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IDS PRACTICE AFTER THERASENSE AND THE AIA: DECOUPLING THE LINK BETWEEN INFORMATION DISCLOSURE AND INEQUITABLE CONDUCT

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ABSTRACT

An essential element of filing and prosecuting a patent application in the United States is the duty to disclose material information to the United States Patent and Trademark Office (“Patent Office”) under 37 C.F.R. § 1.56 (Rule 56). The failure to disclose information can result in a later ruling of inequitable conduct and unenforceability of the patent. The Federal Circuit’s en banc decision in Therasense heightened the “materiality” and “intent” standards for finding inequitable conduct, but there has been much uncertainty in the patent community regarding the future of the duty of disclosure under Rule 56. The majority in Therasense theorized that curing the “plague” of inequitable conduct would solve the over-disclosure problem faced by the Patent Office. Others, including the dissent in Therasense, have argued that without the threat of inequitable conduct, patent applicants and practitioners will ignore their duty to disclose and that the information gap between the Patent Office and applicants will widen and result in impaired patent quality. The supplemental examination provision in the America Invents Act (AIA), which is the legislative cure for the proliferation of inequitable conduct charges, has heightened the concern among critics that information submission to the Patent Office will dwindle.

The Therasense Court’s answer to the over-disclosure problem and the concerns raised by critics are premised on the notion that inequitable conduct and the duty of disclosure always go in tandem. However, inequitable conduct and the duty of disclosure are not inseparably tied, and changes in the inequitable conduct landscape may not have a significant effect on information disclosure practice before the Patent Office. First, despite the tightening of the inequitable conduct standard, information submission to the Patent Office will likely not decrease from the pre-Therasense level, because there are many other incentives within the patent system for applicants and practitioners to continue to err on the side of over-disclosure. Second, supplemental examination will not sound the death knell for the duty of disclosure, because patentees are not likely to use this provision to purge willful omissions or misrepresentations from the examination record. And third, over-disclosure is likely to remain a problem for the Patent Office and needs to be addressed in other ways. The Article concludes with suggestions for the Patent Office to consider in order to rein in over-disclosure, while encouraging applicants and practitioners to be forthcoming with information relevant to patent examination.
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I. INTRODUCTION

The Code of Federal Regulations, at 37 C.F.R. § 1.56, also known as Rule 56,\(^1\) establishes a duty of candor and good faith in dealing with the United States Patent and Trademark Office (hereinafter “Patent Office”). The duty of candor and good faith encompasses a duty to disclose to the Patent Office all information known to be material to patentability and examination of an application (popularly known as the “duty of disclosure”). The duty of disclosure attaches to each individual who is involved with the preparation, filing and/or prosecution of the patent application.\(^2\) Rule 56 is intended to improve the quality of examination and the validity of patents,\(^3\) but its influence is not limited to patent applications and the examination process. Rule 56 has long guided the determination of the materiality prong of the inequitable conduct defense,\(^4\) which has had far-reaching effects in patent litigation. A finding of inequitable conduct can render the patent and potentially an entire patent family unenforceable.\(^5\) Referring to the sweeping effects of

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\(^1\) 37 C.F.R. § 1.56(a) (1992) (“A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability. . . . [N]o patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.”).

\(^2\) Id.

\(^3\) See Rene D. Tegtmeyer, The Patent and Trademark Office View of Inequitable Conduct or Attempted Fraud in the Patent and Trademark Office, 16 AIPLA Q.J. 88, 88 (1998) (quoting former Assistant Commissioner of the Patent Office that “[t]he purpose of the duty of disclosure requirement, as the Patent and Trademark Office (PTO) views it, is to improve the quality of examination and the validity of patents by assuring that material information is called to the examiner’s attention and considered in the patent examining process.”); see also Christopher A. Cotropia, Modernizing Patent Law’s Inequitable Conduct Doctrine, 24 BERKELEY TECH. L.J. 723, 733 (2009).

\(^4\) Christian Mammen, Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct, 24 BERKELEY TECH. L.J. 1329, 1334 (2009); 76 Fed. Reg. 43632 (July 21, 2011) (“Historically, the Federal Circuit connected the materiality standard for inequitable conduct with the PTO’s materiality standard for the duty of disclosure. That is, the Court has invoked the materiality standard for the duty of disclosure to measure materiality in cases raising claims of inequitable conduct. In doing so, the Court has utilized both the ‘reasonable examiner’ standard set forth in the 1977 version of § 1.56(b) and current § 1.56(b) promulgated in 1992.”) (citing Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1363 (Fed. Cir. 1984); Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Inc., 394 F.3d 1348, 1352–53 (Fed. Cir. 2005)).

a finding of inequitable conduct, Chief Judge Rader, writing for the majority in *Therasense, Inc. v. Becton, Dickinson & Co.*, famously called the doctrine of inequitable conduct the “atomic bomb” of patent law. Furthermore, an allegation of inequitable conduct forms “a dark cloud over the [litigated] patent’s validity,” increases overall litigation costs, discourages settlements, portrays the patentee as a “bad actor,” and can destroy the reputation of patent prosecutors.

Due to the potential windfalls and lack of disincentives for alleging inequitable conduct, defendants in patent infringement suits routinely use this defense as a part of their litigation strategy. The United States Court of Appeals for the Federal Circuit (“Federal Circuit”) has long recognized this problem, prompting Judge Nichols in *Burlington Industries, Inc. v. Dayco Corp.*, to call it an “absolute plague” upon the patent litigation system.

Proliferation of inequitable conduct charges have led patent applicants and practitioners to err on the side of over-disclosure in their Information Disclosure Statement (IDS) practices,

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6 649 F.3d 1276 (Fed. Cir. 2011).
7 *Therasense*, 649 F.3d at 1288; see also *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).
9 *Therasense*, 649 F.3d at 1289 (“One study estimated that eighty percent of patent infringement cases included allegations of inequitable conduct. Inequitable conduct ‘has been overplayed, is appearing in nearly every patent suit, and is cluttering up the patent system.’”) (citations omitted); Kevin Mack, *Note, Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147, 155–56 (2006) (noting that the inequitable conduct defense is adjudicated in sixteen to thirty-five percent of all infringement cases that make it to trial and inferring that the percentage of cases in which defendants plead inequitable conduct, but do not make it to trial, is substantially higher).
10 849 F.2d 1418 (Fed. Cir. 1988).
11 *Burlington*, 849 F.2d at 1422 (“[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client’s interests adequately, perhaps.”) (emphasis added).
12 It is widely accepted that the drastic consequences of inequitable conduct finding motivates applicants and practitioners to submit any reference that has the slightest connection to the invention, which causes detrimental information overload and hurts patent quality. *See*, e.g., Cotropia, * supra* note 3, at 768 (“The most common method of overcomplying under the current legal regime is to submit everything of even remote relevance in one’s possession to the USPTO.”); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 315 (2001) (“Where the applicant is already well informed of the prior art, the
which some argue reduces the quality of patent examination. The *Therasense* Court expressed concern that the specter of inequitable conduct allegations has caused many patent applicants and practitioners to overflow the Patent Office with a “deluge of prior art references, most of which have marginal value,” to avoid inequitable conduct allegations. The Court further noted that over-disclosure puts unnecessary strain on the Patent Office’s limited examining resources, increases backlog, and ultimately hurts the quality of patents issued by the Office.

Recognizing the problems created by the expansion and overuse of the inequitable conduct doctrine, the Federal Circuit sought to address the issue *en banc* in *Therasense* with an eye towards curing the “plague” of inequitable conduct. It is far too early to tell whether the standards articulated in *Therasense* will restrain the proliferation of inequitable conduct charges, and consequently reduce the incentive for patent applicants to inundate the Patent Office with marginally relevant information. Despite such efforts, there remain many detractors, including the dissent in *Therasense*, who argue that without the threat of inequitable conduct, patent applicants and practitioners will have no incentive to comply with the Rule 56 duty of disclosure.

