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**INEQUITABLE CONDUCT:
A FLAWED DOCTRINE WORTH SAVING**

Lisa A. Dolak¹

A growing chorus of voices is calling for reform or even elimination of the doctrine of inequitable conduct. Critics argue that innocent or even irrelevant prosecution mistakes can be met with the ultimate penalty: unenforceability of the entire patent.

There is no question the doctrine is in need of repair. Patent owners are subject to different materiality standards in both the U.S. Patent and Trademark Office and in the courts. Inequitable conduct charges can be based on information completely immaterial to patentability. Findings of deceptive intent are increasingly based on inference and not evidence. And the one-size-fits-all remedy of total unenforceability deprives the courts of the ability to tailor the "punishment" to the offense.

This paper argues that retaining the defense is essential for maintaining the integrity of, and continuing public confidence in, the U.S. patent system. It sets forth specific recommendations for much-needed modifications designed to better serve the doctrine's essential purposes, and to ameliorate the key problems with its current application. Although these changes can be implemented by the courts, legislative action would be more appropriate, because the recommended modifications affect virtually every aspect of the doctrine, and it is unlikely that a given case or series of cases will present appropriate facts for judicial resolution in the near future.

¹ Angela S. Cooney Professor of Law, Syracuse University College of Law. Blaine T. Bettinger, Ph.D and Alison Taroli supported this project with excellent and much-appreciated research support. I can be reached at ladolak@law.syr.edu.

I. INTRODUCTION**II. RECENT DEVELOPMENTS: DOCTRINAL EXPANSIONS, PRACTICAL DILEMMAS****III. THE INEQUITABLE CONDUCT DEFENSE SHOULD BE RETAINED**

- A. There is a crisis of confidence in the U.S. patent system.*
- B. Inequitable conduct happens!*
- C. Other proposed enforcement mechanisms are unsatisfactory.*
- D. Applicants would not voluntarily elaborate on references.*

IV. RECOMMENDATIONS FOR REFORM

- A. Prosecution conduct should be judged in the courts by the standards which govern applicants and practitioners inside the USPTO.*
- B. Only conduct which undermines the integrity of the prosecution process should qualify for judicial sanction.*
- C. The evidentiary standards governing intent findings should be revised.*
- D. Courts should abandon the materiality-intent balancing inquiry.*
- E. Trial judges should be permitted to tailor the remedy to the circumstances.*
- F. Patentees who prevail on the issue of inequitable conduct could be awarded attorney fees.*

V. CONCLUSION

I. INTRODUCTION

A growing chorus of voices is calling for reform or even elimination of the doctrine of inequitable conduct.² Critics cite the high costs and unpredictability associated with litigating the issue,³ and argue that innocent or even irrelevant prosecution mistakes can be met with the ultimate penalty: unenforceability of the entire patent.⁴

² Br. for Interested Patent Law Professors as Amici Curiae Supporting Panel Reh'g or Reh'g en banc at 9-10, *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334 (Fed. Cir. 2008) (No. 2007-1280), 2008 WL 2967559 (noting that a "loud call for reform from academics and practitioners shows that concern is shared both by those whose interests lie in the broader health of the patent system as well as by those immediately affected by this Court's decisions," and that "legislative proposals show Congress is concerned about the doctrine's impact on innovation, litigation, and liquidity." (citing Patent Reform Act of 2007, S. 1145, H.R. 1908, 110th Cong. (2007))); Kate McElhone, *Inequitable Conduct: Shifting Standards for Patent Applicants, Prosecutors, and Litigators*, 17 TEX. INTELL. PROP. L.J. 385, 405 (2009) ("To settle the law of inequitable conduct and provide definitive guidance in this area, Congress should overrule recent Federal Circuit precedent and the PTO's proposed rules by amending the Patent Act."); Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control*, 157 U. PA. L. REV. 2051, 2079 (2009) ("The progress that could be achieved through inequitable-conduct reform is difficult to overstate."); Chris Mammen, *A Call to Reform Inequitable Conduct This Year*, IPWATCHDOG (Apr. 9, 2009), <http://www.ipwatchdog.com/2009/04/09/a-call-to-reform-inequitable-conduct-this-year/id=2482/> ("Reform of the inequitable conduct doctrine is needed.").

³ NAT'L RESEARCH COUNCIL, COMM. ON INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECONOMY, A PATENT SYSTEM FOR THE 21ST CENTURY 82-83 (2004) [hereinafter 21ST CENTURY REPORT]; Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 740 (2009) ("[P]leading inequitable conduct is problematic because litigation of inequitable conduct claims is particularly costly."); McElhone, *supra* note 2, at 387-88 ("Resolution of highly subjective elements of the law leads to extraordinary litigation costs, and the current inequitable conduct standard forces the courts to make just such determinations of an applicant's state of mind."); Sean M. O'Connor, *Defusing the "Atomic Bomb" of Patent Litigation: Avoiding and Defending Against Allegations of Inequitable Conduct After McKesson et al.*, 9 J. MARSHALL REV. INTELL. PROP. L. 330, 331 (2010) ("[T]here is something troubling and unpredictable about the [inequitable conduct] doctrine.").

⁴ See, e.g., *The Patent Reform Act of 2007: Hearings on H.R. 1908 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 110th Cong. 43-44 (2007) [hereinafter *Hearings on H.R. 1908*] (statement of Kevin Sharer, CEO and Chairman of the Board of Amgen, Inc.) ("When a patent is litigated, the most innocent statements, or failures to disclose the smallest thing, can become the bases for charges of inequitable conduct."); *Patent Reform: The Future of American Innovation: Hearing on S. 1145 Before the S. Comm. on the Judiciary*, 110th Cong. (2007), available at http://judiciary.senate.gov/hearings/testimony.cfm?renderforprint=1&id=2803&wit_id=6506 (statement of Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office). ("[A]pplicants or their attorneys fear

It is not surprising that reform-minded critics have turned their attention to the inequitable conduct doctrine. None of the various comprehensive congressional patent reform proposals introduced over the last several years⁵ has yet garnered sufficient support in both houses to reach the desk of the President. However, it is clear that there is still significant appetite for wide-ranging reforms,⁶ and therefore a real opportunity for proponents of legislative alteration of the inequitable conduct defense.

Further, the remarkable level of Supreme Court attention to the patent system in recent years⁷ has no doubt encouraged patent litigants

that the legal doctrines of inequitable conduct and unenforceability may unfairly punish them with draconian penalties for innocently omitting information.”).

⁵ See, e.g., Patent Reform Act of 2009, S. 610, 111th Cong. (2009); Patent Reform Act of 2009, S. 515, H.R. 1260, 111th Cong. (2009); Patent Reform Act of 2007, S. 1145, H.R. 1908, 110th Cong. (2007); Patent Reform Act of 2006, S. 3818, 109th Cong. (2006); Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2006); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

⁶ H.R. 1908 was approved in the House of Representatives in September 2007, and the key congressional supporters have promised to press ahead with reform legislation. See, e.g., Ass’n of Am. Univ., Am. Council on Educ., Nat’l Ass’n of State Univ. and Land-Grant Coll., Ass’n of Am. Med. Coll., The Ass’n of Univ. Tech. Managers, & Council on Gov’t Relations, *University Views on S. 515, the Patent Reform Act of 2009*, 1, (last visited Sep. 16, 2010) <http://www.acenet.edu/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=31850> (“We strongly support Congress’ efforts on patent reform, believing that our U.S. patent system, although robust and productive in many respects, can be improved significantly to be an even more effective instrument for supporting this nation’s competitiveness in the 21st century global economy.”); Horacio Gutierrez, *A Solid Step Forward in the Road to Sensible Patent Reform*, MICROSOFT ON THE ISSUES (OCT. 5, 2009) (“We support the administration’s thoughtful approach to a balanced patent reform discussion and remain strongly committed to working with Congress, the administration and other stakeholders in all industries to make sensible patent reform legislation a reality in the short term.”); Michelle Lee, *Patent Reform Needed More Than Ever*, GOOGLE PUBLIC POLICY BLOG (Mar. 3, 2009), <http://googlepublicpolicy.blogspot.com/2009/03/patent-reform-needed-more-than-ever.html> (“Passage of patent reform is long overdue.”); Letter from 28 CEOs, Coal. for Patent Fairness, to Barack Obama, President of the U.S. (Mar. 23, 2009), available at http://www.patentfairness.org/pdf/CEO_letter.pdf (“The Congress has been working on patent reform for nearly 8 years. Our country cannot afford to wait. The status quo is not good enough.”); Donald Zuhn, *Senate Patent Reform Legislation—One Old Bill and One New Bill*, PATENT DOCS (Aug. 11, 2008), http://www.patentdocs.org/net/patent_docs/2008/08/senate-patent-r.html.

