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THE INEQUITABLE CONDUCT DEFENSE IN PATENT LITIGATION: WHERE WE ARE, WHERE WE HAVE BEEN, AND WHERE WE SHOULD GO FROM HERE

Brett Ira Johnson[†]

Abstract

This paper examines the current status of the inequitable conduct defense in patent litigation, the historical evolution of the inequitable conduct defense in patent litigation, and problems and concerns with the administration of the inequitable conduct defense. This paper then reviews patent reform legislation and the various ways in which each would address the issue of inequitable conduct and opines on the desirability of the different proposals. Finally, this paper concludes that the inequitable conduct defense should be eliminated.

In the alternative to the inequitable conduct defense, section 282 of the Patent Act, should be interpreted to presume validity of an issued patent only when all non-cumulative material information was considered during examination. This change would serve the purpose for which inequitable conduct was created: to encourage full disclosure of all material information to the United States Patent and Trademark Office, while eliminating the problems and resources expended with the assertion of the inequitable conduct defense during patent litigation.

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I. INTRODUCTION

Inequitable conduct is a judicially created equitable doctrine that was intended to provide incentive to patentees to fully disclose material information to the Patent and Trademark Office (“PTO”) during prosecution of patent applications.¹ Under the doctrine, patent claims could be rendered unenforceable in subsequent litigation if a patentee failed to disclose material information.² To prove inequitable conduct, the challenging party must show that the patentee: (1) made an affirmative misrepresentation of material fact or submitted false material information; and (2) intended to deceive the PTO.³ A showing of inequitable conduct renders all of the claims of a patent and potentially all claims of related applications unenforceable.⁴

The expansion of the inequitable conduct doctrine has caused concern among patent experts⁵ and among judges on the Federal Circuit Court of Appeals.⁶

[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

1. See *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006).

2. See *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349, 1350, 1352-53 (Fed. Cir. 2008) (Rader, J., dissenting).

3. See, e.g., *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362 (Fed. Cir. 2003) (citing *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001)).

4. See *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,”) (citing *Consolidated Aluminum Corp. v. Fosco Int’l Ltd.*, 910 F.2d 804 (Fed. Cir. 1990));

When a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent is rendered unenforceable. We, *in banc*, reaffirm that rule as set forth in *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1561 (Fed. Cir. 1984), *cert. denied*, 474 U.S. 822 (1985).

Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989) (parallel citations omitted); See also *Digital Control*, 437 F.3d at 1313.

5. See, e.g., NAT’L RESEARCH COUNCIL OF THE NAT’L ACADEMIES, A PATENT SYSTEM FOR THE 21ST CENTURY 123 (Stephen A. Merrill et al. eds., 2004) [hereinafter NAT’L RESEARCH COUNCIL], available at <http://www.nap.edu/catalog/10976.html>.

6. See, e.g., *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc); *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

interests adequately, perhaps. They get anywhere with the accusation in but a small percentage of the cases, but such charges are not inconsequential on that account. They destroy the respect for one another's integrity, for being fellow members of an honorable profession, that used to make the bar a valuable help to the courts in making a sound disposition of their cases, and to sustain the good name of the bar itself.⁷

In 2008, the Federal Circuit remarked that “[t]he need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability.”⁸ The Court observed that “[t]his penalty was originally applied only in cases of ‘fraud on the Patent Office.’”⁹ However, “[s]ubsequent case law has broadened the doctrine to encompass misconduct less egregious than fraud but the severity of the penalty has not changed, and thus courts must be vigilant in not permitting the defense to be applied too lightly.”¹⁰

The second element of inequitable conduct, intent to deceive, also raises concerns.¹¹ Being a subjective inquiry, it is generally difficult to know the actual intent of the relevant individual and cases most often rely on circumstantial evidence to prove intent.¹² Other concerns about application of the inequitable conduct doctrine include: increasing the costs of litigation, prejudicing the patentee,¹³

7. *Burlington*, 849 F.2d at 1422. The Federal Circuit further observed that a patent litigant should be made to feel, therefore, that an unsupported charge of “inequitable conduct in the Patent Office” is a negative contribution to the rightful administration of justice. The charge was formerly known as “fraud on the Patent Office,” a more pejorative term, but the change of name does not make the thing itself smell any sweeter.

Id.; see also *Therasense*, 649 F.3d at 1289; *Kingsdown*, 863 F.2d at 876 & n.15 (writing that the court desired to avoid a ruling that would “encourage the present proliferation of inequitable conduct charges” and quoting *Burlington* for the proposition that “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”).

8. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365-66 (Fed. Cir. 2008), *aff'd in part, rev'd in part*, 655 F.3d 1364 (Fed. Cir. 2011).

9. *Id.* at 1365-66 (citing *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250-51 (1944); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)).

10. *Id.* (citation omitted).

11. See generally *id.*

12. NAT'L RESEARCH COUNCIL, *supra* note 5, at 122.

13. See *Target Tech. Co., LLC v. Williams Advanced Materials, Inc.* No. 04-CV-1083, 2007 WL 6201689, at *42-43 (C.D. Cal. Feb. 6, 2007). It is at the trial court's discretion whether to bifurcate or try the issues of infringement, validity, and inequitable conduct

and the Federal Circuit's inconsistent and unpredictable articulation and application.¹⁴

Ultimately, the burdens imposed by the availability of an unenforceability defense during litigation due to inequitable conduct outweigh the benefits. Moreover, there are more efficient and less prejudicial ways to address inequitable conduct. For example, when the alleged misconduct is the withholding of known art, asserted claims will generally be held invalid in light of that art—along with a finding of inequitable conduct—rendering the doctrine of inequitable conduct superfluous.¹⁵ Moreover, the PTO has, and could at its discretion: exercise the authority to administer disciplinary sanctions for misconduct before the Office without need for litigation to arise where the unenforceability defense due to inequitable conduct is raised by a party.¹⁶

Concerns about the application of the inequitable conduct doctrine during patent litigation have led to proposed legislative changes to the Patent Act.¹⁷ Naturally, some of the revisions are better than others.

As discussed below the inequitable conduct doctrine could be eliminated from litigation without adverse effects on candor before the PTO,¹⁸ the conduct the doctrine was created to encourage,¹⁹ by not awarding the 35 U.S.C. Section 282 presumption of validity to patents issued where material information was not before the Examiner during prosecution of the subject patent.

separately or together. If tried separately, inefficiency and additional expense from overlap of facts and evidence will necessarily occur. If tried together, however, there is a risk that the jury's focus may shift from relevant factual issues to the alleged wrongdoings of the patentee and/or his representatives and prejudice to the jury's findings on other issues may occur.

14. See generally *Astrazeneca Pharm. LP v. Teva Pharm. USA, Inc.*, 583 F.3d 766, 769 (Fed. Cir. 2009).

15. Katherine Nolan-Stevaux, Note, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 163 (2005) (“[I]n 89% of cases, courts found patents both unenforceable and invalid.”).

16. See 37 C.F.R. § 10.20 (2010).

17. See generally Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005); Patent Reform Act of 2006, S. 3818, 109th Cong. (2006); Patent Reform Act of 2007, S. 1145, 110th Cong. (2007); Patent Reform Act of 2008, S. 3600, 110th Cong. (2008); Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009).

18. The PTO could address issues of insufficient candor by disciplinary proceedings.

19. See *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).

A. *Overarching Approaches to Application of the Inequitable Conduct Doctrine: Notice versus Discretion*

One perceived problem with the application of the common law doctrine of inequitable conduct is a lack of notice and predictability regarding the conduct proscribed due to a lack of a clear articulation of materiality and intent.

Inequitable conduct, like most rules of law, faces at least two competing policy goals in this regard. On the one hand, it is desirable to give notice of what is required to comply with the law.²⁰ This provides notice and leads to predictability in the application of the law.²¹ On the other hand, it is desirable to allow for flexibility so that the law can be specifically tailored to the circumstances presented rather than requiring a blanket application based on rigid readings.²² Unfortunately, these broad policy goals are inconsistent, and the line is often drawn in favor of one set of goals—at the expense of others.²³ Indeed, predictability and notice on one hand, and flexibility and discretion on the other, are antithetical to one another.²⁴

In areas of patent law other than inequitable conduct, such as claim construction, the Federal Circuit generally draws the line more toward the side of notice and predictability—at the expense of flexibility and discretion.²⁵ Indeed, commentators have described the Federal Circuit as being “preoccupied with predictability and the notice function of patents.”²⁶

20. *Edwards v. Aguillard*, 482 U.S. 578, 639-40 (1987) (Scalia, J., dissenting). Observing in a different context that

[i]n the past we have attempted to justify our embarrassing Establishment Clause jurisprudence on the ground that it “sacrifices clarity and predictability for flexibility.” One commentator has aptly characterized this as “a euphemism . . . for . . . the absence of any principled rationale.” I think it time that we sacrifice some “flexibility” for “clarity and predictability.”

Id. (internal citations omitted).

21. *See id.*

22. *See Holmberg v. Armbrecht*, 327 U.S. 392, 396 (1946).

23. *See United States v. Criden*, 648 F.2d 814, 818 (3d Cir. 1981).

24. *See id.*

25. *See Meredith Martin Addy, Is the Federal Circuit Ready to Accept Plenary Authority for Patent Appeals?*, 4 J. MARSHALL REV. INTELL. PROP. L. 583, 587 (2005) (quoting Donald R. Dunner, *Jefferson Medalist – 2004 Address*, IP MALL (June 4, 2004), http://ipmall.info/hosted_resources/jefferson_medalists_2004_address.asp).

26. *Id. Compare Wright Co. v. Paulhan*, 177 F. 261, 266 (S.D.N.Y. 1910) (holding that—in light of the fact that the patent was a pioneering patent—and thus entitled to broad protection—a pilot of an aircraft that manually adjusted the controls of an aircraft was equivalent to a rope specified in the claim to automatically adjust the controls). Judge Learned Hand was more concerned with the flexibility and discretionary side of patent law. By contrast,

It is of course desirable to provide predictability and notice while maintaining discretion and flexibility. The proposed 2007 version of patent reform legislation seems to accomplish that goal.²⁷ The 2007 version of patent reform would have accomplished this inconsistent objective by codifying and standardizing the definition of “materiality” and “intent to deceive,” thereby promoting predictability regarding the requirements for compliance with the inequitable conduct doctrine.²⁸ The discretionary component in the 2007 version of patent reform would have come from the ability of a court to fashion a remedy to the particular facts after a finding of inequitable conduct, rather than being bound to find all claims invalid.²⁹ The 2007 version, as well as other versions of patent reform, is discussed below. Before discussing patent reform, the concerns with the common law doctrine of inequitable conduct should be addressed in more detail in order to determine the desired changes through legislative or judicial reform.

II. DISCUSSION

A. *Therasense—the Current—but Uncertain and Unstable State of the Law*

On May 25, 2011, the Federal Circuit *en banc*, in deciding *Therasense, Inc. v. Becton, Dickinson & Co.*, attempted to rein in the consequences of inequitable conduct in patent litigation. The majority opinion, joined by six judges and authored by Judge Rader, “[r]ecogniz[ed] the problems created by expansion and overuse of the inequitable conduct doctrine,” as the reason for granting the *en banc* petition.³⁰ The majority opinion outlined the history of the inequitable conduct doctrine and observed that the doctrine was initially concerned “with particularly egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence.”³¹

The majority opinion disapproved of inequitable conduct’s role

the Federal Circuit would most likely not consider anything more than a steel cable as being equivalent to a rope in such a patent.

27. See S. 1145, 110th Cong. § 298 (2007).

28. See *id.*

29. See, e.g., *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 n.15 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989).

30. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011) (*en banc*).

31. *Id.* at 1287.

as “a significant litigation strategy. A charge of inequitable conduct conveniently expands discovery into corporate practices before patent filing and disqualifies the prosecuting attorney from the patentee’s litigation team.”³² Indeed, “[l]eft unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system.”³³

The majority thus disapproved of the “sliding scale” approach, where a weak showing of intent may be found sufficient based on a strong showing of materiality and vice versa.³⁴ “[A] court must weigh the evidence of intent to deceive independent of its analysis of materiality.”³⁵ The majority opinion observed that it had in the past attempted to reduce the proliferation of inequitable conduct charges by “raising the intent standard” and making clear that “gross negligence alone was not enough to justify an inference of intent to deceive.”³⁶ The majority stated that the intent to deceive prong of inequitable conduct requires showing 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” and when only circumstantial evidence of intent to deceive was discovered, the conclusion of intent to deceive must be “the most reasonable inference.”³⁷

Because the majority felt that raising the intent standard alone was not effective in reducing the number of inequitable conduct allegations, the majority opinion adjusted the materiality standard to require but-for materiality.³⁸ However, the majority opinion left open the door for allegations of inequitable conduct where an act was not material under a but-for test, but where misconduct was “egregious.”³⁹ Thus, while purporting to eliminate the “sliding scale” the majority opinion seems to retain a sliding scale by tying “egregious misconduct” to the required showing of materiality.⁴⁰

32. *Id.* at 1288 (citing NAT’L RESEARCH COUNCIL, *supra* note 5, at 122).

