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IDS Practice After *Therasense* and the AIA: Decoupling the Link Between Information Disclosure and Inequitable Conduct

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ARTICLES

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

Arpita Bhattacharyya[†] and Michael R. McGurk^{††}

Abstract

The duty to disclose material information to the United States Patent and Trademark Office under 37 C.F.R. § 1.56 (Rule 56) is a critical requirement when prosecuting a patent application in the United States. The failure to disclose information can result in a later ruling of inequitable conduct rendering the patent unenforceable. The Federal Circuit’s en banc decision in Therasense heightened the “materiality” and “intent” standards for finding inequitable conduct. However, 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, argue that without the threat of inequitable conduct, patent applicants and practitioners will ignore their duty to disclose and the information gap between the Patent Office and applicants will widen; this will result in further impaired patent quality. The supplemental examination provision in the America Invents Act (AIA), a legislative cure for the proliferation of inequitable conduct charges, has heightened the concern among critics that information submission to

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Any discussions set forth in this Article are the personal views of the authors and do not reflect the views of Finnegan. This Article is for informational purposes only and is not intended to constitute legal advice.

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. This is 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. This is 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. This Article concludes with suggestions for the Patent Office to consider on how 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), establishes a duty of candor and good faith in dealing with the United States Patent and Trademark Office (hereinafter “Patent Office”).¹ This requires patent applicants and practitioners to disclose to the Patent Office all information known to be material to patentability (popularly known as the “duty of disclosure”). The duty of disclosure attaches to every 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

1. 37 C.F.R. § 1.56(a) (2012).

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.

Id.

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).

The 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.

Id. Mr. Tegtmeyer is the former Assistant Commissioner of the Patent Office. See also Christopher A. Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 733 (2009).

4. See Christian E. Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 BERKELEY TECH. L.J. 1329, 1334 (2009); Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 Fed. Reg. 43,631, 43,632 (proposed July 21, 2011) (to be codified at 37 C.F.R. pt. 1).

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

finding of inequitable conduct can render an entire patent family unenforceable.⁵ Chief Judge Rader, writing for the majority in *Therasense, Inc. v. Becton, Dickinson & Co.*,⁶ famously called the doctrine of inequitable conduct the “atomic bomb” of patent law.⁷ Allegations of inequitable conduct form “a dark cloud over the [litigated] patent’s validity.”⁸ It increases overall litigation costs, discourages settlements, portrays the patentee as a “bad actor,” and can destroy the reputation of patent prosecutors.⁹

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.¹⁰ The United States Court of Appeals for the Federal Circuit (“Federal Circuit”) has long recognized this problem. Judge Nichols in *Burlington Industries, Inc. v. Dayco Corp.*¹¹ calls it an “absolute plague” upon the patent litigation system.¹²

forth in the 1977 version of § 1.56(b) and current § 1.56(b) promulgated in 1992. See, e.g., *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).

Id.

5. See Bruce D. DeRenzi & Sean E. Jackson, *A Procedural Remedy for the “Plague”?* *Pleading Inequitable Conduct after Exergen Corp. v. Wal-Mart Stores, Inc.*, N.Y. INTELL. PROP. L. ASS’N BULL., Aug.-Sept. 2010, at 9, available at <http://www.nyipla.org/images/nyipla/Documents/Bulletin/2010/August-September2010.pdf>; see also *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230 (Fed. Cir. 2007) (“[I]nequitable conduct with respect to one or more patents in a family can infect related applications . . .”).

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

7. *Id.* at 1288; see also *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).

8. *Therasense, Inc.*, 649 F.3d at 1288; see also Zhe (Amy) Peng et al., *A Panacea for Inequitable Conduct Problems or Kingsdown Version 2.0? The Therasense Decision and a Look into the Future of U.S. Patent Law Reform*, 16 VA. J.L. & TECH. 373, 398 (2011).

9. *Therasense, Inc.*, 649 F.3d at 1288; Peng et al., *supra* note 8, at 398.

10. See *Therasense, Inc.*, 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.’”) (citation omitted); Kevin Mack, Note, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147, 155–56 & tbl.1(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).

11. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418 (Fed. Cir. 1988).

12. *Id.* 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)).

The proliferation of inequitable conduct charges has led patent applicants and practitioners to err on the side of over-disclosure in their Information Disclosure Statement (IDS) practices,¹³ which some argue reduces the quality of patent examination.¹⁴ 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,” in order to avoid inequitable conduct allegations.¹⁵ 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.¹⁶

The Federal Circuit recognized the problems created by the expansion and overuse of the inequitable conduct doctrine. It addressed the issue *en banc* in *Therasense* with an eye towards curing the “plague” of inequitable conduct.¹⁷ 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

13. It is widely accepted that the drastic consequences of an 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 specter of inequitable conduct too often causes applicants to submit virtually every reference of which they are aware.”). *But see* Dennis Crouch & Jason Rantanen, *References Cited*, PATENTLY-O (Feb. 19, 2009), <http://www.patentlyo.com/patent/2009/02/references-cite.html> (stating that analysis of applicant disclosure rates from January 1, 2009 to February 18, 2009 revealed that applicants submit over 200 references in only 2% of cases, and 15% of patented cases include absolutely no applicant-cited references).