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13 See Cotropia, supra note 3, at 770-772.
14 *Therasense*, 649 F.3d at 1289 (The Court expressed concern that the pre-*Therasense* inequitable conduct doctrine required patent applicants to over-disclose, resulting in a flood of references with questionable materiality. The Court’s opinion shows that the relationship between inequitable conduct and over-disclosure was effectively advocated by *amici* (citing the briefs submitted by the United States and the Biotechnology Industry Organization)).
15 Id. at 1290 (“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.”).
16 See id. (“This court [] tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”).
17 *Therasense*, 649 F.3d at 1306 (Bryson, J., dissenting) (“It is unrealistic to expect that other means will provide an effective deterrent to ensure that material information will not be withheld during patent prosecutions. The PTO advises us that the prospect of enforcing the duty of disclosure other than through the threat of inequitable conduct claims is not possible or practical.”); Jason Rantanen & Lee Petherbridge, *Therasense v. Becton Dickinson: A First Impression* 14-15 (U Iowa Legal Studies Research Paper No. 11-38; Loyola-LA Legal Studies Paper No. 2012-02, 2011), available at http://ssrn.com/abstract=1859764; see Zhe Peng et al., supra note 8, at 398.
AIA’s supplemental examination provision, also designed to reduce inequitable conduct charges, has heightened the concern that information submission to the Patent Office will decrease substantially and impair the quality of patents.\(^\text{18}\)

The common belief among the Therasense majority and the critics of inequitable conduct reform is that inequitable conduct and information disclosure are inseparably tied. This logic, as argued below, is flawed because inequitable conduct and information disclosure to the Patent Office are not always tied together.

First, information disclosure to the Patent Office will probably not decrease from the pre-Therasense level because there are many factors, aside from the fear of inequitable conduct allegation, that incentivize patent applicants and practitioners to bring prior art references to the attention of the Patent Office. For instance, such submissions bolster a patent against post-issuance challenges at the Patent Office and strengthen the presumption of validity that attaches to an issued patent. These factors will continue to serve as incentives for patent applicants and practitioners to bring material (and perhaps even marginally relevant information) to the attention of the Patent Office during prosecution. The “egregious misconduct” caveat in Therasense, and the uncertainty surrounding the type of affirmative act that is likely to rise to the level of egregious misconduct, will highly motivate patent applicants and practitioners to adhere to their pre-Therasense diligence in submitting information to the Patent Office. Specifically, the practice of over-disclosing is often less risky and more cost-effective to an applicant than determining the materiality of all known references. Since at present there are no disincentives to over-disclosure in the U.S. patent system, many applicants and practitioners will simply continue with their pre-

Therasense IDS practices instead of taking on the added costs and risks associated with subjectively evaluating the materiality of each and every known prior art reference.

Second, the AIA’s supplemental examination is not likely to change the amount and quality of information disclosure to the Patent Office. It is highly doubtful that patent applicants or practitioners will purposefully misrepresent or withhold relevant information during prosecution, and then present the same information to the Patent Office after issuance via the supplemental examination provision. A patentee will have very little to gain from such deceitful behavior, particularly because of the high likelihood of ex parte reexamination being prompted by a supplemental examination request and the risks associated with reexamination. The fraud provision in supplemental examination and the cost associated with this process will certainly deter misuse or overuse of this provision, particularly abuse of the provision to cure knowing and deliberate omissions during the initial examination.

Lastly, it seems highly unlikely that the changes in the inequitable conduct landscape, as a result of Therasense and supplemental examination, will stem the overflow of information to the Patent Office, particularly because the costs and risks associated with under-disclosure are very high compared to that of over-compliance with the duty of disclosure. The problem of over-disclosure is likely to continue unabated unless addressed by the Patent Office in other ways. This Article proposes some changes to the Information Disclosure Statement (IDS) requirements of the Patent Office to discourage over-disclosure, limit undue strain on the examination resources of the Patent Office, and improve the quality of patents.

II. INEQUITABLE CONDUCT AND THE DUTY OF DISCLOSURE: RECENT DEVELOPMENTS

Part II of this Article first explores the evolution of the law of inequitable conduct, with a particular focus on post-Therasense Federal Circuit cases that help to clarify the current standards
for materiality and intent required for finding inequitable conduct. Second, the amendments to Rule 56 that have been proposed by the Patent Office following the Therasense decision are discussed. And finally, the supplemental examination provision of the AIA, which is likely to have a substantial impact on inequitable conduct litigation, is considered.

A. THE LAW OF INEQUITABLE CONDUCT\(^{19}\)

Inequitable conduct is a judicially created defense to patent infringement that evolved from the equitable doctrine of unclean hands.\(^{20}\) Thus, inequitable conduct requires inequity arising from a patentee's actions or deliberate omissions before the Patent Office in the course of obtaining a patent.\(^{21}\) The next few sections of this Article address the law of inequitable conduct before the landmark Therasense decision, the new standards for materiality and intent promulgated in Therasense, and the post-Therasense Federal Circuit cases addressing the issue of inequitable conduct.

1. INEQUITABLE CONDUCT DOCTRINE BEFORE THERASENSE

To successfully assert the defense of inequitable conduct, an alleged infringer must show that the patentee “(1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive” the

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\(^{20}\) Mammen, *supra* note 4, at 1333; see Precision Instrument Mfg. v. Automotive Maintenance Mach. Co., 324 U.S. 806, 814 (1945) (discussing that the doctrine of unclean hands evolved from requirements of conscience and good faith, and gives a court of equity discretion to close its doors to claimants who are tainted with inequitableness or bad faith).

\(^{21}\) 4 Annotated Patent Digest (Matthews) § 27:58 (2012); Cotropia, *supra* note 3, at 733-35 (discussing the requirements of the inequitable conduct doctrine).
Patent Office during prosecution of the patent application.\textsuperscript{22} If the court determines that the threshold levels of both materiality and intent are met, then the court must balance materiality and intent “with a greater showing of one factor allowing a lesser showing of the other.”\textsuperscript{23} In other words, the court could equitably balance the intent and materiality showings to determine whether the patentee’s conduct was sufficiently culpable to warrant rendering the entire patent unenforceable.\textsuperscript{24} Under the balancing test, courts assessed inequitable conduct using a “sliding scale” of intent and materiality, which created a legal notion that a reduced showing of intent could be offset by a strong showing of materiality and vice versa. The “sliding scale” doctrine blurred the fact that materiality and intent are separate elements, and that threshold levels for both of these elements must be established by the party alleging inequitable conduct. Because it is usually difficult to find smoking-gun evidence of intent to deceive, the lowered standard for intent made inequitable conduct allegations very attractive to defendants.

With \textit{Kingsdown Med. Consultants, Ltd. v. Hollister Inc.},\textsuperscript{25} the Federal Circuit attempted to stem the growing tide of inequitable conduct cases. The \textit{Kingsdown} Court overturned prior precedent which held that a showing of “gross negligence” was sufficient to meet the intent to deceive prong of inequitable conduct, and instead established a “sufficient culpability” standard.\textsuperscript{26} Nevertheless, proliferation of the inequitable conduct defense has proven difficult to control, particularly over the last decade, due to several post-\textit{Kingsdown} Federal Circuit decisions that gradually chipped away at the “sufficient culpability” standard and reduced it to a mere “should

\textsuperscript{22} Star Scientific, Inc. v. R. J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008) (citation omitted).
\textsuperscript{24} See Monsanto Co. v. Bayer BioScience N. V., 363 F.3d 1235, 1239 (Fed. Cir. 2004).
\textsuperscript{25} 863 F.2d 867 (Fed. Cir. 1988).
\textsuperscript{26} \textit{Kingsdown}, 863 F.2d at 876 (“We adopt the view that a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive; the involved 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.”) (citing Norton v. Curtiss, 433 F.2d 779, 167 USPQ 532 (CCPA 1970)).
have known” standard, which is arguably a lower standard than the pre-Kingsdown “gross negligence” standards. For instance, in *Ferring B. V. v. Barr Labs., Inc.*, the court held that a patentee’s failure to disclose his prior business relationship with declarants (who provided affidavits in support of patentability during prosecution) was a material misrepresentation to the Patent Office, and since the applicant “knew or should have known” that the undisclosed relationship was material, the intent to deceive prong was also satisfied.

The materiality standard for finding inequitable conduct also flip-flopped considerably since Kingsdown. Even though Rule 56 had been modified following Kingsdown to replace the “reasonable examiner” standard with a more objective set of rules, the Federal Circuit resurrected the pre-1992 “reasonable examiner” standard in *Digital Control*. Then in *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, decided a year after *Digital Control*, the Federal Circuit held that the rejection of claims during prosecution of one patent is material to the prosecution of a co-pending application if “a reasonable Examiner would substantially likely consider [such information] important in deciding whether to allow an application to issue as a patent.” And if there was any uncertainty left after *Digital Control* and *McKesson*, the Federal Circuit clarified in *Star Scientific* that the “reasonable examiner” test was the controlling standard for materiality.