33. *Id.* at 1289.

34. *Id.* at 1290.

35. *Id.*

36. *Id.* at 1291 (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989)).

37. *Id.* at 1290.

38. *Id.* at 1291. In adopting that standard of materiality, the majority opinion specifically held that the PTO articulation of the broader definition of materiality in PTO Rule 56 is not controlling for purposes of inequitable conduct allegations in litigation. *Id.* at 1293-94.

39. *Id.* at 1292-93.

40. *Id.*

By including the “egregious conduct” exception, the majority opinion also significantly weakens any benefit that might have been gained from the opinion. Just as the Federal Circuit’s prior attempt to reduce the role of inequitable conduct in litigation by clarifying the required intent threshold to exclude gross negligence largely failed, the majority’s attempt to curb the role of such inequitable conduct allegations in litigation by clarifying the materiality standard will likely fail. Attorneys will continue to assert inequitable conduct in nearly every litigation based on “egregious misconduct” or by claiming that the information “but-for” caused at least one claim to issue.⁴¹ Thus, the majority’s attempt to retain flexibility in the application of the inequitable conduct doctrine will result in continued problems with the application of such doctrine during litigation.

Judge O’Malley concurred-in-part and dissented-in-part in *Therasense*.⁴² Judge O’Malley favored a flexible approach with an undefined standard of materiality, apparently at the expense of notice and certainty during litigation.⁴³ A four-judge dissent in *Therasense* advocated retaining the current state of inequitable conduct and use of the PTO’s current standard of materiality, set forth in Rule 56.⁴⁴

While the effects of *Therasense* are yet to be seen, it is not likely to significantly change the role of inequitable conduct during patent litigation. The charge of inequitable conduct will continue to appear in most major patent litigations. Moreover, the United States Supreme Court might hear the case during its new term, and the Defendant in *Therasense* intends to seek a stay of the Federal Circuit’s ruling in the interim.⁴⁵

41. The difference of course between this standard of materiality and a finding of invalidity based on the subject information is “but-for materiality” sufficient to find a single claim invalid under the inequitable conduct doctrine would render every claim of the patent and possible all claims of related patents unenforceable.

42. *Therasense*, 649 F.3d at 1296 (O’Malley, J., concurring in part and dissenting in part).

43. *Id.* at 1298.

44. *Id.* at 1303.

45. Mike Sobolev, *Therasense, Inc. v. Becton, Dickinson and Co.: A Radical Change in the Legal Standard of Inequitable Conduct*, BERKELEY TECH. L.J. BOLT (June 22, 2011), <http://btlj.org/?p=1290>.

Allegedly, Becton-Dickinson filed a motion to stay the issuance of the mandate of the case pending its petition for writ of certiorari to the Supreme Court. Due to the drastic changes affected by *Therasense* and the Supreme Court’s recent penchant for reviewing Federal Circuit decisions, it would not be surprising if these new standards are rejected or modified within the next few years.

Id.

*B. Concerns with the Application of the Common Law
Inequitable Conduct Doctrine—Pre-Therasense Case Law*

Because of the uncertain status of *Therasense*, it is helpful to examine issues with the inequitable conduct doctrine that lead the Federal Circuit to attempt to change the state of the inequitable conduct law in *Therasense*.

1. The “Materiality” Standard

a. The Materiality Standard Has Been Articulated in Varying Manners in an Apparent Attempt to Retain Discretion, at the Expense of Notice and Predictability.

As discussed above, in an apparent attempt to retain discretion in the application of the inequitable conduct doctrine, the Federal Circuit struggled with a single materiality standard for purposes of litigation.⁴⁶ The PTO defines the term “material” in Rule 56.⁴⁷ Before *Therasense*, courts would generally cite to Rule 56 when considering the materiality prong of an inequitable conduct charge during litigation, but the Federal Circuit, even before *Therasense*, indicated that it is not bound by the PTO’s articulation of materiality, which served as a useful “starting point” in a materiality determination.⁴⁸ However, before *Therasense*, the Federal Circuit failed to adopt any other useful definition of materiality.⁴⁹ Indeed, the Federal Circuit recognized that at least four different standards of materiality have been used by the court in determining inequitable conduct.⁵⁰ Adding to the mix, in 1992, the PTO adopted a different definition of materiality in Rule 56, which has also been referenced by, but not

46. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363-64 (Fed. Cir. 2003).

47. 37 C.F.R. § 1.56(b) (2010).

48. *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1559 (Fed. Cir. 1984) (“The PTO standard is the appropriate starting point because it is the broadest and because it most closely aligns with how one ought to conduct business with the PTO.”).

49. *Id.*

It has been indicated that the threshold can be established by any of four tests: (1) objective “but for”; (2) subjective “but for”; (3) “but it may have been”; and (4) PTO Rule 1.56(a), *i.e.*, whether there is a substantial likelihood that a reasonable examiner would have considered the omitted reference or false information important in deciding whether to allow the application to issue as a patent.

Id.

50. *Id.*

clearly adopted by the Federal Circuit during litigation.⁵¹ Therefore, there are at least five definitions of materiality that have been referenced by the Federal Circuit.⁵²

The pre-1992 version of Rule 56 provided that information is material “where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent” (the “reasonable examiner standard”).⁵³ The “*prima facie* case standard” is codified in the current version of Rule 56, which provides that:

information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (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 in: (i) opposing an argument of unpatentability relied on by the Office, or (ii) asserting an argument of patentability.⁵⁴

Over time, before *Therasense*, the Federal Circuit moved away from the more restrictive “but for tests” for materiality, while struggling to clearly establish whether the appropriate standard in litigation was the old version or the new version of Rule 56.⁵⁵ In 2003, The Federal Circuit analyzed which of the two Rule 56 materiality standards should apply, but ultimately wrote that “[b]ecause . . . the outcome of this appeal would be the same under either materiality standard, we leave for another day a final disposition of this issue.”⁵⁶

51. 37 C.F.R. § 1.56 (1992).

52. See *J.P. Stevens*, 747 F.2d at 1559; *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1134-35 (Fed. Cir. 2006).

53. 37 C.F.R. § 1.56 (1991). The “reasonable examiner” standard is generally considered the broadest interpretation of materiality. It is not clear, however, why it is broader than the *prima facie* case standard because it is not clear why a reasonable examiner would want to know about something that does not constitute a *prima facie* case of unpatentability. Regardless, the Federal Circuit has stated that the older “reasonable examiner” standard is “arguably” broader than the new “*prima facie* case of unpatentability” standard. *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006). The “but for” tests were narrower, requiring a showing that the patent would not have issued but for the information being omitted. *Id.* at 1316.

54. 37 C.F.R. § 1.56 (2010). It remains to be seen whether compliance with Rule 56 will be a consideration in whether an applicant acted with “egregious misconduct” such that a “but-for” finding of materiality need not be shown, under the *Therasense* test. Logically, it is difficult to see how “egregious misconduct” could occur if an applicant complied with Rule 56.

55. See *Astrazeneca Pharm. LP v. Teva Pharm. USA, Inc.*, 583 F.3d 766, 773 (Fed. Cir. 2009).

56. *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1364 (Fed. Cir.

Thereafter, on February 1, 2006, the Federal Circuit in *Purdue Pharma, L.P. v. Endo Pharms., Inc.*⁵⁷ applied the new Rule 56 *prima facie* case of patentability test, writing, that “[i]n evaluating materiality, this court has consistently referred to the standard set forth in PTO Rule 56.”⁵⁸ The court continued, “[b]ecause all of the patent applications at issue in this case were pending on or filed after March 16, 1992,⁵⁹ we look to the current version of Rule 56, rather than the pre-1992 version of the rule.”⁶⁰

Just one week later, however, the Federal Circuit applied the old reasonable examiner test, writing that “[f]or many years, we have held that ‘materiality for purposes of an inequitable conduct determination require[s] a showing that ‘a reasonable examiner would have considered such prior art important in deciding whether to allow the parent application.’”⁶¹ The court ultimately concluded that the “reasonable examiner” standard and case law interpreting that standard were not supplanted by the PTO’s adoption of a new Rule 56, and thus materiality during litigation was determined according to the older and “arguably broader” “reasonable examiner” standard.⁶² Thus, according to pre-*Therasense* Federal Circuit precedent, even if a prosecuting attorney complied with the current version of Rule 56 at trial she could be found to have committed inequitable conduct under the older, arguably broader “reasonable examiner standard.”⁶³

Since then the Federal Circuit has primarily used the old “reasonable examiner standard” in determining materiality during

2003).

57. *Purdue*, 438 F.3d 1123.

58. *Id.* at 1129.

59. March 16, 1992, is the date that the new version of Rule 56 took effect. 57 Fed. Reg. 2021, 2021-34 (Jan. 17, 1992) (to be codified at 37 C.F.R. § 1.56).

60. *Purdue*, 438 F.3d at 1129.

61. *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314 (Fed. Cir. 2006) (quoting *Dayco*, 329 F.3d at 1363).

62. *Id.* at 1316. This was despite the fact that one week prior, in *Purdue* (cited by the *Digital Control* court), the court had said that the new version of Rule 56 applied to materiality determinations for patents filed after 1992, as the patents were in *Digital Control*. *Id.*

63. The PTO generally gives claims their broadest reasonable interpretation consistent with the specification when determining patentability. *See, e.g., In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Therefore, it is possible that even if the same standard of materiality is used both during prosecution and litigation, a reference could be material during prosecution of an application but not during litigation, if the district court construes the claims more narrowly than did the examiner. In theory, however, the opposite should not be true. Unless the examiner errs in construing the claim terms during prosecution—giving them too narrow of an interpretation—there should not be a time when a reference is material during litigation, but it was not during prosecution—provided the same standard of materiality is applied in both venues.

litigation.⁶⁴ However, the Federal Circuit occasionally referred to the new version of Rule 56.⁶⁵ In 2009, the Federal Circuit again acknowledged that a uniform standard for materiality had yet to be established, observing that twenty-four years earlier⁶⁶ it had identified four tests for materiality but still failed to conclusively identify a particular standard.⁶⁷ The court did write, however, that “[w]hile a uniform standard has not been rigorously applied in the courts, the fourth test of whether a reasonable examiner would have considered the information important in deciding whether to grant the patent, even when the omitted information does not negate patentability, is most often employed.”⁶⁸

Ultimately, while *Therasense* provides some guidance that generally “but for” materiality must be shown, wherein at least one claim of the patent at issue must be shown invalid by the undisclosed information, the majority’s opinion remains unclear as to the scope of its “egregious misconduct” exception to “but for” materiality and whether one of the other previously used standards of materiality might be employed to make a determination of “egregious misconduct.”

b. Materiality Determinations Necessarily Require Attorney or Agent Judgment

Regardless of what standard for “materiality” is applied during litigation, patent prosecuting attorneys and agents must make judgments regarding whether a reference is “material” on limited budgets. The best practice for prosecuting attorneys appears to be a policy of being overly inclusive and submitting all references that are

64. See, e.g., *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008), *aff’d in part, rev’d in part*, 655 F.3d 1364 (Fed. Cir. 2011).

65. See, e.g., *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1236-37 (Fed. Cir. 2008) (discussing both the old “reasonable examiner” standard and the new “prima facie” case version of Rule 56); *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1371 (Fed. Cir. 2006).

We see no error in the ruling of the district court that the [data was] not material under either Rule 56 standard. There is no evidence that the withheld comparative test data establishes by itself or in combination with other information a prima facie case of unpatentability of a claim.

Id. at 1377.

66. See *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 166 n.19 (Fed. Cir. 1985).

67. *Astrazeneca Pharm. LP v. Teva Pharm. USA, Inc.*, 583 F.3d 766, 773 (Fed. Cir. 2009).

68. *Id.* (citing *Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000)).

remotely related to the invention that the prosecuting attorney is aware of, regardless of whether the prosecuting attorney subjectively believes that the references are “material” or “cumulative” in order to avoid a later charge of inequitable conduct because of a different subjective understanding of the reference.

