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“THERE’S A HOLE IN THE BUCKET:” THE EFFECTIVE ELIMINATION OF THE INEQUITABLE CONDUCT DOCTRINE

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ABSTRACT

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.

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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”⁷ 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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¹ *Therasense Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011).

² Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) [hereinafter AIA].

³ See 24 Fed. Reg. 10322, 10336–37 (Dec. 22, 1959) (codified at 37 C.F.R. § 1.56 (2011)).

⁴ See 35 U.S.C. § 102 (2006) (setting forth what is considered prior art).

⁵ See *Norton v. Curtiss*, 433 F.2d 779, 793–94 (C.C.P.A. 1970) (recognizing the necessary relationship of trust between applicants and the Patent Office requires expanding the types of misconduct courts must police).

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.⁹ 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.¹⁰ 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.”¹¹ This process has been coined a “patent amnesty program”¹² because it tolerates all but the most egregious forms of fraud on the PTO.¹³ 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.”¹⁴ In fulfilling its duty, Congress, since the country’s founding, has passed laws to encourage inventors to disclose their inventions publicly.¹⁵ For the social contract to work, inventors are granted an exclusive monopoly over their inventions for a period of years¹⁶ 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.¹⁷ Accordingly, disclosing patentable inventions, which are new and nonobvious advancements over what has come before,¹⁸ benefits society and future inventors.¹⁹

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

⁹ See *Therasense*, 649 F.3d at 1290.

¹⁰ See AIA, *supra* note 2, § 12; see also 35 U.S.C. § 257 (2006).

¹¹ *Id.*

¹² Jason Rantanen & Lee Petherbridge, *Toward a System of Invention Registration: The Leahy-Smith America Invents Act*, 110 MICH. L. REV. 24, 25 (2011).

¹³ *Id.*

¹⁴ U.S. CONST. art. I, § 8, cl. 8.

¹⁵ See Patent Act of 1790, ch. 7, § 1, 1 Stat. 109.

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.”).

¹⁷ See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1580 (2003).

¹⁸ 35 U.S.C. §§ 102–103 (authorizing new and nonobvious advances over the prior art to be patentable).

¹⁹ America Invents Act, H.R. REP. NO. 112-98, pt. 1, at 38 (2011) [hereinafter AIA Report].

patentability. The inventor (or patent applicant)²⁰ generally has the best information available to assist the patent examiner.²¹ 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”),²² has a “duty of candor and good faith” in dealing with the PTO.²³ In other words, the inventor is required to disclose any known prior art to help the PTO establish whether the invention is patentable.²⁴ Traditionally, patents obtained in bad faith, or through intentional misrepresentations or omissions are invalid or unenforceable.²⁵ 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.²⁶ The remedy for an inequitable conduct finding makes a patent entirely and utterly unenforceable.²⁷

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.²⁸ Tarnishing one patent with inequitable conduct could also spread to other related applications and patents, making them also unenforceable.²⁹ Promoting candor before the PTO is a worthy goal because it assists patent examiners in performing their duties more effectively.³⁰ 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.*

²⁵ *Precision Instrument Mfg. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 819 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250 (1944); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244–45 (1933); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988); *Norton*, 433 F.2d at 793.

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.

²⁹ *Id.* at 1288 (“[T]he taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family.”); see also *Cordis Corp. v. Boston Scientific Corp.*, 658 F.3d 1347, 1359 (Fed. Cir. 2011) (regarding the enforceability of two patents as “inextricably linked, with the enforceability of [one] patent a predicate issue necessary to our determination of the enforceability of the [other] patent”); *The Duty of Candor Under Rule 56 and the Evolution of Proposed Rule 57: The Doctrine of Inequitable Conduct and The Duty of Candor in Patent Procurement: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 76 (1988) [hereinafter AIPLA Committee Paper] (“Fraudulent procurement could even render claims in related patents unenforceable.”).

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 *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”⁴⁰ 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 *Burlington*, 849 F.2d at 1422; *see also* 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 *Therasense*, 649 F.3d at 1289.

³³ *Id.* at 1290.

³⁴ *See* AIA Report, *supra* note 19, at 28–29; *see Therasense*, 649 F.3d at 1288.

³⁵ *Therasense*, 649 F.3d at 1288.

³⁶ *Id.* at 1276.

³⁷ *Id.* at 1290.

³⁸ 35 U.S.C. § 257; AIA Report, *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.

Id.

³⁹ *See* Rantanen & Petherbridge, *supra* note 12, at 24.