The vague and inconsistently defined standards for materiality and intent since Kingsdown, combined with the powerful remedy incentives, resulted in overuse of the inequitable conduct

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27 Mammen, supra note 4, at 1331; see, e.g., Bristol-Myers Squibb Co. v. Rhône-Poulenc Rorer, Inc., 326 F.3d 1226, 1239-40 (Fed. Cir. 2003) (“[W]here withheld information is material and the patentee knew or should have known of that materiality, he or she can expect to have great difficulty in establishing subjective good faith sufficient to overcome an inference of intent to mislead.”) (emphasis added).

28 437 F.3d 1181 (Fed. Cir. 2006).

29 *Ferring*, 437 F.3d at 1188, 1190-91.

30 *Digital Control*, 437 F.3d at 1316 (stating that the “reasonable examiner” standard should continue to exist as one of the tests for materiality).

31 487 F.3d 897 (Fed. Cir. 2007).

32 *McKesson*, 487 F.3d at 913 (citation omitted).

33 *Star Scientific*, 537 F.3d at 1367 (reciting only the “reasonable examiner” standard for materiality).
defense.\textsuperscript{34} The expansion of the doctrine in turn fueled over-compliance with the duty of disclosure, resulting in detrimental information overload on the Patent Office.\textsuperscript{35}

2. INEQUITABLE CONDUCT UNDER \textit{THERASENSE}

Citing the ubiquity of the inequitable conduct defense and its far-reaching consequences on both patent prosecution and litigation, the Federal Circuit sitting \textit{en banc} in \textit{Therasense}, addressed the issue of inequitable conduct charges that have been “overused to the detriment of the public.”\textsuperscript{36}

The \textit{Therasense} Court raised the standard for finding inequitable conduct in three principal ways. Starting with the intent to deceive prong, the majority decided that an accused infringer must prove that the patentee acted with a “specific intent” to deceive the Patent Office.\textsuperscript{37} Under the new test, intent can be established only by clear and convincing evidence that (1) the applicant knew of the reference, (2) knew it was material, and (3) made a deliberate decision to withhold it.\textsuperscript{38} Gross negligence or proving that the applicant “should have known” that the reference was material is not sufficient to establish the intent prong of the inequitable conduct charge.\textsuperscript{39}

Second, the \textit{Therasense} Court determined that “the materiality required to establish inequitable conduct is a but-for materiality.”\textsuperscript{40} In other words, information undisclosed by the applicant is deemed material only if the Patent Office would not have allowed a claim had it been aware of the undisclosed information.\textsuperscript{41} In making this “but-for” materiality determination, the Federal Circuit directed the district courts to apply the preponderance of the evidence standard

\textsuperscript{34} Mammen, \textit{supra} note 4, at 1361 (discussing that the prevalence of the inequitable conduct cases has expanded as a result of the overbroad doctrine).
\textsuperscript{35} Cotropia, \textit{supra} note 3, at 767-72 (discussing the high-cost of non-compliance and the low cost of compliance as causing overcompliance, which ultimately hurts patent quality).
\textsuperscript{36} \textit{Therasense}, 649 F.3d at 1290.
\textsuperscript{37} \textit{Id}. (citing \textit{Star Scientific}, 537 F.3d at 1366).
\textsuperscript{38} \textit{Id}.
\textsuperscript{39} \textit{Id}. (citing \textit{Kingsdown}, 863 F.2d at 876).
\textsuperscript{40} \textit{Therasense}, 649 F.3d at 1291.
\textsuperscript{41} \textit{Id}.
used by the Patent Office, not the clear and convincing standard used by courts in determining patent invalidity. After describing the heightened standard for materiality, the Federal Circuit recognized an exception to the “but-for” standard for “cases of affirmative egregious conduct,” such as the submission of false affidavits, manufacturing of false evidence, perjury, suppression of evidence, and bribery.

And finally, the Federal Circuit abolished the “sliding scale” test and explained that materiality and intent are separate elements that cannot be inferred from or weighed against each other. In particular, the Federal Circuit found that "to meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." That is, if multiple reasonable inferences may be drawn from a piece of evidence, intent to deceive cannot be found.

A petition for a writ of certiorari was not filed in the United States Supreme Court after the Federal Circuit’s Therasense decision, and so the Therasense decision is the law of the land, at least for now. Following the Therasense decision in May 2011, the Federal Circuit has not reversed a single lower court’s finding of no inequitable conduct, and except in Aventis Pharma S.A. v. Hospira, Inc., the Federal Circuit has not affirmed any lower court’s determination of inequitable conduct. Several post-Therasense Federal Circuit cases elucidate the new materiality and intent standards for finding inequitable conduct.

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42 Id. at 1291-92.
43 Id. at 1292-93.
44 Id. at 1290.
45 Id. at 1290-91.
46 Id.
a) Materiality Standard Under Therasense

In American Calcar, Inc. v. American Honda Motor Co., Inc., the Federal Circuit’s first post-Therasense case addressing the issue of inequitable conduct, the Court explained that to prove inequitable conduct the accused infringer must provide evidence that the applicant (1) misrepresented or omitted material information, and (2) did so with the specific intent to deceive the PTO. The Court further explained that the misrepresented or omitted information must be but-for material as established in Therasense. Applying this standard, the Federal Circuit agreed with defendants that the undisclosed information was but-for material to one of the asserted patents, because the district court had found that the asserted claims of that patent are anticipated by the undisclosed information. With regard to a second set of asserted patents, the Court found that although the jury rejected defendant’s invalidity arguments based on the undisclosed information, the withheld information may still be but-for material if it would have blocked issuance of the patent claims under the Patent Office’s preponderance of the evidence standard, giving those claims their broadest reasonable construction. Because the Court was not able to infer that finding from the district court’s opinion, it vacated the district court’s findings of materiality as to the second set of patents and remanded the issue.

In August Technology Corp. v. Camtek, Ltd., the Federal Circuit affirmed the district court’s dismissal of Camtek’s inequitable conduct defense on the ground that an undisclosed reference was not but-for material prior art because it would not have rendered the claims of the asserted patent obvious in view of the other prior art references of record. Specifically, the district

48 651 F.3d 1318 (Fed. Cir. 2011).
49 Id. at 1334.
50 Id.
51 Id.
52 Id. at 1335.
53 Id.
54 655 F.3d 1278 (Fed. Cir. 2011).
court had found that one of applicant’s devices, information about which was not disclosed to the Patent Office during examination, was not on sale prior to the critical date of the asserted patent, and therefore, the undisclosed information was not prior art under 35 U.S.C. § 102(b). Based on this reasoning, the district court dismissed as moot defendant’s inequitable conduct charge.\(^{55}\) On appeal, the Federal Circuit found that even if the undisclosed device was on sale and constituted prior art, it would not render the asserted claims obvious in view of the other cited prior art.\(^{56}\) On this basis, the Court concluded that the undisclosed information was not material prior art under the but-for materiality standard set forth in *Therasense*. Accordingly, the Court affirmed the district court’s dismissal of defendant’s inequitable conduct counterclaim.\(^{57}\)

In *Powell v. Home Depot USA Inc.*,\(^{58}\) the Federal Circuit affirmed the district court’s finding that a patent applicant's failure to notify the Patent Office of a change in status for a Petition to Make Special is neither a ground for finding of inequitable conduct under the but-for materiality standard, nor does it constitute “affirmative egregious misconduct” under *Therasense*.\(^{59}\)

In light of the post-*Therasense* Federal Circuit cases, the but-for materiality standard can be viewed as requiring a defendant to show by a preponderance of the evidence that one or more claims of the asserted patent would have been anticipated or rendered obvious if the patent examiner had been aware of the undisclosed (or misrepresented) information.

\(^{55}\) *Id.* at 1288.

\(^{56}\) *Id.* at 1290.

\(^{57}\) *Id.* (citing *Therasense*, 649 F.3d at 1291-92).

\(^{58}\) 663 F.3d 1221 (Fed. Cir. 2011).