This incentive to over-cite references is problematic. This practice increases the burden on the PTO by causing the examiner to review references of marginal relevance.⁶⁹ More troubling from the perspective of the patentee and its representatives—there is case law holding that intent to deceive and inequitable conduct may be based on a finding that the prosecuting attorney cited too much art and intended to hide a reference by “burying” it along with other references cited to the PTO.⁷⁰

Consequently, a prosecuting attorney or agent must necessarily make certain subjective judgments regarding whether to submit prior art.⁷¹ If he makes an error in judgment or uses the wrong standard of materiality⁷² and submits too little or too much art, his client could

69. Brief of Amicus Curiae Boston Patent Law Association Neutral as to Parties at 11, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc) (Nos. 04-CV-2123, 04-CV-3327, 04-CV-3732, 05-CV-3117). See generally Benjamin K. Sovacool, *Placing a Glove on the Invisible Hand: How Intellectual Property Rights May Impede Innovation in Energy Research and Development (R&D)*, 18 ALB. L.J. SCI. & TECH. 381, 407 (2008).

70. See, e.g., *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co., Inc.*, 837 F. Supp. 1444, 1477 (N.D. Ind. 1992), *aff'd*, 11 F.3d 1072 (Fed. Cir. 1993), *cert. denied*, 511 U.S. 1128 (1994).

The court further holds that it is likewise a violation of the duty of candor and fair dealing with the Patent Office for an applicant or its attorney to disclose a pertinent prior art patent reference to the examiner in such a way as to “bury” it or its disclosures in a series of disclosures of less relevant prior art references, so that the examiner would be likely to ignore the entire list and permit the application to issue.

Id.

71. See *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 642 F. Supp. 2d 329, 377 n.57 (D. Del. 2009).

There is an undeniable tension between, on the one hand, cases that say that “[a]n applicant can not [sic] be guilty of inequitable conduct if the reference was cited to the examiner,” *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000), and those that say, on the other, that “‘burying’ a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith,” *Molins [PLC] v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995).

Id.

72. As long as the prosecuting attorney complies with the new “prima facie” case standard of materiality under new Rule 56 during prosecution, even if the older, and “arguably broader” old version of Rule 56, the “reasonable examiner” standard, is employed during litigation, the standards are probably sufficiently similar that an attorney may not be found to

face a charge of unenforceability due to inequitable conduct during litigation. In light of limited budgets, the subjective nature of the analysis, whether information is cumulative, and the not-yet clearly defined term “materiality” discussed above, this doctrine can place prosecuting attorneys in a difficult position.⁷³

c. Materiality Does Not Require that a Withheld Reference Render any of the Claims of the Asserted Patent Invalid in Litigation

Until *Therasense*, “but-for”⁷⁴ causation for materiality was not required—a patent could be rendered unenforceable for inequitable conduct even though the withheld information would not render any of the claims of the patent invalid.⁷⁵ Although disciplinary action by the PTO might be appropriate under those circumstances, there does not appear to be a compelling reason why a patent should be rendered unenforceable if the withheld information would not render any of the claims invalid.⁷⁶ Under those circumstances, neither the public nor the accused infringer was prejudiced⁷⁷ by the information not⁷⁸ being

have withheld material information (or submitted too much information in an attempt to “bury” the reference) based on that distinction alone. In light of the seriousness of the charge, both in the sense of the monetary value of some patents and the reputational value of such a charge to the subject prosecuting attorney, fundamental fairness dictates that notice should be clearly provided regarding the actual standards to be employed in determining materiality during litigation.

73. In some areas of technology understanding each reference sufficiently to make such judgment about materiality and cumulativeness can be very time consuming.

74. Again, even under the *Therasense* majority opinion, “but for” materiality is not required for undefined “egregious misconduct.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc). See *supra* text accompanying notes 39, 40.

75. See, e.g., *Frazier v. Roessel Cine Photo Tech, Inc.*, 417 F.3d 1230, 1240 (Fed. Cir. 2005) (Bryson, J., concurring-in-part and dissenting-in-part) (“The doctrine of inequitable conduct is not so narrow that it applies only when patent claims are invalid. *Li Second Family Ltd. P’ship v. Toshiba Corp.*, 231 F.3d 1373, 1380 (Fed. Cir. 2000) (‘Information concealed from the PTO may be material even though it would not invalidate the patent.’)”; *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1421 (Fed. Cir. 1989) (“That the claimed invention may have been superior . . . to both the cited and withheld prior art may be a basis for patentability; it cannot serve automatically to render the withheld prior art either cumulative or immaterial.”); *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1396 (Fed. Cir. 1986) (noting that whether the claims may be patentable over the withheld prior art is not the test for materiality).

76. See generally 37 C.F.R. § 10.23 (2010).

77. If “but for” causation was required before withheld information was considered material the patent would generally be held invalid in litigation based on that withheld information (depending upon relative claim interpretation during prosecution and litigation).

78. The PTO could still issue sanctions under those circumstances for a violation of its rules. See generally 37 C.F.R. § 11.18 (2010).

before the examiner. Such a result amounts to a windfall for the accused infringer and seems to be an overly harsh result for the patentee.

2. The Intent Element of Inequitable Conduct is Inconsistently Applied, Difficult to Administer, and Expensive to Litigate

a. *Intent Has Been Applied in Varying Manners in the Inequitable Conduct Analysis*

The common and ordinary meaning of “intent” is: “Design, resolve, or determination with which [a] person acts[; a] state of mind in which a person seeks to accomplish a given result through a course of action.”⁷⁹ Intent therefore refers to a subjectively desired result.

With respect to the inequitable conduct doctrine, “the intent to deceive may be inferred from the surrounding circumstances rather than by direct evidence.”⁸⁰ “[T]he intent necessary to establish inequitable conduct is based on a sliding scale related to materiality of the omission.”⁸¹ “[T]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa.”⁸²

Early on, the Federal Circuit held that “intent” is a subjective term that can be demonstrated by an objective showing of “gross negligence.”⁸³ “Aside from direct evidence of wrongful intent—i.e., deliberate scheming—intent may be proven by a showing of acts the natural consequences of which are presumably intended by the actor.”⁸⁴ The court thus held that “[t]he lower threshold for finding intent is therefore satisfied by evidence of gross negligence.”⁸⁵ The Federal Circuit, by the above-quoted language in *Hycor Corp. v.*

79. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995) (alteration in original) (quoting BLACK’S LAW DICTIONARY 810 (6th ed. 1990)).

80. *Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1380 (Fed. Cir. 2002) (citing *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997)).

81. *Id.*

82. *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1261 (Fed. Cir. 2001) (quoting *Critikon*, 120 F.3d at 1256); *Akzo N.V. v. U.S. Int’l Trade Comm’n*, 808 F.2d 1471, 1481-82 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987). The *Therasense* majority opinion will likely prove unsuccessful in eliminating the sliding scale, based on its “egregious misconduct” exception.

83. *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1540 (Fed. Cir. 1984).

84. *Id.* (citing *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1151 (Fed. Cir. 1983); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984)).

85. *Id.*

Schlueter Co., apparently combined objective and subjective standards. The court asserted that the actor “presumably intended” consequences of his actions when in fact, negligence or gross negligence means that the actor did not necessarily presume or was not even necessarily aware of the consequences of his actions.⁸⁶ Indeed, intent is irrelevant to a finding of negligence, which is based on an objective reasonable person standard rather than any subjectively desired result of the actor.⁸⁷

Over time, Federal Circuit cases generally came to reject its earlier decisions indicating that gross negligence may be sufficient to infer an intent to deceive. In *Astrazeneca Pharm. LP v. Teva Pharm. USA, Inc.*, the court stated:

[e]vidence of mistake or negligence, even gross negligence, is not sufficient to support inequitable conduct in patent prosecution. To establish the requisite deceptive intent, “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.”⁸⁸

The Federal Circuit’s more stringent articulation of the intent element of inequitable conduct may be seen as a recognition that the doctrine of inequitable conduct has grown⁸⁹ beyond its original purpose.⁹⁰ For example, in a strongly worded dissent, Judge Rader

86. See *Sedgmer v. McElroy Coal Co.*, 640 S.E.2d 129, 133 (W. Va. 2006) (noting that negligence is irrelevant to a discussion of deliberate intent).

87. See *id.* at 134.

88. *Astrazeneca Pharm. LP v. Teva Pharm. USA, Inc.*, 583 F.3d 766, 776 (Fed. Cir. 2009) (quoting *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (internal citation omitted)).

89. Judge Rader observed that the Federal Circuit still appears to give too little weight to the intent element but instead tends to merge it with the materiality element. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1350 (Fed. Cir. 2008) (Rader, J., dissenting) (“More recently, however, the judicial process has too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct. Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic.”).

90. The Federal Circuit’s cases seem to show an evolution requiring a higher showing of actual intent to deceive. In initially moving away from the gross negligence standard the court articulated that

[w]e 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.

Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989) (emphasis added). That articulation seems to indicate that gross

observed that “[a]lthough designed to facilitate USPTO examination, inequitable conduct has taken on a new life as a litigation tactic.”⁹¹

Indeed, in *Therasense*, the majority opinion again appeared to tighten the intent requirement, by stating that gross negligence was not enough to satisfy the intent element and that intent could only be shown by clear and convincing evidence that “the applicant knew of the reference, knew it was material, and made a deliberate decision to withhold it.”⁹² However, the *Therasense* court left open the possibility that intent could be proven by circumstantial evidence when intent to deceive was “the single most reasonable inference.”⁹³

b. Intent Usually Must Be Proven by Circumstantial Evidence

Intent is generally inferred from the facts and circumstances surrounding the applicant’s overall conduct; taking into account evidence of good and bad faith.⁹⁴ Because there generally is not direct evidence of bad faith, most cases rely on circumstantial⁹⁵ evidence.⁹⁶

negligence may be relevant to the inquiry, supports a showing of intent, but insufficient in itself to show intent. However, the most recent cases have indicated that gross negligence does not “support a ruling of inequitable conduct,” which appears to be a more stringent standard for a showing of intent. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1353 (Fed. Cir. 2008).

91. *Aventis*, 525 F.3d at 1349 (Rader, J., dissenting). Judge Rader also noted that [t]his phenomenon is not new or unprecedented. At an earlier time, the Federal Circuit also observed that inequitable conduct as a litigation strategy had become a “plague.” *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). In response, this court took a case to reduce abuse of inequitable conduct. *Kingsdown Med. Consultant, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc). In light of the rejuvenation of the inequitable conduct tactic, this court ought to revisit occasionally its *Kingsdown* opinion.

Id. at 1350 (Rader, J., dissenting).

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

93. *Id.*

94. *See Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005).

95. *See, e.g., Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008), *aff’d in part, rev’d in part*, 655 F.3d 1364 (Fed. Cir. 2011) (“We have also held that because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence.”); *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1151 (Fed. Cir. 1983) (stating that intent need not be proven by direct evidence; it is most often proven “by a showing of acts the natural consequences of which are presumably intended by the actor.”); *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189-90 (Fed. Cir. 1993) (observing that generally, intent must be inferred from the facts and circumstances surrounding the applicant’s conduct).

96. This is not to suggest that circumstantial evidence categorically is inherently less reliable than direct evidence. Indeed, the Federal Rules specifically reject that categorical

c. The Sliding Scale

Although the Federal Circuit has emphasized that minimum thresholds of both materiality and intent must be shown by clear and convincing evidence, after making such a showing, the district court “look[s] to the equities by weighing the facts underlying those showings.”⁹⁷ “The more material the omission or the misrepresentation, the lower [the] level of intent [is] required to establish inequitable conduct, and vice versa.”⁹⁸ The Federal Circuit explained at one point that

At this second stage, however, the question is no longer whether materiality and/or intent to deceive were proven with evidence that is sufficiently clear and convincing. While the facts of materiality and intent to deceive must be proven by clear and convincing evidence, the district court must balance the *substance* of those now-proven facts and all the equities of the case to determine whether the severe penalty of unenforceability should be imposed.⁹⁹

Many cases have confirmed that regardless of the degree of materiality, intent cannot be inferred.¹⁰⁰ As recently as 2006 the Federal Circuit wrote that when materiality is low “there is less basis for inferring intent from materiality alone,” implying that there may be circumstances where intent could be inferred from materiality alone.¹⁰¹

It is not readily apparent why a high degree of materiality should lessen the separate element of intent.¹⁰² As the courts have

approach. See Richard K. Greenstein, *Determining Facts: The Myth of Direct Evidence*, 45 HOUS. L. REV. 1801, 1803 (2009) (but noting that many states imply or directly state to juries that circumstantial evidence is less reliable than direct evidence). Any time a fact finder must ascertain what a person was actually thinking there is likely to be a high degree of error (absent the extraordinarily rare occasion where there might be a tangible record of actual intent in the form of a document or third-party testimony of actual expressed intent).

