Inequitable Conduct and Supplemental Examination: Promise, Procedure, and Particulars

Amanda K. Murphy
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Jonathan R. K. Stroud
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Follow this and additional works at: https://digitalcommons.law.buffalo.edu/buffaloipjournal
Part of the Intellectual Property Law Commons

Recommended Citation
Available at: https://digitalcommons.law.buffalo.edu/buffaloipjournal/vol10/iss1/4

This Article is brought to you for free and open access by the Law Journals at Digital Commons @ University at Buffalo School of Law. It has been accepted for inclusion in Buffalo Intellectual Property Law Journal by an authorized editor of Digital Commons @ University at Buffalo School of Law. For more information, please contact lawscholar@buffalo.edu.
INEQUITABLE CONDUCT AND SUPPLEMENTAL EXAMINATION: PROMISE, PROCEDURE, AND PARTICULARS

AMANDA K. MURPHY, PH.D.\(^1\) & JONATHAN R.K. STROUD\(^2\)
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP\(^3\)

\(^1\) Amanda K. Murphy is a patent attorney at Finnegan, Henderson, Farabow, Garrett, & Dunner, LLP. Amanda focuses her practice on client counseling and patent prosecution for a range of clients including small startup companies, research foundations, and large pharmaceutical companies. Amanda received her J.D. from the Georgetown University Law Center, her Ph.D. in Biochemistry, Molecular and Cellular Biology from Cornell University, and her B.S. in Biology also from Cornell University. Amanda is admitted to practice in the District of Columbia, Virginia, and before the U.S. Patent and Trademark Office (USPTO). Amanda wishes to thank her co-author, Jonathan Stroud, without whom this publication never would have happened.

\(^2\) Jonathan R.K. Stroud is a patent attorney at Finnegan, Henderson, Farabow, Garrett, & Dunner, LLP. Jonathan focuses his practice on litigating and counseling on patent and trade secret disputes before the U.S. Court of Appeals for the Federal Circuit, the federal district courts, the Patent Trial and Appeal Board of the USPTO, and the U.S. International Trade Commission (ITC), with an emphasis on PTAB litigation and its interaction with other forms of litigation. Jonathan received his J.D. from American University, Washington College of Law; his M.A. in Journalism from The University of Southern California; and his B.S. in Biomedical Engineering from Tulane University. Jonathan is admitted to practice in the District of Columbia, Maryland, before the U.S. Court of Appeals for Veterans Claims, and before the U.S. Patent and Trademark Office. Jonathan wishes to thank Amanda for her hard work, ability, and continual cheer, and his mentors and family for their longstanding support, trust, and encouragement.

\(^3\) These materials reflect only the personal views of the authors, are not individualized legal advice, and do not reflect the views of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP (including Finnegan Europe LLP, and Fei Han Foreign Legal Affairs Law Firm) ("Finnegan"). It is understood that each case is fact-specific and that the appropriate solution in any case will vary. Therefore, this article may or may not be relevant to any particular situation. Thus, Finnegan cannot be bound either philosophically or as representatives of their various present and future clients to the comments expressed in these materials. This article does not establish any form of attorney-client relationship with Finnegan or the author. While every attempt was made to insure that these materials are accurate, errors or omissions may be contained therein, for which liability is disclaimed.
ABSTRACT

The America Invents Act, signed into law on September 16, 2011, ushered in an array of patent reforms. One overlooked procedure, Supplemental Examination, seeks to purge putative instances of inequitable conduct prior to litigation by allowing patent owners to submit prior art and short statements to the USPTO after patent issuance. Few parties have used it. We analyze the law of inequitable conduct, explain the Supplemental Examination procedure, and discuss potential reasons for its lack of popularity among patent owners.

TABLE OF CONTENTS

ABSTRACT .................................................................................................................. 93
I. BACKGROUND ........................................................................................................ 95
   A. The Origins of the Doctrine of Inequitable Conduct........................ 96
II. THE FEDERAL CIRCUIT’S TREATMENT OF INEQUITABLE CONDUCT ........................................... 98
   A. The Materiality Standard................................................................. 98
   B. The Standard for Intent ................................................................. 107
III. NAVIGATING THE QUAGMIRE ................................................................. 112
IV. ENTER CONGRESS ................................................................................. 113
   A. The America Invents Act ......................................................... 113
   B. Supplemental Examination .................................................. 114
   C. Statistics and Recommendations ........................................ 116
V. CONCLUSION .......................................................................................... 120
The defense of inequitable conduct, one of the most powerful litigation tools available to an accused infringer, ensures against the fraudulent procurement of patents. Every person associated with the filing and prosecution of a U.S. patent application owes to the USPTO a duty of candor and good faith. If an accused infringer has evidence to suggest that the patent owner breached his duty, he may raise a defense of inequitable conduct. When found, inequitable conduct renders the patent unenforceable against all past, present, and future infringers, even potentially affecting the enforceability of related patents. The Damocles' sword of unenforceability due to inequitable conduct drastically complicates patent valuation and investment in cutting-edge technology.

The AIA offers patent owners an opportunity to reduce uncertainty through a new procedure called supplemental examination. This new procedure allows any patent owner to request that the USPTO consider, reconsider, or correct information in the patent or its file history. Within three months, the Director will determine whether information in the request raises a substantial new question of patentability. If so, he will order *ex parte* reexamination in view of the submitted evidence, during which the patent owner can argue for patentability of the claimed invention. Importantly, anything considered in the request for supplemental examination or the ensuing *ex parte* reexamination is, by statute, barred as the basis for a later finding of inequitable conduct.

Still, there are important limitations to what supplemental examination can accomplish. First, supplemental examination becomes unavailable once inequitable conduct has been raised in either a paragraph IV notice letter or a pending litigation. The cleansing effect of supplemental examination occurs only once the proceeding and any *ex parte* reexamination ordered therefrom has drawn to a close. So, if the patent becomes involved in litigation before the USPTO completes its review, the accused infringer may raise an inequitable conduct defense regarding any information that the patent owner asked the USPTO to consider in its request for supplemental examination.

---


---


This Article analyzes inequitable conduct and the availability of AIA supplemental examination. Part I provides a brief history of inequitable conduct; Part II discusses the legal standards for inequitable conduct in district court and at the Federal Circuit; Part III discusses strategies for navigating the district court; and Part IV discusses recent developments via Supplemental Examination. Part V briefly concludes.