\(^{59}\) *Home Depot*, 663 F.3d at 1235 (“[w]here, as here, the patent applicant fails to update the record to inform the PTO that the circumstances which support a Petition to Make Special no longer exist—that conduct does not constitute inequitable conduct. That is so because Mr. Powell’s conduct obviously fails the but-for materiality standard and is 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.’”) (citing *Therasense*, 649 F.3d at 1290, 1292-93).
b) Intent to Deceive Standard Under *Therasense*

In *American Calcar*, the Federal Circuit’s first inequitable conduct case after *Therasense*, the Court concluded that the district court applied an incorrect standard in determining intent to deceive the Patent Office by the applicant.\(^{60}\) The Court explained that under the *Therasense* standard, "the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it."\(^{61}\) The Court found that the district court had relied on the sliding scale standard that was rejected *en banc* in *Therasense*.\(^{62}\) Accordingly, the Court vacated the district court’s finding of intent and remanded the issue.\(^{63}\) Similarly, in *Cordis Corp. v. Boston Scientific Corp.*,\(^{64}\) the Federal Circuit affirmed the district court’s finding of lack of inequitable conduct, because the defendant had failed to prove deceptive intent by clear and convincing evidence as required under *Therasense*.\(^{65}\)

In *Aventis Pharma*, the Federal Circuit for the first time since *Therasense* affirmed a holding by the district court that rendered two of the asserted patents unenforceable due to inequitable conduct. Materiality was not an issue on appeal, since the district court had invalidated the patents using undisclosed references.\(^{66}\) As for the intent to deceive prong, the Federal Circuit upheld the district court's rejection of the inventor's rationale for withholding certain references.\(^{67}\) The Court explained that *Therasense* "confirmed that inequitable conduct requires clear and convincing evidence of a specific intent to deceive the [Patent Office] and that the specific intent

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\(^{60}\) *American Calcar*, 651 F.3d at 1335.

\(^{61}\) *Id.* (citation omitted).

\(^{62}\) *Id.*

\(^{63}\) *Id.*

\(^{64}\) 658 F.3d 1347 (Fed. Cir. 2011).

\(^{65}\) *Id.* at 1361. (The Federal Circuit explained in a footnote that “this appears to be a case where [defendant] proved the threshold level of intent to deceive, but that proof was rebutted by [applicant’s] good faith explanation. [Defendant’s] argument therefore hinges, as it did below, on [applicant’s] credibility. . . . [I]t was the province of the district court to determine credibility, and ‘[t]his court gives great deference to the district court's decisions regarding credibility of witnesses.’”).

\(^{66}\) *Aventis Pharma*, No. 2011-1018, slip op. at 15-16.

\(^{67}\) *Id.*, slip op. at 17-21.
to deceive must be the single most reasonable inference able to be drawn from the evidence." But while the inventor had testified that he withheld the references because they described only "failed experiments," the Court noted the contrary evidence in the record and the district court's finding that the inventor's testimony lacked credibility, and held that the district court's finding of specific intent to deceive the Patent Office was not clearly erroneous.

Based on the outcomes of the post-Therasense inequitable conduct cases before the Federal Circuit, it is now clear that determination of inequitable conduct requires distinct findings of intent and materiality (rather than employing the sliding scale approach) and that deceptive intent has to be established by clear and convincing evidence. Despite the more rigorous intent standard adopted in Therasense, at least the Aventis Pharma case demonstrates that the Federal Circuit is willing to affirm well-reasoned and unequivocal findings of intent to deceive the Patent Office.

Time will tell how much Therasense changes the inequitable conduct landscape and whether the goals envisioned by the Therasense majority will be achieved. In the meantime, the Patent Office has taken a position consistent with the Therasense majority that the change in the inequitable conduct standard will minimize the impulse to over-comply with the duty of disclosure. As explained below, the Patent Office has also proposed to revise Rule 56 to reduce the incentive to inundate the Patent Office with marginally relevant information.

B. POST-THERASENSE CHANGES TO RULE 56

In 1989, a year after the Kingsdown decision that heightened the standard for finding inequitable conduct, the Patent Office proposed amendments to Rule 56 seeking to replace the

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68 Id., slip op. at 17 (citation omitted).
69 Id., slip op. at 17-21.
“reasonable examiner” standard with a clearer and more objective set of rules. In 1992, the Patent Office adopted the amended version of Rule 56, which remains in place today. Historically, the Federal Circuit has followed the Patent Office’s materiality standard for the duty of disclosure to measure materiality for inequitable conduct claims; however, in the past decade the Federal Circuit has only loosely followed the standard for materiality adopted in the 1992 version of Rule 56. In Digital Control, decided in 2006, the Federal Circuit reverted back to the “reasonable examiner” standard and reasoned that the 1992 version of Rule 56 was “not intended to replace or supplant the ‘reasonable examiner’ standard.”

Following the Therasense decision, the Patent Office has once again proposed to revise Rule 56 to mend the disjunction between the Federal Circuit’s materiality standard for inequitable conduct and the Patent Office’s materiality standard for the duty of disclosure. In particular, the Patent Office announced its plan to “revise the standard for materiality for the duty to disclose” in light of the Federal Circuit’s decision in Therasense. Rule 56 as proposed to be amended would provide that information is material to patentability under Therasense if it falls under the “but-for-plus” standard, i.e., 1) the Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or 2) the applicant engages in affirmative egregious misconduct before the Office as to the information. The Patent Office further stated that “neither mere nondisclosure of

73 Mammen, supra note 4, at 1334-35.
74 Digital Control, 437 F.3d at 1316 (identifying the Patent Office’s material to patentability standard as one of the many standards the courts could apply).
76 Id.
77 Id. at 43632.
information to the Office nor failure to mention information in an affidavit, declaration, or other statement to the Office constitutes affirmative egregious misconduct.”

The Patent Office emphasized that its proposed changes to Rule 56 was voluntary and not required by *Therasense*, because the Patent Office’s materiality standard and the court’s inequitable conduct standard are “not inseparably tied.” Nevertheless, the Patent Office noted that harmonization of the two materiality standards had several benefits. In particular, the Patent Office stated that it expects the “but-for-plus” standard from *Therasense* to result in “patent applicants providing the most relevant information and reduce the incentive for applicants to submit information disclosure statements containing only marginally relevant information out of an abundance of caution.” At the same time, by creating an exception to punish affirmative egregious acts without penalizing mere failure to disclose information that would not have changed the issuance decision, the “but-for-plus” standard “will continue to prevent applicants from deceiving the Office and breaching their duty of candor and good faith.” Additionally, the Patent Office stated that it believes a unitary materiality standard would be simpler for the patent bar to implement.

The Patent Office’s proposed changes to Rule 56 have been welcomed by the patent community for the most part. But it is yet to be seen whether the proposed amendments to Rule 56 would have any significant impact on IDS practices, and solve the over-disclosure problem as anticipated by the *Therasense* majority and the Patent Office.

Another recent development that lies at the intersection of Rule 56 and inequitable conduct is the AIA’s supplemental examination, which also was designed to reduce the rampant overuse of

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78 Id. at 43633.
79 Id. at 43632.
80 Id.
81 Id. (citations omitted).
82 Id.
inequitable conduct charges in patent litigation. The following section of this Article provides an overview of the supplemental examination provision and the intended objectives.

C. SUPPLEMENTAL EXAMINATION

The supplemental examination provision of the AIA, enacted on September 16, 2011, provides a patentee with an avenue to ask the Patent Office “to consider, reconsider, or correct information believed to be relevant to [a] patent” at any time after the issuance of that patent. This provision took effect on September 16, 2012, and applies to any patent issued before, on, or after that date. This procedure allows the patentee to have information that was not considered during the initial examination of the patent to be considered after the grant of the patent. Once such information is considered, the patent cannot be held unenforceable on the basis of conduct relating to such information. That is, the patentee is shielded from allegations of inequitable conduct stemming from the information that was presented to the Patent Office in the supplemental examination request. There is also a possibility that the patentee can get protection from sweeping discovery of information related to the supplemental examination. If the information submitted in the supplemental examination request raises a substantial new question of patentability, the patent shall be subjected to reexamination according to the current ex

83 35 U.S.C. § 257(a) (2011) ("A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent, in accordance with such requirements as the Director may establish. Within 3 months after the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conduct the supplemental examination and shall conclude such examination by issuing a certificate indicating whether the information presented in the request raises a substantial new question of patentability.").