97. *Star Scientific*, 537 F.3d at 1365.

98. *Id.* at 1367 (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997)). Again, despite language that disapproves of the “sliding scale” in the majority opinion, the effect of *Therasense* on this analysis is unclear—at least where “egregious misconduct” is alleged.

99. *Star Scientific*, 537 F.3d at 1367.

100. See, e.g., *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988); *Star Scientific*, 537 F.3d at 1366.

101. *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1134-35 (Fed. Cir. 2006). The continued validity of this statement is questionable in light of *Therasense*.

102. See, e.g., *Star Scientific*, 537 F.3d at 1366.

recognized, these two elements are entirely separate inquiries.¹⁰³

In addition to this analytical problem, it is also unclear exactly how this balancing is to proceed. Initially, it is unclear whether the lower level of intent is in reference to the amount¹⁰⁴ of intent or the amount of proof of intent that is required for a finding of inequitable conduct. The former is troublesome because “intent” does not seem to have varying degrees—it is either present or it is not.¹⁰⁵ In contrast to terms that may have varying degrees or amounts an individual cannot have varying degrees or amounts of intent, just as an individual cannot have varying degrees or amounts of death.¹⁰⁶

If the sliding scale of a lesser showing of intent instead refers to a lesser amount of proof¹⁰⁷ being required for a finding of intent to deceive where there is also a high degree of materiality shown, this analysis is also troubling. First, because as previously mentioned, the initial step requires that the finder of fact¹⁰⁸ determine that both materiality and intent have been shown by clear and convincing evidence before the court balances the two and makes the ultimate determination of whether inequitable conduct has occurred.¹⁰⁹ Thus, the sliding scale should not even be considered by the court unless intent has already been proven by clear and convincing evidence,

103. *See id.*

104. This would seem to be the appropriate reading of some Federal Circuit case law. *See Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1439 (Fed. Cir. 1991) (“The more material the omission, the less culpable the intent required, and vice versa.”).

105. BLACK’S LAW DICTIONARY 881 (9th ed. 2009) (emphasis omitted) (“intent. (13c) 1. The state of mind accompanying an act, esp. a forbidden act. • While motive is the inducement to do some act, intent is the mental resolution or determination to do it.”).

106. Benjamin Franklin is credited with coining the phrase “[i]n this world nothing is certain but death and taxes.” *Benjamin Franklin Quotes*, BRAINYQUOTE, <http://www.brainyquote.com/quotes/quotes/b/benjaminfr151592.html> (last visited Dec. 15, 2011). To the extent that the Federal Circuit has rejected the idea of gross negligence serving as a ground for “intent,” see *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1353 (Fed. Cir. 2008), and as long as the term “intent” is used in its pure, subjective state of mind sense—the desire to bring about a certain result—intent is either present or it is not.

107. In *Purdue*, the Federal Circuit indicated that a lesser amount or quantum of *proof* of intent was required when a high degree of materiality was shown. *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1135 (Fed. Cir. 2006). *See also PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1319 (Fed. Cir. 2000) (citation omitted) (in cases where the omission or misrepresentation is highly material, “less evidence of intent will be required in order to find that inequitable conduct has occurred.”).

108. *Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1360 (Fed. Cir. 2008) (“Materiality . . . and intent are both questions of fact, and require proof by clear and convincing evidence.”).

109. *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008), *aff’d in part, rev’d in part*, 655 F.3d 1364 (Fed. Cir. 2011).

meaning that regardless of the degree of materiality, intent cannot drop below the clear and convincing quantum of proof.¹¹⁰ Moreover, and maybe more importantly, it simply does not make sense to require less proof of intent where there is higher showing of materiality, where the two prongs are entirely separate¹¹¹ and unrelated in some circumstances.¹¹²

In actuality, the sliding scale was most likely a means for the courts to retain discretion in the application of the inequitable conduct doctrine. The sliding scale was an attempt to “balance the *substance* of” all of the facts and all the equities “to determine whether the severe penalty of unenforceability should be imposed.”¹¹³ However, as discussed above, the sliding scale does not make sense¹¹⁴—and its

110. *See id.* at 1367 (“At this second stage, however, the question is no longer whether materiality and/or intent to deceive were proven with evidence that is sufficiently clear and convincing.”).

111. This is analogous to saying in cases of a person being charged with driving under the influence of alcohol, where she was shown to be very drunk, less proof that she was actually driving need be shown than if she was just a little drunk. In both instances the elements are separate and there does not seem to be a logical reason to reduce the burden of proof with respect to a showing on one element in the face of a higher degree or showing on the other element.

112. For instance, if the applicant asserts that she was unaware of a prior art reference—the degree of materiality of the reference is not probative of whether she was indeed aware of it with respect to the intent prong of the inequitable conduct inquiry. The high degree of materiality does not make it more likely that she was aware of such reference than a low degree of materiality would. If it is established that the applicant was aware of the reference but the dispute is whether she intended to withhold or deceive by withholding the reference one might be able to make an argument that an applicant might be more likely to withhold a highly material reference than a less material reference and thus intent to deceive could properly be inferred from the withholding of a more material reference. However, that may not always be the case. *See* Thomas C. Fiala & Jon E. Wright, *Preparing and Prosecuting a Patent that Holds up in Litigation*, in PATENT LITIGATION 515, 523 (2006). Indeed, an applicant might be more likely to disclose to the examiner a highly material reference—at least where the reference is publically available—so that the applicant has an opportunity to address the reference in the patent application and during prosecution (because the PTO does its own search and may find the subject reference). *See id.* This would seem to be a theory behind many applicants choosing to conduct prior art searches when filing applications. *See id.* Ultimately, there are simply too many variables and the materiality and intent prongs are too far removed and distinct from one another to draw any inference with respect to intent based on the degree of materiality.

113. *Star Scientific*, 537 F.3d at 1367.

114. A better way than the sliding scale to retain that discretion and flexibility is set forth in the 2007 version of patent reform. It requires, for a finding of inequitable conduct, that intent and materiality be separately proven without respect to any sliding scale. After such a finding, however, it provides the court discretion in the application of a remedy. This is discussed below, but in essence it would provide clear notice of requirements to avoid a finding of inequitable conduct while retaining flexibility with respect to the remedy imposed under all of the facts and circumstances.

application has been reduced by *Therasense*.¹¹⁵

3. The Inequitable Conduct Doctrine Increases the Cost of Litigation

The cost of litigation has become a real concern.¹¹⁶ In patent infringement cases, the cost of litigating inequitable conduct during patent prosecution is particularly high because of the factually intensive nature of the charge.¹¹⁷ In particular, the subjective intent to deceive element generally lacks direct evidence and must be proven¹¹⁸ by costly-to-obtain circumstantial evidence.¹¹⁹ Moreover, third-party discovery is nearly always sought from the prosecuting attorney, often both in the form of document requests and live deposition testimony.¹²⁰ This often leads to difficult questions of privilege¹²¹ that must be decided by the court through discovery motions. The high cost of obtaining discovery and litigating charges of inequitable conduct militates against the continuation of the availability of the inequitable conduct defense—at least in its current form.

4. The Inequitable Conduct Doctrine May Tarnish the Reputation of Prosecuting Attorneys and the Bar in General

Allegations of inequitable conduct often involve a charge of

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

116. *See, e.g., id.* at 1288; *see also* THE AM. COLL. OF TRIAL LAWYERS TASK FORCE ON DISCOVERY & THE INST. FOR THE ADVANCEMENT OF THE AM. LEGAL SYS., FINAL REPORT (2009) (discussing inefficiency and burden of litigation and discovery in general and recommending streamlining procedures to help reduce the cost).

117. *See* Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 740 (2009).

118. Being an equitable doctrine, the ultimate decision of whether inequitable conduct has occurred is a question for the court but it is based on underlying factual issues that, in a jury trial, must be determined by the jury. *See, e.g., Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359-60 (Fed. Cir. 2008); *see also* HERBERT F. SCHWARTZ & ROBERT J. GOLDMAN, PATENT LAW AND PRACTICE 277 n.67 (6th ed. 2008) (gathering cases which decided, among other things, that if a jury determines underlying factual issues relating to inequitable conduct or common factual issues affecting both inequitable conduct and legal issues, the court is bound by those findings).

119. *See* NAT'L RESEARCH COUNCIL, *supra* note 5.

120. Cotropia, *supra* note 117, at 740 (footnotes omitted) (“[T]he deposition of the prosecuting attorney who handled the application is almost always necessary in the inequitable conduct inquiry. Such depositions are uniquely costly because they are littered with complex attorney-client privilege issues that generate their own legal questions which demand additional attorney and judicial resources to resolve.”).

121. *Id.*

misconduct by the prosecuting attorney.¹²² These allegations are generally not successful.¹²³ However, they still may tarnish the reputation of the attorneys implicated by the allegations.¹²⁴ This tarnishment also diminishes the reputation of all lawyers.¹²⁵

In light of these concerns, another federal court has recently attempted to curb the liberal use of inequitable conduct during litigation.¹²⁶ In reality, it is not the fault of the litigation attorneys who assert the defense but rather a built-in consequence of the doctrine itself. During litigation, a litigating attorney arguably has an ethical obligation to assert the defense of inequitable conduct if there is any good faith basis for doing so.¹²⁷ Consequently, as long as the law remains in its current form, an abundance of marginal inequitable conduct assertions undoubtedly continue to be raised.

Patent prosecuting attorneys and patent agents generally do not intend to deceive the PTO. In addition, there is often little incentive for a prosecuting attorney to do so. Most patent attorneys charge a relatively small amount—between \$10,000 and \$30,000—to draft and prosecute a patent application¹²⁸ and prosecuting attorneys will often be involved with the prosecution of dozens, if not hundreds of applications, at any given time. It seems unlikely that most prosecuting attorneys would risk their reputation and livelihood by intentionally making misrepresentations to the PTO in order to get a single application issued.¹²⁹ Indeed, even without regard to the doctrine of inequitable conduct, if a prosecuting attorney is found to have withheld material information he is subject to sanctions by the

122. See *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

123. *Id.*

124. See *id.* (observing that allegations of inequitable conduct tarnish the reputation of prosecuting attorneys even when the allegations are not proven).

125. *Id.*

126. Mem. & Order Re: Def.'s Mot. for Summ. J.; Pl.'s Rule 56(f) Mot. at 8, *Z-Line Designs, Inc. v. Planet 3, LLC*, No. C 09-01153 (N.D. Cal. Aug. 25, 2009), 2009 WL 2710122 (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995)) (“The court reminds counsel for defendant of the Federal Circuit’s admonition concerning the practice of routinely accusing adversaries of inequitable conduct: ‘[U]njustified accusations of inequitable conduct are offensive and unprofessional.’”).

127. “A lawyer has the responsibility of representing his client to the fullest extent possible, within the bounds of the law.” *Commonwealth v. Rubright*, 414 A.2d 106, 110 (Pa. 1980) (citing the MODEL CODE OF PROF'L RESPONSIBILITY Canon 7, EC 7-1).

128. Leah C. Fletcher, *Equal Treatment Under Patent Law: A Proposed Exception to the On-Sale Bar*, 13 TEX. INTELL. PROP. L.J. 209, 230 (2005).

129. There may be exceptions for complex applications that during the prosecution stage are expected to be asserted in litigation after issuance, in which case there may be incentives for prosecuting attorneys to withhold material information from the PTO.

PTO including suspension of his ability to practice before the PTO.¹³⁰

The abundance of inequitable conduct charges involving prosecuting attorneys may be a product of the relatively small prosecution budget relative to the large budgets that usually accompany patent litigation. Attorneys' fees to try a patent case range from one million dollars for a very simple case, to four to six million dollars for a case of average complexity, to ten to twelve million dollars or more for complex cases.¹³¹ Therefore, the charges of inequitable conduct involving a prosecuting attorney may reflect in part the benefit of 20/20 hindsight, with the advantage of millions of dollars of litigation resources devoted to second-guessing choices made on a limited budget, rather than any conscious decision on the part of the prosecuting attorney or agent to intentionally deceive the PTO.