⁷ The Supreme Court has decided eight patent cases during the last four terms. See *Quanta Computer, Inc. v. LG Elec., Inc.*, 128 S. Ct. 2109, 2122 (2008) (holding that “[t]he authorized sale of an article that substantially embodies a patent exhausts the patent holder’s rights and prevents the patent holder from invoking patent law to control postsale use of the article.”); *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 441-45 (2007) (addressing the extraterritorial reach of U.S. patent law); *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 403 (2007) (revising the standard for establishing

to file certiorari petitions⁸ and has raised hopes that the Court might accept an inequitable conduct case for review. In addition, the fact that the Supreme Court has reversed or vacated eight decisions of the U.S. Court of Appeals for the Federal Circuit in the last five years⁹ might have been perceived, at least, as potentially increasing the likelihood that the Federal Circuit would grant en banc review in an attempt to preempt Supreme Court review with respect to increasingly controversial patent law doctrines.¹⁰ Thus, parties who have lost on an issue at the Federal Circuit have had reason to hope that the courts will be receptive to certiorari or rehearing petitions and an expectation that they may be able to enlist or enjoy the support of interested amici.

obviousness); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 136-37 (2007) (expanding the availability of declaratory relief); *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006) (holding that district courts are to apply generally applicable equitable principles in deciding whether to grant injunctions in patent cases); *Ill. Tool Works, Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45-46 (2006) (rejecting the premise that a patent necessarily confers market power on its owner, and holding that “in all cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product.”); *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394, 407 (2006) (applying the requirements of Fed. R. Civ. P. 50(b) to foreclose review of the sufficiency of the evidence); *Merck KGaA v. Integra LifeSciences I, Ltd.*, 545 U.S. 193, 207-08 (2005) (interpreting the patent statute’s safe harbor provision relating to the development and submission of data to the Food & Drug Administration). The Court also granted certiorari in a ninth patent case during this period, but ultimately dismissed the writ of certiorari as “improvidently granted.” *Lab. Corp. of Am. v. Metabolite Lab., Inc.*, 548 U.S. 124, 125-26 (2006) (per curiam). Even the latter case, however, resulted in an opinion on the merits by three justices. *Id.* (Breyer, J., dissenting).

⁸ *Pet. for Writ of Cert., Patent Enforcement Team, L.L.C. v. Dickson Indus.*, (No. 09-476) 2009 WL 3417607 (U.S. Oct. 20, 2009) (No. 09-476); *Pet. for Writ of Cert., Line Rothman v. Target Corp.*, (No. 09-304) 2009 WL 2904599 (U.S. July 7, 2009) (No. 09-304); *Pet. for Writ of Cert., Mylan Labs., Inc. v. Takeda Chem. Indus.*, (No. 08-1461) 2009 WL 1497815 (U.S. May 26, 2009) (No. 08-461); *Pet. for Writ of Cert., Qualcomm, Inc. v. Broadcom Corp.*, (No. 08-1228) 2009 WL 907850 (U.S. Apr. 1, 2009) (No. 08-1228); *Pet. for Writ of Cert., Dippin’ Dots, Inc. v. Mosey*, (No. 08-1158) 2009 WL 698523 (U.S. Mar. 13, 2009) (No. 08-1158); *Pet. for Writ of Cert., Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, (No. 08-937) 2009 WL 180872 (U.S. Jan. 23, 2009) (No. 08-937); *Pet. for Writ of Cert., R.J. Reynolds Tobacco Co. v. Star Scientific, Inc.*, (No. 08-918) 2009 WL 180861 (U.S. Jan. 16, 2009) (No. 08-918); *Petition for Writ of Certiorari, Bayer Bioscience N.V. v. Monsanto Co.*, (No. 08-90) 2008 WL 2794280 (U.S. July 16, 2008) (No. 08-90); *Pet. for Writ of Cert., Nilssen v. Osram Sylvania, Inc.*, (No. 07-1293) 2008 WL 1757247 (U.S. Apr. 15, 2008) (No. 07-1293); *Pet. for Writ of Cert., Ferring B.V. v. Barr Labs., Inc.*, (No. 06-372) 2006 WL 2667968 (U.S. Sept. 11, 2006) (No. 06-372).

⁹ See *infra* note 67.

¹⁰ The Federal Circuit’s recent *sua sponte* decision to rehear an appeal relating to statutory subject matter is one possible example. See *In re Bilski*, 264 Fed. App’x 896, 897 (Fed. Cir. 2008).

In fact, on April 26, 2010, the Federal Circuit agreed to rehear *en banc* the appeal in *Therasense, Inc. v. Becton, Dickinson and Co.*¹¹ The court asked the parties to brief six categories of questions, and invited the participation of amici curiae.¹² Specifically, the court requested input as follows:

1. Should the materiality-intent balancing framework for inequitable conduct be modified or replaced?
2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? See *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), overruled on other grounds by *Standard Oil Co. v. United States*, 429 U.S. 17 (1976); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933). If so, what is the appropriate standard for fraud or unclean hands?
3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
4. Under what circumstances is it proper to infer intent from materiality? See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc).
5. Should the balancing inquiry (balancing materiality and intent) be abandoned?
6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.¹³

The questions suggest that the Court is willing to revisit most of the key tenets of the inequitable conduct doctrine.¹⁴ The Court has

¹¹ *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 08-1511374 Fed. App'x 35, 35 (Fed. Cir., April 26, 2010) (en banc Order).

¹² *Id.* at *5-7.

¹³ *Id.*

¹⁴ Inequitable conduct is the affirmative misrepresentation of a material fact, the failure to disclose material information, or the submission of false material

set oral argument for November 9, 2010.¹⁵ Thus, as of this writing, the extent and shape of potential judicial reform is uncertain.

But abrogation of the defense would be a mistake, particularly as concerns about patent quality echo in the U.S. Patent and Trademark Office (USPTO), the Congress, the courts, the practitioner's office, and the media.

This essay argues that retaining the defense will help maintain the integrity of, and continuing public confidence in, the U.S. patent system. It sets forth specific recommendations for much-needed modifications designed to better serve the doctrine's essential purposes, and to ameliorate the key problems with its current application. Although these changes can be implemented by the courts, legislative action would be more appropriate because the recommended modifications affect virtually every aspect of the doctrine, and because it is unlikely that a given case or series of cases will present appropriate facts for judicial treatment of all of these aspects of the doctrine in the near future.

Consideration of the reforms proposed herein, as well as of the proposals of others to reform or eliminate the doctrine of inequitable conduct,¹⁶ should be undertaken, however, with an understanding of

information, coupled with an intent to deceive. See *Molins P.L.C. v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). The patent challenger must establish the materiality of the omission or misrepresentation, and the requisite intent to deceive the USPTO, by clear and convincing evidence. *Key Pharm. v. Hercon Lab. Corp.*, 161 F.3d 709, 719 (Fed. Cir. 1998) (citing *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1556-57 (Fed. Cir. 1995)). Materiality and intent are fact determinations, reviewable under the clearly erroneous standard of Fed. Rule of Civ. Pro. 52(a). *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998) (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988) (en banc)). If both materiality and intent are established, the trial court must decide whether the patent applicant's conduct was so culpable as to justify a holding of unenforceability. See *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546-47 (Fed. Cir. 1998) (citing *Kingsdown*, 863 F.2d at 872). The court is to weigh the levels of materiality and intent for this purpose: a high level of materiality will balance a lower level of intent, and vice versa. See *Baxter*, 149 F.3d at 1327 (citing *N.V. Akzo v. E.I. Dupont de Nemours*, 810 F.2d 1148, 1153 (Fed. Cir. 1987)); see also *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997). A determination of inequitable conduct renders all of the claims of the subject patent unenforceable. See *Baxter*, 149 F.3d at 1332 (citing *Kingsdown*, 863 F.2d at 874).

¹⁵ *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 08-1511, U.S. App. LEXIS 11373, at *4 (Fed. Cir., June 3, 2010) (en banc scheduling order).

¹⁶ Robert A. Armitage, *Inequitable Conduct and Post-Grant Review: Why the Imperative to Eliminate the "Inequitable Conduct" Defense? What Relates Eliminating the Defense to Expanding Post-Grant Review?*, 2009 Mid-Winter Institute Speaker Papers, AMERICAN INTELL. PROP. LAW ASS'N 18 (Jan. 29, 2009),

how the doctrine has changed and expanded in recent years. These changes have created or contributed to dissatisfaction with the current regime and to calls for reform.¹⁷ When considering proposed reforms, therefore, it is important to first review “how we got here.”

<http://www.aipla.org/html/mw/2009/papers/Armitage-paper.pdf> (“Like any ‘plague,’ there are a number of countermeasures that may have merit. Clearly, patent applicants are today undertaking many practices designed to immunize them from later allegations of ‘inequitable conduct’ in patent enforcement . . . [T]he immunization protocol—the defensive patent procurement practices of ‘over-disclosure’ and ‘under-explanation’—have cost the patent system dearly. Outright eradication would obviate the need for this type of immunization and its pernicious side effects.”); Melissa Feeney Wasserman, *Limiting the Inequitable Conduct Defense*, 13 VA. J.L. & TECH. 7, 16 (2008) (“I propose limiting the current inequitable conduct jurisprudence and providing a second tier of remedies for less offensive behavior. Inequitable conduct would be limited to cover only common law fraud. The defendant must have (i) failed to disclose or misrepresented material information with an intent to deceive and (ii) known of the materiality of the information not disclosed or misrepresented. My proposed heightened standard for inequitable conduct requires the defendant to have culpability not only with the intent to deceive but also with respect to the materiality of the omission or misrepresentation. This standard differs from the current inequitable conduct jurisprudence, as it abandons the Federal Circuit’s weighing of intent and materiality—a defendant must meet each bar, and the materiality of the omission or misrepresentation has no effect on whether the defendant has the prerequisite intent. Also, in contrast to the current jurisprudence, this heightened standard allows the subjective good faith of the accused to avert a finding of inequitable conduct.”); Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 164 (2005) (“Reforms should be implemented to strengthen the inequitable conduct doctrine based on policy rationales, while lessening the doctrine’s effect on patentees who are unjustly forced to defend against it. Specifically, such proposals should decrease the number of unsubstantiated inequitable conduct charges and should encourage applicants to submit all relevant prior art references.”).

