. v. Food Mach., 382 U.S. 172 (1965); Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998); Katherine E. White, A Rule For
a public use more than one year before the patent application is filed, then the patents would be invalid under section 102. Patentee did not disclose it. Under the old rule “reasonable examiner” standard, certainly these misrepresentations would be highly material and under the sliding scale they would be sufficient to show intent to deceive. Is it the intent of Therasense to not prohibit this behavior? The but-for causation is strong. It may be too easy now, under Therasense, to lie now and ask for forgiveness later. This is putting pressure on the integrity of the ex parte patenting process.

3. Apotex Inc. v. Cephalon

In Apotex Inc. v. Cephalon, the dispute in this case surrounds the validity and enforceability of Cephalon’s patented drug for sleep disorders, Provigil®, otherwise known as modafinil. Apotex sought approval to sell its generic version of Provigil® in an abbreviated new drug application (“ANDA”) for U.S. Food and Drug Administration (“FDA”) approval. Because defendant’s drug was still patented at the time of Apotex’s application, a technical infringement. Apotex filed a declaratory judgment that defendant’s patent was, inter alia, unenforceable.240

Plaintiff’s primary argument is defendant derived the patented invention from Lafon, a French company.241 Defendant does not dispute it received the drug from LaFon. Instead defendant argues the “invention” is appreciating that a smaller particle size of the drug improves bioavailability and dissolution, characteristics Lafon never appreciated.242 At trial, the court found Lafon “conducted numerous tests with batches of [active pharmaceutical ingredients] that fell within the claim limits,” and found these were effective in treating narcolepsy.243

To meet the conception requirements for invention, an inventor, to conceive a pharmaceutical compound must “know of its specific chemical structure, ha[ve] a method for making it, and appreciate[] that it has a utility.”244 Thus, here, Lafon was aware of the compounds specific structure, had a method for manufacturing it, and appreciated the compound’s utility in treating narcolepsy. Thus, Lafon is a true inventor.245 The court emphasized “patent law imposes certain fundamental conditions for patentability, paramount among them being the condition that what is

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240 Id. at *3.
241 Id. at *1.
242 Id. at *2. It should be noted that Cephalon purchased Lafon on December 28, 2001. Id. Lafon had discovered modafinil in 1976, but had not included any references to particle size. Id. Cephalon patented the RE’516, entitled “[Acetamide] Derivative Having Defined Particle Size.” Id. But, Cephalon had received the drug from Lafon, in particle sizes falling within the RE’516 claims from 1989–93. Id.
243 Id. at *18.
244 Id.
245 Id. at *19.
sought to be patented... be new." Here, Cephalon’s argument fails to take into account that the drug it claims to have invented was previously tested, manufactured, and used by Lafon for the treatment of narcolepsy. Cephalon did not even make a new form of the drug, it “in fact, did nothing to it at all.” Cephalon received, from Lafon, the claimed invention in the exact chemical properties as that which defendant patented. Consequently, the court found clear and convincing evidence Lafon communicated the invention to Cephalon prior to the application filing date, and thus derived the invention.

In applying *Therasense*, the court looked at both materiality and intent. The court found Cephalon failed to disclose Lafon’s prior art manufacturing and testing batches of the patented drug, modafinil, with characteristics, including particle size, that fell within the claim limitations. Cephalon also failed to disclose the agreement in which Lafon agreed to supply Cephalon the drug. Cephalon also failed to disclose Lafon’s test results and data concerning the small particle modafinil, which also demonstrated derivation. “Had the PTO been aware [of Lafon’s substantial role in Cephalon’s claimed invention], it would not have allowed the patent to issue.” Thus, the materiality prong was met.

As for the intent prong, there was no smoking gun showing specific intent to deceive. But, the court found the clear and convincing standard of intent to deceive was met because it was the “the single most reasonable inference.” The complete concealment of Lafon’s involvement in the development of the claimed invention “establishes Cephalon’s deception by clear and convincing evidence.” To further add to its deception, Cephalon mislead the PTO and stated it had modified the particle size, which had not been changed from the product Lafon had supplied. In this case, the new standards for inequitable conduct under *Therasense* are sufficient to appropriately address Cephalon’s misconduct.