I. BACKGROUND

Inequitable conduct is an equitable defense invoked by a party accused of patent infringement. It is brought when there is evidence to suggest that the patent owner breached his duty of good faith and candor to the USPTO.\(^8\) To successfully prove inequitable conduct, an accused infringer must show by clear and convincing evidence that the patent owner misrepresented, withheld, or falsified material information during prosecution of the patent and that the patent owner intended to deceive the USPTO through such conduct.\(^9\)

Courts apply a two-part test to analyze allegations of inequitable conduct. A court first determines whether the information misrepresented, withheld, or falsified meets threshold levels of materiality, and whether there was intent to deceive. If the court determines the evidence meets the threshold levels for materiality and intent, the court then weighs the evidence—in light of all the circumstances—to determine whether the patent owner’s conduct was so culpable as to require that the patent be declared unenforceable.\(^10\)

A ruling finding inequitable conduct renders a patent unenforceable against all past, present, and future infringers, and may also affect the enforceability of related applications.\(^11\) In view of these powerful, far-reaching effects, unsurprisingly parties raised inequitable conduct as a defense in approximately 80% of all patent litigations.\(^12\)

---

\(^9\) See id. at 1287.
\(^10\) Id.
\(^11\) Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1230 (Fed. Cir. 2007).
\(^12\) Melissa Feeney Wasserman, *Limiting the Inequitable Conduct Defense*, 13 VA. J.L. & TECH. 7, 8 (2008); however the accuracy of this statistic has been called into question, see, e.g., Benjamin Brown, *Inequitable Conduct: A Standard in Motion*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 593, 626 (stating that the inequitable conduct defense is “pled in a mere 20% of patent infringement cases”).
A. The Origins of the Doctrine of Inequitable Conduct

*Ex turpi causa non oritur actio*—He who comes in equity must come with clean hands.13

The inequitable conduct defense is a product of both common and legislative law. The common-law origins of inequitable conduct grew out of three cases in which the Supreme Court refused to enforce patents tainted with fraud.14 Beginning in 1933 with *Keystone Driller Co. v. General Excavator Co.*, the Court found the patent owner had suppressed evidence of a potentially invalidating prior use of the claimed invention to prevail in a patent infringement suit.15 Invoking the equitable doctrine of “unclean hands,” which denies a party relief if he has acted fraudulently or in bad faith,16 the Court held that the plaintiff’s actions were so unconscionable that they estopped any relief for the alleged infringement.17

In 1944, the Court revisited the issue. In *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, the patent owner had fabricated a printed publication from an ostensibly disinterested expert who described the invention as “a remarkable advance in the art” in order to overcome “apparently insurmountable Patent Office opposition.”18 Invoking the equitable principles discussed in *Keystone*, the *Hazel-Atlas* Court held: “The total effect of all this fraud, practiced both on the Patent Office and the courts, calls for nothing less than a complete denial of relief... for the claimed infringement of the patent thereby procured and enforced.”19

The triad of Supreme Court cases culminated with *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, which the patent owner had asserted a patent after learning that someone else invented the claimed invention.20 Relying on *Keystone* and *Hazel-Atlas’s* equitable principles,21 the *Precision* Court affirmed the district court’s finding of inequitable conduct, holding that the

---

15 Keystone, 290 U.S. at 243-46.
17 Keystone, 290 U.S. at 247.
18 Hazel-Atlas, 322 U.S. at 240.
19 Id. at 250.
20 Precision, 324 U.S. at 808-14.
patent owner's hands were so soiled that all of the relief they requested should be denied.\textsuperscript{22} The Court stated a rule that patent applicants "have an uncompromising duty to report to [the USPTO] all facts concerning possible fraud or inequitableness underlying the applications in issue,"\textsuperscript{22} and announced that inequitable conduct exists whenever a patent owner knew or reasonably should have known that this duty to the USPTO had been breached.\textsuperscript{24}

Complementing this common-law foundation, inequitable conduct also has legislative origins. Every patent statute passed by Congress has contained a provision creating a form of private remedy against the procurement of patents by fraud. The Patent Acts of 1790 and 1793 authorized private actions to repeal a patent procured by fraud, stating that "upon oath or affirmation . . . that any patent which shall be issued in pursuance of this act, was obtained surreptitiously by, or upon false suggestion, . . . it shall and may be lawful to . . . repeal such patents."\textsuperscript{25} Similarly, the Patent Acts of 1836 and 1870 codified an affirmative defense to infringement if the applicant obtained the patent intending to deceive the public.\textsuperscript{26} Finally, like the Patent Act of 1952, the current America Invents Act ("AIA") gives an accused infringer an equitable defense of patent "unenforceability"\textsuperscript{27} based on the patent

\textsuperscript{22} Id. at 819.
\textsuperscript{23} Id. at 818.
\textsuperscript{24} See id. at 817-19 ("Automotive had every reason to believe and did believe that Larson's application was fraudulent and his statements perjured . . . . But where, as here, the settlement is grounded upon knowledge or reasonable belief of perjury which is not revealed to the Patent Office or to any other public representative, the settlement lacks that equitable nature which entitles it to be enforced and protected in a court of equity.").
\textsuperscript{25} Patent Act of 1790, ch. 7, § 5, 1 Stat. 111 (1790); see also Patent Act of 1793, Ch. 11, § 10, 1 Stat. 323.
\textsuperscript{26} See Patent Act of 1836, Ch. 357, § 15, 5 Stat. 123 (1836) ("the defendant . . . shall be permitted to plead . . . that the description and specification filed by plaintiff does not contain the whole truth relative to his invention or discovery, or that it contains more than is necessary to produce the described effect; which concealment or addition shall fully appear to have been made for the purpose of deceiving the public . . . in either of which cases judgment shall be rendered for the defendant, with costs."); see also Patent Act of 1870, Ch. 230, § 61, 16 Stat. 208 ("in any action for infringement the defendant may plead . . . any one or more of the following special matters:— First. That for the purpose of deceiving the public the description and specification filed by the patentee in the patent office was made to contain less than the whole truth relative to his invention or discovery, or more than is necessary to produce the desired effect . . . and if any one or more of the special matters alleged shall be found for the defendant, judgment shall be rendered for him with costs.").
\textsuperscript{27} See Patent Act of 1952, 35 U.S.C. § 282 (1952) ("The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded: (1) Noninfringement, absence of liability for infringement or unenforceability . . . "); America Invents Act 35 U.S.C. § 282 (2006 & Supp. 2011) ("The following shall be defenses in any action involving the validity or infringement of a patent and shall be
The defense of inequitable conduct finds further administrative support in Rules of Practice in Patent Office Cases promulgated by the USPTO following the Supreme Court's decision in Precision. Specifically, Rule 56 prohibits fraud on the USPTO and imposes a duty of candor and good faith on every individual associated with the filing and prosecution of a patent application.

The doctrine of inequitable conduct can trace its origins to the equitable fraud-based defenses codified in each of the Patent Acts, and recognized by the Supreme Court in Keystone, Hazel-Atlas, and Precision, and by the USPTO in its administrative regulations. But beyond the “knew or should have known” test established in Precision, none provides guidance for determining when inequitable conduct would be deemed to have occurred.