85 35 U.S.C. § 257(c)(1) (2011) ("A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.").
parte reexamination rules.\textsuperscript{86} To take advantage of the “shielding effect” of the provision, the patentee must request supplemental examination before a patent challenger raises an allegation of inequitable conduct in a declaratory judgment action or an Abbreviated New Drug Application (ANDA) notice.\textsuperscript{87} In a patent enforcement action, the patentee is insulated from inequitable conduct allegations only if the examination (including reexamination of the patent pursuant to the supplemental examination request) is concluded before the date on which the action is brought.\textsuperscript{88}

Supplemental examination can be helpful in maximizing the value of a patent in at least the following situations—1) to address certain information that came to the attention of the patentee between allowance and issuance without having to resort to a Request for Continued Examination (RCE); 2) to address the concerns of investors and potential partners during a due diligence investigation, valuation, or licensing negotiations; and 3) to cure issues that may be raised by an adverse party challenging the enforceability of the patent. Accordingly, supplemental examination is a powerful tool to address problems with issued patents. The patent community anticipates that as part of a pre-litigation strategy, supplemental examination will give patentees an opportunity to reduce or eliminate known weaknesses in their patents prior to initiating a patent infringement action, and thereby minimize the chances of the patent being held unenforceable due to inequitable conduct.\textsuperscript{89} Thus, supplemental examination can be said to be the AIA’s cure for the “plague” of inequitable conduct.

\textsuperscript{86} 35 U.S.C. § 257(b) (2011).
\textsuperscript{89} McNeill et al., \textit{supra} note 87.
III. THE IMPACT OF INEQUITABLE CONDUCT REFORM ON INFORMATION DISCLOSURE

With the *Therasense* decision, the Federal Circuit created a new, heightened standard for finding inequitable conduct. The new standard for materiality and intent under *Therasense*, coupled with the heightened standard for pleading inequitable conduct under *Exergen Corp. v. Wal-Mart Stores, Inc.*,90 is expected to make pleading and proving inequitable conduct much harder for defendants. A quick review of the post-*Therasense* Federal Circuit cases demonstrate the difficulty faced by defendants in proving inequitable conduct. The supplemental examination provision provides an additional avenue for patentees to cleanse their prosecution record in the pre-litigation phase and insulate against inequitable conduct charges arising from information not submitted to the Patent Office during the initial examination.

In addition to raising the bar for finding inequitable conduct, *Therasense* is expected to provide clearer guidance to patent applicants and practitioners on what information must be submitted to the Patent Office during prosecution. According to the *Therasense* majority, the but-for materiality framework provides “clear guidance to patent practitioners and courts, while the egregious misconduct exception gives the test sufficient flexibility to capture extraordinary circumstances.”91 The Patent Office has similarly expressed the hope that *Therasense* will reduce the rampant overuse of inequitable conduct, consequently reducing the incentive to file Information Disclosure Statements (IDSs) laden with “marginally relevant” information.92

Despite the confidence exuded by the Patent Office that applicants will continue to be forthcoming with information relevant to patent examination,93 many commentators have

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90 575 F.3d 1312 (Fed. Cir. 2009) (the Federal Circuit adopted strict pleading standards for the defense of inequitable conduct, requiring deceptive intent to be pleaded with particularity).
91 *Therasense*, 649 F.3d at 1293.
93 Id.
expressed concern that without the threat of inequitable conduct, patent applicants and practitioners will have no incentive to disclose relevant information to the Patent Office. The Patent Office’s lack of resources and expertise to monitor, adjudicate and enforce compliance with Rule 56 adds fuel to the concern that the heightened standard for inequitable conduct will simply widen the information asymmetry between patent examiners and applicants.

Regardless of the diminished threat of inequitable conduct allegations and/or findings, there are many reasons for patent applicants and practitioners to not change their pre-Therasense prosecution practices. First, the patent system inherently has many incentives for patent applicants to continue submitting relevant information to the Patent Office, albeit with less fear of an inequitable conduct allegation and/or finding if an ensuing patent is litigated. Second, the egregious misconduct caveat in Therasense will spur patent applicants and practitioners to continue with any pre-Therasense diligence in submitting information to the Patent Office. Third, there are many economic incentives for patent applicants and practitioners to continue with their pre-Therasense IDS practices. Additionally, supplemental examination is not likely to reduce information submission to the Patent Office because supplemental examination is not a “get out of jail free card” and the decision to request supplemental examination has to be weighed carefully against its potential risks. Over-disclosure is likely to remain a problem for the Patent Office and needs to be addressed in other ways. This Article explores some avenues that the Patent Office should consider to dissuade patent applicants and practitioners from flooding the Office with

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94 *See supra* note 17 and accompanying text.


96 157 Cong. Rec. E1208 (daily ed. June 24, 2011) (statement of Rep. Henry A. Waxman arguing that supplemental examination is a “card” that, if played properly, will encourage applicants to use a variety of strategies to obtain a patent that would not have been available previously, and immunize such conduct before a competitor can challenge the patent).
immaterial or marginally relevant information.

A. Therasense Will Not Stifle Information Flow to the Patent Office

The threat of an inequitable conduct allegation is not the only impetus driving patent applicants and practitioners to abide by their duty of disclosure to the Patent Office. Although the Therasense decision and the supplemental examination provision are expected to shield many applicants and practitioners from successful inequitable conduct charges, there are many other reasons for them to continue submitting information to the Patent Office. The following are some of the primary factors why the information submission practice of patent applicants and practitioners is not likely to change considerably in the near future.

1. Incentives Within the Patent System to Comply with the Duty of Disclosure

Patent applicants and practitioners have always had, and will continue to have, many good reasons, aside from the threat of inequitable conduct allegation, to present information—both material and marginally relevant ones—to the Patent Office during prosecution. The following are two crucial factors that will continue to motivate patent applicants and practitioners to comply with the disclosure obligation the Patent Office places upon them.

a) Bolstering against post-issuance challenges at the Patent Office

The AIA introduces two new inter partes mechanisms, namely, post-grant review and inter partes review, for levying challenges to the validity of a granted patent at the Patent Office. These post-grant proceedings are relatively inexpensive compared to litigation, and therefore, the Patent Office is expected to become an attractive forum for patent challengers.

Any party, except the patent owner, may file a petition to institute post-grant review within nine months from grant or reissue of a patent as long as it is not challenging the patent's validity in
a civil action. The petitioner may request cancellation of one or more claims on any basis set forth in § 282(b) ¶¶ 2 or 3 for invalidity, including for example, novelty, obviousness, written description, enablement and statutory subject matter. The *inter partes* review provision allows additional attacks on a patent’s validity after the period during which post-grant review may be initiated or, if post-grant review is initiated, at the conclusion of the post-grant review. The basis for *inter partes* review is limited to patents or printed publications, as in the current *inter partes* reexamination process. While post-grant review provides a petitioner a forum to challenge a patent on any basis of patentability, *inter partes* review is limited to novelty and non-obviousness.

The AIA raises the bar of entry for initiating a post-grant review or *inter partes* review. In particular, the AIA mandates that the Director may institute an *inter partes* review or a post grant review proceeding only where a petitioner meets the threshold requirements. For an *inter partes* review, the petitioner must demonstrate a “reasonable likelihood” that he/she would prevail as to at least one of the claims challenged. And for a post-grant review, the petitioner must demonstrate that it is “more likely than not” that at least one of the claims challenged is unpatentable. Additionally, for a post-grant review, the petitioner may show a novel or unsettled legal question that is important to other patents or patent applications. The “reasonable likelihood standard allows for the exercise of discretion but encompasses a 50/50 chance whereas

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98 Id.


the ‘more likely than not’ standard requires greater than a 50% chance of prevailing.”

For both post-grant and *inter partes* review, the decision of the Patent Office whether to institute a review is final and non-appealable.

The standards for post-grant and *inter partes* review are much higher than the current standard for *ex parte* reexamination—that a substantial new question (SNQ) of patentability be raised—which is met in almost 95% of the reexamination requests filed. In view of the higher bar for initiating *inter partes* post-issuance challenges at the Patent Office, petitioners will likely have to set forth “the best ground of unpatentability as to each challenged claim to facilitate early resolution of the issues.”

The AIA also provides that “[i]n determining whether to institute or order a [post-grant] proceeding . . . , the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.”

This provision provides only a discretionary duty (i.e., “may”) to take into account the previously considered prior art; nevertheless, it is highly probable that it would factor into the threshold determination, because failure to exercise the discretion would invite harassment of patentees and misuse of Patent Office resources. Chief Judge Smith’s explanation that “[i]n instituting an *inter partes* review or *post-grant* review, the Board may take into account whether the same or substantially same prior art or arguments previously were presented to the Office.”