In *Light Guard Sys., Inc. v. Spot Devices, Inc.* the plaintiff is assignee of a patent on a pedestrian crosswalk signal apparatus. Plaintiff alleges defendant is infringing and moves for a preliminary injunction to stop further sales of the allegedly infringing systems. Defendant argues the patent is invalid and

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246 Id.
247 Id. at *20.
248 Id.
249 Id. (“A party alleging invalidity for derivation must also prove by clear and convincing evidence that the invention conceived was communicated to the patentee prior to the date of the application.”).
250 Id. at *26.
251 Id. at *27.
252 Id.
253 Id.
unenforceable due to inequitable conduct because plaintiff failed to disclose a known material prior art reference, Kanasashi, during patent prosecution.\textsuperscript{255}

Under Therasense, the court evaluates whether patentee had specific intent to deceive in failing to disclose a known material reference. It is undisputed that plaintiff knew of the Kanasashi reference, the difference of opinion surrounds whether it was a material reference and whether there was intent to deceive.\textsuperscript{256}

As for materiality, the court, after evaluating the expert testimony, finds the Kanasashi reference is but-for material because the PTO would not have allowed a claim had it been aware of it.\textsuperscript{257} The court also emphasized a letter from plaintiff’s patent attorney identifying Kanasashi, and patentee’s brother who helped design the invention remarked Kanasashi was as a “major problem” as “the drawings show what appears to be exactly what we are trying to patent.”\textsuperscript{258} Despite the strong materiality of the reference, however, the court did not infer intent to deceive because it was plausible applicant thought the reference was cumulative.\textsuperscript{259} The defendant argued the single most reasonable inference Kanasashi was not submitted to the PTO was to deceive the patent examiner. The plaintiff argued it was equally plausible that there was no intent to deceive because the Kanasashi was in a foreign language and the translation received expressed a different structure from the claimed design. Thus, it was plausible the applicant believed the reference was cumulative of the art already submitted.\textsuperscript{260}

This case exposes the idea that a patentee can always claim it did not submit a reference because it was cumulative. But, whenever the reference meets the but-for materiality standard, arguing that applicant thought it was cumulative should be suspect. If the PTO would not have granted the patent if it had known about the reference, that flies in the face of the argument that the reference was cumulative as to what was already submitted. An applicant can always deny its intent to deceive. This concern is probably what gave rise to the now defunct sliding scale standard, where materiality was valued in terms of how it inferred an intent to deceive. It is just hard to believe there was no intent to deceive where a reference is but-for material and it is the only reference that was not disclosed when all other disclosed references would not have affected patentability. When it is proven the applicant knew of the reference, the intent threshold should not be so low as to just be able to escape liability by stating, “I thought it was cumulative.” If this happens, the pendulum has just swung the other way and inventors will be free to mislead and lie to the PTO. Over time, this will harm the integrity of the system.

\textsuperscript{255} Id. at *4.

\textsuperscript{256} Id. at *6 (mentioning a letter identifying Kanasashi as possible pertinent prior art).

\textsuperscript{257} Id.

\textsuperscript{258} Id.

\textsuperscript{259} Id. at *7.

\textsuperscript{260} Id.
V. Conclusion

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. Furthermore, with the AIA removing of all remnants of the phrase “intent to deceive” from the patent statute, it may be encouraging an intent to deceive or at the very least sending a signal that deception is no longer placed at a premium to enforce against.\textsuperscript{261} Because inequitable conduct has historically policed the integrity of the patent system, such drastic changes to the doctrine’s effectiveness may inevitably encourage deception before the PTO, or at a minimum, fail to discourage deception.\textsuperscript{262} Patent applicants who fail to disclose but-for material information before the PTO can completely correct their behavior through the new supplemental examination process and ask the PTO to consider, reconsider, or correct information not originally examined.\textsuperscript{263} Even though material fraud committed before the PTO may be referred to the Attorney General to pursue under 18 U.S.C. section 1001(a)(1), this statute has a five-year statute of limitations and thus may not be an effective policing mechanism.\textsuperscript{264} Even though excessive charging of inequitable conduct in almost every case had become a plague on the patent system, this extensive attack on the doctrine may have swung the pendulum too far in the other direction.\textsuperscript{265} Congress did leave open opportunities in the AIA section 12, the rule of construction, to further police misconduct.\textsuperscript{266} It is important to finally have discussions about what is required to preserve the integrity of the patenting process now that one of the levers to maintain that process has been weakened.

\textsuperscript{261} See supra Part III.
\textsuperscript{262} See supra Part IV.
\textsuperscript{263} See supra Part III.
\textsuperscript{264} See supra Part IV.
\textsuperscript{265} See supra Part I.
\textsuperscript{266} See supra Part III.