⁴⁰ *See Therasense*, 649 F.3d at 1288.

it is not tenable to police while seeking to protect the future.⁴¹ The forgiveness is what heals the past and reconciles it with moving forward peacefully.⁴² There is generally a cut-off date,⁴³ 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.⁴⁴ Instead the focus was on ending the apparent litigation abuses by charging inequitable conduct in almost every case.⁴⁵ 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.⁴⁶ 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.⁴⁷ 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.⁴⁸ This paper serves to motivate future

⁴¹ See AMNESTY COMMITTEE, *Legal Basis of the Amnesty Process*, in VOL. 6 TRUTH AND RECONCILIATION COMMISSION OF SOUTH AFRICA 1, 4 (2003).

⁴² *Id.* at 90.

⁴³ *Id.*

⁴⁴ See Thomas F. Cotter, *An Economic Analysis of Patent Law’s Inequitable Conduct Doctrine*, 53 ARIZ. L. REV. 736, 740 (2011).

⁴⁵ AIA Report, *supra* note 19, at 50.

Critics of the inequitable conduct defense, including the National Academies and the Federal Trade Commission, argue that our patent system is hampered by provisions that require courts to divine the difficult-to-prove subjective intent of individuals in patent disputes. And most defendants reflexively plead inequitable conduct as a defense to infringement, prompting the Federal Circuit to label the practice a ‘plague’ on the patent system.

Id.

⁴⁶ See *id.*

⁴⁷ *Id.*

⁴⁸ *Larson Mfg. Co. of South Dakota v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1327 (Fed. Cir. 2009) (“[I]nequitable 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.⁴⁹ 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.”⁵⁰ At that time, mere gross negligence in failing to disclose material information to the PTO was grounds for an inequitable conduct finding.⁵¹

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.”⁵² 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.”⁵³ 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.⁵⁴

In 1988, the Federal Circuit began an attempt to fix the aforementioned problems by restoring the intent standard required to prove inequitable conduct.⁵⁵ In *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*,⁵⁶ 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.⁵⁷ But, the applicant incorrectly listed claim 43 as corresponding to allowed claim 50 in the parent application.⁵⁸ Instead, claim 43 actually corresponded to the unamended claim 50, which was rejected for indefiniteness under section 112.⁵⁹ The text of the unamended claim, however, was included in the patent unchanged.⁶⁰

The trial court found the applicant’s misrepresentation material, as it should have been allowed only after being amended.⁶¹ 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.”⁶² 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.⁶³ 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.⁶⁴ 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.”⁶⁵ 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.⁶⁶ 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.”⁶⁷ To clarify conflicting precedent, the Federal Circuit held gross negligence, alone, does not infer an intent to deceive.⁶⁸ To make a determination on whether the intent prong is met,

⁵⁴ *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.”⁶⁹

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.”⁷⁰ Instead, courts began using the materiality standard as a way to expand the reach of the inequitable conduct doctrine.⁷¹ 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.’”⁷² 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.⁷³ In other words, materiality had swallowed up the intent analysis.⁷⁴ 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.⁷⁵ As the sliding scale focused more on materiality than intent, five standards of materiality began to emerge:⁷⁶

⁶⁹ *Id.*

⁷⁰ *Therasense Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011).

⁷¹ *See id.* (“In the past, this court has tried to address the proliferation of inequitable conduct charges by raising the intent standard alone.”).

⁷² *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006).

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 pa[t]ent 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:

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.*

evidence.”⁹² The court emphasized that where “multiple inferences may be drawn, intent to deceive cannot be found.”⁹³

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.⁹⁴ 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.⁹⁵ 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.”⁹⁶ 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.⁹⁷ In other words, the court is to “apply the preponderance of the evidence standard and give claims their broadest reasonable construction.”⁹⁸ 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.⁹⁹ 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.¹⁰⁰

In *Therasense*, the court posits that adding the but-for requirement will add some proportionality to the remedy for inequitable conduct.¹⁰¹ So, instead of any minor misconduct creating unenforceability for the entire patent, this would only occur where a claim is unwarranted.¹⁰² 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.¹⁰³