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107 House Rep. 112-98 (Part 1), at 47, 112th Cong., 1st Sess. (June 1, 2011) (provides, in connection with *inter partes* review, that “[t]he threshold for initiating an inter partes review is elevated from ‘significant new question of patentability’—a standard that currently allows 95% of all requests to be granted—to a standard requiring petitioners to present information showing that their challenge has a reasonable likelihood of success.”)
108 Message from Chief Judge Smith, supra note 105; see also 35 U.S.C. §§315(d), 325(d) (2011).
presented to the Office,” further clarifies that it is unlikely a post-grant proceeding will be granted on the basis of previously-considered art. Accordingly, it is highly likely that a petitioner will have to set forth prior art reference(s) or other information that was previously not before the Patent Office to institute a post-grant challenge; more so if the patent examiner had previously applied the disclosed information for Office Action rejections and those rejections were successfully traversed.  

Defending a post-issuance challenge at the Patent Office can be needlessly expensive and time-consuming for a patentee and it can delay enforcement or monetization of an issued patent. Therefore, there are many incentives for patent owners to shore up their patent claims against post-issuance validity challenges at the Patent Office by proactively disclosing known material information during initial examination, so that the same prior art is perhaps less likely to be used later by an adversary to levy a post-issuance challenge at the Patent Office.

b) **Stronger presumption of validity over prior art considered by the Patent Office**

Issued patents are "presumed valid" and the burden of establishing invalidity rests on the party asserting such invalidity. The presumption of validity can be overcome only by clear and convincing evidence, regardless of whether the prior art offered at trial was considered by the

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111 *Message from Chief Judge Smith, supra* note 105 (citing 35 U.S.C. §§ 315(d), 325(d) (2011)).

112 This appears to be in sharp contrast with the *ex parte* reexamination provision, which remains as an option after AIA for challenging the validity of a patent at the Patent Office. *Ex parte* reexamination allows the use of previously considered references (“old art”) to support a SNQ if shown in a “new light.” See 35 U.S.C. § 303(a) (“The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.”); see also *In re Swanson*, 540 F.3d. 1368 (Fed. Cir. 2008).

113 35 U.S.C. § 282 (1988) (“A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.”).
Patent Office.\textsuperscript{114} The theory underlying the presumption is that the Patent Office has scrutinized the patent and their expert judgment is entitled to deference by the courts.\textsuperscript{115}

Although in theory the presumption of validity extends to both disclosed and undisclosed prior art, the presumption is stronger when prior art was considered by the Patent Office and weak when it was not. In the \textit{i4i} case, appellant Microsoft and its \textit{amici} argued that a preponderance standard should apply where the evidence before the fact finder was not before the Patent Office during the examination process.\textsuperscript{116} Previously, in \textit{KSR Int’l Co. v. Teleflex Inc.},\textsuperscript{117} the Supreme Court called into question the application of the presumption to prior art not considered by the Patent Office.\textsuperscript{118} In the \textit{i4i} case, however, the Supreme Court rejected the idea of a two-tier system for the presumption of validity and decided that the clear and convincing evidence standard remains even for prior art not considered by the Patent Office; but, added that when there is new prior art asserted by a defendant during litigation, the jury should ordinarily be given an instruction on that point.\textsuperscript{119} The Court specifically endorsed the “commonsense principle that the Federal Circuit has recognized throughout its existence—namely, that new evidence supporting an

\begin{itemize}
\item \textsuperscript{114} Microsoft Corp. v. i4i Ltd. Partnership, 131 S.Ct. 2238, 2243 (2011) (The Court held that under 35 U.S.C. § 282 the standard for patent invalidity is clear and convincing standard and not mere preponderance of the evidence).
\item \textsuperscript{115} Christopher A. Cotropia, Mark Lemley & Bhaven Sampat, \textit{Do Applicant Patent Citations Matter? Implications for the Presumption of Validity} 4-5 (Stanford Law and Economics Olin Working Paper No. 401, 2012) available at http://ssrn.com/abstract=1656568; Todd L. Juneau & Jill K. MacAlpine, \textit{Protecting Patents from the Beginning: The Importance of Information Disclosure Statements During Patent Prosecution}, 82 JPTOS 577, 580 (2000) (“Because a qualified government agency, which includes one or more examiners who are assumed to have some expertise in interpreting references and to be familiar with the level of skill in the art, is presumed to have done its job properly, a very high level of deference is created.”) (citations omitted).
\item \textsuperscript{116} \textit{i4i}, 131 S.Ct. at 2244.
\item \textsuperscript{117} 550 U.S. 398 (2007).
\item \textsuperscript{118} \textit{KSR}, 550 U.S. at 426 (stating that “the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished here” with regard to art not before the Patent Office).
\item \textsuperscript{119} \textit{i4i}, 131 S.Ct. at 2251-52 (“When warranted, the jury may be instructed to consider that it has heard evidence that the PTO had no opportunity to evaluate before granting the patent. . . . [T]he jury may be instructed to evaluate whether the evidence before it is materially new, and if so, to consider that fact when determining whether an invalidity defense has been proved by clear and convincing evidence.”).
\end{itemize}
invalidity defense may ‘carry more weight’ in an infringement action than evidence previously considered by the PTO.”

Thus, the *i4i* Court ultimately gives the jury the ability to consider the presence of new evidence “when determining whether an invalidity defense has been proved by clear and convincing evidence.” Since judges and juries are not trained to understand the technical details of the prior art, they are generally less likely to second-guess the expertise of the patent examiner, and therefore, fact-finders are far more receptive to arguments that the examiner never considered a particular piece of prior art. Consequently, fact-finders are more likely to invalidate a claim based on prior art not previously considered by the Patent Office.

Hence, it appears that although the presumption of validity and the clear and convincing evidence standard for patent invalidity extends even to undisclosed prior art, the strength of that presumption of validity, at least in the minds of the fact-finder, is largely dependent on whether the prior art was previously considered by the patent examiner. This provides significant incentive to patent applicants and practitioners to bring all known material information to the attention of the Patent Office to gain the complete benefit of the presumption of validity afforded to an issued patent.

The above-described incentives—strengthening against post-grant challenges and perhaps strengthening the presumption of validity—will continue to motivate patent applicants and practitioners to bring material (and perhaps even marginally relevant information out of an overabundance of caution) to the attention of the Patent Office during prosecution.

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120 Id. (citing American Hoist & Derrick Co. v. Sowa & Sons, 725 F.2d 1350, 1360 (Fed. Cir. 1984)).
121 Id.
122 Cotropia et al. *supra* note 115, at 6-7; Juneau et al., *supra* note 115, at 580 (“Even if an infringer provides clear and convincing evidence of invalidity, there is an additional burden of overcoming the deference given to the PTO by the courts.”).
Additionally, disclosure of all known information during the initial examination of a patent application provides protection against discovery of undisclosed information during litigation and the unpleasant questioning that could follow. Even if an applicant subjectively believes that certain information is not material to patentability, discovery of intentional non-disclosure can give rise to claims of inequitable conduct, thereby casting a cloud over the patent’s validity, threatening the practitioner’s reputation, and increasing the overall litigation costs. Therefore, from a litigation perspective, it is advantageous for patent applicants and practitioners to disclose all known information during prosecution, both material and marginally relevant ones, in order to avoid the disruption that can follow from discovery of the same information during litigation.

2. **THE “EGREGIOUS MISCONDUCT” LOOPHOLE IN THERASENSE**

The *Therasense* court ratcheted up the materiality standard for inequitable conduct, but recognized an exception to the requirement for but-for materiality, determining that “[w]hen the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.”123 The Court created this exception to strike a “necessary balance between encouraging honesty before the [Patent Office] and preventing unfounded accusations of inequitable conduct.”124 In *Therasense* and in *Home Depot*, decided a few months after *Therasense*, the Federal Circuit explained that applicant’s misconduct must be an unequivocal act, such as the filing of a false affidavit, to rise to the level of “affirmative egregious misconduct.”125 The *Therasense* court's exception for egregious misconduct appears to be extremely narrow and apply only to deliberately planned and carefully executed schemes to defraud the Patent Office; however, the Court has left the metes and bounds of this exception largely vague. It is unclear whether extraordinary circumstances, such as complete lack

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123 *Therasense*, 649 F.3d at 1292.
124 Id. at 1293.
125 *Home Depot*, F.3d at 1235 (citing *Therasense*, 649 F.3d at 1290, 1292-93).
of diligence in submitting relevant information to the Patent Office, or deliberate attempts to remain unaware of any potentially relevant information, would fall within the exception. As the contours of the egregious misconduct exception are worked out in the forthcoming Federal Circuit and district court case law, it is possible that many litigators will frame their allegations as affirmative acts of “egregious misconduct” to continue to get the benefits of the inequitable conduct defense. Therefore, it is advisable for patent applicants and practitioners to keep their IDS practices after *Therasense* essentially the same, except perhaps in the instances where hundreds of redundant or immaterial references were being submitted out of an overabundance of caution.