¹⁷ *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1350 (Fed. Cir. 2008) (Rader, J., dissenting) (“[R]ecently . . . 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.”); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1203 (Fed. Cir. 2006) (Newman, J., dissenting) (“The panel majority’s holding that deceptive intent is established as a matter of law if the applicant ‘should have known’ that information might be material to patentability, further revives the ‘plague’ of the past, with burdens that far outweigh any conceivable benefits.”); James E. Hanft & Stacey S. Kerns, *The Return of the Inequitable Conduct Plague: When “I Did Not Know” Unexpectedly Becomes “You Should Have Known”*, 19 NO. 2 INTELL. PROP. & TECH. L.J. 1, 1 (2007) (“The court is lowering the bar for when an inventor or attorney ‘should have known’ of the materiality of a fact or omission of fact, resulting in more findings of inequitable conduct ostensibly without the requisite *scienter*. If this trend continues . . . inventors and patent attorneys will need to be more diligent than ever to escape accusations of inequitable conduct or be punished years later for information that

II. RECENT DEVELOPMENTS: DOCTRINAL EXPANSIONS, PRACTICAL DILEMMAS

Recent Federal Circuit cases clearly manifest three significant, distinct lines of expansion in the substantive law of inequitable conduct. Each, independent of the others, tends to make unenforceability challenges easier and more likely to succeed. Combined, these developments pose an even greater threat to patent enforcement efforts and significantly increase prosecution-related information disclosure risks and burdens. It's no wonder that owners, practitioners, and commentators are calling for change!

First, the Federal Circuit affirmed the viability of the older "reasonable examiner" standard for evaluating whether undisclosed or misrepresented information is material for inequitable conduct purposes.¹⁸ In so doing, the court acknowledged that the "new" Rule 56 standard is at least "arguably narrower" than the "reasonable examiner" standard.¹⁹ Accordingly, conduct that does not violate the current USPTO Rule 56 standard may well violate the "reasonable examiner" standard and be material for purposes of inequitable

they may not have had, or not known about, at the time of prosecution."); Elizabeth Peters, *Are We Living in a Material World?: An Analysis of the Federal Circuit's Materiality Standard Under the Patent Doctrine of Inequitable Conduct*, 93 IOWA L. REV. 1519, 1564 (2008) ("The standard for materiality under the doctrine of inequitable conduct has undergone much variation throughout the years. Yet . . . the multifaceted test that the Federal Circuit adopted in *Digital Control*, creates vast uncertainty for future applicants when they prosecute patents at the PTO and when they consider how their present conduct and disclosures may affect future litigation The policy goals of inequitable conduct, coupled with the possibility that applicants will experience increased burdens from searches of prior art, reveal the need for a more concrete standard of materiality."); Matthew M. Peters, *The Equitable Inequitable: Adding Proportionality and Predictability to Inequitable Conduct in the Patent Reform Act of 2008*, 19 DEPAUL J. ART, TECH. & INTELL. PROP. L. 77, 105 (2008) ("The inequitable conduct doctrine is broken. Rather than encouraging honesty and material disclosure during patent prosecution, it is a procedural litigation tool used to cast patent holders in a negative light, drive up the costs of enforcing patents, and subject inventors and assignees to severe consequences that are often exceptionally disproportionate to the harm done to both the PTO and the general public.").

¹⁸ See *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (noting that "there is no reason . . . to be bound by any single standard" (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984))) (alteration in the original). Under the "reasonable examiner" standard, "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." (interpreting 37 C.F.R. § 1.56(a) (1991)).

¹⁹ See *Digital Control*, 437 F.3d at 1315.

conduct.²⁰ Therefore, a challenger need only satisfy the “reasonable examiner” standard to prevail on the issue of materiality.²¹

Second, recent Federal Circuit decisions have expanded the categories of potentially material information. Information that is completely immaterial to substantive patentability, such as false statements in petitions to make special and misrepresentations relating to entitlement to small entity status, has been held material for purposes of inequitable conduct.²² Co-pending applications and the information they contain are other new categories of potentially material information.²³ The Federal Circuit’s materiality and inequitable conduct rulings relating to co-pending applications, in particular, have prompted the adoption of detailed internal practice

²⁰ 37 C.F.R. § 1.56 (2010). This rule defines “information . . . material to patentability” as follows:

[I]nformation 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.

²¹ *Id.*

²² *See, e.g.,* Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V., 528 F.3d 1365, 1375 (Fed. Cir. 2008) (reaffirming that any false statement in a petition to make special that expedites an application is material for assessing inequitable conduct as a matter of law); Nilssen v. Osram Sylvania, Inc., 528 F.3d 1352, 1356 (Fed. Cir. 2008) (affirming the district court’s decision which held that Nilssen engaged in inequitable conduct by misclaiming small entity status and improperly paying small entity maintenance fees); Ulead Systems., Inc. v. Lex Computer & Mgmt. Corp., 351 F.3d 1139, 1146 (Fed. Cir. 2003) (holding that an unjustifiable claim of entitlement to small entity status and accompanying payment of insufficient maintenance fees was material as a matter of law); General Electro Music Corp. v. Samick Music Corp., 19 F.3d 1405, 1407 (Fed. Cir. 1994) (noting that the jury found this statement to be material and intentionally false based on evidence that the applicant’s “search” involved its attorney “ask[ing] numerous individuals in the piano design industry whether they knew of pertinent prior art designs and . . . search[ing] his own files for prior art.”).

²³ *See* Lisa A. Dolak, *The Inequitable Conduct Gyre Widens*, 50 IDEA: J.L. & TECH. 215, 221-30 (2010) (describing the evolution of the co-pending applications disclosure requirement). In upholding a determination of inequitable conduct based on an applicant’s failure to disclose rejections and other information from co-pending applications, the Federal Circuit rejected the patentee’s argument that the disclosure of information in co-pending applications is a new requirement. *See* McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 922-23 (Fed. Cir. 2007) (stating that “[T]he MPEP to which [the prosecuting attorney] would have referred while the . . . application was pending leaves no doubt that material rejections in co-pending applications fall squarely within the duty of candor.”).

procedures designed to facilitate the cross-citing of potentially material co-pending applications, office actions and other potentially material information, as practitioners and applicants strive to steer clear of misconduct allegations.²⁴

Third, a number of the Court's recent opinions evidence the application of a less rigorous deceptive intent analysis—less rigorous than some believe appropriate, at least.²⁵ There are indications that at least some Federal Circuit judges are concerned about this development,²⁶ and those concerns may lead or contribute, ultimately, to changes in the standard for establishing deceptive intent for inequitable conduct purposes. But this development has contributed to calls for reform.²⁷

²⁴ Newsletter, *Federal Circuit Finds Inequitable Conduct for Not Disclosing Material Prior Art in Related Application*, STEIN, MCEWEN & BUI LLP, (June 2007), <http://www.smbiplaw.com/pdf/Newsletter-Vol%203%20Iss%202%202007.pdf> (concluding that patent practitioners must continue to completely disclose co-pending applications and prior art to the Examiner); James J. Mullen, *The Opportunities and Challenges Presented by the Revitalized Defense of Inequitable Conduct to Patent Infringement: Thoughts for Patent Litigators and Prosecutors*, MORRISON & FOERSTER, (Sept. 11, 2007), <http://www.mofo.com/news/updates/files/12745.html> (discussing the precautions that patent prosecutors must take post-*McKesson* to identify and disclose potentially co-pending applications); Charles Niebylski, Ph.D., *Case Brief: McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, THE NATH LAW GROUP (May 18, 2007), <http://www.nathlaw.com/news/publications/2006-1517.pdf> (outlining specific steps that patent practitioners can take to properly disclose co-pending applications).

²⁵ Benjamin Brown, *Inequitable Conduct: A Standard in Motion*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 593, 6058 (2009) (“While *Kingsdown* has not been explicitly overruled, the post-2003 cases relaxing the intent standard indicate—especially when viewed alongside the Federal Circuit’s decision to maintain the “reasonable examiner” test—the Federal Circuit’s attempt to expand the scope of the inequitable conduct doctrine. Such expansion lies in sharp contrast to the limiting reform called for by the Patent Office and Legislature.”); Mitchell G. Stockwell, *Zealous Advocacy Collides with Duties to the Tribunal and the Opponent*, 949 PLI/PAT 593, 605 (2008) (“Two recent Federal Circuit cases, *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, and *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, appear to relax the standard for showing intent sufficient to support finding inequitable conduct. In each case a strongly dissenting judge complained that the majority reverted to a lesser intent standard that may encourage opportunistic and unwarranted allegations of inequitable conduct.”).

²⁶ See Lisa A. Dolak, *Beware the Inequitable Conduct Charge! (Why Practitioners Submit What They Submit)*, 91 J. PAT. & TRADEMARK OFF. SOC'Y 558, 570 (Oct./Nov./Dec. 2009).

²⁷ Chris Henry, *Inequitable Conduct Inequitably Inferred: When Do Patent Applicants' Actions Intend to Deceive?*, 65 WASH. & LEE L. REV. 1159, 1162-63 (2008) (“[T]he Federal Circuit must adopt a heightened standard of objective recklessness for inferring intent to deceive. . . . To establish intent to deceive in an inequitable conduct claim, in the absence of direct evidence of a subjective intent to

As discussed below,²⁸ each of these aspects of the inequitable conduct doctrine should be modified. Other inequitable conduct-related reforms are also warranted.²⁹ However, the inequitable conduct doctrine, appropriately tailored, is a valuable adjunct to the statutory and other boundaries supporting the critical innovation-competition policy compromise our patent system is intended to serve.³⁰

III. THE INEQUITABLE CONDUCT DEFENSE SHOULD BE RETAINED

Several fundamental realities militate against abrogating the doctrine of inequitable conduct. As discussed below, patent quality is widely perceived as lacking. Some applicants or their representatives do engage in egregious misconduct, and other existing and proposed enforcement mechanisms are deficient or problematic.