II. THE FEDERAL CIRCUIT'S TREATMENT OF INEQUITABLE CONDUCT

A. The Materiality Standard

Since Precision, the law of inequitable conduct has continually evolved, as courts fashioned different tests to determine when a patent should be declared unenforceable. When the Federal Circuit was created in 1982, there were four separate tests for materiality: (1) the “objective but for test,” under which information was material only if it would have precluded the patent from issuing; (2) the “subjective but for test,” under which information was material only if it caused the examiner to issue the patent when he would not otherwise have done so; (3) the “but it may have test,” under which information was material only if it might have reasonably affected the examiner’s determination of patentability; and (4) the “reasonable examiner test” recited in the 1977 revision to the USPTO’s Rule 56, under which information is material “where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the

pleaded: (1) Noninfringement, absence of liability for infringement or unenforceability.”

28 See, e.g., Symbol Tech., Inc. v. Lemelson Med., 277 F.3d 1361, 1366 (Fed. Cir. 2002) (“The defenses which may be raised in an action involving the validity or infringement of a patent are specified in general terms, by the second paragraph of section 282, in five numbered items. Item 1 specifies ‘Noninfringement, absence of liability for infringement, or unenforceability’ (the last word was added by amendment in the Senate for greater clarity); this would include ... equitable defenses such as laches, estoppel and unclean hands.”) (citing Commentary on the New Patent Act, 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 215 (1993)).

29 See 37 C.F.R. § 1.56 (1951).
In 1984, the Federal Circuit decided *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, which the defendant accused the patent owner of inequitable conduct for failing to disclose a piece of prior art during a reissue proceeding involving the patent at issue. The Federal Circuit vacated the district court's holding of inequitable conduct and remanded with the instructions that the court may apply any of the four tests for materiality in existence stating that "[t]here is no reason . . . to be bound by any single standard, for the answer to any inquiry of fraud in the PTO does not begin and end with materiality, nor can materiality be said to be unconnected to other considerations . . . ." Yet the court stated that the USPTO's reasonable examiner standard, which is "strikingly similar to the 'but it may have' guideline," is "an appropriate starting point for any discussion of materiality, for it appears to be the broadest, thus encompassing the others, and because that materiality boundary most closely aligns with how one ought to conduct business with the PTO." But the court cautioned that if the information misrepresented, withheld, or falsified satisfies the reasonable examiner test but satisfies none of the more stringent "but for" tests, the low showing of materiality should be offset by using a higher standard for intent before a patent is declared unenforceable for inequitable conduct.

Shortly thereafter, despite having held in *American Hoist* that any of the four tests of materiality could be used in an inequitable conduct analysis, separate Federal Circuit panels rejected both the "objective but for" and "subjective but for" tests adopting the "reasonable examiner test" as the only standard for materiality. Specifically, in 1986 the court decided *A.B. Dick Co. v. Burroughs Corp.*, in which the defendant accused the patent owner of inequitable conduct for having withheld several prior art references, which the examiner

---

32 *Id.* at 1363.
33 *Id.* at 1362.
34 *Id.* at 1363.
35 *Id.* ("where it is demonstrated that a reasonable examiner would merely have considered particular information to be important but not crucial to his decision not to reject, a showing of facts which would indicate something more than gross negligence or recklessness may be required, and good faith judgment or honest mistake might well be a sufficient defense.").
independently discovered during prosecution. The patent owner argued that the references were not material because the claims were allegedly patentable over the prior art all along. In affirming the district court’s decision that the withheld references were material, the Federal Circuit rejected the “objective but for test” offered the patent owner, stating that “the test for materiality is not whether there is anticipation or obviousness but, rather, what a ‘reasonable examiner would consider... important in deciding whether to allow the application to issue as a patent. . . . That the claims may be patentable over the withheld prior art... is not relevant.”

Two years later, the court decided Western Electric Co., Inc. v. Piezo Technology, Inc., which involved an issue of whether an examiner may be compelled to answer questions during a deposition to probe his technical knowledge of the subject of the patent, to determine whether he would have recognized the patent owner’s allegedly inaccurate or misleading statements about the prior art. Below, the district court ordered the examiner and the Commissioner of the USPTO held in civil contempt for violating the court’s order compelling the examiner to testify. Reversing, the Federal Circuit rejected the “subjective but for test” of materiality proposed by the defendant, stating that “[t]he standard to be applied is not whether a particular examiner would consider the material to be important, . . . rather it is that of a ‘reasonable examiner.’ Inquiry into the importance that [an examiner] may have placed on the representations... is therefore wholly irrelevant.”

Although the court’s decisions in A.B. Dick and Western Electric contradicted American Hoist’s approval of all four materiality standards, the court’s adoption of the USPTO’s “reasonable examiner test” as the sole standard for materiality added consistency to the requirements patent owners could expect to encounter during patent prosecution and litigation. Practitioners could rely on the fact they would likely be held to the same standard when disclosing information to the USPTO and when facing charges of inequitable conduct in court.

But Federal Circuit panels continued to struggle with consistently defining the boundaries of the reasonable examiner test, diverging in several factually similar cases. In Kimberly-Clark Corp. v. Johnson & Johnson, the panel found non-disclosed information immaterial when the patent examiner had likely encountered the information when

---

37 A.B. Dick, 798 F.2d at 1393-96.
38 Id. at 1397.
39 Id. at 1397-98 (emphasis in original).
40 W. Electric, 860 F.2d at 430.
41 Id. at 433.
Inequitable Conduct and Supplemental Examination

examining another patent application, but in *J.P. Stevens & Co. v. Lex Tex Ltd.*, the court ruled that to find withheld information immaterial, the evidence must show that the examiner actually, not just possibly, knew of the material information.

The court reached an apparently inconsistent result when responding to the assertion that uncited information was immaterial because the examiner had independently discovered the information. In *Orthopedic Equipment Co. v. All Orthopedic Appliances*, the Federal Circuit affirmed the trial court’s judgment of no inequitable conduct in part because the examiner had found the prior art independently, while in *A.B. Dick*, the Federal Circuit affirmed the trial court’s inequitable conduct holding despite the examiner having independently discovered the uncited art.

Besides these inconsistencies in the court’s application of the “reasonable examiner test,” since it is the broadest of the four tests for materiality, its adoption as the sole standard encouraged accused infringers to raise the defense more frequently by lowering their burden for proving inequitable conduct. Not coincidentally, by the end of the 1980s, the Federal Circuit had observed “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.” To combat the “plague,” the USPTO amended Rule 56 to recite a more objective standard for materiality. The resulting “prima facie/inconsistent test,” which was promulgated in 1992, recites that information is material when: “(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes [during prosecution].”