3. ECONOMIC INCENTIVES TO CONTINUE WITH PRE-*THERASENSE* IDS PRACTICES

Patent applicants sometimes make large disclosures of information during prosecution; however, such profligate applicants form a small fraction of the patent community and are generally limited to specific technology areas. *Therasense* may persuade some of these overzealous submitters to relax their IDS practices and submit fewer immaterial or marginally relevant references. However, for the average applicant citing a modest number of references, typically from a pre-filing search, foreign search reports, or inventors’ personal knowledge, *Therasense* may not significantly change their customary IDS practices. This is primarily because the practice of over-disclosing is often less expensive to an applicant than determining the materiality of all known references. By erring on the side of submission, patent applicants and practitioners can not only enhance their protection from inequitable conduct allegations, but also avoid the cost associated with conducting materiality analysis of each and every piece of reference.

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127 See generally Dennis Crouch, *supra* note 12 (noting that applicants submit over 200 references in only 2% of cases, and 15% of patented cases include absolutely no applicant cited references).
brought to the attention of the applicant and/or the practitioner. Such a practice essentially shifts
the burden and cost of materiality analysis to the Patent Office. Further, determination of whether
a piece of information is material is a complicated process,128 and often it is less risky to submit all
known references remotely related to the invention, regardless of whether the applicant or
practitioner subjectively believes it to be a “material” or “cumulative” reference, so as to avoid a
later charge of inequitable conduct arising from a different subjective understanding of that
reference.129 In other words, there continues to be a strong incentive for applicants to be over-
inclusive in their IDS submissions out of a fear that undisclosed prior art might be discovered
during discovery and successfully argued to be “but for” material during litigation. Even if
unsuccessful, the patentee can have its credibility damaged with the fact-finder for failing to
disclose the reference.

Last but not the least, many applicants and practitioners already have established
procedures and sophisticated databases to track references cited in counterpart foreign applications
and/or in related families of applications. They are less likely to dismantle such established
procedures for cross-citing references, especially given that complete lack of diligence can
potentially ensnare the applicant in the egregious misconduct exception to the but-for materiality
standard.130

Considering all of the above discussed incentives to continue to bring known information
to the attention of the Patent Office, it seems highly unlikely that the information submission
activities of patent applicants and practitioners will change significantly from their pre-Therasense
practice.

128 Cotropia, supra note 3, at 767 (“Determinations of whether a piece of information is material are difficult.
Materiality is a multi-step inquiry, involving the determination of each patent claim's meaning, analysis of the content
of the information in question, and a judgment as to whether the information is relevant to issues of novelty,
nonobviousness, or the disclosure requirements.”).
129 Johnson, supra note 126, at 208-09.
130 See supra Part III.A.2.
B. SUPPLEMENTAL EXAMINATION WILL NOT JEOPARDIZE THE DUTY OF DISCLOSURE

The supplemental examination provision was added to the patent reform bill prior to the issuance of the *Therasense* decision and was intended to curtail allegations and findings of inequitable conduct. The provision provides a patentee with a powerful tool for strengthening its patent against inequitable conduct charges before a patent infringement action is initiated.\(^\text{131}\) It has been argued that the supplemental examination provision will have a deleterious effect on patent quality, because it effectively creates a “patent amnesty program” that encourages patent applicants to “obtain patents despite conduct that would be abhorrent under traditional understandings of a patent applicant’s obligation to be equitable in dealing with the public and with competitors, . . . .”\(^\text{132}\) Supplemental examination is framed as encouraging applicants to violate their duty of candor by intentionally keeping the Patent Office in the dark about prior art that would be detrimental to the prosecution of their application, thereafter monetizing the patent that is known or suspected to be unpatentable, and immunizing the misconduct using supplemental examination if a licensee or competitor threatens litigation.\(^\text{133}\)

Nothing in the above depicted scenario is absolutely new or unique to the supplemental examination provision. For instance, it is possible to cure an intentional non-disclosure via a reissue application, although a reissue proceeding under 35 U.S.C. § 251 is technically available only to correct unintentional errors which make the patent invalid or inoperative. This is possible because recent Federal Circuit case law has held that failure to include a dependent claim is an

\(^{131}\) *See* McNeill et al., *supra* note 87.


\(^{133}\) *Id.* at 231, 244.
error that is correctible by reissue.\footnote{In re Tanaka, 640 F.3d 1246, 1250-52 (Fed. Cir. 2011) (holding that addition of dependent claims can be the sole basis for seeking a reissue application under 35. U.S.C. §251, because it amounts to claiming less than the applicant has a right to claim and constitutes an error that can be corrected by reissue).} Since there is no requirement to mention every single error, adding a dependent claim and initiating a reissue could possibly provide an avenue for correcting a non-disclosure problem, even though a patentee would not be shielded from allegations of inequitable conduct stemming from the conduct related to the error, as is the case with supplemental examination.

Even if corrective measures are not available, a patent applicant or a practitioner may still make a strategic decision to suppress or misrepresent relevant information to try to maximize claim scope. Since the patentee controls whether and when litigation begins (absent enforcement efforts that can result in a declaratory judgment action against the patentee), the unmerited claim scope has the potential to deter market competition and innovation.\footnote{Lisa Dolak, supra note 18, at 20-21.} Supplemental examination is not likely to encourage or escalate such knowing violations of the duty of disclosure at least because of the following reasons.

First, it is highly doubtful that patent applicants or practitioners will purposefully misrepresent or withhold relevant information that was reasonably available during prosecution, and present the same information to the Patent Office after issuance if a lawsuit appears on the horizon. Any competitive advantage gained from such a calculated scheme to deceive the Patent Office will be short-lived, because the Patent Office will automatically declare an \textit{ex parte} reexamination of the patent if a prior art reference presented in the request for supplemental examination raises a substantial new question (SNQ) of patentability.\footnote{35 U.S.C. § 257(b) (2011).} Moreover, the chances of \textit{ex parte} reexamination being prompted by the supplemental examination request are substantially high because patent applicants are not likely to initiate a costly and time-consuming supplemental
examination process unless they have reason to be concerned that the undisclosed information will be found “but-for” material during litigation.\textsuperscript{137} A supplemental examination request introducing a “but-for” material reference is very likely to raise a substantial new question of patentability, consequently prompting an \textit{ex parte} reexamination. During reexamination, the affected claims will either have to be canceled or amended to distinguish over the reference,\textsuperscript{138} resulting in prosecution history estoppels and affecting claim scope under the Doctrine of Equivalents. Lastly, an \textit{ex parte} reexamination proceeding takes a long time, currently approximately 26.3 months from the filing of the request to the grant of the \textit{ex parte} certificate.\textsuperscript{139} To gain the shielding effect of supplemental examination, the patentee will potentially have to delay the start of litigation until reexamination is concluded.\textsuperscript{140}

In view of the high likelihood of \textit{ex parte} reexamination being prompted by a supplemental examination request, and the risk associated with reexamination, a patentee has very little to gain from deliberately withholding potentially material information during prosecution and requesting supplemental examination of the issued patent at a later date to introduce the previously undisclosed information. Contrary to the concerns raised by many critics, the supplemental examination provision was introduced in the AIA to provide patent owners with recourse to cure previously unknown defects in their patents and thwart untoward allegations of inequitable conduct. With or without supplemental examination, there will always be some miscreant practitioners and applicants, who may knowingly suppress or misrepresent relevant information

\textsuperscript{137} See, e.g., Warren D. Woessner, \textit{Supplemental Examination Decision Tree – Lots of Dead Branches?} http://www.patents4life.com/2012/01/supplemental-examination-decision-tree-lots-of-dead-branches/ (last visited April 29, 2012) (discussing that savvy patent applicants and practitioners realize that after \textit{Therasense} a party alleging inequitable conduct must making distinct showings of intent to deceive and but-for materiality, and therefore, they are less likely to initiate supplemental examination if the undisclosed information is not likely to be found but-for material).

\textsuperscript{138} Peter G. Thurlow et al., \textit{supra} note 84, at 3.

\textsuperscript{139} Id.

\textsuperscript{140} Id.
and deceive the Patent Office into issuing claims that should not have issued at all or issued with narrower scope. Supplemental examination cannot be rightfully blamed as encouraging such deceitful behavior, particular since any leverage gained from the misconduct would be eviscerated during the ex parte reexamination process.