14. *See* Cotropia, *supra* note 3, at 770-72.

15. *Therasense, Inc.*, 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*. *Id.* (citing the briefs submitted by the United States and the Biotechnology Industry Organization).

16. *See 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.”).

17. *See id.* (“This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”).

for patent applicants to inundate the Patent Office with marginally relevant information.

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.¹⁸ The 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.¹⁹

The common belief among the *Therasense* majority and the critics of inequitable conduct reform is that inequitable conduct and information disclosure are inseparably tied. The authors argue that this logic is flawed because inequitable conduct and information disclosure to the Patent Office do not always go in tandem.

First, information disclosure to the Patent Office will probably not decrease from the pre-*Therasense* level. This is 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

18. See *id.* 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.”); Peng et al., *supra* note 8, at 398; Jason Rantanen & Lee Petherbridge, *Therasense v. Becton Dickinson: A First Impression*, 14 YALE J.L. & TECH. 226, 256 (2012).

19. Lisa A. Dolak, *America Invents the Supplemental Examination, But Retains the Duty of Candor: Questions and Implications*, 6 AKRON INTELL. PROP. J. 147, 168 (2012); Jason Rantanen, Lee Petherbridge & Jay P. Kesan, *America Invents, More or Less?*, 160 U. PA. L. REV. PENNUMBRA 229, 244 (2012); Jason Rantanen & Lee Petherbridge, *Toward a System of Invention Registration: The Leahy-Smith America Invents Act*, 110 MICH. L. REV. FIRST IMPRESSIONS 24 (2011), <http://www.michiganlawreview.org/assets/fi/110/rantanenpetherbridge.pdf>.

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. Therefore, 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 the information disclosure to the Patent Office. It is highly doubtful that patent applicants or practitioners will purposefully misrepresent or withhold relevant information during prosecution, then present the same information to the Patent Office after issuance via supplemental examination. 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 combined with the cost associated with this process will also deter abuse of the provision to cure knowing and deliberate omissions.

Lastly, it seems highly unlikely that the changes in the inequitable conduct landscape, as a result of *Therasense* and the AIA, will stem from the overflow of information to the Patent Office. This is because the costs and risks associated with under-disclosure are very high compared to that of over-compliance with the duty of disclosure. Unless addressed by the Patent Office in other ways, the problem of over-disclosure is likely to continue unabated. 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*

Inequitable conduct²⁰ is a judicially created defense to patent infringement that evolved from the equitable doctrine of unclean hands.²¹ 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.²²

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 Patent Office during prosecution of the patent application.²³ 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."²⁴ In other words, the court could equitably balance the evidence of intent and materiality to determine whether the patentee's conduct was sufficiently culpable to warrant rendering

20. For scholarship on inequitable conduct, see generally Cotropia, *supra* note 3, at 733-37; Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J.L. & TECH. 37, 49-50 (1993); Brett Ira Johnson, *The Inequitable Conduct Defense in Patent Litigation: Where We Are, Where We Have Been, and Where We Should Go from Here*, 28 SANTA CLARA COMPUTER & HIGH TECH. L.J. 197, 198 (2012); John F. Lynch, *An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct*, 16 AIPLA Q.J. 7, 8 (1988); Mack, *supra* note 10, at 156-61; Mammen, *supra* note 4, at 1332; Lee Petherbridge, Jason Rantanen & Ali Mojibi, *The Federal Circuit and Inequitable Conduct: An Empirical Assessment*, 84 S. CAL. L. REV. 1293, 1295-1303 (2011).

21. See Mammen, *supra* note 4, at 1333. See also Precision Instrument Mfg. Co. v. Auto. Maint. 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 inequitable conduct or bad faith).

22. See Cotropia, *supra* note 3, at 733-35 (discussing the requirements of the inequitable conduct doctrine); 4 ROBERT A. MATTHEWS, ANNOTATED PATENT DIGEST § 27:58 (2012) (titled "Overview of the Requirement of Intent to Deceive").

23. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008) (quoting *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363 (Fed. Cir. 2007)).

24. *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006) (quoting *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001)).

the entire patent unenforceable.²⁵ Under the balancing test, courts assessed inequitable conduct using a “sliding scale” of intent and materiality.²⁶ This established a legal notion that a reduced showing of intent could be offset by a strong showing of materiality, and vice versa.²⁷ The “sliding scale” doctrine blurs the fact that materiality and intent are separate elements; the threshold levels for both of these elements must be established by the party alleging inequitable conduct. Because it is usually difficult to find express evidence of intent to deceive, the lowered standard for intent made inequitable conduct allegations very attractive to defendants.