A. *There is a crisis of confidence in the U.S. patent system.*

If the recent press coverage of the patent system is an accurate reflection, patent quality is the most significant problem faced by the U.S. patent system.³¹ In fact, the importance of improving patent quality may be the only patent reform-related issue on which there is

deceive, an accused infringer should have to prove, by clear and convincing evidence, that a patentee acted objectively reckless.”); AIPLA, *Patent Reform Bills Await Action as Congress Recesses*, AIPLA REPORTS 4 (Aug. 7, 2007) available at http://www.aipla.org/Content/ContentGroups/About_AIPLA1/AIPLA_Reports/20074/070807AIPLAReports.pdf (“The state of mind element for both [patent reform] bills should be ‘knowing and willful deception’ rather than simply ‘intentional deception.’”).

²⁸ See *infra* Part IV A-B.

²⁹ See *infra* Part IV C-D.

³⁰ Bernard Chao, *Rethinking Enablement in the Predictable Arts: Fully Scoping the New Rule*, 2009 STAN. TECH. L. REV. 3, 4 (2009) (“The primary goal of the patent system is to promote innovation without stifling competition.”); Stacie L. Greskowiak, *Joint Infringement After BMC: The Demise of Process Patents*, 41 LOY. U. CHI. L.J. 351, 357 (2010) (“[T]he patent system was carefully crafted to balance the interest in fostering innovation with the interest in avoiding monopolies that stifle competition.”).

³¹ See Lisa A. Dolak & Blaine T. Bettinger, Ph.D., *The United States Patent System in the Media Mirror*, 58 SYR. L. REV. 459, 488 (2008) (reporting results of a study of recent major newspaper coverage of the patent system).

widespread agreement. Concerns about patent quality emanate from scholars,³² members of Congress,³³ policy groups,³⁴ practitioners,³⁵

³² See, e.g., *Patent Quality Improvement: Hearing Before the Subcommittee on Courts, the Internet, and Intellectual Property, of the House Committee on the Judiciary*, 108th Cong. 63 (2003), http://commdocs.house.gov/committees/judiciary/hju88545.000/hju88545_0.htm (statement of John R. Thomas, Professor of Law at Georgetown University) (“[u]nfortunately, despite extraordinary efforts by the USPTO to improve patent quality, the problem [of poor patent quality] remains. Persistent accounts suggest that patent quality remains at less than optimal levels.”); ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 4* (Princeton Univ. Press 2004) (“[m]any people and companies have received patents for trivial or even non-existent inventions.”); John R. Allison & Starling D. Hunter, *On the Feasibility of Improving Patent Quality One Technology at a Time: The Case of Business Methods*, 21 BERKELEY TECH. L.J. 729, 789 (2006) (“[n]ot only does the PTO issue substantial numbers of low quality patents in practically all fields, but it issues many patents across all technology fields that are subsequently invalidated in litigation.”); Mark A. Lemley, Douglas Lichtman & Bhaven N. Sampat, *What to Do About Bad Patents*, 28 (REG.) 10 (Winter 2005-2006), <http://ssrn.com/abstract=869826> (“Bad patents are everywhere: covering obvious inventions like the crustless peanut butter and jelly sandwich, ridiculous ideas like a method of exercising a cat with a laser pointer, and impossible concepts like traveling faster than the speed of light.”); R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135, 2136 (2009) (“[T]he need to improve patent quality is essentially undisputed.”); Robert C. Pozen, *Inventing a Better Patent System*, N.Y. TIMES, Nov. 17, 2009, at A33 (“The quality of American patents has been deteriorating for years.”).

³³ See, e.g., *Patent Quality Improvement: Hearing Before the Subcommittee on Courts, the Internet, and Intellectual Property, of the House Committee on the Judiciary*, 108th Cong. 63 (2003), http://commdocs.house.gov/committees/judiciary/hju88545.000/hju88545_0.htm (statement of John R. Thomas, Professor of Law at Georgetown University) (“[u]nfortunately, despite extraordinary efforts by the USPTO to improve patent quality, the problem [of poor patent quality] remains. Persistent accounts suggest that patent quality remains at less than optimal levels.”); Press Release, U.S. Senator Sen. Patrick Leahy, Leahy, Hatch, Berman And Smith Introduce Bicameral, Bipartisan Patent Reform Legislation (Apr. 18, 2007), available at <http://web.archive.org/web/20070425191953/http://leahy.senate.gov/press/200704/041807a.html> (webpage no longer available) (“[P]oor patent quality has been identified as a key element of the law that needs attention.”); Letter from Sens. Sam Brownback, Tom Coburn, Chuck Grassley, Jon Kyl, and Jeff Sessions to Sens. Patrick Leahy and Arlen Specter (June 17, 2007), available at http://www.filewrapper.com/PDFs/20070612_Judiciarycommitteeletter.pdf (“[M]ore attention should be given to the issue of how to improve patent quality.”); Statement of Sen. Patrick Leahy on Introduction of The Patent Reform Act of 2009 (Mar. 3, 2009), available at http://leahy.senate.gov/press/press_releases/release/?id=2e870f68-afaf-43e4-9403-d142cfc96ae9_press/200903/030309b.html (“[T]here is significant concern that the U.S. Patent and Trademark Office (PTO) is issuing low quality patents.”).

³⁴ See, e.g., George S. Ford, Thomas M. Koutsky & Lawrence J. Spiwak, *Quantifying the Cost of Substandard Patents: Some Preliminary Evidence 1* (Phx. Ctr. for Advanced Legal & Econ. Pub. Studies Paper Number 30, 2007), available at

consumer and industry groups,³⁶ and government agencies—including the USPTO.³⁷ Even the major party candidates in the last presidential election cited patent quality as a problem, particularly as it adversely

<http://www.phoenix-center.org/pcpp/PCPP30Final.pdf> (“Under plausible assumptions, we find that the economic losses resulting from the grant of substandard patents can reach \$21 billion per year by deterring valid research with additional deadweight loss from litigation and administrative cost of \$4.5 billion annually”); 21ST CENTURY REPORT, *supra* note 3, at 51 (“There are several reasons to suspect that more issued patents are deviating from previous or at least desirable standards of utility, novelty, and especially non-obviousness and that this problem is more pronounced in fast-moving areas of technology newly subject to patenting than in established, less rapidly changing fields.”).

³⁵ See, e.g., *Patent Quality Improvement Hearing*, *supra* note 32 (statement of Charles E. Van Horn of Finnegan, Henderson, Farabow, Garrett & Dunner LLP on behalf of the American Intellectual Property Law Association) (improving patent quality is “goal number one.”); Chris J. Katopis, *Perfect Happiness?: Game Theory as a Tool for Enhancing Patent Quality*, 10 YALE J.L. & TECH. 360, 368 (2008) (indicating that patent quality has inevitably suffered as a result of the sheer number and complexity of applications reviewed by the PTO); Letter from National Association of Patent Practitioners to Sens. Harry Reid and Mitch McConnell (May 6, 2009), available at <https://www.napp.org/resources/NAPP-PartialOppTo2009SenateBill.pdf> (“Patent quality is a significant concern”).

³⁶ See, e.g., Press Release, Biotech. Indus. Org., BIO Encourages Congress to Improve Patent System (Mar. 3, 2009), available at http://bio.org/news/pressreleases/newsitem.asp?id=2009_0303_01 (noting that the over 1,200 biotechnology companies, academic institutions, and related organizations represented by BIO welcome improvements to U.S. patent system, particularly those related to patent quality); Brief for Pub. Patent Found. et. al., as Amici Curiae Supp. Appellants at 21, *Tafas v. Dudas*, 541 F. Supp. 2d 805 (2008) (Nos. 1:07cv846, 1:07cv1008), 2008 WL 904800 (“Further, the over-patenting that results from low patent quality leads to thickets of patents that bury first inventors with countless small improvement patents claimed by others”).

³⁷ See, e.g., *Nominee for Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office: Nomination Hearing Before the S. Judiciary Comm.* 110th Cong. 3 (2009), available at <http://judiciary.senate.gov/pdf/07-29-09KapposTestimony.pdf> (statement of David J. Kappos, now Under Secretary of Commerce for Intellectual Property noting that one of the most immediate challenges facing the UPSTO is preserving and enhancing patent quality); FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), available at <http://www.ftc.gov/os/-2003/10/innovationrpt.pdf>; Press Release, U.S. Patent and Trademark Office, USPTO to Publish Measures to Improve Patent Quality: Claims and Continuations Rules Will Improve Effectiveness and Efficiency of Patent Examination (Aug. 20, 2007), available at <http://www.uspto.gov/web/offices/com/speeches/07-33.htm> (according to John Dudas, then Undersecretary of Commerce for Intellectual Property, the proposed changes would “better focus examination and will bring closure to the examination process more quickly, while ensuring quality and maintaining the right balance between flexibility for applicants and the rights of the public.”).

affects innovation.³⁸ But perhaps the most important and reliable indicator of the significance of the problem is the dissatisfaction of those who are most heavily invested in our patent system: the owners. In a 2005 survey of corporate members of the Intellectual Property Owners Association (IPO), 51.3% of responding members “rated the quality of patents issued in the U.S. today as less than satisfactory or poor”³⁹

And even if concerns about patent quality are overstated,⁴⁰ it is clear, at a minimum, that quality is widely perceived as a problem. Abrogation of the inequitable conduct doctrine would only exacerbate this perception and, in some cases, result in illegitimate patent grants.⁴¹

³⁸ John McCain 2008.com, *Technology*, <http://web.archive.org/web/20080822113637/http://www.johnmccain.com/InformingIssues/cbcd3a48-4b0e-4864-8be1-d04561c132ea.htm> (last visited Sept. 15, 2008) (webpage no longer available) (“[T]he lack of an affordable, reliable means to ensure that the Government only grants valid patents has led to overly broad, frivolous lawsuits designed to force innovative companies into big settlements.”); Barack Obama ‘08 and Joe Biden, *Technology*, <http://web.archive.org/web/20080731080054/http://www.barackobama.com/issues/technology/> (last visited Sept. 15, 2008) (webpage no longer available) (“[G]iving the Patent and Trademark Office (PTO) the resources to improve patent quality and opening up the patent process to citizen review will reduce the uncertainty and wasteful litigation that is currently a significant drag on innovation.”).