The Federal Circuit first discussed the new Rule 56 in *Molins PLC v. Textron, Inc.* The defendant in *Molins* had accused the patent owner of inequitable conduct for having failed to disclose a prior art reference cited to and by several foreign patent offices during prosecution of corresponding applications, but which was withheld from the examiner during prosecution of the U.S. application. The Federal Circuit

---

43 J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1563-64 (Fed. Cir. 1984).
44 Orthopedic Equip. Co. v. All Orthopedic Appliances, 707 F.2d 1376, 1383-84 (Fed. Cir. 1983).
45 *A.B. Dick*, 798 F.2d at 1396-97.
46 *Am. Hoist*, 725 F.2d at 1363.
47 Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988).
agreed with the district court that the patent owner’s conduct was inequitable, and indicated that courts should continue to apply the old Rule 56 standard for materiality (i.e., the “reasonable examiner test”) to patents prosecuted before 1992, while reserving the new Rule 56 standard (i.e., the “prima facie / inconsistent test”) for patents prosecuted after 1992. The Molins court also affirmed the decisions in A.B. Dick and Western Electric rejecting the “objective” and “subjective” but-for tests, and acknowledged a general rule that non-cumulative prior art should always be considered per se material.

In Dayco Products, Inc. v. Total Containment, Inc., the court finally faced inequitable conduct in patents prosecuted after 1992. The defendant in Dayco accused the patent owner of inequitable conduct for having failed to disclose an Office Action by another examiner rejecting substantially similar claims. The Federal Circuit agreed with the district court that the withheld information was material, but retreated from the decision in Molins, which would have required the court to apply the new Rule 56 materiality standard since “the patents-in-suit were filed and prosecuted after the January 17, 1992, rule change.” Stating that the court “has not decided whether it should adhere to the preexisting standard for inequitable conduct in prosecutions occurring after the effective date of the new rule,” the Dayco court applied the old Rule 56 reasonable examiner test “[b]ecause we conclude that the outcome of this appeal would be the same under either materiality standard.” In addition, the court created a new per se rule of materiality under which “a contrary decision of another examiner reviewing a substantially similar claim” is always material.

50 See Molins, 48 F.3d at 1179 (“administrative rules will not be construed to have retroactive effect”) (citing the PTO’s notice of final rulemaking accompanying the 1992 amendment to Rule 56).
51 See id. at 1179-80 (“the standard to be applied in determining whether a reference is ‘material’ is not whether the particular examiner of the application at issue considered the reference to be important . . . .”) (citing W. Electric, 860 F.2d at 433) and (“that claims may be patentable over the withheld prior art is not the test for materiality”) (citing A.B. Dick, 798 F.2d at 1396).
52 See Molins, 48 F.3d at 1180.
53 Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1364 (Fed. Cir. 2003).
54 Id.
55 Dayco, 329 F.3d at 1364.
56 Id.
57 Id. at 1368.
Despite the uncertainty in *Dayco* regarding the proper materiality standard for patents prosecuted after 1992, the court did adhere to the decade-old decision in *Molins* by applying the “*prima facie* inconsistent” standard for materiality in two cases, *Bruno Independent Living v. Acorn Mobility Services, Ltd.* and *Purdue Pharma L.P., v. Endo Pharmaceuticals, Inc.*, which involved patents prosecuted after the new Rule 56 was promulgated.58 In *Bruno*, the district court held that the patent owner had committed inequitable conduct by failing to disclose to the USPTO several invalidating prior art references he had disclosed to the Food and Drug Administration in seeking approval to market the invention covered by the patent at issue.59 In *Purdue*, the district court based its inequitable conduct holding on the patent owner’s failure to disclose that the statements made during prosecution regarding unexpected properties of the claimed invention were based on insight without actual experimental proof.60 In both cases, the Federal Circuit agreed with the district court’s decision that the withheld information was material, and applied the new Rule 56 standard for materiality, since the patents were “pending or filed after March 16, 1992,”61 the effective date of the amendment to Rule 56.

However, seven days after the court decided *Purdue*, a separate panel writing in *Digital Control Inc. v. Charles Machine Works* reached back across two decades of precedent to revive the holding in *American Hoist* that “[t]here is no reason . . . to be bound by any single [materiality] standard”62 and, therefore, “if a misstatement or omission is material under the new Rule 56 standard, it is material. Similarly, if a misstatement or omission is material under the ‘reasonable examiner’ standard or under the older three tests, it is also material.”63 In *Digital*, the defendant had accused the patent owner of inequitable conduct for failing to disclose a prior art reference and for filing a declaration that contained an affirmative misstatement regarding the date on which the inventor had reduced his invention to practice.64 The Federal Circuit affirmed the district court’s use of the reasonable examiner test for materiality, although the patent had been prosecuted after the new

59 Bruno, 394 F.3d at 1351.
60 Purdue, 438 F.3d at 1128.
61 Bruno, 394 F.3d at 1352; *see also* Purdue, 438 F.3d at 1129.
62 Digital, 437 F.3d at 1315.
63 Id. at 1316.
64 Id. at 1316-17.
Rule 56 went into effect.\textsuperscript{65}

By holding that the old Rule 56 “reasonable examiner” standard may apply to patents prosecuted after 1992, the \textit{Digital} court indicated once again that defendants face no high burden of proof for establishing materiality. In the cases following \textit{Digital}, the court consistently relied upon the “reasonable examiner test” as the sole standard for determining materiality.\textsuperscript{66} Not surprisingly, therefore, in the year following \textit{Digital}, the number of Federal Circuit cases involving inequitable conduct nearly doubled from 49 cases in 2006 (the year \textit{Digital} was decided) to 95 cases in 2007.\textsuperscript{67} In addition, the percentage of cases in which the Federal Circuit ruled in favor of the accused infringer on inequitable conduct increased from 24.5\% in 2006 to an unprecedented 42.1\% in 2007.\textsuperscript{68}

In view of these trends, former Chief Judge Michel authored an extended discussion of the elements of inequitable conduct in \textit{Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.} to encourage the Federal Circuit and lower courts to “strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context . . . because the penalty for inequitable conduct is so severe.”\textsuperscript{69} However, although the opinion emphasized that inequitable conduct requires “at least a threshold level of . . . materiality . . . proven by clear and convincing evidence,”\textsuperscript{70} the opinion paradoxically set the threshold

\textsuperscript{65} Id. at 1322.

\textsuperscript{66} See, e.g., McKesson Info. Solutions Inc. v. Bridge Med. Inc., 487 F.3d 897, 913 (Fed. Cir. 2007); Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1365 (Fed. Cir. 2007) (discussing new Rule 56 but approving the district court’s use of the “reasonable examiner” standard); Dippin’ Dots, Inc. v. Mosey, 476 F.3d 1337, 1345 (Fed. Cir. 2007) (applying the “reasonable examiner test” but commenting that the information might even satisfy the objective but for test); Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229, 1237, 1240 (Fed. Cir. 2008) (discussing new Rule 56 but later stating that “[t]here is a substantial likelihood that a reasonable examiner would have considered the [withheld information] important in deciding whether to allow the application to issue.”); Eisai Co. Ltd. v. Dr. Reddy’s Lab., Ltd., 533 F.3d 1353, 1360 (Fed. Cir. 2008); Star Scientific v. R.J Reynolds, 537 F.3d 1357, 1365 (Fed. Cir. 2008); \textit{but see} Abbott Lab. v. Sandoz, Inc., 544 F.3d 1341, 1354 (Fed. Cir. 2009) (approving the district court’s use of a higher standard of materiality).