With *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*,²⁸ the Federal Circuit attempted to stem the growing tide of inequitable conduct cases. The *Kingsdown* Court overturned prior precedent that held that a showing of “gross negligence” was sufficient to meet the intent to deceive prong of inequitable conduct, and instead, the court established a “sufficient culpability” standard.²⁹

Nevertheless, over the last decade the proliferation of the inequitable conduct defense has proven difficult to control. Several post-*Kingsdown* Federal Circuit decisions gradually chipped away at the “sufficient culpability” standard and reduced it to a mere “should have known” standard,³⁰ which is arguably a lower standard than the pre-*Kingsdown* “gross negligence” standards. For instance, in *Ferring B.V. v. Barr Labs., Inc.*,³¹ the court held that a patentee’s failure to

25. See *Monsanto Co. v. Bayer BioScience N.V.*, 363 F.3d 1235, 1239 (Fed. Cir. 2004).

26. Peng et al., *supra* note 8, at 378 (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1364 (Fed. Cir. 1984), *abrogated by* *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011)).

27. See *id.* (explaining that the “sliding scale” was interpreted by courts to mean that if the undisclosed or misrepresented information was highly material, there need not be much clear and convincing evidence of intent to deceive).

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

29. *Id.* 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.

Id. (citing *Norton v. Curtiss*, 433 F.2d 779 (C.C.P.A. 1970)).

30. *Mammen, supra* note 4, at 1331. See, e.g., *Bristol-Myers Squibb Co. v. Rhone-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 know[n]* 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)).

31. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181 (Fed. Cir. 2006).

disclose his prior business relationship with declarants (who provided affidavits in support of patentability during prosecution) was a material misrepresentation to the Patent Office.³² Since the applicant “knew or should have known” that the undisclosed relationship was material, the intent-to-deceive prong was also satisfied.³³

The materiality standard for finding inequitable conduct has 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*.³⁴ In *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*,³⁵ decided in 2007, 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.”³⁶ And if there was any uncertainty left after *Digital Control* and *McKesson*, the Federal Circuit in 2008 clarified in *Star Scientific* that the “reasonable examiner” test was the controlling standard for materiality.³⁷

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 defense.³⁸ The expansion of the doctrine in turn fueled over-compliance with the duty of disclosure, resulting in detrimental information overload on the Patent Office.³⁹

32. *See id.* at 1188, 1190-91.

33. *Id.*

34. *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006) (stating that the “reasonable examiner” standard should continue to exist as one of the tests for materiality).

35. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. 2007).

36. *Id.* at 913 (quoting *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998)).

37. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008) (reciting only the “reasonable examiner” standard for materiality).

38. *See Mammen, supra* note 4, at 1361 (discussing that the prevalence of the inequitable conduct cases has expanded as a result of the overbroad doctrine).

39. *See Cotropia, 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).

2. Inequitable Conduct Doctrine under *Therasense*

Citing the ubiquity of the inequitable conduct defense and its far-reaching consequences on both patent prosecution and litigation, the Federal Circuit sitting *en banc* in *Therasense* addressed the issue of inequitable conduct charges that have been “overused to the detriment of the public.”⁴⁰

The *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.⁴¹ 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.⁴² 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.⁴³

Second, the *Therasense* Court determined that “the materiality required to establish inequitable conduct is a “but-for” materiality.”⁴⁴ 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.⁴⁵ In making this “but-for” materiality determination, the Federal Circuit directed the district courts to apply the preponderance of the evidence standard used by the Patent Office, not the clear and convincing standard used by courts in determining patent invalidity.⁴⁶ 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.⁴⁷

Finally, the Federal Circuit abolished the “sliding scale” test and explained that materiality and intent are separate elements that cannot

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

41. *Id.* (citing *Star Scientific, Inc.*, 537 F.3d at 1366).

42. *Id.*

43. *Id.* (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988)).

44. *Id.* at 1291.

45. *See id.*

46. *Id.* at 1291-92.

47. *Id.* at 1292-93.

be inferred from or weighed against each other.⁴⁸ 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.’”⁴⁹ That is, if multiple reasonable inferences may be drawn from a piece of evidence, intent to deceive cannot be found.⁵⁰

After the Federal Circuit’s *Therasense* decision, the defendants did not petition for a writ of certiorari to the United States Supreme Court. The *Therasense* decision is the law of the land, at least for now. Several post-*Therasense* Federal Circuit cases discussed below elucidate the new materiality and intent standards for finding inequitable conduct.

a. Materiality Standard under Therasense

In *American Calcar, Inc. v. American Honda Motor Co., Inc.*,⁵¹ 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.⁵² The Court further explained that the misrepresented or omitted information must be “but-for” material to the patent at issue under the *Therasense* standard.⁵³ Applying this standard, the Federal Circuit agreed with defendants that the undisclosed information was “but-for” material to one of the asserted patents.⁵⁴ This was because the district court had found that the asserted claims of that patent are anticipated by the undisclosed information.⁵⁵ 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 could still have been “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

48. *Id.* at 1290.