Second, the supplemental examination provision recognizes the importance of the duty of candor to the Patent Office by making supplemental examination unavailable where actual fraud has been committed during the initial examination of the patent. The AIA provides that if the Director of the Patent Office becomes aware during the supplemental examination or reexamination "that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination . . . the Director shall also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate." While this provision is untested, the possibility of criminal sanctions could further deter practitioners and patent applicants from committing fraud on the Patent Office during the initial examination of the patent.

Third, the supplemental examination process is expected to be costly. On August 14, 2012, the Patent Office published the final Rules and Regulations for implementing the supplemental examination provision of the AIA. According to the Rules, the Patent Office will charge $5,140 for conducting supplemental examination of up to 12 items of information believed to be relevant to the patent. If the request for supplemental examination raises a substantial new question of patentability, the Patent Office will initiate an ex parte reexamination. The patentee must submit an additional $16,120 for conducting ex parte reexamination when submitting the request for

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141 McNeill et al., supra note 87.
144 Id.
supplemental examination, which would be refunded if the request does not raise a substantial new question of patentability.\(^{145}\) Thus, the total up-front cost of filing a supplemental examination request would, at a minimum, be $21,260. If the patentee needs to have more than 12 items of information considered, the Rules require the patentee to submit a separate request and an additional $21,260 in fees. In addition, the Patent Office proposes to charge $170 for each non-patent document having from 21 to 50 sheets and $280 for each additional 50-sheet increment or a fraction thereof.\(^{146}\) All in all, supplemental examination is expected to be very expensive. The cost associated with this process will certainly deter misuse or overuse of this provision, particularly abuse of the provision to cure knowing and deliberate omissions during the initial examination.

Accordingly, patent applicants and practitioners have many reasons, viz. the risk of reexamination, the fraud provision, and the cost associated with requesting supplemental examination, to err on the side of full disclosure to the Patent Office during initial examination. If relevant information is inadvertently withheld from the Office, supplemental examination will rightly insulate such inadvertent omission from an attack of inequitable conduct.

In light of the discussions in Parts III.A and III.B of this Article, it seems highly unlikely that changes in the inequitable conduct landscape, as a result of *Therasense* and supplemental examination, will corrupt the patent system and suppress flow of relevant information to the Patent Office. On the contrary, overflow of information to the Patent Office is likely to continue to an appreciable extent, because the costs and risks associated with under-disclosure are enormous, while there are minimal disincentives for over-disclosure. The problem of over-disclosure has to be addressed by the Patent Office in other ways. The following section of this Article presents a few suggestions for reining in some of the incentives to over-disclose.

\(^{145}\) *Id.*  
\(^{146}\) *Id.*
C. SUGGESTIONS TO THE PATENT OFFICE FOR DETERRING OVER-DISCLOSURE

The majority in *Therasense* reasoned that if the materiality standard for finding inequitable conduct is raised, patent applicants and practitioners would no longer be motivated to inundate the Patent Office with marginally relevant information out of an abundance of caution.\(^{147}\) The Patent Office echoed similar views when it proposed to raise the materiality standard for the duty to disclose under Rule 56.\(^{148}\) However, there is a very slim possibility that patent applicants and practitioners will change their information submission practice in view of the Patent Office’s proposed “but-for-plus” standard of materiality. This is primarily because at present there are no deterrents to over-citing in the proposed amendments to Rule 56. Many patent applicants and practitioners are likely to conclude that it is easier, more cost-effective, and less risky to just disclose everything, especially from related applications, than sorting through all the references and making a judgment on materiality. To add to this problem of over-citing, the Federal Circuit raised the standard for finding deceptive intent in *Therasense*, which is likely to lower the chances of finding inequitable conduct on the ground that the relevant reference was buried amongst far less relevant references. Under the *Therasense* standard, specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence. It is uncertain whether deceptive intent can be the single most reasonable inference that can be drawn from evidence that a material reference was cloaked or buried by an enormous amount of marginal or cumulative references.\(^{149}\) Therefore, currently there are no disincentives for over-compliance with the duty of

\(^{147}\) *See* Therasense, 649 F.3d at 1291.


\(^{149}\) *See, e.g., Cordis Corp.,* 658 F.3d at 1353, 1361 (Applicant submitted a material reference in an IDS with 60 other references and without emphasis. The district court found, and the Federal Circuit affirmed, that defendants had failed to prove deceptive intent by clear and convincing evidence. The evidence of record, including the instance of burying the material reference, failed to unequivocally demonstrate specific intent to deceive. Applicant’s patents were found to be not unenforceable due to inequitable conduct).
disclosure. As such, the problem of over-disclosure is likely to persist unless the Patent Office adds more teeth to their information disclosure requirements.

One effort to do this was made by the Patent Office in July 2006 when it published a set of Proposed Rules regarding the IDS practice. But the proposed changes to the IDS requirements were challenged in court and ultimately withdrawn by the Obama administration. Briefly, the 2006 Rules proposed that only IDSs with a limited number of cites (20 or less) can be submitted before first Office Action without any “additional disclosure” requirement, except for large cites (more than 25 pages) or foreign language documents, and IDSs submitted after first Office action must meet increasing “additional disclosure” requirements. The primary objective of the 2006 Patent Office Rules was to reduce the number of references cited in an IDS such that only the most pertinent references were being brought to the attention of the Patent Office.

Under the Patent Office’s current IDS requirements, there are no numerical limits on the number of references that can be filed in an IDS, no page restrictions on filing of large documents, and no extra fees levied for filing large IDSs. In other words, the current rules provide no deterrent to over-citing. Therefore, applicants and practitioners tend to over-comply with their duty of disclosure, because the cost of over-compliance is minimal compared to the cost of under-compliance.

In light of the heightened standard of materiality for inequitable conduct and the duty of disclosure, the Patent Office should consider revisiting the 2006 Rules and implementing new IDS requirements that would shift the burden of determining materiality to the applicants. The Patent Office can, for example, require applicants to pay a certain fee per reference in excess of twenty

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151 Cotropia et al., supra note 115, at 24.
153 Cotropia, supra note 3, at 767-768.
and an additional fee for documents over twenty-five pages. By making IDS submission more costly, applicants will be encouraged to review the prior art and submit only those references that are relevant to examination and patentability. As was previously proposed in the 2006 Rules, the Patent Office can also require applicants to submit an explanation of the cited references if an IDS contains more than twenty references. Another alternative would be to require applicants to emphasize the most relevant reference(s) on the IDS if they are submitting more than twenty references. Such actions by the Patent Office will impose a responsibility on the applicant or practitioner to sort through the prior art, assess the materiality of the references, and submit only the relevant references in order to keep the number of cited references under twenty.

In short, the Patent Office should consider further actions to deter patent applicants and practitioners from flooding the Patent Office with marginal or barely relevant references, otherwise the problem of over-disclosure will not be solved. In the Notice of Proposed Rulemaking published on July 21, 2011, the Patent Office announced that it is “considering further actions that may provide an incentive for applicants to assist the Office by explaining/clarifying the relationship of prior art to the claimed invention.”154 The Notice further states that the Patent Office “believes it is worthwhile to explore ways to encourage applicants to submit information, beyond that required under the Therasense materiality standard, that would be helpful and useful in advancing examination.”155 It is yet to be seen what actions the Patent Office is considering to incentivize applicants to be forthcoming with information, while deterring applicants from over-citing. The patent community can at least have some assurance that the Patent Office is cognizant of the deficiencies in their current IDS requirements and is contemplating further actions to require more applicant participation in the examination process,

155 Id. at 43632-33.
limit over-disclosure of information, and ultimately improve the quality of the patent examination process.

IV. CONCLUSION

*Therasense* heightened the standards for materiality and intent required for a finding of inequitable conduct, and the Patent Office subsequently proposed to revise the materiality standard for the duty of disclosure to “match” the materiality standard for inequitable conduct. Despite these changes in the materiality standards, patent applicants and practitioners are not likely to change their pre-*Therasense* IDS practices, because there are many additional incentives within the patent system for applicants and practitioners to be over-inclusive in information disclosure to the Patent Office. The supplemental examination provision of the AIA is also not likely to promote intentional breaches of the duty of disclosure and repress information submission to the Patent Office. Accordingly, *Therasense* and supplemental examination is not likely to result in diminution in the amount of information submitted to the Patent Office for examination. To solve the problem of over-disclosure, the Patent Office must consider revising its current IDS requirements to actively deter patent applicants and practitioners from overwhelming the Patent Office with immaterial or marginally material references.

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156 *Id.* at 43631.