³⁹ Press Release, Intell. Prop. Owners Ass’n, U.S. Patent Quality Questioned in Industry Poll: Patent Litigation Costing More (Sept. 13, 2005), <http://www.ipo.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentID=1659>.

⁴⁰ Some worry that the proposed reforms are unnecessary and potentially harmful. See, e.g., Douglas E. Schoen, Editorial, *Protecting U.S. Patents Should be Top Priority*, BALTIMORE SUN, Feb. 21, 2008 at 17A (“[R]ather than overhaul the system that has fostered more than 200 years of technological breakthroughs, lawmakers ought to devote their energies to strengthening U.S. patents against the threats posed by foreign counterfeiters.”); Press Release, Biotech. Indus. Org., Study Finds Lack of Evidence to Support Draconian Efforts to Weaken Patent Rights (Jan. 31, 2008), http://www.bio.org/news/pressreleases/newsitem.asp?id=2008_0131_02 (citing study conclusions that “contrary to the assertions of the industry proponents of the pending patent reform legislation, the evidence contained in [the three reports most often relied upon] actually demonstrates that the current patent system is working well to promote innovation.”); Chief Intellectual Property and Licensing Officer for InterDigital Communications Bernstein Testifies on Patent Reform Before Senate Judiciary Committee, U.S. FED. NEWS, June 6, 2007, available at 2007 WLNR 20182240 (“In InterDigital’s view, claims [of a broken patent system with poor quality patents] are grossly exaggerated and dangerous in their potential impact on our patent system.”).

⁴¹ See Christopher Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 753-62 (2009) (articulating how and why the inequitable conduct doctrine affects patent quality). In particular, Professor

B. Inequitable conduct happens!

There is no question that inequitable conduct allegations drain resources and inject uncertainty into litigation.⁴² And, no doubt, the defense is over-pled.⁴³ But it is also undeniable that serious breaches of the duty of candor occur.⁴⁴

Furthermore, the reported determinations of inequitable conduct likely represent only a small fraction of the cases that involve credible evidence of inequitable conduct. A reasonable patent owner confronted with such evidence would presumably prefer to avoid a judgment of unenforceability and the expenses likely to be incurred in a futile enforcement attempt.⁴⁵

Cotropia argues that the doctrine enhances the quality of the information available to the USPTO, including by producing relevant information for the USPTO's consideration. *Id.* at 753-55. He further asserts that it improves the quality of the patent application, by increasing both the patent practitioner's knowledge of the invention and related technology, and the care the practitioner takes in drafting the application and related correspondence. *Id.* at 757-762.

⁴² See *supra* note 2.

⁴³ See, e.g., Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 163-64 (2005) (presenting "data suggest[ing] that the patent system often enables potentially infringing parties to attack valid patents by alleging inequitable conduct where none exists."); Benjamin Brown, Comment, *Inequitable Conduct: A Standard in Motion*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 593, 626-627 (2009) ("[A]s indicated by the fact that courts dismiss inequitable conduct claims on summary judgment 50% of the time, inequitable conduct remains an over-pled defense.").

⁴⁴ See, e.g., *Applied Materials, Inc. v. Multimetrixx, L.L.C.*, No. C 06-07372 MHP, 2008 WL 2892453 (N.D. Cal. July 22, 2008) (holding patent unenforceable for inequitable conduct based on the submission of signature forged after the inventor's death); *Armament Sys. & Procedures, Inc. v. IQ Hong Kong Ltd.*, No. 00-C-1257, 2007 WL 2154237, at *22 (E.D. Wis. July 24, 2007) (concluding that a drawing submitted as part of a Rule 131 declaration and dated 1997 was actually drawn in 2002, and holding the affected patent unenforceable); *Grefco, Inc. v. Kewanee Indus.*, 499 F. Supp. 844 (D. Del. 1980) (holding patent unenforceable as procured through fraud where the patentee misrepresented test results and told the examiner that the invention had been successfully tested when in fact it had actually failed two tests), *aff'd without publ. opinion*, 671 F.2d 495 (3d Cir. 1981). Concerns that patent applicants might be tempted to misrepresent essential facts have motivated aspects of our patent policy for more than 100 years. See, e.g., Lisa A. Dolak, *Patents Without Paper: Proving a Date of Invention with Electronic Evidence*, 36 HOUS. L. REV. 472, 496 (1999) (noting that in an 1869 opinion, *Doughty v. Clark*, the Commissioner awarded priority to the party whose own testimony was corroborated by the testimony of non-inventors assistants over the unsupported testimony of the other party).

⁴⁵ AM. INTELL. PROP. LAW ASS'N, 2009 REPORT OF THE ECONOMIC SURVEY (2009) (reporting that the median cost to litigate a patent infringement suit when \$1 to \$25 million is at stake is \$2.5 million).

Thus, many, if not most, cases in which patent challengers adduce credible proof that the patent at issue was procured via misconduct settle before trial. And to the extent that the enforceability of other patents owned by the patentee could be jeopardized or called into question,⁴⁶ the patentee may be even more motivated to settle. Accordingly, the inequitable conduct doctrine, like other defenses to patent infringement, curtails litigation in some cases, and presumably tends to function most efficiently where the evidence is the most compelling and the allegations the most meritorious. Eliminating the defense would lead to an increase in the instances of successful enforcement of patents procured through deception, and to a likely increase in attempts to mislead the USPTO.⁴⁷

C. Other proposed enforcement mechanisms are unsatisfactory.

It is not clear how some of those who advocate abrogation of the defense⁴⁸ propose to deal with these consequences.⁴⁹ Others suggest

⁴⁶ Under certain circumstances, the Federal Circuit has held the connection between related patents to be sufficient to justify extending the reach of an unenforceability determination from one to another. *See, e.g.,* *Consol. Aluminum Corp. v. Fosco Int'l Ltd.*, 910 F.2d 804, 809-12 (Fed. Cir. 1990) (upholding a district court determination that unenforceability resulting from inequitable conduct committed during the prosecution of one patent extended to a patent claiming related subject matter and its two continuation patents); *Fox Indus. v. Structural Preservation Pres. Sys.*, 922 F.2d 801, 803-04 (Fed. Cir. 1990) (determining that the duty of candor continues throughout a patent's prosecution history and a breach of that duty can render unenforceable all claims from the same or related applications).

⁴⁷ Because the doctrine seeks to affect the subjective decisions of practitioners, inventors, and application owners, it is not possible to measure the doctrine's deterrent value. But it is illogical to assert or believe that there is no such effect.

⁴⁸ *See, e.g.,* John F. Lynch, "An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct," 16 *AIPLA Q.J.* 7, 10-12 (1988) (arguing that the doctrine should be eliminated because, among other articulated reasons, it is "subjective" and the concepts of materiality and intent are "vague").

⁴⁹ For example, it has been argued that the doctrine "has ceased to serve a useful purpose in our patent system" because "patent applications are no longer secret." *See, e.g., Hearings on H.R. 1908, supra* note 4, at 43. However, some patent applications are still held in secrecy. 35 U.S.C. § 122(b)(2)(B)(i) (2006) (allowing patent applicants to "opt out" of the automatic pre-grant publication after eighteen months); William C. Rooklidge, *Reform of the Patent Laws: Forging Legislation Reflecting Disparate Interests*, 88 *J. PAT. & TRADEMARK OFF. SOC'Y* 9, 12 (2006) (stating that approximately 10% of patent applications are withheld from pre-grant publication). Beyond that, patent application publication does not guarantee that misconduct will come to light. For one thing, opportunities for interested parties to challenge bad patents in the USPTO remain limited. Shelby M. Knowles, Thomas E. Vanderbloemen, & Charles E. Peeler, *Inter Partes Patent Reexamination in the United States*, 86 *J. PAT. & TRADEMARK OFF. SOC'Y* 611, 612 (2004) (noting that inter partes reexamination invokes strict litigation estoppel rules, and an

that alternative existing enforcement mechanisms and doctrines would suffice to deter misconduct and protect the integrity of the prosecution system.⁵⁰ But each of the alternatives has significant limitations. For one thing, not all misconduct which would undermine the integrity of the patent prosecution system would qualify the affected claims for invalidation.

For example,⁵¹ suppose that an applicant attends a conference and learns, during another's presentation, of experimental results that undermine a patentability argument that has recently been made to the USPTO in his application. Assume further that the results are not themselves in a form which qualifies as prior art under 35 U.S.C. § 102; for example, assume the results were orally presented, but not included in any written materials published as of, or at, the conference.⁵² The presenter's data are valid and credible, and

interested party who loses an inter partes reexamination cannot later claim the patent is invalid if the asserted argument was raised or could have raised in the reexamination); Anna Mayergoyz, *Lessons from Europe on How to Tame U.S. Patent Trolls*, 42 CORNELL INT'L L.J. 241, 262-63 (2009) (observing that while reexamination proceedings concern only issues of novelty and obviousness, the USPTO does not have opposition proceedings similar to those in Europe which allow a broader contestable scope of issues, including patentable subject matter, enablement, and disclosure); Haitao Sun, *Post-Grant Patent Invalidation in China and the United States, Europe, and Japan: A Comparative Study*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 273, 310 (2004) (noting that issues available for consideration during reexamination are limited to those which raise a substantial new question of patentability and have not been seen by the examiner during prosecution). For another, even full-blown federal court litigation may not succeed in exposing prosecution misconduct. However, the threat of potential unenforceability may deter such activity.