49. *Id.* at 1290-91 (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

50. *See id.*

51. *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318 (Fed. Cir. 2011).

52. *Id.* at 1334.

53. *Id.*

54. *Id.*

55. *Id.*

their broadest reasonable construction.⁵⁶ 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.⁵⁷

In *August Technology Corp. v. Camtek, Ltd.*,⁵⁸ the Federal Circuit affirmed the district court's dismissal of Camtek's inequitable conduct defense. It reasoned 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.⁵⁹ Specifically, the district 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).⁶⁰ The district court dismissed as moot defendant's inequitable conduct charge.⁶¹ 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.⁶² 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.⁶³

In *Powell v. Home Depot USA Inc.*,⁶⁴ 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" material standard, nor does it constitute "affirmative egregious misconduct" under *Therasense*.⁶⁵

56. *Id.* at 1335.

57. *Id.*

58. *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1281 (Fed. Cir. 2011).

59. *Id.* at 1290.

60. *Id.* at 1288.

61. *Id.*

62. *Id.* at 1290.

63. *Id.* (citing *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291-92 (Fed. Cir. 2011)).

64. *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1228 (Fed. Cir. 2011).

65. *Id.* at 1235.

Where, 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

In light of the post-*Therasense* Federal Circuit cases, the “but-for” material 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.

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.⁶⁶ 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.”⁶⁷ The Court found that the district court had relied on the sliding scale standard that was rejected *en banc* in *Therasense*.⁶⁸ Accordingly, the Court vacated the district court’s finding of intent and remanded the issue.⁶⁹

Similarly, in *Cordis Corp. v. Boston Scientific Corp.*,⁷⁰ 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*.⁷¹

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.’

Id. (citation omitted) (quoting *Therasense, Inc.*, 649 F.3d at 1292-93).

66. *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1335 (Fed. Cir. 2011).

67. *Id.* (quoting *Therasense, Inc.*, 649 F.3d at 1290) (internal quotation marks omitted).

68. *Id.*

69. *Id.*

70. *Cordis Corp. v. Bos. Scientific Corp.*, 658 F.3d 1347, 1350 (Fed. Cir. 2011).

71. *Id.* at 1361. The Federal Circuit explained in a footnote:

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.’

Id. n.6 (last alteration in original) (citations omitted) (quoting *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1378-79 (Fed. Cir. 2000)).

In *Aventis Pharma S.A. v. Hospira, Inc.*,⁷² 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, because the district court had invalidated the patents using the undisclosed references.⁷³ Regarding the intent to deceive prong, the Federal Circuit upheld the district court's rejection of the inventor's rationale for withholding certain references.⁷⁴ 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 to deceive must be the single most reasonable inference able to be drawn from the evidence."⁷⁵ While the inventor 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.⁷⁶ It held that the district court's finding of specific intent to deceive the Patent Office was not clearly erroneous.⁷⁷

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 in a manner envisioned by the majority. 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. The Patent Office has also proposed to revise Rule 56 to reduce the incentive to inundate it with marginally relevant

72. *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1337 (Fed. Cir. 2012).

73. *Id.* at 1334.

74. *Id.* at 1335-37.

75. *Id.* at 1335 (quoting *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011)) (internal quotation marks omitted).

76. *Id.* at 1335-37.

77. *Id.*

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 “reasonable examiner” standard with a clearer and more objective set of rules.⁷⁸ In 1992, the Patent Office adopted the amended version of Rule 56, which remains in place today.⁷⁹

Historically, the Federal Circuit has followed the Patent Office’s materiality standard for the duty of disclosure to measure materiality for inequitable conduct claims.⁸⁰ In the past decade, however, the Federal Circuit has only loosely followed the standard for materiality adopted in the 1992 version of Rule 56.⁸¹ In *Digital Control*, 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.”⁸²

Following *Therasense*, the Patent Office has once again proposed to revise Rule 56.⁸³ It hopes 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.⁸⁴ The proposed amendment to Rule 56 would define that information is material to patentability under *Therasense* if it falls under the “but-for-plus” standard, i.e., (1) the Patent 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 Patent Office as to the

78. See Duty of Disclosure, 56 Fed. Reg. 37,321 (proposed Aug. 6, 1991) (to be codified at 37 C.F.R. pts. 1 & 10).

79. See 37 C.F.R. § 1.56(a) (2012); Duty of Disclosure, 57 Fed. Reg. 2021 (Jan. 17, 1992) (to be codified at 37 C.F.R. pts. 1 & 10).

80. See Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 Fed. Reg. 43,631, 43,631 (proposed July 21, 2011) (to be codified at 37 C.F.R. pt. 1).