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

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 (“[I]t 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.¹⁰⁴ 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.¹⁰⁵ In *Keystone Driller Co. v. Gen. Excavator Co.*,¹⁰⁶ the patentee bribed a prior inventor to say he abandoned the invention when he had not.¹⁰⁷ The patentee conspired with the prior inventor to suppress evidence of prior use to lessen the chance the patent would be invalidated.¹⁰⁸ In *Hazel-Atlas Glass Co. v. Hartford-Empire*,¹⁰⁹ 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.¹¹⁰ After submitting this article to the PTO, the patent was granted.¹¹¹ Patentee later sued Hazel-Atlas for patent infringement.¹¹² At trial, the patent was found not infringed.¹¹³ On appeal, patentee drew attention to the ill-gotten article and the court overturned the trial court, finding infringement.¹¹⁴ In *Precision Instrument Mfg. v. Automotive Maintenance Machinery*,¹¹⁵ 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 . . ." ¹¹⁶ Instead of disclosing the perjury, patentee entered into a settlement agreement with the prior inventor and suppressed the evidence of perjury.¹¹⁷ Then, patentee enforced its patent against alleged infringers, knowing it was ill-gotten.¹¹⁸

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,¹¹⁹ the Court denied relief for any claimed infringement of the patent procured in the pertinent action.¹²⁰ In other words, the

¹⁰⁴ *Id.*

¹⁰⁵ See *Precision Instrument Mfg. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 806 (1945); *Hazel-Atlas Glass v. Hartford-Empire Co.*, 322 U.S. 238, 238 (1944); *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933).

¹⁰⁶ *Keystone*, 290 U.S. at 240.

¹⁰⁷ *Id.* at 243.

¹⁰⁸ *Id.*

¹⁰⁹ *Hazel-Atlas Glass*, 322 U.S. at 238.

¹¹⁰ *Id.* at 240–42.

¹¹¹ *Id.* at 240–41.

¹¹² *Id.* at 241.

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Precision Instrument Mfg. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 806 (1945).

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.").

¹²⁰ See, e.g., *Precision Instrument*, 324 U.S. at 819 ("Such inequitable conduct impregnated [plaintiff's] entire cause of action and justified dismissal by resort to the unclean hands doctrine."); *Hazel-Atlas Glass v. Hartford-Empire Co.*, 322 U.S. 238, 250 (1944) ("The total effect of all this fraud . . . calls for nothing less than a complete denial of relief . . . for the claimed infringement . . ."); *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 247 (1933) (holding plaintiffs did not come into court with clean hands).

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

¹²¹ *Therasense Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011).

¹²² *Id.* at 1292.

¹²³ *But see* 77 Fed. Reg. 3666, 3667 (Jan. 25, 2012) (to be codified at 37 C.F.R. § 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 . . . *Therasense* . . .”).

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.”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”¹³² This is what has been called in effect a “patent amnesty program.”¹³³

There are exceptions to this estoppel provision, however.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.¹³⁵ But for both exceptions, it is worth noting the patentee has great control over whether these exceptions would apply.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.¹³⁷ The Declaratory Judgment Act¹³⁸ does not provide an independent basis for jurisdiction in federal court; it only provides a remedy.¹³⁹ Only the patentee’s actions can trigger declaratory judgment jurisdiction.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.¹⁴¹

To combat “material fraud”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).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

¹³¹ AIA Report, *supra* note 19, at 31.

¹³² AIA, § 12 (to be codified 35 U.S.C. § 257(c)(1)).

¹³³ Rantanen & Petherbridge, *supra* note 12 at 25.

¹³⁴ AIA, § 12 (to be codified 35 U.S.C. § 257(c)(2)).

¹³⁵ *Id.*

¹³⁶ *See* Rantanen & Petherbridge, *supra* note 12, at 25.

¹³⁷ 35 U.S.C. § 282 (2006) (listing noninfringement, invalidity and unenforceability as affirmative defenses).

¹³⁸ 28 U.S.C. § 2201 (2006)

¹³⁹ *Cat Tech L.L.C. v. TubeMaster, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008).

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).

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).

¹⁴² *But see* 77 Fed. Reg. 3666, 3667 (Jan. 25, 2012) (to be codified at 37 C.F.R. § 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 . . . *Therasense* . . .”).

¹⁴³ AIA, § 12 (to be codified 35 U.S.C. § 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,

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).

¹⁵⁰ *Performance and Accountability Report FY 2011*, U.S. PAT. & TRADEMARK OFF. (2011), <http://www.uspto.gov/about/stratplan/ar/2011/USPTOFY2011PAR.pdf>.

¹⁵¹ *Id.* at 14.