⁵⁰ See, e.g., 21ST CENTURY REPORT, *supra* note 3, at 122-23 ("If invalidity, disciplinary action, and reputational concerns are not sufficient deterrent to misconduct, other civil and even criminal remedies exist—antitrust, unfair competition, common law fraud, and tortious interference. Moreover, since the creation of the inequitable conduct doctrine by the courts, other safeguards have been adopted by Congress and the USPTO to support the integrity of the patent system. These include third-party- and USPTO-initiated reexamination on withheld prior art, publication of pending applications, and third-party access to pending prosecution papers and the ability to submit material information.").

⁵¹ This hypothetical is adapted from the facts of *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229 (Fed. Cir. 2008).

⁵² By specifying that, "[a] person shall be entitled to a patent unless" certain disclosures or events have occurred before the applicant's invention or filing date, Section 102 delineates the information (i.e., publications and events) which qualifies as prior art for purposes of the novelty requirement. 35 U.S.C. § 102; see also Leanne M. Fecteau, *The Ayahuasca Patent Revocation: Raising Questions about Current U.S. Patent Policy*, 21 B.C. THIRD WORLD L.J. 69, 97 (2001) (noting that Section 102 does not include foreign prior knowledge, use, or invention as disqualifying prior art); Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity,*

ultimately they are included in a “printed publication,”⁵³ but the publication does not issue early enough to qualify as invalidating in a subsequent action to enforce the patent.⁵⁴

The applicant knows that the examiner, if told of the results presented at the conference, might not accept the previously-made patentability argument, and decides therefore not to reveal what he learned there. The applicant’s previously-submitted patentability argument persuades the examiner to issue the patent, but the issuance is unjustified under the circumstances. The patent is valid under the statute, but the applicant has violated his duty of candor,⁵⁵ and the examiner would not have withdrawn her claim rejection had she had the opportunity to consider the applicant’s argument in light of the results presented at the conference.

More significantly, however, a pure validity-based regime⁵⁶—at least as the U.S. system currently operates—does not adequately police patent quality. First, there is good reason to question the adequacy of examination by the USPTO.⁵⁷ The USPTO is struggling

Foreign Prior Art and the Neem Patent Controversy, 37 IDEA 371, 380 (1997) (“Prior foreign activity anticipates a U.S. patent only when the foreign activity is fixed in a tangible, accessible form such as by a description in a printed publication, or in a document related to either the applicant’s own foreign patent . . . or some other person’s foreign patent. However, prior *foreign* knowledge, use and invention are all excluded from the prior art related to a U.S. patent application.”).

⁵³ See 35 U.S.C. §§ 102(a)–(b).

⁵⁴ To qualify as prior art, a printed publication must be published prior to the applicant’s invention date, *id.* § 102(a), or more than a year before the applicant’s U.S. filing date. *Id.* § 102(b).

⁵⁵ See 37 C.F.R. § 1.56(b) (2009) (defining “information material to patentability” for purposes of the applicant’s duty of candor as including information that “refutes, or is inconsistent with, a position the applicant takes in: (i) [o]pposing an argument of unpatentability relied on by the Office, or (ii) [a]sserting an argument of patentability”).

⁵⁶ See, e.g., Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 162–63 (2005) (implying that the defenses of patent invalidity and inequitable conduct are redundant because in 89% of district court cases between 1995 and 2004 where the court found inequitable conduct, the court also found that the patent at issue was invalid); Melissa Feeney Wasserman, *Limiting the Inequitable Conduct Defense*, 13 VA. J.L. & TECH. 7, 18 (2008) (indicating that “in the vast majority of cases in which inequitable conduct is found, the doctrine results only in enlarging the possibility of remedies because the patent at issue will be found invalid anyway”).

⁵⁷ 21ST CENTURY REPORT, *supra* note 3, at 47 (identifying a lowered standard for non-obviousness, fewer prior art search resources at the Patent Office, lower examiner qualifications and experience, and increased workload as factors contributing to low quality patents); Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 70 (2009) (asserting that the quality of patents has been reduced as a result of the increasing number of applications and

to retain experienced examiners, and to cope with an increasingly challenging workload. These are among the factors contributing to concerns about patent quality.⁵⁸

Second, the enforcement “deck” is “stacked” in the patent owner’s favor. U.S. patents enjoy a statutory presumption of validity.⁵⁹ In addition, challengers must overcome an additional, significant evidentiary hurdle: invalidity must be established via clear and convincing evidence.⁶⁰ Furthermore, the presumption of validity and the heightened evidentiary standard apply even when the prior art on which the validity challenge is based was not considered by the USPTO while the patent application was pending.⁶¹ Thus, the judicial playing field is not level: patent owners enjoy the benefit of a significant evidentiary “headstart” when they embark upon enforcement.⁶² That some categories of prior art, such as prior public

ensuing burden placed on the USPTO); Aaron Homer, *Whatever It Is . . . You Can Get It on eBay . . . Unless You Want an Injunction—How the Supreme Court and Patent Reform are Shifting Licensing Negotiations from the Conference Room to the Courtroom*, 49 S. TEX. L. REV. 235, 238 (2007) (“[T]he PTO currently receives 375,000 patent applications each year and awards approximately 3,500 patents each week This volume of patent applications, coupled with the increasing complexity of modern patent applications, has resulted in the issuing of many low quality patents.”).

⁵⁸ See *supra* notes 29–36 and accompanying text.

⁵⁹ 35 U.S.C. § 282 (2006) (“A patent shall be presumed valid”).

⁶⁰ See *Iovate Health Sci., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, 586 F.3d 1376, 1380 (Fed. Cir. 2009) (“Patents enjoy a presumption of validity . . . and a party seeking to invalidate a patent must overcome this presumption by facts supported by clear and convincing evidence.”). In contrast, the patent owner’s burden of proof on the issue of infringement is a preponderance of the evidence. *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008) (“[T]he patentee bears the ultimate burden of proof to demonstrate infringement by a preponderance of the evidence.”).

⁶¹ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359-60 (Fed. Cir. 2007) (citing *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986) (“The presumption [of validity] remains intact and [the burden of proof remains] on the challenger throughout the litigation, and the clear and convincing standard does not change.”)); *Z4 Techs, Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1354 (Fed. Cir. 2007) (citing *Bio-Rad Labs., Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 615 (Fed. Cir. 1984) (“The introduction of prior art not considered by the PTO does not change the burden of proof or the requirement that evidence establish the presumption-defeating facts clearly and convincingly.”) *abrogated by* *Markman v. Westview Instruments Inc.*, 52 F.3d 967 (Fed. Cir. 1995)).

⁶² The judge-made “clear and convincing evidence” requirement for validity challenges has itself been the subject of recent criticism. *Pet. for Reh’g En Banc, Lucent Tech., Inc., v. Gateway, Inc.* (2009) (Nos. 2008-1485, -1487, -1495) *available at* http://www.patentlyo.com/lucent_20petition.pdf (arguing that the invalidity burden of proof should be a preponderance of the evidence rather than clear and convincing evidence); B.D. Daniel, *Heightened Standards of Proof in*

uses and invention sales and offers,⁶³ are not readily searchable further exacerbates the challenger's disadvantage in some cases.

Accordingly, relying on the validity defense as insurance against unjustified enforcement of patent rights may not adequately protect accused infringers or the public. A challenger who does not succeed in overcoming the patent owner's evidentiary advantages may well find itself subject to a money judgment or injunction under an invalid patent. And the public interest, for example, in opportunities to compete with the patent owner, or benefit from such competition by others, may also be adversely affected as a result.⁶⁴

Likewise, the potential for USPTO practitioner disciplinary action would deter or punish some, but not all, of the affirmative misrepresentations and willful omissions applicants might be tempted to make.⁶⁵ In some cases, the misconduct is attributable to someone other than the patent attorney or agent,⁶⁶ but only practitioners are subject to USPTO discipline.⁶⁷ And other identified remedies—such

Patent Infringement Litigation: A Critique, 36 AIPLA Q.J. 369, 417 (2008) (maintaining that the Federal Circuit's use of a clear and convincing evidence standard for patent validity challenges is inappropriate); Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 49 (2007) (“[T]he strong ‘clear and convincing evidence’ presumption of patent validity that today is accorded to every patent by default should be removed and replaced with a much weaker presumption that accused infringers could rebut under a ‘preponderance of the evidence’ standard.”).

⁶³ See, e.g., 35 U.S.C. §§ 102(a)–(b).

⁶⁴ See *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (“A patent by its very nature is affected with a public interest [I]t is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.”).

⁶⁵ The conduct of inventors and other persons associated with the patent applicant can qualify as inequitable conduct. See, e.g., *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1340, 1346 (Fed. Cir. 2007) (inventor submitted a sworn statement that initial sales of the ice cream were in March of 1988 despite selling the product starting in July 1987); *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1371, 1373 (Fed. Cir. 2005) (inventor submitted a 37 C.F.R. § 1.132 declaration that conflicted with a paper the inventor had co-authored, but failed to bring the paper to the attention of the examiner).

⁶⁶ A review of precedential decisions of the Federal Circuit affirming inequitable conduct determinations during the period of January 2006 through August 2008 reveals that in six out of ten cases, the court attributed at least some of the misconduct in question to someone (e.g., an inventor) other than the patent practitioner.

⁶⁷ 35 U.S.C. § 32 (2006) (“The Director may, after notice and opportunity for a hearing, suspend or exclude, either generally or in any particular case, from further

as antitrust, unfair competition, common law fraud, and tortious interference claims⁶⁸—are affirmative claims for relief which require the proof of elements beyond those required to establish the defense of inequitable conduct.