81. Mammen, *supra* note 4, at 1334-35.

82. See *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006) (identifying the Patent Office’s material to patentability standard as one of the many standards the courts could apply).

83. Revision of the Materiality to Patentability Standard, 76 Fed. Reg. at 43,631.

84. *Id.*

information.⁸⁵ Moreover, “neither mere nondisclosure of information to the Office nor failure to mention information in an affidavit, declaration, or other statement to the Office constitutes affirmative egregious misconduct.”⁸⁶

The Patent Office emphasized that its proposed changes to Rule 56 was voluntary and not required by *Therasense*.⁸⁷ This is because the Patent Office’s materiality standard and the court’s inequitable conduct standard are “not inseparably tied.”⁸⁸ Nevertheless, the Patent Office noted that harmonization of the two materiality standards had several benefits.⁸⁹ 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.”⁹⁰ 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.”⁹¹ Additionally, the Patent Office stated that it believes a unitary materiality standard would be simpler for the patent bar to implement.⁹²

It is yet to be seen whether the proposed amendments to Rule 56 would have any impact on IDS practices. It is unclear whether they would solve the over-disclosure problem as anticipated by the *Therasense* majority and the Patent Office.

C. Supplemental Examination

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 inequitable conduct charges in patent litigation. The supplemental examination provision of the AIA, enacted on September 16, 2011, provides a

85. *Id.* at 43,632.

86. *Id.* at 43,633.

87. *Id.* at 43,632.

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

patentee with an avenue to ask the Patent Office “to consider, reconsider, or correct information believed to be relevant to [a] patent”⁹³ at any time after the issuance of that patent. This provision took effect on September 16, 2012; it applies to any patent issued before, on, or after that date.⁹⁴

Supplemental examination 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.⁹⁵ 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 parte* reexamination rules.⁹⁶

93. 35 U.S.C. § 257(a) (2011).

Request for supplemental examination.—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.

Id.

94. Peter G. Thurlow & Maya Elbert, *Inequitable Conduct: Analysis of Post-Therasense Court Decisions and the Supplemental Examination Provision of the America Invents Act*, BLOOMBERG L. REPS.: INTELL. PROP., Nov. 16, 2011, at 3, available at <http://www.jonesday.com/files/Publication/4501f180-8a8d-4c84-8c99-2c0c93e79ed1/Presentation/PublicationAttachment/a67e906e-d07d-4c06-b736-98c68fe8d60e/Bloomberg.pdf>.

95. See 35 U.S.C. § 257(c)(1) (2011).

In general.—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.

Id.

96. *Id.* § 257(b).

To take advantage of the “shielding effect” of supplemental examination, 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.⁹⁷ 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.⁹⁸

Supplemental examination can be helpful in maximizing the value of a patent in 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.

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.⁹⁹ This will minimize the chances of the patent being held unenforceable due to inequitable conduct.¹⁰⁰ Thus, supplemental examination can be said to be the AIA’s cure for the “plague” of inequitable conduct.

III. THE IMPACT OF INEQUITABLE CONDUCT REFORM ON INFORMATION DISCLOSURE

With *Therasense*, 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.*

97. *Id.* § 257(c)(2)(A); see also Clara N. Jimenez & Rebecca M. McNeill, *Using Supplemental Examination Effectively to Strengthen the Value of Your Patents*, 82 PAT., TRADEMARK & COPYRIGHT J. (BNA) 751 (Sept. 30, 2011), available at <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=0aa7d6b6-e467-46f6-b9e8-3ace89e1f58e>.

98. 35 U.S.C. § 257(c)(2)(B).

99. Jimenez & McNeill, *supra* note 97.

100. *Id.*

Wal-Mart Stores, Inc.,¹⁰¹ is expected to make pleading and proving inequitable conduct much harder for defendants.

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.”¹⁰² 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.¹⁰³

Despite the confidence exuded by the Patent Office that applicants will continue to be forthcoming with information relevant to patent examination,¹⁰⁴ many commentators have 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.¹⁰⁵ 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.¹⁰⁶

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

101. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009) (adopting strict pleading standards for the defense of inequitable conduct, which required deceptive intent to be pleaded with particularity).

102. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1293 (Fed. Cir. 2011).

103. *See* Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 Fed. Reg. 43,631, 43,631 (proposed July 21, 2011) (to be codified at 37 C.F.R. pt. 1).

104. *Id.*

105. *See supra* note 18 and accompanying text.

106. *See* Lisa Dolak, *supra* note 19, at 170 & n.111 (citing Harry F. Manbeck, Jr., *Evolution and Future of New Rule 56 and the Duty of Candor: The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136, 138–40 (1992)) (noting that the Patent Office had previously determined it was ill-equipped to investigate possible instances of fraud that came to its attention); *Therasense, Inc.*, 649 F.3d at 1306 (Bryson, J., dissenting).