\textsuperscript{68} Id. (calculated as the percentage of cases in which the Federal Circuit ruled for the defendant on the issue of inequitable conduct out of the total number of cases involving the issue of inequitable conduct. The Federal Circuit ruled for the accused infringer on the issue of inequitable conduct in 31.5\% of cases from 2000-2004, in 28.2\% of cases during 2005, in 24.5\% of cases during 2006, in 42.1\% of cases during 2007, and in 29.3\% of cases during 2008.).

\textsuperscript{69} \textit{Star Scientific}, 537 F.3d at 1365.

\textsuperscript{70} Id. at 1365.
for materiality low by adopting the reasonable examiner standard as the sole test for materiality, in contradiction with the opinion’s stated purpose of elevating the standard of proof in inequitable conduct cases. Less than two months later, Judge Newman, who has authored the vast majority of the post-1988 opinions characterizing inequitable conduct as a “plague,” attempted to remedy Star Scientific’s oversight by approving a high standard for materiality in Abbott Lab. v. Sandoz, Inc. The defendant in Abbott accused the patent owner of inequitable conduct for allegedly submitting a false declaration to the USPTO and withholding certain test data inconsistent with the information in the patents at issue. The Abbott majority affirmed the district court’s decision that the information was not material under “such a high bar for materiality that in essence no statement or withholding of information would be material if it would not change the ultimate outcome of allowing the patent.” Although the district court characterized its test for materiality as a combination of the new and old Rule 56 standards, it applied, and the Federal Circuit approved, an “objective but for test,” by asking whether the examiner would have refused to allow the patent to issue in view of the withheld information. Although the decision in Abbott follows the court’s sentiments in Star Scientific that the burden of proof in inequitable conduct cases should be elevated, it stood in contrast to the actual decision in Star Scientific reinstating the “reasonable examiner test” as the only standard for materiality.

Two years after Abbott v. Sandoz, the court again sat en banc in Therasense, Inc. v. Becton, Dickinson & Co. to “tighten the standards for finding [inequitable conduct] in order to redirect a doctrine that has been overused to the detriment of the public.” The defendant in Therasense argued that the patent at issue should be found unenforceable due to inequitable conduct resulting from the patent

---

71 See id. at 1367.
73 Abbott, 544 F.3d 1341 (Fed. Cir. 2009).
74 Id. at 1343.
75 Id. at 1380 (Gajarsa J. dissenting) (citing the Court’s prior rejection of a “but for” standard of materiality).
76 See id. at 1354.
77 Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d at 1290.
owner's failure to disclose information allegedly inconsistent with representations made to the USPTO. The district court agreed and held the patent unenforceable for inequitable conduct.

On appeal, a three-judge panel of the Federal Circuit affirmed the district court's finding of inequitable conduct. But on petition for rehearing en banc, a majority of six judges vacated the panel's decision and the district court's finding of inequitable conduct, and remanded the case for further consideration in view of the new standards in the opinion. Specifically, regarding materiality, the en banc majority adopted a "but-for" materiality test, defined as follows:

[P]rior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. . . . [E]ven if a district court does not invalidate a claim based on a deliberately withheld reference, the references may be material if it would have blocked patent issuance under the PTO's different evidentiary standards.\(^78\)

Stated differently, if a court concludes that the examiner would have allowed the claims anyway, then the undisclosed information is not material.

The opinion also enunciated an "affirmative egregious misconduct" exception to the "but-for" materiality standard that should be applied where it would be unjust to allow the patentee to enforce the patent despite having satisfied the "but-for" test.\(^79\) Specifically, the majority held that if the patentee has engaged in affirmative acts of egregious misconduct, such as filing an unmistakably false affidavit, the misconduct is material. The "affirmative egregious misconduct" exception incorporates elements of the Supreme Court's early unclean hands cases that dealt with deliberate plans to defraud the USPTO and the courts. But beyond the example of filing an unmistakably false affidavit, the en banc majority left it for future courts to decide exactly what constitutes "affirmative egregious misconduct."

We have yet to see whether the "but-for" test for materiality will survive in the Federal Circuit as the sole standard for materiality. The last en banc inequitable conduct decision (Kingsdown) did not prove successful in establishing a particular standard for materiality. The fate of the Therasense standard largely depends on how the decision is interpreted, applied, and developed by trial and appellate judges in

\(^{78}\) Id. at 1291-92.

\(^{79}\) Id. at 1292-93.
cases going forward. No one can know exactly how this will unfold, especially since inequitable conduct is a fact-based inquiry that must be decided on a case-by-case basis. And although there was no petition for certiorari in *Therasense*, the possibility still exists that the Supreme Court will weigh in on inequitable conduct. Only time will tell whether *Therasense* has changed the standard for materiality.

### B. The Standard for Intent

Shortly after the Federal Circuit was founded in October of 1982, it decided *Kansas Jack, Inc. v. Kuhn* and *J.P. Stevens*, which adopted the Supreme Court’s gross negligence standard, set forth in *Precision*, as the test for the intent prong of the inequitable conduct analysis.\(^{80}\)

Although the court reached different conclusions regarding the ultimate question of inequitable conduct in each case, it applied the same “knew or should have known” standard of intent in reaching those decisions.

The defendant in *Kansas Jack* had accused the patent owner of having submitted false statements to the USPTO regarding the improved safety of the invention compared to prior art devices, and having failed to disclose that an aspect of the invention (“the Kuhn post”) was known in the prior art.\(^{81}\) The Federal Circuit affirmed the district court’s decision that the defendant had not established fraud, since the defendant had “submitted no evidence that [the patent owner] had any reason... to disbelieve his statements to the PTO about safety” and that merely because “the Kuhn post, years later, was determined to be prior art, here the closest prior art, does not alone establish that [the patent owner] should have made a similar evaluation during prosecution.”\(^{82}\) Instead, the court held that the proper test for intent in an inequitable conduct analysis is whether “the one charged with non-disclosure knew or should have known of its materiality at the time.”\(^{83}\)

In *J.P. Stevens*, the district court had determined that although the patent applicants knew of and failed to disclose two prior art patents to the examiner during prosecution, there was no clear and convincing evidence that the applicants intended to deceive the USPTO by withholding the references.\(^{84}\) In reversing the district court’s decision, the Federal Circuit stated that unlike common law fraud, “[p]roof of

---

80 Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 1151 (Fed. Cir. 1993); J.P. Stevens, 747 F.2d at 1560 (Fed. Cir. 1984).
81 See Kansas Jack, 719 F.2d at 1151.
82 Id. at 1151-52.
83 Id. at 1152.
84 See J.P. Stevens, 747 F.2d at 1557.
deliberate scheming is not needed [to establish inequitable conduct];
gross negligence is sufficient." The court further stated “[g]ross 
egligence is present when the actor, judged as a reasonable person in 
his position, should have known of the materiality of a withheld 
reference.” The court held that a defendant may satisfy the requisite 
threshold level of intent “where an actor in applicant’s position would 
have reasonably known that the reference was material.”