C. Statutory Reforms Affecting the Inequitable Conduct Doctrine

1. The Current Reform—H.R. 1249

On September 16, 2011, President Barack Obama signed into law H.R. 1249.¹³² This legislation affects patents in major ways including implementing a modified “first to file” rather than first to invent framework.¹³³ The effects of those modifications to 35 U.S.C. are well beyond the scope of this paper.

However, H.R. 1249 also will have some effect on allegations of inequitable conduct during litigation. Although the Act does not mention the words “inequitable conduct” it provides for a new section to 35 U.S.C., section 257.¹³⁴ Section 257 provides for a “supplemental examination proceedings” before the Patent and Trademark Office in order to reduce the effects of charges of inequitable conduct in patent litigation.¹³⁵ The amendment allows the patent owner to request

130. See, e.g., 37 C.F.R. § 11.18 (2010); Jeanne C. Curtis et al., *Litigation Issues Relevant to Patent Prosecution – The Defense of Inequitable Conduct*, in FUNDAMENTALS OF PATENT PROSECUTION 229 (2007).

131. Bryan W. Cooper, *Patent Enforcement Through Litigation*, in FUNDAMENTALS OF PATENT PROSECUTION 137, 167 (2005).

132. Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, 125 Stat. 284 (2011), available at <http://www.gpo.gov/fdsys/pkg/PLAW-112publ29/pdf/PLAW-112publ29.pdf> (to be codified in scattered sections of 35 U.S.C.).

133. See *id.* § 3.

134. *Id.* § 12.

135. *Id.*

consideration of new information for an issued patent.¹³⁶ If a “substantial question of patentability” is shown, the patent is put into reexamination proceedings.¹³⁷ Information considered during a supplemental examination proceeding may not be used during litigation on that patent to hold the subject patent unenforceable for inequitable conduct.¹³⁸ However, the supplemental examination safeguard is only available to a patent owner if the supplemental proceeding request is completed before allegations of inequitable conduct are pleaded in a patent infringement case in the district court.¹³⁹ Therefore, charges of unenforceability for inequitable conduct before the PTO will likely remain a large part of patent litigation for conduct that was not considered during the initial prosecution of the patent or during a Supplemental Proceeding. Rather than eliminating inequitable conduct charges during patent litigation, H.R. 1249 may increase proceedings before the PTO, while leaving charges of inequitable conduct in play in most major patent litigations.

2. Prior Versions of Patent Reform, Which Might be Better Alternatives to the Current Law

Prior to the passage of H.R. 1249, there were various versions of un-passed Patent Reform Legislation that addressed inequitable conduct. Some of the proposed reform was spurred by a National Academy of Science Report in 2004. As discussed below, some of the past versions of patent reform might have provided better alternatives to inequitable conduct reform than the current version of the law.

3. The 2003 FTC Report and National Academy of Science 2004 Report

In 2004, the National Academy of Sciences released a report (“NAS Report”) that addressed patent reform.¹⁴⁰ The NAS Report

136. *Id.* A third party may initiate the proceeding. Both ex-parte and inter-parte reexamination can currently be initiated by a third party but both are limited to consideration of validity of an issued patent in light of prior art in the form of patents and printed publications. *See* 35 U.S.C. §§ 301-307, 311 (2002).

137. Leahy-Smith America Invents Act § 12.

138. *Id.*

139. *Id.*

140. NAT'L RESEARCH COUNCIL, *supra* note 5, at 123. Prior to that, in 2003 the FTC issued a report addressing patent reform. Although the FTC report touches on the issue of inequitable conduct briefly, the report does not focus on that aspect of patent law nor make recommendations specific thereto. *See* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE

recommended that all subjective components should be eliminated from patent litigation—or at least modified and their role in litigation reduced.¹⁴¹ The NAS Report identified “willful” infringement, “best mode” and “inequitable conduct” as subjective inquires that were specific areas of concern.¹⁴² The NAS Report observed that subjective state-of-mind factors increase the cost and decrease the predictability of patent infringement litigation.¹⁴³ The NAS Report further noted that discovery on those subjective inquires is time-consuming, expensive, and ultimately, “a principal source of soaring litigation costs.”¹⁴⁴ “The committee believes that significantly modifying or eliminating these rules would increase the predictability of patent dispute outcomes without substantially affecting the principles that these aspects of the enforcement system were meant to promote.”¹⁴⁵

The NAS Report also observed that since the creation of the inequitable conduct doctrine by the courts, other procedures had been adopted by Congress and the PTO to support the integrity of the patent system.¹⁴⁶ Specifically, the NAS Report pointed to “third-party- and USPTO-initiated re-examination on withheld prior art, publication of pending applications, and third-party access to pending prosecution papers and the ability to submit material information.”¹⁴⁷

The NAS Report concluded that:

In view of its cost and limited deterrent value the committee recommends the elimination of the inequitable conduct doctrine or changes in its implementation. The latter might include ending the inference of intent from the materiality of the information that was withheld, *de novo* review by the Federal Circuit¹⁴⁸ of district court

PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 5, at 11 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>. (“Another modification discussed during the Hearings would extend the disclosure duty to an inventor’s co-employees. Some panelists opposed expanded search duties as adding to patent preparation costs, raising difficult enforcement problems, fueling frivolous inequitable conduct defenses, or not necessarily contributing additional useful disclosure.”).

141. NAT’L RESEARCH COUNCIL, *supra* note 5, at 7.

142. *Id.* at 7, 118-23.

143. *Id.* at 7.

144. *Id.*

145. *Id.*

146. *Id.* at 122-23.

147. *Id.* at 123. The NAS Report also proposes an “open review process” that would further contribute to the integrity of the system. *Id.*

148. The Federal Circuit purports to review inequitable conduct under an abuse of discretion standard. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989). It is not clear that reviewing findings of inequitable conduct *de novo* would reduce the assertion of the defense and such a standard

findings of inequitable conduct, award of attorney's fees to a prevailing patentee, or referral to the USPTO for re-examination and disciplinary action.¹⁴⁹

It seemed apparent that changes to the implementation of the inequitable conduct doctrine were needed.

4. The Various Versions of Proposed Legislative Reform

Following the FTC Report and NAS Report, beginning in 2005, patent reform legislation was proposed and introduced every year, until finally H.R. 1249 was passed into law in 2011.¹⁵⁰ The various versions of proposed patent reform can generally be lumped into four categories. The first category, characterized by the 2006 and 2009¹⁵¹ versions, failed to mention inequitable conduct; presumably intending to leave the doctrine in its current form under the common law.¹⁵² The second category, characterized by the 2007 version of patent reform, would have codified the common law doctrine of inequitable conduct, with some important changes.¹⁵³ The third category, the 2005 and 2008 versions, would have reduced the applicability of the inequitable conduct defense in litigation and would shift the responsibility more

would further reduce certainty and increase delay. Indeed, some have argued that the Federal Circuit should give deference to a district court's claim construction rather than reviewing such *de novo*. See Lauren Maida, Note, *Patent Claim Construction: It's Not a Pure Matter of Law, So Why Isn't the Federal Circuit Giving the District Courts the Deference They Deserve?*, 30 CARDOZO L. REV. 1773, 1775, 1795-1801 (2009).

149. NAT'L RESEARCH COUNCIL, *supra* note 5, at 123.

150. See, e.g., Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005), available at <http://www.gpo.gov/fdsys/pkg/BILLS-109hr2795ih/pdf/BILLS-109hr2795ih.pdf>; Patent Reform Act of 2006, S. 3818, 109th Cong. (2006), available at <http://www.gpo.gov/fdsys/pkg/BILLS-109s3818is/pdf/BILLS-109s3818is.pdf>; Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007), available at <http://www.gpo.gov/fdsys/pkg/BILLS-110hr1908ih/pdf/BILLS-110hr1908ih.pdf>; Patent Reform Act of 2008, S. 3600, 110th Cong. (2008), available at <http://www.gpo.gov/fdsys/pkg/BILLS-110s3600is/pdf/BILLS-110s3600is.pdf>; Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009), available at <http://www.gpo.gov/fdsys/pkg/BILLS-111hr1260ih/pdf/BILLS-111hr1260ih.pdf>; Patent Reform Act of 2010, S. 515, 111th Cong. (2010), available at <http://www.gpo.gov/fdsys/pkg/BILLS-111s515is/pdf/BILLS-111s515is.pdf>; Patent Reform Act of 2011, S. 23, 112th Cong. (2011), available at <http://www.gpo.gov/fdsys/pkg/BILLS-112s23is/pdf/BILLS-112s23is.pdf>.

151. There does not seem to be a partisan bias with respect to Patent Reform generally or specifically with respect to the issue of inequitable conduct. For example, the 2009 Senate version was a bipartisan effort by conservative Republican Senator Orrin Hatch from Utah and Democratic Senator Patrick Leahy from Vermont. Press Release, Senator Orrin Hatch, Senators Hatch, Leahy Introduce Patent Reform Act of 2009 (Mar. 3, 2009), available at <http://hatch.senate.gov/public/index.cfm/2009/3/senators-hatch-leahy-introduce-patent-reform-act-of-2009-->.

152. See S. 3818; H.R. 1260.

153. See H.R. 1908.

to the PTO to handle inequitable conduct allegations.¹⁵⁴ The fourth category, the 2010 version and the eventually passed 2011 version, H.R. 1249 creates a “Supplemental Examination” proceeding before the PTO designed to cure conduct that could be considered inequitable after the issuance of the subject patent.¹⁵⁵ Because of the uncertain current state of the law and potential need for further reform, each of the 2005, 2007, and 2008, versions is worth examining separately.

a. The 2007 Version of Patent Reform

The 2007 version of patent reform (“2007 Version”) codified substantial aspects of the common law inequitable conduct defense.¹⁵⁶ Section 328 of the 2007 Version leaves the burden of proving inequitable conduct by clear and convincing evidence on the challenging party.¹⁵⁷ While the House¹⁵⁸ and Senate¹⁵⁹ versions varied in some respects, both substantially adopted the common law of inequitable conduct. The 2007 Version required demonstration of intent to deceive and precluded negligence or gross negligence as being a sufficient showing for inequitable conduct.¹⁶⁰ With respect to materiality, it adopted the “*prima facie* case” standard.¹⁶¹ The 2007 Version did not mention the “sliding scale” standard of the common law, instead simply requiring that both materiality and intent be proven by clear and convincing evidence.¹⁶²

While the substantive showing required for inequitable conduct under the 2007 Version essentially codified common law, the remedial component was more discretionary and flexible. It allowed a court, in balancing the equities, to impose a choice of three remedies: (1) denying equitable relief to the patent holder and limiting the remedy for infringement to a reasonable royalty; (2) holding the

154. See S. 3600; H.R. 2795.

155. See S. 515; S. 23.

156. H.R. 1908 § 12 (amending § 282(c)).

157. *Id.* at § 6 (proposing § 328).

158. Democratic Congressman Howard Berman introduced the House Bill, H.R. 1908 on April 17, 2007. This bill passed the House by a vote of 222-175 with 37 not present or not voting. H.R. 1908.

159. Democratic Senator Patrick Leahy introduced the Senate Bill, S. 1145 on April 18, 2007. Patent Reform Act of 2007, S. 1145, 110th Cong. (2007), available at <http://www.gpo.gov/fdsys/pkg/BILLS-110s1145is/pdf/BILLS-110s1145is.pdf>.

160. *Id.* at § 12 (proposing § 298(c)).

161. *Id.* at § 12 (proposing § 298(b)).

162. *Id.* at § 12 (proposing § 298(a)).

claims in suit unenforceable or only the claims in which the inequitable conduct occurred unenforceable; or (3) holding the patent unenforceable.¹⁶³

As discussed above, the application of the common law inequitable conduct defense is problematic because of the inconsistency of its application, in apparent exchange for discretion. While there may be advantages to discretion—the disadvantages in this circumstance outweigh the advantages. The lack of certainty put applicants and prosecuting attorneys in too difficult of a position by failing to provide notice—requiring them to guess, for example, which materiality standard will be employed in litigation. It is especially important to have a clearly defined standard of materiality in light of case law holding that citing too much art, or failing to cite sufficient art, could potentially lead to a finding of inequitable conduct.¹⁶⁴

Being an equitable doctrine, it is understandable that courts would want to retain discretion in application of the inequitable conduct doctrine.¹⁶⁵ Paradoxically, under the common law there is little discretion regarding the imposition of a remedy upon a finding of inequitable conduct; at least all of the claims of the subject patent—and possibly claims of related patents—are rendered unenforceable.¹⁶⁶

The 2007 Version provided the benefit of certainty by clarifying the standard of materiality and omitting the uncertainty and analytical problems associated with the sliding scale, with respect to the substantive aspect of the inequitable conduct. However, it retained for the courts discretion and flexibility to “do equity” in the remedial component after a finding of inequitable conduct. Preferable to the current common law, that version provided notice and certainty of what was required of applicants and prosecuting attorneys, while retaining discretion in the form of the remedy imposed after such a finding is made.¹⁶⁷

163. See *id.* at §12 (proposing § 298(e)).

164. See, e.g., *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co.*, 837 F. Supp. 1444, 1477 (N.D. Ind. 1992), *aff'd without opinion*, 11 F.3d 1072 (Fed. Cir. 1993), *cert. denied*, 511 U.S. 1128 (1994).