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.”¹⁰⁷

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.

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 to the Patent Office during prosecution.

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

107. 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).

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.¹⁰⁸ The petitioner may request cancellation of one or more claims on any basis set forth in paragraphs two or three of § 282(b) for invalidity, including for example, novelty, obviousness, written description, enablement and statutory subject matter.¹⁰⁹ 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.¹¹⁰ The basis for *inter partes* review is limited to patents or printed publications, as in the current *inter partes* reexamination process.¹¹¹ 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.¹¹²

The AIA raises the bar of entry for initiating a post-grant review or *inter partes* review. Specifically, it mandates that the Director may institute an *inter partes* review or a post grant review proceeding only where a petitioner meets the threshold requirements.¹¹³ 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.¹¹⁴ 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.¹¹⁵

Additionally, for a post-grant review, the petitioner may show a novel or unsettled legal question that is important to other patents or

108. 35 U.S.C. § 321(a)-(c) (2011); Anthony C. Tridico & Erin M. Sommers, *What's Next for the U.S.—The Metric System?: A Quick Look at the "Imminent" Major U.S. Patent Law Reform*, CIPA J. (June 2011), available at <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=df7a4aa5-9c71-4a8c-b2b8-350c91d2bf00>.

109. *Id.*

110. 35 U.S.C. § 311 (a)-(c).

111. *Id.* § 312.

112. *Id.* § 311(b).

113. See generally Justin A. Hendrix & Robert F. Shaffer, *Post Grant Proceedings of the AIA Provide New Opportunities and Require Reconsideration of Old Patent Litigation Strategies*, MED. DEVICE (June 15, 2012), available at <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=598696f7-7eba-4fcb-83b8-2369caa91dd3>.

114. 35 U.S.C. § 314(a).

115. *Id.* § 324(a).

patent applications.¹¹⁶ The “reasonable likelihood standard allows for the exercise of discretion but encompasses a 50/50 chance whereas the ‘more likely than not’ standard requires greater than a 50% chance of prevailing.”¹¹⁷ For both post-grant and *inter partes* review, the decision of the Patent Office whether to institute a review is final and non-appealable.¹¹⁸

The current *ex parte* reexamination standard requires that a substantial new question (SNQ) of patentability be raised; this requirement is met in almost 95% of the reexamination requests filed.¹¹⁹ The standards for post-grant and *inter partes* review are much higher than the standard for *ex parte* reexamination. 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.”¹²⁰

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.”¹²¹ This provision provides only a discretionary duty 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.¹²² Chief Judge Smith’s explanation that “[i]n instituting an [*inter partes* review] or [post-grant review], the Board may take into

116. *Id.* § 324(b).

117. *Message from Chief Judge James Donald Smith, Board of Patent Appeals and Interferences: USPTO Discusses Key Aspects of New Administrative Patent Trials*, USPTO.GOV, http://www.uspto.gov/aia_implementation/smith-blog-extravaganza.jsp (last modified May 21, 2012) [hereinafter *Message from Chief Judge Smith*].

118. 35 U.S.C. §§ 314(d), 324(e).

119. H.R. REP. NO. 112-98, pt. 1, at 47 (2011) (“The 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.”).

120. *Message from Chief Judge Smith, supra* note 117; *see also* 35 U.S.C. §§ 315(d), 325(d).

121. 35 U.S.C. § 325(d) (emphasis added).

122. *See* Scott A. McKeown, *Will Post Grant Patent Proceedings Revisit Failed Arguments?*, PATENTS POST-GRANT (Apr. 11, 2012), <http://www.patentspostgrant.com/lang/en/2012/04/will-post-grant-patent-proceedings-reconsider-failed-arguments>.

account whether the same or substantially same prior art or arguments previously were presented to the Office,”¹²³ further clarifies that the Patent Office is unlikely to institute a post-grant proceeding 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.¹²⁴

Defending a post-issuance challenge at the Patent Office can be needlessly expensive and time-consuming for a patentee. 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.¹²⁵ The presumption of validity can be overcome only by clear and convincing evidence, regardless of whether the prior art offered at

123. *Message from Chief Judge Smith, supra* note 117 (citing 35 U.S.C. §§ 315(d), 325(d)).

124. 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).

125. See 35 U.S.C. § 282.

In general.—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.

Id. § 282(a).

trial was considered by the Patent Office.¹²⁶ The logic underlying the presumption is that the Patent Office has scrutinized the patent and their expert judgment is entitled to deference by the courts.¹²⁷ Although in theory the presumption of validity extends to both disclosed and undisclosed prior art, the presumption appears to be stronger when prior art was considered by the Patent Office and weaker when it was not.¹²⁸

In the *i4i* case, appellant Microsoft and its *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.¹²⁹ Previously, in *KSR International Co. v. Teleflex, Inc.*,¹³⁰ the Supreme Court had called into question the application of the presumption to prior art not considered by the Patent Office.¹³¹ However, in *i4i*, 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.¹³² The Court specifically endorsed the “commonsense principle that the Federal

126. *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2243 (2011) (holding that under 35 U.S.C. § 282 the standard for patent invalidity is clear and convincing, not mere preponderance of the evidence).