The gross negligence/knew or should have known standard for 
intent prevailed until 1988, when the Federal Circuit declared “the 
habit of charging inequitable conduct in almost every major patent case 
has become an absolute plague.” To combat the plague, the court 
decided Kingsdown Medical Consultants v. Hollister Inc., which raised 
the defendant’s burden for establishing deceptive intent. During 
prosecution of the patent at issue in Kingsdown, the examiner had 
rejected one of the claims for indefiniteness. In response, Kingsdown 
submitted an amended version of the claim, which the examiner found 
allowable. Kingsdown then filed a continuation application containing 
the unamended version of the claim rejected for indefiniteness. Hollister contended that Kingsdown’s presentation of a previously rejected claim in the continuation application constituted inequitable conduct and rendered the resulting patent unenforceable. The district court agreed, holding that Kingsdown’s conduct satisfied the gross negligence standard for intent. The Federal Circuit reversed, holding that “Kingsdown’s counsel may have been careless, but it was 
clearly erroneous to base a finding of intent to deceive on that fact 
alone.” The court stated en banc 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 of good faith, must indicate 
sufficient culpability to require a finding of intent to deceive.”

The higher standard for intent established in Kingsdown persisted 
for nearly a decade until a panel of judges, all three of which had 
participated in the en banc portion of Kingsdown, decided Critikon,
The defendant in *Critikon* contended that the asserted patents were unenforceable due to the patent owner’s failure to disclose a prior art patent during prosecution. The district court, applying the intent standard in *Kingsdown*, held that the defendant was unlikely to establish that the patent owner intended to deceive the USPTO by failing to disclose the withheld reference. The Federal Circuit reversed, and without mentioning *Kingsdown*, reestablished a gross negligence/knew or should have known standard for intent. Reaching back to a pre-*Kingsdown* case for support, the *Critikon* court stated that “intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO’s consideration of a patent application.”

In the decade following *Critikon*, the Federal Circuit ignored the *en banc* decision in *Kingsdown*, and continued to apply a gross negligence/knew or should have known standard for intent in nearly all inequitable conduct cases.

To limit the influence of the court’s decisions that had loosened the standard for intent articulated in *Kingsdown*, then Chief Judge Michel authored an extended discussion of the elements of inequitable conduct in *Star Scientific*, reitering that “gross negligence [is] insufficient to prove intent to deceive,” and instead stating that “[w]hen the absence of a good faith explanation is the only evidence of intent . . . that evidence alone does not constitute clear and convincing evidence warranting an inference of intent.” The patents in *Star Scientific* related to methods of curing tobacco that resulted in reduced amounts of carcinogens. During prosecution, the applicant learned of several pieces of potentially invalidating prior art, which were not disclosed to the USPTO. In holding that the district court erred by

---

97 See id. at 1255.
98 Id. at 1256 (citing Driscoll v. Cebalo, 731 F.2d 878, 885 (Fed. Cir. 1984)).
99 See, e.g., Brassler U.S.A. v. Stryker Sales Corp., 267 F.3d 1370, 1376 (Fed. Cir. 2001); Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1239 (Fed. Cir. 2003); *Bruno*, 394 F.3d at 1352; Novo Nordisk Pharm., Inc. v. Bio-Tech, Gen. Corp., 424 F.3d 1347, 1362 (Fed. Cir. 2005); Pharmacia Corp. v. Par Pharm., Inc., 417 F.3d 1369, 1373 (Fed. Cir. 2005); *Purdue*, 438 F.3d at 1134; *But see Dayco* 329 F.3d at 1367 (“the district court also erred in concluding that the mere fact that the prosecuting attorney knew of the Wilson reference and decided not to submit it to the examiner established intent.”).
100 *Star Scientific*, 537 F.3d at 1366.
101 Id. at 1368.
102 Id. at 1361.
103 Id. at 1362-63.
concluding that the patent owner intended to deceive the USPTO during prosecution, the Federal Circuit acknowledged that “because direct evidence of deceitful intent is rarely available, such intent can be inferred from indirect and circumstantial evidence.” However, the court stipulated that any inference of intent “must . . . be the single most reasonable inference able to be drawn from the evidence” and that “[i]f a threshold level of intent to deceive or materiality is not established by clear and convincing evidence, the district court does not have any discretion to exercise and cannot hold the patent unenforceable regardless of the relative equities and how it might balance them.”

A month after Star Scientific was decided, one of its panel members authored Praxair, Inc. v. ATMI, Inc., which notably ignored Star Scientific in its intent analysis. The defendant in Praxair alleged that the asserted patents were unenforceable because the patent owner had withheld three items of prior art from the examiner during prosecution. In affirming the district court’s conclusion that “the level of materiality of [one of the pieces of prior art] is sufficiently high so as to support an ultimate finding of inequitable conduct,” the Federal Circuit effectively ignored the holding in Star Scientific that gross negligence is insufficient to prove intent to deceive, instead ruling that “[a]n inference of intent to deceive is generally appropriate . . . when (1) highly material information is withheld; (2) ‘the applicant knew of the information [and] . . . knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.”

Despite the Praxair court’s initial indication that its efforts in Star Scientific to raise the standard for intent back to its Kingsdown level would be largely ignored, subsequent cases heeded the call for reform and refused to infer intent from gross negligence. However, since two were by judges who have written the fewest number of majority opinions finding inequitable conduct, it was uncertain whether the

104 Id. at 1366-67 (emphasis added).
106 Id. at 1310-14.
107 Id. at 1313-14 (quoting Ferring B.V v. Barr Labs, Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006); alterations in original)).
109 See Christian E. Mammen, Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct, 24 BERKELEY TECH. L.J., 1329 (2009) (None of Judge Newman’s majority opinions and only 9% of Judge Linn’s involve findings of inequitable conduct.).
rest of their colleagues would follow suit and finally move away from the gross negligence/knew or should have known standard for intent.

Two years later, however, the court again sat en banc in Therasense. One of the goals of the en banc majority in Therasense was to "tighten[] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." Specifically, regarding intent, the en banc majority eradicated the "should have known" standard articulated in its previous cases, instead requiring a showing that "the patentee acted with the specific intent to deceive the PTO." "A finding that a misrepresentation or omission amounts to gross negligence or negligence under a 'should have known standard' does not satisfy this intent requirement."

Instead, for there to have been intent to deceive the PTO, "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."

In addition, the en banc majority adopted Star Scientific's "single most reasonable inference" standard for proving the intent prong of inequitable conduct, holding that if multiple reasonable inferences can be drawn from the evidence, intent to deceive cannot be found. The majority further held that "[t]he absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive." In addition, unless "the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence," the patentee need not offer any good faith explanation at all. These standards articulated by the en banc majority set a high burden for satisfying the intent prong.