Another proposed alternative mechanism would have transferred the authority to adjudicate most inequitable conduct charges to a new tribunal within the USPTO.⁶⁹ However, at a time when the USPTO is under fire for how it carries out its existing responsibilities,⁷⁰ it is not clear that creating a new enforcement bureaucracy inside the agency is advisable.⁷¹ Furthermore, there is no reason to believe that the USPTO is better qualified than the federal courts to apply the applicable standards for evaluating alleged applicant misconduct.⁷²

D. Applicants would not voluntarily elaborate on references.

The inequitable conduct doctrine has been criticized on the ground that it leads applicants and practitioners to disclose too much information to the USPTO during prosecution, and to refrain from

practice before the Patent and Trademark Office, any person, agent, or attorney shown to be incompetent or disreputable, or guilty of gross misconduct, or who does not comply with the regulations established under Section 2(b)(2)(D) of this title, or who shall, by word, circular, letter, or advertising, with intent to defraud in any manner, deceive, mislead, or threaten any applicant or prospective applicant, or other person having immediate or prospective business before the Office.”).

⁶⁸ See 21ST CENTURY REPORT, *supra* note 3, at 122.

⁶⁹ See Patent Reform Act of 2005, H.R. 2795, 109th Cong. §§ 136(e)(1), (6)(A) (2005); *see also* Patent Reform Act of 2009, S. 610, 111th Cong. §§ 299(c)(2), (3)(A) (2009) (providing authority for the USPTO Director to investigate all allegations of inequitable conduct and impose civil penalties).

⁷⁰ See *supra* notes 32–39 and accompanying text.

⁷¹ See, e.g., Joseph N. Hosteny, *Litigator’s Corner: The Patent Reform Act and Inequitable Conduct*, INTELL. PROP. TODAY, March, 2006, at 22, 22–23 available at <http://www.hosteny.com/archive/Hosteny%2003-06.pdf> (“The Patent Reform Act of 2005, H.R. 2795, would make major changes to how inequitable conduct is handled. But unfortunately, it wouldn’t make the changes that need to be made On the contrary, [the subject inequitable conduct provision] complicates things and adds delay.”).

⁷² See, e.g., Steven R. Ludwig, Ted J. Ebersole & Donald J. Featherstone, *U.S. Patent Reform and the Future of Nanotechnology*, 20 THE LEGAL BACKGROUNDER NO. 37 (Wash. Legal Found., Wash., D.C.), Aug. 12, 2005, at 3, available at <http://www.wlf.org/upload/081205LBLudwig.pdf> (“The Patent Act of 2005 would transfer determinations of inequitable conduct to the USPTO. While many companies support decreasing litigation costs, many wonder whether such a transfer of jurisdiction achieves this goal. Moreover, the USPTO may not have the resources and investigatory procedures to properly develop evidence to competently rule on these issues.”).

explaining the relevance of the information submitted.⁷³ The USPTO itself has decried such practices, asserting that they undermine the USPTO's efforts to improve patent quality:

The USPTO has observed that applicants sometimes provide information in a way that hinders rather than helps timely, accurate examination. For example, some applicants send a very large number of documents to the examiner, without identifying why they have been submitted, thus tending to obscure the most relevant information. Additionally, some applicants send very long documents without pointing out what part of the document makes it relevant to the claimed invention. Sometimes applicants delay sending key information to the examiner. These practices make it extremely difficult for the patent examiner to find and properly consider the most relevant information in the limited time available for examination of an application.⁷⁴

Eliminating the doctrine could alleviate the “over-disclosure” problem, depending on what other information disclosure incentives and requirements would remain or be imposed.⁷⁵ However, abrogating the defense of inequitable conduct would not likely affect the extent to which applicants voluntarily comment on information they submit during prosecution.

Such characterizations can certainly ground inequitable conduct charges,⁷⁶ although the Federal Circuit has, on several occasions,

⁷³ See Armitage, *supra* note 16, at 3.

⁷⁴ Press Release, U.S. Patent & Trademark Office, USPTO Requesting More Timely and Useful Information from Patent Applicants (July 10, 2006), <http://www.uspto.gov/news/pr/2006/06-41.jsp>.

⁷⁵ The inventor(s), prosecuting attorney(s) and/or agent(s), and “[e]very other person who is substantively involved in the preparation or prosecution of [an] application and who is associated with the inventor” or assignee would presumably still be subject to the duty of candor, “include[ing] the duty to disclose . . . all information known to that individual to be material to patentability . . .” 37 C.F.R. § 1.56 (2009). And Congress, in recent years, has entertained proposals to authorize the USPTO to require applicants to submit analyses of the pertinence of references found in prior art searches. Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 12 (2007); S. REP. NO. 110-259, at 108 (2008).

⁷⁶ See, e.g., *Hoffman-LaRoche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1369–72 (Fed. Cir. 2003) (upholding a district court determination of inequitable conduct based on inaccurate statements in the application and an office action response characterizing the prior art and comparing it to the claimed invention); *CFMT, Inc. v. Yieldup Int’l Corp.*, 144 F. Supp. 2d 305, 323 (D. Del. 2001) (concluding the inventors engaged in inequitable conduct in misrepresenting the effectiveness of their invention to overcome an obviousness rejection and failing to disclose

turned back inequitable conduct challenges based on alleged applicant (or practitioner) mischaracterizations of prior art references.⁷⁷ Nevertheless, applicants and the practitioners who speak on their behalf are understandably—and advisedly—reluctant to make such statements.⁷⁸

However, aside from the risk of being accused of inequitable conduct, there are other good reasons to avoid unnecessary elaboration

information material to enablement), *rev'd*, 349 F.3d 1333, 1341–43 (Fed. Cir. 2003) (reversing the district court finding of inequitable conduct stating that the undisclosed subject matter had low materiality and little basis to infer intent to deceive and that their response to the obviousness rejection at most overemphasized the benefits of the invention and did not rise to the level of misrepresentation).

⁷⁷ See, e.g., *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325–27 (Fed. Cir. 2000) (holding that in allegedly mischaracterizing a reference, “the inventors merely advocated a particular interpretation of the teachings of the [reference] and the level of skill in the art, which the Examiner was free to accept or reject”); *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1581–82 (Fed. Cir. 1997) (rejecting the defendant’s contention that the patentee’s mischaracterization of a cited prior art reference constituted inequitable conduct because the examiner had access to the reference at issue, and thus, the opportunity to “place [the applicant’s] comments in their proper context”).

⁷⁸ See, e.g., Letter from State Bar of California, Intellectual Property Law Section, Commission on Patent Rule Proposals to Hon. Jon Dudas, Undersecretary of Commerce for Intell. Prop. and Director of the USPTO 3, *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab95/state_bar_california.pdf (“[M]alpractice claims against attorneys and agents may arise foreseeably from any mishandling of the new disclosure requirements which results in a successful inequitable conduct claim”); Letter from Susan Barbieri Montgomery, Chair, American Bar Assoc. Section of Intell. Prop. Law, to Hon. Jon Dudas, Undersecretary of Commerce for Intell. Prop. and Director of the USPTO 4, *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab95/aba_ipl.pdf (“The additional requirements imposed on Applicants by the proposed rules will expose Applicants to a possible greater risk of having to defend charges of inequitable conduct and will impose an often unnecessary new burden on knowledgeable Applicants.”); Letter from Norman F. Oblon, Partner, Oblon, Spivak, McClelland, Maier & Neustandt P.C., to Honorable Jon Dudas, Undersecretary of Commerce for Intell. Prop. and Director of the USPTO 2–3, *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab95/oblon_spivak.pdf (“In view of the harsh penalties for inequitable conduct, practitioners cannot take [the duty to provide an explanation for each reference cited in an IDS] lightly.”).

Similar concerns were raised in response to the USPTO’s proposal (in its 2007 proposed rules relating to continuation applications and limits on the number of claims) to require applicants to submit “Examination Support Documents” for patent applications containing five or more independent claims, or twenty-five or more total claims. See, e.g., Letter from Michael K. Kirk, Executive Director, AIPLA, to Honorable Jon Dudas, Under Sec’y of Commerce for Intellectual Property and Director of the USPTO 14 (Apr. 24, 2006) [hereinafter AIPLA Claims Comments], *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_claims/aipla.pdf (“[T]his requirement [to submit an ESD] makes the applicant an easy target for an inequitable conduct charge in an enforcement action.”).

during prosecution.⁷⁹ As a result, careful applicants and practitioners can be expected to avoid voluntarily elaborating during prosecution, including regarding information they submit to the USPTO.⁸⁰

IV. RECOMMENDATIONS FOR REFORM

For the above reasons, eliminating the inequitable conduct doctrine would be bad policy. However, that the doctrine should be revised is just as certain. But what change is appropriate? At a minimum, the following changes should be implemented.

A. *Prosecution conduct should be judged in the courts by the standards which govern applicants and practitioners inside the USPTO.*

Currently, patent owners are subject to different materiality standards in the USPTO and the courts. The Federal Circuit has not only declined to adopt the “new” Rule 56 materiality standard (thus denying accused practitioners and parties the comfort of its relative clarity), but has expressly reaffirmed its 1984 decree that no “single standard” will govern materiality determinations in the court’s inequitable conduct analysis.⁸¹ This decision effectively displaces the agency’s standard, except that, because of the consequences that may result from a court finding that a particular piece of withheld or omitted information was relatively more material,⁸² it adds complexity and expense to the litigation of inequitable conduct by encouraging accused infringers and forcing patentees to litigate the issue under both standards.

⁷⁹ See, e.g., Thomas C. Fiala & Jon E. Wright, *Preparing and Prosecuting a Patent That Holds Up in Litigation*, 875 PLI/PAT 515 (2006) (“One of the hallmarks of a “bullet-proof” patent is a silent prosecution history. This is because arguments in favor of patentability made on the record during prosecution can come back to haunt the patentee during litigation. For example, when such arguments characterize the claims, they may later be used during litigation to advance a narrow claim construction or even to support an assertion of prosecution history estoppel. Also, when such arguments characterize the prior art, they may be attacked as misleading and thus used to support a claim of inequitable conduct.”).