127. See Christopher A. Cotropia, Mark A. Lemley & Bhaven N. Sampat, *Do Applicant Patent Citations Matter? Implications for the Presumption of Validity* 4-5 (Stanford Law Sch., John M. Olin Program in Law & Econ., Working Paper No. 401, 2012), available at <http://ssrn.com/abstract=1656568>; Todd L. Juneau & Jill K. MacAlpine, *Protecting Patents from the Beginning: The Importance of Information Disclosure Statements During Patent Prosecution*, 82 J. PAT. & TRADEMARK OFF. SOC’Y 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.”).

128. See Cotropia et al., *supra* note 127, at 6-7.

129. *i4i Ltd. P’ship*, 131 S. Ct. at 2244.

130. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

131. *Id.* 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).

132. *i4i Ltd. P’ship*, 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.

Id. at 2251.

Circuit has recognized throughout its existence—namely, that new evidence supporting an invalidity defense may ‘carry more weight’ in an infringement action than evidence previously considered by the PTO.”¹³³

In *i4i*, the Supreme 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.”¹³⁴ Because 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.¹³⁵ Consequently, fact-finders are more likely to invalidate a claim based on prior art not previously considered by the Patent Office.

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.¹³⁶ 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) to the attention of the Patent Office during prosecution.

Additionally, disclosure of all known information during the initial examination of a patent application provides protection against discovery of undisclosed information during litigation as well as any unpleasant questioning that could follow. Even if an applicant

133. *Id.* (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984), *abrogated by* *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011)).

134. *Id.*

135. *See* *Cotropia et al.*, *supra* note 127, at 6-7; *Juneau & MacAlpine*, *supra* note 127, 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.”).

136. *See* *Cotropia et al.*, *supra* note 127, at 6-7; *Juneau & MacAlpine*, *supra* note 127, at 580.

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.

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 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."¹³⁷ The Court created this exception to strike a "necessary balance between encouraging honesty before the [Patent Office] and preventing unfounded accusations of inequitable conduct."¹³⁸ In both *Therasense* and *Home Depot*, 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."¹³⁹

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 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

137. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011).

138. *Id.* at 1293.

139. *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1235 (Fed. Cir. 2011) (citing *Therasense, Inc.*, 649 F.3d at 1290, 1292-93).

benefits of the inequitable conduct defense.¹⁴⁰ 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. Such profligate applicants form a small fraction of the patent community and are generally limited to specific technology areas.¹⁴¹ *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 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. Determination of whether a piece of information is material is a complicated process.¹⁴² 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

140. Johnson, *supra* note 20, at 204.

141. See generally Crouch & Rantanen, *supra* note 13 (noting that applicants submit over 200 references in only 2% of cases, and 15% of patented cases include absolutely no applicant cited references).

142. 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.

Id. (footnote omitted).

different subjective understanding of that reference.¹⁴³

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 materiality standard.¹⁴⁴

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.

B. Supplemental Examination Will Not Jeopardize the Duty of Disclosure

The supplemental examination provision in the AIA is intended to curtail allegations and findings of inequitable conduct.¹⁴⁵ The provision provides a patentee with a powerful tool for strengthening its patent against inequitable conduct charges before a patent infringement action is initiated.¹⁴⁶

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” encouraging 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.”¹⁴⁷ Supplemental examination is framed as a means to encourage applicants to violate their duty of candor by intentionally keeping the

143. Johnson, *supra* note 20, at 208-09.

144. See *supra* Part III.A.2.

145. See Dolak, *supra* note 19, at 148.

146. See generally Jimenez & McNeill, *supra* note 97.

147. Jason Rantanen et al., *supra* note 19, at 244.

Patent Office in the dark about prior art that would be detrimental to the prosecution of their application, allowing parties to monetize a patent that is known or suspected to be unpatentable, and thereafter immunizing the parties from the misconduct using supplemental examination if a licensee or competitor threatens litigation.¹⁴⁸

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 error that is correctible by reissue.¹⁴⁹ 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.¹⁵⁰ Supplemental examination is not likely to encourage or escalate such knowing violations of the duty of disclosure at least because of the following reasons.

1. Risk of *Ex Parte* Reexamination

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

148. *Id.* at 231, 244.

149. *See In re Tanaka*, 640 F.3d 1246, 1250-52 (Fed. Cir. 2011) (holding that the 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).