Again, only time will tell whether the Therasense decision will have a lasting impact on the law of inequitable conduct. The Federal Circuit has taken inconsistent approaches to the standard for intent, and there is no guarantee that the court will adhere to Therasense's new stricter standard. In addition, the Therasense court left several questions unanswered, including what constitutes "a threshold level of intent." Since inequitable conduct is not an exact science, and each case presents its own unique set of facts, we must wait and see whether the Therasense standard for intent takes root in future cases.

110 Therasense, 649 F.3d at 1290.
111 Id.
112 Id.
113 Id.
114 Id. at 1290-91.
115 Id. at 1291.
116 Id. (alteration in original) (quoting Star, 537 F.3d at 1368).
III. NAVIGATING THE QUAGMIRE

Since its inception in 1982, the Federal Circuit has tried to uniformly apply to the defense of inequitable conduct. The court has consistently stated (although not consistently applied) the following elements: (1) a requirement for threshold showings of materiality and intent; followed by (2) a weighing of the evidence to determine if a holding of patent unenforceability is appropriate. The court has also consistently held that the defendant carries the ultimate burden of proving inequitable conduct and that, if successful, the effect on an issued patent is unenforceability. However, the Federal Circuit’s contrary decisions regarding the proper tests for materiality and intent have left the standards in disarray and have led to more confusion than clarity.

In addition, the USPTO has failed to provide guidance that would allow patent applicants to know which materiality standard will apply at the patent prosecution stage. The USPTO’s Rule 56 prohibits inequitable conduct by imposing a duty of candor and good faith on every individual associated with the filing and prosecution of a patent application. The current version of Rule 56 provides that information is material if it is not cumulative and (1) “establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim,” or it (2) “refutes, or is inconsistent with” positions taken by the applicant during prosecution. This “prima facie/inconsistent” test has remained the USPTO’s standard for materiality since 1992, despite the Federal Circuit’s shifting positions.

Two months after Therasense, however, the USPTO issued proposed changes to Rule 56 in light of the Federal Circuit’s en banc decision. The proposed changes cite Therasense and adopt the standard of materiality set forth by the majority. Specifically, under the proposed new Rule 56, information is material to patentability if: (1) “[t]he Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction,” or (2) “the applicant engages in affirmative egregious misconduct before the Office as to the information.”

However, the USPTO’s proposed changes to Rule 56 have yet to be implemented, and the “prima facie/inconsistent” standard from the

---

119 Id. at 43,633.
Inequitable Conduct and Supplemental Examination

1992 version of Rule 56 remains the USPTO’s current standard. Practitioners thus face two conflicting standards for materiality: a “prima facie/inconsistent” standard that applies during prosecution, and a “but-for” test that applies during litigation. This creates confusion for patent practitioners when they prosecute patents and when they consider how their conduct and disclosures may affect future litigation, and makes it difficult for applicants to predict which steps to take during prosecution to lessen their vulnerability to inequitable conduct allegations.

Unless the legislature steps in, it may be time to recognize that, unlike in other areas of patent law, the facts that present themselves in inequitable conduct cases are so diverse and so dependent on the reactions of the triers of fact to the witnesses and documents at trial, that true uniformity is not possible from the courts.

IV. ENTER CONGRESS

A. The America Invents Act

Championed by Senator Orrin Hatch,\textsuperscript{120} the America Invents Act (AIA) authorized a new post-grant proceeding, “supplemental examination,” allowing patent owners to submit to the USPTO any information “relevant to the patent” to possibly provoke an ex parte examination.\textsuperscript{121} One of the most groundbreaking changes the AIA added to U.S. patent law, the supplemental examination process of section 257 changed the way inequitable conduct cases are handled.

According to a leading authority on the legislative history of the AIA, “the concept grew out of Senator Hatch’s advocacy over several of Congresses’ proposals to restrict the inequitable-conduct doctrine.”\textsuperscript{122} The first Senate version of the AIA included a provision that sharply limited the courts’ authority to hold a patent unenforceable for inequitable conduct, but the provision was dropped in 2007.\textsuperscript{123} But Senator Hatch continued to advocate for reform, stating inequitable conduct “has been overpleaded and has become a drag on the litigation process.”\textsuperscript{124}

After finally settling on the supplemental examination provision,

\begin{footnotesize}
\bibliography{references}
\end{footnotesize}
Senator Hatch stated “the supplemental examination provision satisfies a long-felt need in the patent community to be able to identify whether a patent would be deemed flawed if it ever went to litigation and enables patentees to take corrective action. This process enhances the quality of patents, thereby promoting greater certainty for patentees and the public.” Senator Kyl noted, “in evaluating whether a fraud is ‘material’ for purpose of referral, the Director should look to the Federal Circuit’s decision in Therasense, Inc. v. Becton, Dickinson & Co.”

B. Supplemental Examination

The new supplemental examination procedure allows a patent owner to file a petition requesting that the USPTO consider, reconsider, or correct information in a patent or its file history. Within three months, the USPTO will determine whether the information in the request raises a substantial new question of patentability. If so, it will order ex parte reexamination in view of the submitted evidence, during which the patent owner can argue for patentability of the claimed invention.

Importantly, the AIA bars as the basis for a finding of inequitable conduct anything considered in the request for supplemental examination or during the ensuing ex parte reexamination. Specifically, “[a] patent shall not be held unenforceable . . . if the information was considered, reconsidered, or corrected during a supplemental examination . . .” Any omission or misrepresentation that was not previously considered, was inadequate, or was incorrect can be submitted to the USPTO and expunged after a patent has issued. This is a powerful tool for purging inequitable conduct post facto.

Still, there are important limitations to what supplemental examination can accomplish. For instance, supplemental examination becomes unavailable once an accused infringer has raised an inequitable conduct defense. In addition, the cleansing effect of a supplemental examination occurs only once the proceeding and any ex

---

127 37 C.F.R. § 1.605 (2014) “[a]n item of information includes a document submitted as part of the request that contains information, believed to be relevant to the patent, that the patent owner requests the Office to consider, reconsider, or correct.”).
129 § 257(b).
130 § 257(c).
Inequitable Conduct and Supplemental Examination

parte reexamination ordered therefrom has drawn to a close, which could take years. So if the patent becomes involved in litigation before the USPTO completes its review, the accused infringer may raise an inequitable conduct defense regarding any information that the patent owner asked the USPTO to consider in its request for supplemental examination.

A "fraud" exception also limits supplemental examination. If the Director learns that a material fraud had been committed on the USPTO during patent prosecution, the matter will be referred to the Attorney General for disciplinary proceedings against the patent attorney. The patent owner may also face criminal and antitrust claims under § 257(f).