¹⁵² AIA, § 12 (to be codified 35 U.S.C. § 257(f)).

antitrust or unfair trade practices,¹⁵³ or limit the authority of the Director to investigate misconduct and impose sanctions,¹⁵⁴ or restrain the Director from issuing regulations to sanction misconduct by those authorized to practice before the PTO.¹⁵⁵

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”¹⁵⁶ 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.¹⁵⁷ 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*.¹⁵⁸ 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 \$5180.¹⁵⁹ If *ex parte* reexamination is ordered, the fee is an additional \$16,120.¹⁶⁰ This compares to the cost of *ex parte* reexamination, before the proposed changes, of \$2520.¹⁶¹ If enacted, these fees will increase the cost by tenfold.¹⁶² But, in exchange, a patentee can maintain the enforceability of its patent.¹⁶³

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),¹⁶⁴ 251(a),¹⁶⁵ and 256.¹⁶⁶ The Savings Clause found in section 115(h)(3) makes

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)).

¹⁵⁶ *Therasense Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1292 (Fed. Cir. 2011).

¹⁵⁷ *Id.*

¹⁵⁸ 77 Fed. Reg. 3666, 3667 (Jan. 25, 2012) (to be codified at 37 C.F.R. § 1). [hereinafter *Supplemental Examination Provisions*].

¹⁵⁹ *Id.* at 3668.

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ Gregory VNovak, *Concurrent Reexaminations as a Strategic Patent Litigation Defense Tool*, in PATENT LITIGATION 2009, at 661, 663 (PLI Pats., Copyrights, Trademarks, & Literary Prop., Course Handbook Ser. No. 982, 2009), available at WL, 982 PLI/Pat 661.

¹⁶⁴ 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, of through error an inventor is not names 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.*

¹⁶⁵ 35 U.S.C. § 251. Reissue of defective patents (a) removed “without any deceptive intention” language and allows patents to be reissued “[w]henver 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*

A. *Powell v. Home Depot U.S.A., Inc.: A Federal Circuit Case Since 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 special¹⁷⁶ 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.

¹⁶⁷ 35 U.S.C. § 115(h)(3).

¹⁶⁸ 18 U.S.C. §§ 1001, 3282 (2006).

¹⁶⁹ AIPLA Committee Paper, *supra* note 29, at 74–75.

¹⁷⁰ *Contra Supplemental Examination Provisions*, *supra* note 158, at 3667.

¹⁷¹ *Powell v. The Home Depot U.S.A., Inc.*, 663 F.3d 1221 (Fed. Cir. 2011).

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.¹⁷⁸ 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.¹⁷⁹ After the patent issued, Powell sued Home Depot for patent infringement.¹⁸⁰ Home Depot alleged Powell committed inequitable conduct when he failed to update his petition.¹⁸¹

The trial court found Powell, with intent to deceive, failed to disclose to the PTO he no longer had an obligation to manufacture.¹⁸² 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.¹⁸³ On appeal, the Federal Circuit affirms the trial court applying the new standards in *Therasense*.¹⁸⁴ 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."¹⁸⁵ 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.'"¹⁸⁶

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 *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."¹⁸⁷ 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 *Powell*, the trial court did find an intent to deceive.¹⁸⁸

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

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Id.* at 1228.

¹⁸¹ *Id.* at 1234.

¹⁸² *Id.* at 1235.

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

special were considered material when the petition would not have been granted, but-for the misstatement.¹⁸⁹ 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.”¹⁹⁰ 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.¹⁹¹ 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*.¹⁹²

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*.¹⁹³

B. District Court Cases Since *Therasense*

1. *Metris U.S.A. Inc., v. Faro Techs., Inc.*¹⁹⁴

The two patents comprising the inventions use scanning technology to create accurate three-dimensional digital models of physical objects.¹⁹⁵ Patentee sued

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.

¹⁹² *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

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

¹⁹⁴ *Metris U.S.A., Inc., v. Faro Techs., Inc.*, No. 08-CV-11187, 2011 WL 434682 (D. Mass. Sept. 19, 2011).

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

¹⁹⁵ *Id.* at *1.

¹⁹⁶ *Id.*

¹⁹⁷ *Metris U.S.A. v. Faro Techs., Inc.*, 768 F. Supp. 2d 338 (D. Mass. 2011).

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).

²⁰¹ *Metris*, 2011 WL 434682, at *2.

²⁰² *Metris*, 768 F. Supp. 2d at 357.

[W]here 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.

²⁰³ *Metris*, 2011 WL 434682, at *3.

²⁰⁴ *Id.*

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

In addition to the changes made by *Therasense*, the AIA amends the provisions regarding inventorship and correction of inventorship.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.²¹⁰ If an inventor were omitted, with deceptive intent, the error could not be cured and the patent was void.²¹¹ Under the AIA, the language “without any deceptive intent” has been removed.²¹² Now, any error in identifying inventors may not be the basis of invalidating a patent²¹³ or make the patent unenforceable.²¹⁴

²⁰⁵ *Id.* at *4.