150. Dolak, *supra* note 19, at 168.

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 *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.¹⁵¹ Moreover, the chances of *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.¹⁵²

A supplemental examination request introducing a “but-for” material reference is very likely to raise a substantial new question of patentability, consequently prompting an *ex parte* reexamination. During reexamination, the affected claims will either have to be canceled or amended to distinguish over the reference,¹⁵³ resulting in prosecution history estoppels and affecting claim scope under the Doctrine of Equivalents.

Lastly, an *ex parte* reexamination proceeding takes a long time, currently approximately 26.3 months from the filing of the request to the grant of the *ex parte* certificate.¹⁵⁴ To gain the shielding effect of supplemental examination, the patentee will potentially have to delay the start of litigation until reexamination is concluded.¹⁵⁵

In view of the high likelihood of *ex parte* reexamination being prompted by a supplemental examination request, a patentee has very little to gain from deliberately withholding potentially material information during prosecution and requesting supplemental examination at a later date. 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

151. 35 U.S.C. § 257(b) (2011).

152. See, e.g., Warren D. Woessner, *Supplemental Examination Decision Tree—Lots of Dead Branches?*, PATENTS4LIFE (Jan. 31, 2012), <http://www.patents4life.com/2012/01/supplemental-examination-decision-tree-lots-of-dead-branches/> (last visited Apr. 29, 2012) (discussing that savvy patent applicants and practitioners realize that after *Therasense*, a party alleging inequitable conduct must make 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).

153. Thurlow & Elbert, *supra* note 94, at 3.

154. *Id.*

155. *Id.*

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 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.

2. The Fraud Provision in Supplemental Examination

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.¹⁵⁶ 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.”¹⁵⁷ 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.

3. Cost Associated with Supplemental Examination

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.¹⁵⁸ 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.¹⁵⁹ If the request for supplemental examination raises a substantial new

156. See generally Jimenez & McNeill, *supra* note 97.

157. 35 U.S.C. § 257(e) (2011).

158. Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and to Revise Reexamination Fees, 77 Fed. Reg. 48,828 (Aug. 14, 2012) (to be codified at 37 C.F.R. pt. 1).

159. *Id.* at 48,831.

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 supplemental examination, which would be refunded if the request does not raise a substantial new question of patentability.¹⁶⁰ 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.¹⁶¹ 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.

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.

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

160. *Id.*

161. *Id.*

Office with marginally relevant information out of an abundance of caution.¹⁶² The Patent Office echoed similar views when it proposed to raise the materiality standard for the duty to disclose under Rule 56.¹⁶³

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. 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.¹⁶⁴ Therefore, currently there are no disincentives for over-compliance with the duty of 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.¹⁶⁵ The proposed changes to the IDS requirements were

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

163. See Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 Fed. Reg. 43,631, 43,631 (July 21, 2011) (to be codified at 37 C.F.R. pt. 1).

164. See, e.g., *Cordis Corp. v. Bos. Scientific Corp.*, 658 F.3d 1347, 1353, 1361 (Fed. Cir. 2011). Under the *Therasense* standard, specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence. *Therasense, Inc.*, 649 F.3d at 1290. In *Cordis*, the applicant submitted a material reference in an IDS with 60 other references and without emphasis. *Cordis*, 658 F.3d at 1353. The district court found, and the Federal Circuit affirmed, that defendants had failed to prove deceptive intent by clear and convincing evidence. *Id.* at 1361. The evidence of record, including the instance of burying the material reference, failed to unequivocally demonstrate specific intent to deceive. *Id.* Applicant's patents were found to be not unenforceable due to inequitable conduct. *Id.*

165. Changes to Information Disclosure Statement Requirements and Other Related

challenged in court; they were ultimately withdrawn by the Obama administration.¹⁶⁶ The 2006 Proposed Rules suggested that only IDSs with a limited number of cites (20 or less) can be submitted before first Office Action without any “additional disclosure” requirement. Large cites (more than 25 pages) or foreign language documents, and IDSs submitted after first Office action must meet increasing “additional disclosure” requirements.¹⁶⁷ The primary objective of the proposed 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.¹⁶⁸

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. 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. The Patent Office can, for example, require applicants to pay fees for documents comprising an excessive number of pages or references. 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

Matters, 71 Fed. Reg. 38,808, 38,808-823 (proposed July 10, 2006) (to be codified at 37 C.F.R. pt. 1).

166. Cotropia et al., *supra* note 127, at 24.

167. Changes to Information Disclosure Statement Requirements, 71 Fed. Reg. at 38,808.

168. See Cotropia, *supra* note 3, at 767-68.

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 (Proposed Rules) 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.”¹⁶⁹ The 2011 Proposed Rules 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.”¹⁷⁰ 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, 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”¹⁷¹ the materiality standard for inequitable conduct. Despite these changes in the materiality standards, patent applicants and practitioners are unlikely 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

169. Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 Fed. Reg. 43,631, 43,632 (proposed July 21, 2011) (to be codified at 37 C.F.R. pt. 1).

170. *Id.* at 43,633.

171. *Id.* at 43,631.

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.