165. See, e.g., *Holmberg v. Armbrrecht*, 327 U.S. 392, 396 (1946).

166. See, e.g., *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1227-30 (Fed. Cir. 2007); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 n.15 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989).

167. The 2007 Version also provides for the court to refer the matter to the PTO for disciplinary action should it be shown that a prosecuting attorney or patent agent was involved

b. The 2008 Version of Patent Reform

The 2008 version of Patent Reform (“2008 Version”) set forth detailed procedures for the administration of the inequitable conduct doctrine that primarily shifted the burden of determining inequitable conduct from the courts to the PTO.¹⁶⁸ Proposed section 298(a) of that version provides that “[e]xcept as provided under this section or section 299,¹⁶⁹ a patent shall not be held invalid or unenforceable based upon misconduct before the Office.”¹⁷⁰ Proposed section 298(b)(1)(B) sets forth essentially a restrictive “but for” causation requirement for materiality providing that “information is material if it is not part of the record or cumulative to information in the record and either establishes that a patent claim is not patentable or refutes a position that the applicant or patent owner took in response to a rejection of the claim as unpatentable.”¹⁷¹

The 2008 Version essentially deals with inequitable conduct through special reissue proceedings in the PTO.¹⁷² The 2008 Version provided a mechanism for a court to refer the matter to the PTO if inequitable conduct charges arose during litigation.¹⁷³ It provided that, upon a motion by a party in litigation and a finding by the court that it is more likely than not that a person “knowingly and intentionally deceived the [PTO] by concealing material information or by submitting false material information in such matter or proceeding, the court shall order the patent to be made the subject of a reissue application under [35 U.S.C.] section 251.”¹⁷⁴ The 2008 Version then set forth specific procedural guidelines for the special reissue proceeding and potential appeal to the Patent Trial and Appeal Board.¹⁷⁵

in inequitable conduct. Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 12 (2007) (amending 282(c)(5)).

168. Patent Reform Act of 2008, S. 3600, 110th Cong. (2008), *available at* <http://www.gpo.gov/fdsys/pkg/BILLS-110s3600is/pdf/BILLS-110s3600is.pdf>.

169. *Id.* § 11. Section 299 is discussed below and provides for civil sanctions for a showing of inequitable conduct, as determined in a proceeding before the PTO.

170. S. 3600 § 11 (proposing § 298(a)). Proposed section 298(a) further clarifies that “[n]othing in this section shall be construed to create a cause of action or a defense in a civil action.” *Id.*

171. *Id.* (proposing § 298(b)(1)(B)). *See also* *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc) (generally adopting a “but for” causation requirement but leaving open an undefined exception for “egregious misconduct”).

172. S. 3600 § 11 (proposing § 298(b)(1)(A)).

173. *Id.* (proposing § 298(b)(1)-(2)).

174. *Id.* (proposing § 298(b)(1)(A)).

175. *Id.* (proposing § 298(e)(5)(E)).

The contemplated special reissue proceeding would have been *ex parte*.¹⁷⁶ Under the special reissue proceeding for inequitable conduct allegations, claims may have been substituted or omitted, but they could not be broadened—as claims may be under current 35 U.S.C. section 251,¹⁷⁷ within two years of the grant of the patent.¹⁷⁸ The 2008 Version outlines procedural guidelines for the special reissue proceedings and it allowed for discovery including production of documents and depositions,¹⁷⁹ as well as for an appeal from reissue proceeding.¹⁸⁰

The 2008 Version also provided for civil sanctions for misconduct of prosecuting attorneys, patent examiners and parties to an office proceeding, up to ten million dollars.¹⁸¹

The 2008 Version had advantages over the common law with respect to reducing the distraction and cost generally associated with an assertion of inequitable conduct during litigation by shifting that burden to the PTO. However, shifting the burden to the PTO to determine inequitable conduct—through the use of reissue proceedings—raises additional concerns.

Proposed section 298(b)(4) of the 2008 version provided that a court shall not stay the litigation proceedings after referral to the PTO for the inequitable conduct reissue proceedings unless: (1) the Director rejects at least one claim of the patent; (2) the allegations of infringement remain pending in the litigation for at least one of the rejected claims; *and* (3) the court determines that the interests of justice require a stay.¹⁸² Thus, the parties may spend an abundance of time and resources in litigation—only to have some or all of the relevant claims rejected by the PTO—and consequently rendering moot issues in litigation.¹⁸³

176. *Id.* (proposing § 298(e)(5)(A)).

177. *Id.* (proposing § 298(f)). Current law also allows for *ex parte* reexamination, which may be requested by anyone. 35 U.S.C. § 302 (2006). The reexamination is limited to consideration of patents and printed publications not previously considered by the PTO, however. 35 U.S.C. § 301 (2006). *Inter partes* reexamination is also available under current law but it is not commonly requested by third parties because it gives rise to collateral estoppel. 35 U.S.C. § 315 (2006).

178. 35 U.S.C. § 251 (2006). Current section 251 requires that the error sought to be corrected by a reissue proceeding occur “without deceptive intention,” so it would not be available under current law to cure a charge of inequitable conduct. *Id.*

179. S. 3600 § 11 (proposing § 299(c)).

180. *Id.* (proposing § 299(d)).

181. *Id.* (proposing § 299(b)(3)(C)).

182. *Id.* (proposing § 298(b)(4)).

183. Conversely, if a stay was the default rule after initiation of the inequitable conduct-

The idea of parallel proceedings also creates a concern about inconsistent results. A finder of fact in the litigation could determine that an asserted claim of a patent was not invalid and the PTO could still find that such claim was invalid in the reissue proceeding.¹⁸⁴ The 2008 Version was not clear regarding the consequences in such a case. Presumably, the PTO's determination of patentability would trump that of the litigation fact finder, as the subject patent claim would not issue from the PTO, and there would in effect retroactively be no claim for the fact-finder to pass upon in the litigation.¹⁸⁵ Under the 2008 Version it appears that an accused infringer would have been able to escape liability based on a finding of invalidity by convincing either the PTO or the finder of fact in the litigation that the relevant claims of the asserted patent were invalid.¹⁸⁶ Thus, the reissue proceeding would have likely become a common-place part of most major patent litigation.¹⁸⁷

Another disadvantage of the 2008 Version is the PTO, which is already understaffed,¹⁸⁸ would undoubtedly have to be expanded and further funded to take on the additional responsibility of conducting the reissue proceedings relating to a charge of inequitable conduct.¹⁸⁹

Ultimately, the 2008 Version does not appear to have been a good legislative reform choice with regard to inequitable conduct.

based reissue proceedings, an alleged infringer could most likely use the reissue proceedings as a stall tactic. It is becoming more common for alleged infringers to seek *ex parte* reexamination of asserted patents during litigation—most likely in part—for that same reason (it is at the discretion of the district court whether to issue a stay pending reexamination of an asserted patent in litigation).

184. See, e.g., *Abbott Labs., Inc. v. Medtronic, Inc.*, No. C-08-4962-DLJ, 2009 WL 799404, at *3 (N.D. Cal. Mar. 24, 2009) (identifying problem of inconsistent findings by the PTO and the court in different parallel proceeding context).

185. See S. 3600 § 11 (proposing § 298(e)(2) which provides that the reissue proceedings—unless substitute claims are filed—shall “address only whether original claims continue to be patentable after consideration of the additional information . . .”).

186. No preference is stated for whether the special reissue would be before the same examiner who examined the original application, when possible. See *id.* However, considering the high turn-over rate of examiners it seems likely that the reissue proceeding would commonly be conducted before a different examiner than the original application, who would of course bring with him his own set of understandings, opinions, and bias, with respect to the patentability of the invention—irrespective of the new information to be considered.

187. As mentioned above, the 2008 Version would require a motion to refer the matter to the PTO but it only requires a preponderance of the evidence that material information was withheld during the original prosecution, see *id.* § 298(b)(1)(A), and based on the amount of resources spent during litigation compared to prosecution it is likely that an accused infringer could regularly be successful on such a motion.

188. See John DeQ. Briggs, *Intellectual Property & Antitrust: Two Scorpions in a Bottle*, 10 SEDONA CONF. J. 65, 66 (2009).

189. See *id.*

c. The 2005 Version of Patent Reform

The 2005 version of patent reform¹⁹⁰ (“2005 Version”) would have reduced¹⁹¹ the applicability and role in litigation of common law inequitable conduct doctrine.¹⁹² Under the 2005 Version, as under the 2008 Version, the PTO would have been primarily responsible for determining inequitable conduct¹⁹³ (with the court retaining jurisdiction in limited circumstances, addressed below).¹⁹⁴ The PTO would have had sole authority to administer sanctions for violations by prosecuting attorneys or patent agents registered to practice before the PTO.¹⁹⁵

The 2005 Version also provided for the creation of a special unit within the PTO to investigate allegations of inequitable conduct,¹⁹⁶ and provided for certain discovery to occur and for appeal to the Patent and Trademark Appeal Board.¹⁹⁷ If inequitable conduct was found to have occurred in a proceeding before the PTO, the PTO

190. Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005), *available at* <http://www.gpo.gov/fdsys/pkg/BILLS-109hr2795ih/pdf/BILLS-109hr2795ih.pdf>.

191. The proposed revisions would have eliminated the common law inequitable conduct defense instead making it governed exclusively by the revised act. *Id.* § 5 (proposing § 136(a) which provides “Any allegation of any type of violation of the duty of candor and good faith under this subsection shall be governed exclusively by this chapter.”).

192. The proposed revisions provide that individuals associated with the filing of a patent application have a duty of candor and that duty is violated if:

- (1) the individual failed to disclose information or misrepresented information;
- (2) the information not disclosed was material or, in the case of a misrepresentation, the misrepresentation was material;
- (3) the individual had knowledge of the materiality of the information not disclosed or, in the case of a misrepresentation, of the misrepresentation and materiality of the misrepresentation; and
- (4) the individual had the intent to deceive or mislead.

Id. (proposing § 136(b)).

193. *Id.* Proposed § 136(c)(1) provides:

No court or Federal department or agency other than the Office, and no other Federal or State governmental entity, may investigate or make a determination or an adjudication with respect to an alleged violation of the duty of candor and good faith under subsection (a) or with respect to an alleged fraud, inequitable conduct, or other misconduct in any proceeding before the Office involving a patent or in connection with the filing or examination of an application for patent, except as expressly permitted in this section.

Id. § 136(c)(1).

194. *Id.* Proposed § 136(a) would have imposed the duty of candor on “individuals associated with the filing and prosecution of an application for patent and on individuals assisting a patent owner in proceedings before the Office involving a patent.” *Id.* § 136(a).

195. *Id.* (proposing § 136(e)(1)).

196. *Id.* (proposing § 136(e)).

197. *Id.* (proposing §§ 136(e)(2), (4)).

could have issued a fine in an amount sufficient to deter future violations, not to exceed one million dollars or five million dollars for particularly egregious conduct, without affecting the enforceability of the patent.¹⁹⁸

The 2005 Version also imposed certain procedural requirements before unenforceability for inequitable conduct could be asserted in court.¹⁹⁹ Unenforceability based on inequitable conduct could only be raised by motion.²⁰⁰ Before such a motion could be granted, one or more asserted claims would have to have been found invalid and judgment entered on those claims.²⁰¹ The 2005 Version directed that the court may not grant the motion unless the PTO relied on one or more material misrepresentations that are attributable to the patent owner (and excluding conduct by patent agents or prosecuting attorneys), which caused one or more invalid claims of the subject patent to issue.²⁰²

Under the 2005 Version, assertions of unenforceability because of inequitable conduct in litigation would have been reduced. By delaying the timing of an assertion of inequitable conduct and requiring at least one claim first be held invalid, some allegations of inequitable conduct would become moot because it would be unnecessary to find claims unenforceable if they are already invalid. Unenforceability would only be an issue in litigation where one or more claims were invalid but other claims of the subject patent were both infringed and not invalid.²⁰³

5. Advantages and Disadvantages of the Various Unpassed Versions of Reform Relating to Inequitable Conduct

The precise effects of the “Supplemental Examination” provisions, section 257 of United States Code, added by H.R. 1249 remain unclear. Consequently, further legislative reform might be desirable. The following discusses the general advantages and

198. *Id.* (proposing § 136(e)(6)).