²⁰⁶ *Id.*

²⁰⁷ *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).

²⁰⁸ *Id.*

²⁰⁹ 35 U.S.C. §§ 115, 256 (2006).

²¹⁰ 35 U.S.C. § 256.

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 *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.

Id. (emphasis added).

²¹¹ *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 . . .”).

²¹² AIA, *supra* note 2, § 20(f)(1)–(2) (to be codified 35 U.S.C. § 256).

Correction. Whenever error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent, 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.

Id. (note removal of “without deceptive intention” language).

²¹³ *Id.* at § 20(f)(1)–(2) (to be codified 35 U.S.C. § 256).

(b) Patent valid if error corrected. The error of omitting inventors or naming persons who are not inventors *shall not invalidate the patent* in which such error occurred if it can be corrected as provided in this section . The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

Id. (emphasis added).

²¹⁴ *Id.* at § 4(a)(1) (to be codified 35 U.S.C. § 115 (h)(3)).

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 1001²¹⁸ by fine, not more than five years imprisonment, or both.²¹⁹ 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

(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.

²¹⁵ AIA Report, *supra* note 19, at 43 (discussing increasingly high percentages of patent applications being filed by corporate assignees); Jerry C. Liu, *Overview of Patent Ownership Considerations in Joint Technology Development*, 2005 SYRACUSE SCI. & TECH. L. REP. 1 (2005).

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

²¹⁷ See 35 U.S.C. § 256; see AIA, *supra* note 2, § 4(a)(1) (to be codified, 35 U.S.C. § 115 (2012)).

²¹⁸ 18 U.S.C. § 1001.

(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.

²¹⁹ 35 U.S.C. § 115(i).

(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(n)(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

2. *Jersey Asparagus Farms, Inc. v. Rutgers Univ.*

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 Process*²²³ 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

Inc. v. Faro Rechs, Inc., No. 08-CV-11187, 2011 WL 434682 (D. Mass. Sept. 19, 2011) (stating the patent was granted in 1997).

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. Ouickturn 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).

²²² 803 F. Supp. 2d 295 (D.N.J. 2011).

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.²²⁹ 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.²³⁰ 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.”²³¹

The court agreed with defendants, that the patents themselves indicate prior uses were disclosed to the PTO.²³² 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.²³³ 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.²³⁴ 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.²³⁵

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.²³⁶ “[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.”²³⁷ 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.²³⁸ If there is a sale or

the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States

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*,²³⁹ 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

Determining When Patent Misuse Should be Applied, 11 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 671 (2001).

²³⁹ *Apotex Inc. v. Cephalon*, No. 06-cv-2768, 2011 WL 6090696 (E.D. Pa, Nov. 7, 2011).

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.”²⁴⁶ 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.”²⁴⁷ Cephalon received, from Lafon, the claimed invention in the exact chemical properties as that which defendant patented.²⁴⁸ 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.²⁴⁹

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.”²⁵⁰ 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.”²⁵¹ The complete concealment of Lafon’s involvement in the development of the claimed invention “establishes Cephalon’s deception by clear and convincing evidence.”²⁵² To further add to its deception, Cephalon misled the PTO and stated it had modified the particle size, which had not been changed from the product Lafon had supplied.²⁵³ In this case, the new standards for inequitable conduct under *Therasense* are sufficient to appropriately address Cephalon’s misconduct.

4. *Light Guard Sys., Inc. v. Spot Devices, Inc.*

In *Light Guard Sys., Inc. v. Spot Devices, Inc.*,²⁵⁴ 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

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.*

²⁵⁴ *Light Guard Sys., Inc. v. Spot Devices, Inc.*, No. 3:10-CV-0737, 2011 WL 3022530 (D. Nev., July 22, 2011).

unenforceable due to inequitable conduct because plaintiff failed to disclose a known material prior art reference, *Kanasashi*, during patent prosecution.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.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.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.”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.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.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.

²⁵⁵ *Id.* at *4.

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

²⁵⁷ *Id.*

²⁵⁸ *Id.*

²⁵⁹ *Id.* at *7.

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.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.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.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.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.²⁶⁵ Congress did leave open opportunities in the AIA section 12, the rule of construction, to further police misconduct.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.

²⁶¹ See *supra* Part III.

²⁶² See *supra* Part IV.

²⁶³ See *supra* Part III.

²⁶⁴ See *supra* Part IV.

²⁶⁵ See *supra* Part I.

²⁶⁶ See *supra* Part III.