The USPTO also places high burdens on patent owners seeking supplemental examination. First, it has set a steep fee for the procedure. Second, it requires patent owners to make, on the record, fairly substantial admissions regarding errors made during prosecution. For errors involving omitted references, parties must admit the document is "relevant to the patent" and must explain its relevance; however, they specifically do not have to address the item's "materiality." Third, it limits the number of items that a patent

---

132 § 257(c)(2)(B).
133 See Changes To Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees, 77 Fed. Reg. 48828 (Aug. 14, 2012) (“This final rule requires the following supplemental examination fees:
(1) A fee of $5,140.00 for processing and treating a request for supplemental examination;
(2) a fee of $16,120.00 for an ex parte reexamination ordered as a result of a supplemental examination proceeding; and
(3) for processing and treating, in a supplemental examination proceeding, a non-patent document over 20 pages in length, a fee of $170.00 for a document of between 21 and 50 pages, and a fee of $280.00 for each additional 50 pages or a fraction thereof.
This final rule also requires the following reexamination fees:
(1) $17,750.00 for filing a request for ex parte reexamination;
(2) $1,930.00 for filing a petition in an ex parte or inter partes reexamination proceeding, except for those specifically enumerated in 37 CFR 1.550(i) and 1.937(d); and
(3) $4,320.00 for a denied request for ex parte reexamination under 37 CFR 1.510 (this amount is included in the request for ex parte reexamination fee, and is the portion not refunded if the request for reexamination is denied).”).
134 37 C.F.R. § 1.605 (2014) (“(b) An item of information includes a document submitted as part of the request that contains information, believed to be relevant to the patent, that the patent owner requests the Office to consider, reconsider, or correct.”).
135 77 Fed. Reg. at 48845 (“The Office must determine whether any of the items of information raises a substantial new question of patentability, not whether any of the items of information is ‘material.’ Therefore, the Office is not adopting a requirement that the patent owner state whether or why an item of information is or is not
owner may raise in a request for supplemental examination. Fourth, the USPTO's decision regarding whether the patent owner has presented a substantial new question of patentability is rendered without the right to an interview regarding the merits of the request, and without the right to make any amendments to the patent. However, interviews and amendments are permitted if the USPTO grants the request and initiates ex parte reexamination.

C. Statistics and Recommendations

In view of these limitations, not surprisingly, supplemental examination has lagged behind the other new post-grant proceedings created by the America Invents Act. In the first two years after their availability, the USPTO received over 2,000 inter partes review and covered business method post-grant review petitions. During that same period, there were only 81 requests for Supplemental Examination.

\footnote{37 C.F.R. § 1.605 (a) (limiting items of information to twelve items). (2014) ("Items of information") (limiting parties to twelve "items").}
Figure 1: PTAB Monthly Submissions, as of August 31, 2014 (retrieved December 1, 2014)
Of those 81 requests for Supplemental Examination, 57 have publicly available file histories. A review of those file histories reveals that they are fairly evenly dispersed across the technologies:

<table>
<thead>
<tr>
<th>Technology</th>
<th>% of total requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical</td>
<td>30% (17/57)</td>
</tr>
<tr>
<td>Electrical</td>
<td>30% (17/57)</td>
</tr>
<tr>
<td>Biological/Chemical</td>
<td>37% (21/57)</td>
</tr>
<tr>
<td>Design</td>
<td>3% (2/57)</td>
</tr>
</tbody>
</table>

Figure 2: Breakdown of Technologies in early Supplemental Examinations

Figure 3: Breakdown of Technologies in Early Supplemental Examinations
In addition, the USPTO is finding a substantial new question of patentability in the vast majority (74%) of cases:

![Figure 4: Outcomes of USPTO determinations regarding substantial new question of patentability](image)

Before filing a request for supplemental examination, practitioners may want to visit http://www.uspto.gov/blog/aia/entry/from_janet_gongola_patent_reform, which was created in December of 2012 by the USPTO and contains Tips for Filing a Complaint Supplemental Examination Request. In addition, patent owners ought to carefully consider the timing of any effort at supplemental examination if they might soon seek to enforce the patent. While a decision on the request for supplemental examination may be made in three months, the patent could be tied up in the Patent Office for over a year if the Director orders *ex parte* reexamination. And appealing an adverse decision in the *ex parte* reexamination could delay any effort to enforce a patent for at least another year.

We suggest assessing the enforceability of valuable patent portfolios early to determine if requesting supplemental examination is a strategy. In the pharmaceutical industry, patent holders might want to make such an analysis when listing a patent in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"). Patent owners can be fairly certain that an Orange Book-listed patent will be litigated, but usually not for at least several years, providing good odds that a supplemental examination (and any subsequent *ex parte* reexamination) would run its course before the
patent owner seeks to enforce the patent against accused infringers. Patent owners in litigation may request and be granted a stay pending the outcome of the supplemental examination and subsequent reexamination. If they are granted a stay, the patent is preserved, valid, and can be used against other licensees and infringers. The inequitable conduct allegation survives regarding the then-current litigants, 35 U.S.C. §257(c)(2)(B), but the patent could emerge from the proceeding free from future inequitable conduct charges. Thus, despite its slow acceptance by patent owners, supplemental examination is likely to be viewed by at least some as an appealing “safety net” for rectifying possible deficiencies in the duty of disclosure during initial prosecution.

Interestingly, the AIA also may have unintentionally provided other options for curing inequitable conduct. For instance, in amending the reissue sections of the statute, Congress removed the requirement that any errors corrected through reissue were made without deceptive intent. The Federal Circuit has noted that inequitable conduct cannot be cured through reissue. But if the USPTO considers an item of information during a reissue proceeding and still reissues the patent, an accused infringer would be hard-pressed to argue that the item of information was “but for” material under the Therasense test for inequitable conduct. Congress' removal of the “without deceptive intention” requirement from the reissue statute, in combination with the Federal Circuit's en banc decision in Therasense requiring but-for materiality to establish inequitable conduct, arguably opens the door for patent owners to address questions of materiality via reissue.

V. CONCLUSION

Most inventions require significant expenditures of time and money, and are burdened with high risk. Investors are unlikely to contribute to the research and development of new inventions unless they believe they will receive a return on their investment. Patents provide this assurance. However, the defense of inequitable conduct, with its inconsistent standards of materiality and intent established by

137 See Englishtown, Inc. v. Rosetta Stone Inc., 962 F. Supp. 2d 355, 361 (D. Mass. 2013) (the office granted ex parte reexam, and the court stayed the inequitable conduct claims; thus, the inequitable conduct claim survives stay, but at least the patent survives as to the world).
140 It's important to bear in mind, however, that there is no way to address the deceptive intent prong of the inequitable conduct analysis through reissue.
the Federal Circuit, can, depending on all facts and circumstances, cast serious doubts over the value of issued patents.

To ensure that patents remain a reliable support for commercial investment in new innovations, and given the long history of a lack of judicial uniformity in inequitable conduct, true reform probably will not come from the courts or the Patent Trial and Appeal Board. If we are ever to reach a consistent standard for inequitable conduct, it may have to come from Congress in future patent reform.

Supplemental Examination may help cure certain instances of inequitable conduct, but in practice seems little used. We predict, however, that patent owners will continue to use supplemental examinations to strengthen valuable patents against future attacks of inequitable conduct.