199. *Id.* (proposing § 136(d)(2)).

200. *Id.*

201. *Id.* See also *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc) (holding that at least one claim of the patent at issue must be found to be invalid before unenforceability due to inequitable conduct could be found).

202. H.R. 2795 § 5 (proposing 136(d)(2)(D)).

203. See *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (noting that under the current system inequitable conduct is alleged in nearly every major litigation).

disadvantages of the various proposed versions of patent reform, including the current version, H.R. 1249.

*a. Courts Should Retain Responsibility for
Administration of Unenforceability of an Issued
Patent with the PTO Having Sanctioning
Authority for Violations of the Duty of Candor*

The ultimate determination of unenforceability due to inequitable conduct should be left with the court, as set forth in the 2007 Version, rather than shifted to the PTO, as in the 2005 and 2008 versions, in order to avoid inconsistencies, delay, and other inherent problems caused by parallel proceedings.²⁰⁴ The current law, H.R. 1249, passed in 2011 will probably increase proceedings before the PTO in the form of Supplemental Examination but would not dramatically decrease inequitable conduct during litigation because of the limitation that the Supplemental Examination only provides for a safe harbor if the supplemental examination request is completed before inequitable conduct is charged in litigation.²⁰⁵

Practically speaking, a Plaintiff to a patent litigation suit might not be aware of or be able to anticipate what the Defendants might allege constitutes inequitable conduct. This creates an incentive for a Defendant to make allegations of inequitable conduct before obtaining all relevant factual information to prevent the Plaintiff from availing itself of the Supplemental Proceedings safe harbor provision.²⁰⁶ In reality, Plaintiffs, in major patent litigation, might seek Supplemental Examination as a prophylactic measure, unnecessarily increasing the burden on the PTO.

If the doctrine of inequitable conduct continues, it makes sense to have the court rather than the PTO make the ultimate determination because the court has been presented with all relevant information, and because equity requires a determination based on all of the facts surrounding a case.²⁰⁷

However, the PTO should continue to have sanctioning authority for violations of the duty of candor and in fact this investigative and

204. See generally *Abbott Labs., Inc. v. Medtronic, Inc.*, No. C-08-4962-DLJ, 2009 WL 799404, at *3 (N.D. Cal. Mar. 24, 2009) (identifying problem of inconsistent findings by the PTO and the court in different parallel proceeding context).

205. See *Leahy-Smith America Invents Act of 2011*, Pub. L. No. 112-29, § 12, 125 Stat. 284, 325-27 (2011) (codified in 35 U.S.C. § 257).

206. See *id.*

207. Cf. *Holmberg v. Armbrecht*, 327 U.S. 392, 396 (1946).

sanctioning authority could be expanded as provided for by the 2005 and 2008 Versions.²⁰⁸ Potential monetary sanctions and disciplinary action against those licensed to practice before the PTO have the effect of providing incentives for compliance with rules but without the concerns for the disproportionate remedy that accompany the current form of unenforceability due to inequitable conduct in litigation.²⁰⁹

b. Materiality and Intent Should be Specifically Set Forth and Defined

As discussed above, the Federal Circuit has recently attempted to more clearly define materiality and intent requirements for a showing of inequitable conduct.²¹⁰ Unfortunately, the Court, while providing general rules, has left gaping exceptions, such as an “egregious misconduct” exception to materiality, which threaten to swallow the rule.²¹¹

Under the current version of Patent Reform H.R. 1249, inequitable conduct will most likely continue to be a major factor in patent litigation because allegations of misconduct will be alleged before a patent owner can request “Supplemental Examination” of the subject patent.²¹²

208. See Patent Reform Act of 2008, S. 3600, 110th Cong. § 11(a) (2008), available at <http://www.gpo.gov/fdsys/pkg/BILLS-110s3600is/pdf/BILLS-110s3600is.pdf>; H.R. 2795, 109th Cong. § 5 (2005), available at <http://www.gpo.gov/fdsys/pkg/BILLS-109hr2795ih/pdf/BILLS-109hr2795ih.pdf>.

209. See Nicole M. Murphy, Note, *Inequitable-Conduct Doctrine Reform: Is the Death Penalty for Patents Still Appropriate?*, 93 MINN. L. REV. 2274, 2274 (2009) (“Recent application of the doctrine has been likened to ‘imposing the death penalty for relatively minor acts of misconduct.’”) (citing Robert Pear, *Candor at Heart of Debate over Patents in Congress: Should Firms Lose Rights Won by Misrepresentation?*, INT’L HERALD TRIB., Apr. 30, 2008, at 11); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008), *aff’d in part, rev’d in part*, 655 F.3d 1364 (Fed. Cir. 2011) (“[I]t is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith.”); *Patent Reform: The Future of American Innovation: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 131 (2007) (statement of Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director, U.S. Patent and Trademark Office noting that uncertainty surrounding the inequitable-conduct doctrine creates the potential for “draconian penalties” for innocent omissions); Paul M. Janicke, *Inequitable Conduct: Out of the Frying Pan?*, PATENTLY-O (Aug. 7, 2008, 12:04 PM), <http://www.patentlyo.com/patent/2008/08/inequitable-con.html> (“[C]redible-sounding explanations” for innocent omissions by applicants years after a patent filing and application “are not that easy to come by”).

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

211. See *id.*

212. See Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, § 12, 125 Stat.

If the inequitable conduct doctrine persists in patent litigation, the 2007 Version's requirements of a specific articulation of materiality,²¹³ and intent should be adopted. Such specificity provides consistency and notice of requirements for compliance by prosecuting attorneys, agents, and patentees in order to avoid the problems with a lack of notice and uncertainty present in the common law application of inequitable conduct, discussed above.²¹⁴ Both intent and materiality should be required to be separately proven by clear and convincing evidence without regard to any sliding scale. As suggested by the NAS Report, no inference should be drawn with respect to intent to deceive based upon the degree of materiality.²¹⁵ As addressed above, materiality and intent are separate inquiries. There is no compelling reason that a sliding scale should be used to diminish the requirement of intent, or that an inference of intent should be drawn based on the degree of materiality.

*c. Discretionary and Flexible Remedial Provisions
Are Desirable to the Rigid Remedies in the
Inequitable Conduct Context*

The remedial provisions of the 2007 Version of Patent Reform are favorable to a harsh rule because of the discretion it offers in the choice of remedy after a finding of inequitable conduct.²¹⁶ For example, a court could decide to deny injunctive relief and require that a certain percent of the royalty is paid in trust to the PTO rather than to the patentee, where the court finds that although there was inequitable conduct, it did not affect the validity of the patent. This remedy would avoid a windfall to the infringer,²¹⁷ while

284, 325-27 (2011) (codified in 35 U.S.C. § 257).

213. The 2007 Version adopts the “prima facie case” standard of materiality. See Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 12(b) (2007), available at <http://www.gpo.gov/fdsys/pkg/BILLS-110hr1908ih/pdf/BILLS-110hr1908ih.pdf>. It makes sense to adopt the same standard of materiality for litigation that is used by the PTO—although the Federal Circuit has made clear that it is not bound by the PTO’s rule in that regard. See *Therasense*, 649 F.3d at 1293-94. Patentees and prosecuting attorneys should be in compliance with litigation standards if they comply with the PTO rules and its current standard of materiality. Ultimately, there may not be a real difference between the “reasonable examiner” and “prima facie case” standards of materiality. The precise definition of materiality in this regard is probably not as important as actually clearly adopting some workable definition in order to give notice to patentees and their agents of requirements for conduct before the PTO.

214. See *Edwards v. Aguillard*, 482 U.S. 578, 639-40 (1987) (Scalia, J., dissenting).

215. See NAT’L RESEARCH COUNCIL, *supra* note 5, at 123.

216. See Patent Reform Act of 2007, S. 1145, 110th Cong. § 12 (2007), available at <http://www.gpo.gov/fdsys/pkg/BILLS-110s1145is/pdf/BILLS-110s1145is.pdf>.

217. There are other possible remedies that a court in equity may determine to be

compensating the public in two ways. First, it would allow competition by denying injunctive relief. Second, it would compensate the PTO and in effect the public for the lack of full disclosure during prosecution of the application, which violates the “bargain” the patentee makes with the public of full disclosure in exchange for a limited monopoly.²¹⁸

d. Attorneys’ Fees

Finally, one issue that is not addressed by any of the patent reform legislation, but that was raised by the NAS Report is the award of attorneys’ fees.²¹⁹

The general reasoning behind the “American Rule”, where each party bears its own attorneys’ fees, is to prevent parties from being dissuaded from bringing or defending meritorious claims because of fear of being burdened with the opposing side’s attorneys’ fees,²²⁰ should the opposing party ultimately prevail.²²¹ Awarding attorneys’ fees to the prevailing party as a matter of right when inequitable conduct was asserted would probably not be desirable because of the likelihood of chilling meritorious assertions and defenses. However under 35 U.S.C. section 285, proof of inequitable conduct can form the basis for the award of attorneys’ fees in favor of the accused infringer if inequitable conduct makes the case exceptional.²²²

Therefore, if an attorneys’ fees provision was added to reduce the frequency of inequitable conduct claims, in line with the NAS Report, it would be advisable to include an explicit provision stating that an unsuccessful assertion of inequitable conduct may make the case exceptional, allowing the patentee to recover its attorneys’ fees relating to an unsuccessful charge of inequitable conduct. However, a

appropriate after a finding of inequitable conduct. As another example, for minor violations, a court may decide to deny lost profits but allow a full reasonable royalty.

218. See *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) (“[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.”).

219. See NAT’L RESEARCH COUNCIL, *supra* note 5, at 122.

220. *Bregstone v. United States*, 4 Cl. Ct. 507, 511 (1984).

221. Of course the high percentage of cases that are overturned on appeal suggests that reasonable minds can vary on the ultimate merits of a case and a case certainly could be brought in good faith but ultimately lost. For example, the Federal Circuit overturns roughly 40% of the claim construction cases it hears on appeal. See DONALD W. RUPERT, *COMMERCIAL LITIGATION STRATEGIES: LEADING LAWYERS ON CASE PREPARATION, SETTLEMENT OPPORTUNITIES, AND BEST PRACTICES FOR CLIENT SUCCESS* (2008), available at 2008 WL 5939923 at *24.

222. See *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 455 (Fed. Cir. 1985).

finding that an assertion of inequitable conduct may make the case exceptional should remain discretionary with the district court rather than adopted as a matter of right, in order to align with case law.

If the procedural requirements of the 2005 Version were adopted, an attorneys' fees provision would be unnecessary. Borderline assertions of inequitable conduct might be reduced by the requirement of a finding that at least one claim is invalid and the requirement that the district court grant a motion to allow an assertion of the inequitable conduct defense in litigation.²²³

III. A PROPOSAL TO ELIMINATE THE INEQUITABLE CONDUCT DEFENSE BASED ON VARYING THE PRESUMPTION OF VALIDITY, DEPENDING UPON FULL DISCLOSURE

Both Congress²²⁴ and the Federal Circuit have recently taken steps to reduce the role of inequitable conduct in patent litigation.²²⁵ The ultimate effect of these changes remains unclear, as discussed above, but a better alternative would be to entirely eliminate the doctrine of inequitable conduct from patent litigation and replace it with an interpretation of 35 U.S.C. section 282 that the presumption of validity of an issued patent only arises when all material information was before the Examiner during prosecution of the issued patent.²²⁶ This makes sense because the validity presumption is based on the belief that governmental officials normally do their jobs but if the Examiner was lacking material information he or she would not be able to make an informed decision. That would also serve the current purpose of the inequitable conduct doctrine by giving incentive to provide all material information to the PTO to obtain the presumption of validity.

The inequitable conduct defense arose as a result of a belief that it was necessary to ensure the duty of candor in patent prosecution, because of its nature as an *ex parte* proceeding.²²⁷ "When a patent has

223. See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc) (similarly holding that at least one claim must be invalidated by non-disclosed art before inequitable conduct may be asserted).

224. Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in various sections of 35 U.S.C.).

225. *Therasense*, 649 F.3d at 1292.

226. This section provides in pertinent part: "A patent shall be presumed valid. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282 (2006).

227. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting) ("Without doubt, candor and truthful cooperation are essential to an

been examined and duly granted, judicial review must give due weight to the presumption of validity. . . . The presumption of validity is based on the presumption of administrative correctness of actions of the agency charged with examination of patentability.”²²⁸ Importantly, under existing Federal Circuit precedent,²²⁹ the “presentation at trial of additional evidence that was not before the PTO does not change the presumption of validity or the standard of proof, although the burden may be more or less easily carried because of the additional evidence.”²³⁰ Therefore, even if material information was not before the examiner during prosecution, the Federal Circuit has ruled that there is still a presumption of validity of an issued patent that must be overcome by clear and convincing evidence at trial to find the subject patent invalid.²³¹

In *KSR International Co. v. Teleflex Inc.*,²³² the United States Supreme Court indicated that material information that was not before the examiner during prosecution of a patent could render the presumption of validity of an issued patent inapplicable, or at least

ex parte examination system. . . . The threat of inequitable conduct, with its ‘atomic bomb’ remedy of unenforceability, ensures that candor and truthfulness.”)

228. *Applied Materials v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996).

229. Prior to the creation of the Federal Circuit, case law had held that when there was art that was “closer to” the subject of the application that was introduced during litigation but was not before the examiner the presumption of validity did not apply and the burden of proof for showing validity rested with the patentee. *See Tveter v. AB Turn-O-Matic*, 633 F.2d 831, 833 (9th Cir. 1980); *accord* *Photo Elecs. Corp. v. England*, 581 F.2d 772, 775 (9th Cir. 1978); *Deere & Co. v. Sperry Rand Corp.*, 513 F.2d 1131, 1132 (9th Cir. 1975); *Hewlett-Packard Co. v. Tel-Design Inc.*, 460 F.2d 625, 628 (9th Cir. 1972). Of course whether a reference is “closer to” the invention than art that was before the examiner does not necessarily coincide with whether the art is material but it does recognize that the presumption of validity should be affected when the examiner was not aware of certain information. *See Tveter*, 633 F.2d at 833. However, in *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984), the Federal Circuit specifically stated that it disagreed with that precedent and that the presumption of validity attached to an issued patent could only be overcome by a showing of invalidity by clear and convincing evidence, regardless of what information the examiner might have been lacking when making a determination of patentability. *Id.* at 1359-60.

230. *Applied Materials*, 98 F.3d at 1569.

231. *See id.* There was a pre-Federal Circuit split among the circuits regarding the required burden to overcome the presumption of validity of an issued patent with at least the Second Circuit and the Sixth Circuit holding that only a preponderance of evidence was necessary. *Compare* *Dickstein v. Seventy Corp.*, 522 F.2d 1294 (6th Cir. 1975) (recognizing circuit split and that some circuits required clear and convincing evidence), *with* *Rains v. Niaqua, Inc.*, 406 F.2d 275, 278 (2d Cir. 1969) (“a preponderance of the evidence determines the issue”), *and* *Lorenz v. F. W. Woolworth Co.*, 305 F.2d 102, 105 (2d Cir. 1962) (indicating that a preponderance of the evidence was sufficient). *See also supra* note 229 regarding the Ninth Circuit’s varying burden depending upon what art was before the examiner.

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

severely lowers the burden of overcoming the presumption.²³³ Following the Supreme Court's lead, section 282 of the Patent Act²³⁴ should be interpreted so the presumption of validity depends upon whether all non-cumulative material information was before the examiner of the application resulting in the subject patent. If the current requirement, that the presumption of validity must be overcome by clear and convincing evidence, was seen as being insufficient incentive for the patentee to provide all non-cumulative material information to the examiner, the presumption could be raised to require the accused infringer to show that the PTO's decision to grant the patent was arbitrary,²³⁵ or that the PTO's decision to grant the patent is not supported by substantial and competent evidence.

If non-cumulative material information was not before the Examiner, one option would be to have the burden remain on the challenging party to show invalidity by a mere preponderance of the evidence. Alternatively, the burden could shift to the patentee²³⁶ to show validity of the patent by a preponderance of the evidence if the non-cumulative material information was not before the examiner during litigation.²³⁷

233. *See id.* at 426.

234. 35 U.S.C. § 282 (2006).

235. This standard would treat the PTO's decision to grant the patent as an administrative decision subject only to review under the highly deferential arbitrary and capricious standard afforded administrative agencies, based upon the rationale that the agency is experienced in dealing with its particular subject matter. *See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984). When all non-cumulative material information is before the examiner it might make sense to use such a highly deferential standard during litigation in deference to the examiner's expertise in the field.

236. *Applied Materials v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996); *Tveter v. AB Turn-O-Matic*, 633 F.2d 831, 833 (9th Cir. 1980) (pre-Federal Circuit case law shifting the burden to the patentee to prove validity when "closer" art was not before the examiner).

237. It would be a difficult judicial interpretation for a court to adopt a standard whereby the patentee had the burden of proving validity where material information was not before the examiner under the current version of section 282 which provides in part that "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282. That change would probably have to come from Congress. Conversely, a differing standard, such as where a challenger during litigation bore the burden of proving invalidity of an issued patent by a preponderance of the evidence if non-cumulative material information was not before the examiner, instead bore the burden of proving invalidity by a higher standard such as: (1) demonstrating by clear and convincing evidence that the patent should not have issued; (2) that there is no substantial evidence to support the issuance of the patent; or (3) an appropriate court (the United States Supreme Court or the Federal Circuit *en banc*) could rule that the decision to grant the patent was arbitrary and capricious without legislative intervention because section 282 does not set forth an appropriate burden of proof for a challenge to the validity of an issued patent.

Regardless of which standard of proof is ultimately required, the key would be to provide a sufficiently higher burden on the party challenging validity during litigation to provide adequate incentive to the patentee to disclose all non-cumulative material during prosecution of the application. Indeed, the patentee would have more incentive to provide material information to the examiner under the proposed system,²³⁸ as under the current system neither the patentee nor the attorney representing him has an obligation to search for material prior art.²³⁹

In addition to providing the desired incentive to patentees to disclose all non-cumulative material information, this varying burden would also make sense logically because the examiner is more likely to make the correct decision on patentability when she is in possession of all material information. The precise burdens adopted would then depend upon policy considerations regarding whether more or less patents should ultimately be found invalid during litigation,²⁴⁰ taking into account relevant desired societal incentives for encouragement of innovation and the necessary burdens related thereto.

Considering the positive effect on innovation that a strong patent system provides, adopting the agency's deferential standard of

238. Admittedly the severity of the result of not disclosing material information would not be as great as in the current system. However, especially with respect to patent applications that are likely to be litigated the incentive to receive the benefit of the presumption would likely be sufficient, especially in conjunction with the threat of sanctions from the PTO for noncompliance with disclosure obligations, to ensure disclosure of non-cumulative material information. *See* 37 C.F.R. pt. 10, 11 (2010).

239. *See* *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1330 (Fed. Cir. 2009) (citing *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1382 (Fed. Cir. 2001) (“The mere possibility that material information may exist will not suffice to give rise to a duty to inquire; sufficient information must be presented to the attorney to suggest the existence of specific information[,] the materiality of which may be ascertained with reasonable inquiry.”)); *id.* (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984) (“Nor does an applicant for patent, who has no duty to conduct a prior art search, have an obligation to disclose any art of which, in the [district] court’s words, he ‘reasonably should be aware.’”)).

240. This determination concerns an entirely separate issue of the policy of the desired relative strength of patent protection and the effects thereof, which has been analyzed and disputed at length by economists and legal scholars. *See generally* Shawn G. Hansen, *Perspectives on U.S. Patent Reform: The Next Steps are Crucial*, in UNDERSTANDING PATENT REFORM IMPLICATIONS: LEADING LAWYERS ON DEFINING KEY ISSUES, INTERPRETING CURRENT PROPOSED LEGISLATION, AND PROJECTING FUTURE DEVELOPMENTS 141, 141-74 (2009); *see also* Ian Ayres & Gideon Parchomovsky, *Tradable Patent Rights*, 60 STAN. L. REV. 863 (2007). The relative ease or difficulty of proving invalidity of an issued patent is one of the most effective ways to alter the relative strength of the patent system, based on determined desired incentives and burdens.

requiring the challenging party to prove that the PTO's decision to grant the patent was arbitrary and capricious, or was not supported by substantial and competent evidence if all non-cumulative material information was before the examiner, and requiring the challenging party to prove the patent is invalid by a mere preponderance of the evidence if non-cumulative material information was not before the examiner would probably be the best choice. This would provide sufficient incentive for the patentee to provide all material information to the PTO while protecting the integrity of the patent system.²⁴¹ That change in the law,²⁴² if adopted, would make the doctrine of inequitable conduct unnecessary.

Under the proposed new system, instead of the "atomic bomb" inequitable conduct presents,²⁴³ the patentee would be provided with an incentive to disclose all non-cumulative material art to the examiner during prosecution of an application in order to obtain a favorable burden of proof regarding validity during litigation of the subject patent.²⁴⁴ during prosecution of an application in order to

241. If these burdens were adopted, that may not result in a substantially different number of patents being held valid and enforceable than under the current system because the current burden of proof of clear and convincing evidence, applied to all issued patents, falls somewhere between the two proposed alternative burdens of proof. Moreover, the defense of inequitable conduct is rarely successful so its elimination would not likely dramatically affect the number of successful infringement actions. *See Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

242. The Federal Circuit has ruled that while the clear and convincing evidence standard burden of proof never changes even when material information was not before the examiner, in such a case, additional deference to the PTO's decision is reduced or eliminated. *See, e.g., Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60 (Fed. Cir. 1984), *abrogated by Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

When an attacker simply goes over the same ground traveled by the PTO, part of the *burden* is to show that the PTO was wrong in its decision to grant the patent. When new evidence touching validity of the patent not considered by the PTO is relied on, the tribunal considering it is not faced with having to *disagree* with the PTO or with *deferring* to its judgment or with taking its expertise into account. The evidence may, therefore, carry more weight and go further toward sustaining the attacker's unchanging burden.

Id. The effect, if any, of this is unclear but it may not be a great enough incentive in itself to cause patentees to seek out and disclose all material information to the examiner absent the threat of inequitable conduct.

243. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).

244. Professor Mark Lemley has asserted that because the vast majority of patents never get litigated, it is better that the PTO does not spend an abundance of time and resources evaluating each application in what he calls "rational ignorance." *See Mark A. Lemley, Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1497 (2001). The proposed burden shifting would facilitate that goal in the sense that patentees who know that the patent is likely to

obtain a favorable burden of proof regarding validity during litigation of the subject patent.

Of course this change would mean that the issue of whether non-cumulative material prior art was not before the examiner would have to be determined in litigation when the validity of the patent is challenged in order to determine the appropriate burden on the issue of validity.²⁴⁵ However, the issue of whether non-cumulative material prior art was before the examiner is currently an issue in nearly every major patent litigation as an element of an inequitable conduct charge.²⁴⁶ At a minimum, the proposed new system would eliminate the troublesome intent element of inequitable conduct, along with the prejudice, burden, expense, unpredictability, and distraction accompanied by an inequitable conduct allegation allowed for under the current system.

IV. CONCLUSION

The strength of the presumption of validity of an issued patent should depend on whether the Examiner who reviewed the application was in possession of all non-cumulative material information.²⁴⁷ In addition the inequitable conduct doctrine should be eliminated as a defense in patent litigation because it would no longer be a necessary incentive for the patentee to present all material information to the Examiner during prosecution of a patent. The incentive for full disclosure would come from the desire to receive a favorable burden of proof relating to a challenge of the validity of the issued patent during litigation.

never be litigated would probably not spend an abundance of resources searching out prior art and overburdening the PTO with an abundance of references. *Id.* However, where a patent is likely to be litigated the patentee would have incentive to seek out and submit all references, allowing the PTO to spend most often its time examining patent applications that are likely to be litigated. *Id.*

245. Because it would continue to be relevant, the definition of “materiality” should be clarified and a single standard adopted so that patentees, litigants and prosecuting attorneys are aware of what is required of them during prosecution of a patent application.

246. The determination of whether all non-cumulative information was before the examiner might properly be determined by the court as a matter of law, possibly in conjunction with a Markman proceeding. Claim construction bears on the issue of materiality and a materiality determination would naturally follow from a Markman proceeding.

247. The growth of the inequitable conduct doctrine (and the arguable need therefore) coincided with the change in case law that held that the presumption of validity, which must be overcome by clear and convincing evidence, attached regardless of what information was not before the examiner. *See supra* note 231.