⁸⁰ See *supra* notes 73–75 and accompanying text.

⁸¹ *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984) (“There is no reason . . . to be bound by any single standard . . .”).

⁸² See *infra* Section IV D.

Congress should redefine materiality with a standard that binds both the courts and the USPTO, and that standard should be at least as specific and objectively determinative as the current Rule 56 standard.

B. Only conduct which undermines the integrity of the prosecution process should qualify for judicial sanction.

Under current law, inequitable conduct charges can be based on information completely immaterial to patentability. For example, in *Ulead Systems, Inc. v. Lex Computer & Management Corp.*,⁸³ a split panel of the Federal Circuit held that an unjustifiable claim of entitlement to small entity status and accompanying payment of insufficient maintenance fees was material as a matter of law.⁸⁴ And in *General Electro Music Corp. v. Samick Music Corp.*,⁸⁵ the Federal Circuit upheld a jury finding of materiality based on a statement—found false—that a “search” had been made in a petition to make special.⁸⁶

Thus, *Ulead* and *General Electro* support the general proposition that inequitable conduct can be based on gaining an advantage⁸⁷ before the PTO if the gain is based on a deceitful misrepresentation. Instead, the qualifying conduct should be limited to acts which undermine the *substantive* examination function of the USPTO—conduct which, objectively viewed—could reasonably have induced the USPTO to err in the application of a substantive patentability requirement, i.e., novelty, nonobviousness, utility, statutory subject matter, or compliance with the disclosure or definiteness requirements of Section 112.

C. The evidentiary standards governing intent findings should be revised.

The Federal Circuit’s inequitable conduct intent prong jurisprudence has, of late, been the target of increasing criticism.⁸⁸

⁸³ 351 F.3d 1139 (Fed. Cir. 2003).

⁸⁴ *Id.* at 1146.

⁸⁵ 19 F.3d 1405 (Fed. Cir. 1994).

⁸⁶ *Id.* at 1411.

⁸⁷ For example, maintenance of an issued patent, *Ulead*, 351 F.3d at 1139, or early issuance, *Gen. Electro*, 19 F.3d at 1405.

⁸⁸ See e.g., *Ferring B.V. v. Barr Lab., Inc.*, 437 F.3d 1181, 1202–03 (Fed. Cir. 2006) (Newman, J., dissenting) (“[T]here is a wide gulf between a rule that intent ‘may’ be inferred by a jury upon consideration of all the circumstances, in accordance with *Kingsdown [Med. Consultants, Ltd. v. Hollister, Inc.]*, 863 F.2d 867 (Fed. Cir. 1988), and a rule that intent ‘must’ be inferred as a matter of law against a

The split panel's decision in *Ferring B.V. v. Barr Laboratories, Inc.*⁸⁹ is the focal point of much of the criticism,⁹⁰ and with good reason. In *Ferring*, the determination of inequitable conduct was based upon withheld information not directly bearing on substantive patentability which the majority held the applicants "knew or should have known" and which was regarded as "highly material," thus justifying an inference of deceptive intent.⁹¹ Moreover, the majority upheld the district court's conclusion that there was no genuine issue of fact as to any of this.⁹²

Ferring thus exemplifies the type of inequitable conduct "snowball" that can result under recent Federal Circuit interpretations. Notably, the court appears to be cognizant of the problem. In an August 2008 inequitable conduct decision, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*,⁹³ the panel emphasized that a "district court may infer facts supporting an intent to deceive from indirect evidence. But no inference can be drawn if there is no evidence, direct or indirect, that can support the inference."⁹⁴

Admittedly, whenever subjective intent is at issue, the lines that separate reasonable inferences from conjecture are not always easy to

party opposing summary judgment, based solely on a material omission, in violation of *Kingsdown* and in violation of the rules of summary judgment."); James E. Hanft & Stacey S. Kerns, *The Return of the Inequitable Conduct Plague: When "I Did Not Know" Unexpectedly Becomes "You Should Have Known,"* 19 No. 2 INTELL. PROP. & TECH. L.J. 1, 3 (2007) ("Materiality and intent are separate components of inequitable conduct and require clear and convincing evidence for each. Intent to deceive can be inferred from circumstantial evidence, especially from the facts and circumstances of a knowing failure to disclose material information. While inferences may be drawn from circumstantial evidence, an inference based on a should-have-known standard given these facts is not an inference based on circumstantial evidence.").

⁸⁹ 437 F.3d at 1181.

⁹⁰ See, e.g., Hanft, *supra* note 88, at 4 ("The interesting aspect of this case is that the court acknowledged that materiality does not presume intent, which is a separate and essential component of inequitable conduct, but then stated that '[i]n a case such as this, when the materiality of the undisclosed information is relatively low, there is less basis for inferring intent from materiality alone.' The only other evidence of intent was found only 'marginally related' to the determination of intent to deceive. This implies that, if the court found the undisclosed information to be moderately or highly material, then intent would be inferred based on materiality alone. Such an inference, once again, does not hold up to the clear-and-convincing-evidence standard emphasized in *Kingsdown*.").

⁹¹ *Ferring*, 437 F.3d at 1187–94.

⁹² *Id.* at 1190, 1194.

⁹³ 537 F.3d 1357 (Fed. Cir. 2008).

⁹⁴ *Id.* at 1368 (citation omitted) (setting aside the district court's finding of deceptive intent).

draw. For this reason, a renewed and invigorated emphasis should be placed on carefully evaluating evidence of good faith proffered by the patentee.

In this regard, the most important directive in *Star Scientific* is this:

[I]nferences drawn from [less-than-clear-and-convincing] evidence cannot satisfy the deceptive intent requirement Further, the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but *it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.*⁹⁵

A firm resolve on the part of the courts to carefully observe this dictate should go a long way toward limiting erroneous deceptive intent findings and affirmances.

However, because so much is at stake, and the risk of error associated with discerning subjective intentions so great, the Federal Circuit (or Congress) should go further and adopt what is in effect a presumption of good faith on the part of the practitioner or inventor in question. In particular, where the patentee offers a plausible alternative explanation for the allegedly deceptive conduct, a finding of deceptive intent should be precluded. For one thing, this would significantly limit the situations where inequitable conduct could be established based upon the actions of an inventor or other non-practitioner who credibly asserts that he or she did not know the applicable law.⁹⁶

⁹⁵ *Id.* at 1366–67 (emphasis added) (citing *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”)).

⁹⁶ On several occasions, the Federal Circuit has upheld inequitable conduct determinations even where the misrepresentation or omission has assertedly resulted from an inventor’s (or other non-practitioner’s) unfamiliarity with relevant law and the practitioner’s unfamiliarity with the relevant facts. *See, e.g.*, *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1361–62 (Fed. Cir. 2005) (“Thus, Novo asks us to hold, on the one hand, that the failure of Dr. Christensen and his co-inventors to disclose the truth about Example 1 to Novo’s attorneys absolves them of their duty to disclose this information to the PTO or the Board, because without their attorney’s consultation, they could not have known that this information was material. At the same time, Novo asks us to hold that its counsel’s failure to disclose the truth about Example 1 to the PTO or Board is excused because the inventors failed to fully inform them of the details surrounding Example 1. As we have done in similar situations in the past, we reject the ‘circular logic’ of this request.”); *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380,

Importantly, however, successful implementation of a more rigorous intent standard, whether imposed by or on⁹⁷ the Federal Circuit, would depend on the commitment of the Federal Circuit to speak with one voice. Panels must strictly observe the “Rule of Newell”⁹⁸ and resist the temptation to articulate new and different formulations of the governing standards. Non-panel members must aid their colleagues by carefully scrutinizing precedential opinions before they issue, and take steps to prevent the issuance of opinions that relax or undermine what should be a very exacting standard.

D. Courts should abandon the materiality-intent balancing inquiry.

It is black-letter law, recently reinvigorated by the Federal Circuit, that district courts must undertake an equitable balancing of the evidence of materiality and intent in a given case “to determine whether a finding that inequitable conduct occurred is warranted.”⁹⁹ On many occasions, the court has explained how that balancing can affect the ultimate conclusion on the issue of inequitable conduct, namely, that where the materiality of the omission or misrepresentation is high, a lesser showing of intent is required.¹⁰⁰

1385 (Fed. Cir. 2001) (rejecting as “circular logic” the patentee’s argument that it could not have known—without its attorneys’ assistance—that a pre-critical date sale was material, and that its failure to fully apprise its attorneys of the facts surrounding the sale absolves them, emphasizing that “inventors represented by counsel are presumed to know the law.”).

⁹⁷ I.e., by Congress.

⁹⁸ *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988) (“This court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *en banc*.”).

⁹⁹ *Novo Nordisk Pharm.*, 424 F.3d at 1359; *see also* *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001) (describing the two steps of the inequitable conduct analysis as “first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all the circumstances to determine whether the applicant’s conduct is so culpable that the patent should be held unenforceable”); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 551 (Fed. Cir. 1990) (“A threshold showing of both materiality and intent to mislead or deceive must be first established, and then those fact-findings are balanced to make the determination whether ‘the scales tilt to a conclusion that inequitable conduct occurred.’” (quoting *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984))).

¹⁰⁰ *See, e.g.,* *Bristol-Myers Squibb Co. v. Rhone Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003); *Baxter Int’l Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1328 (Fed. Cir. 1998).

As a practical matter, however, because varying degrees of materiality can often be discerned but direct evidence of deceptive intent is rarely available, this “balancing” inquiry almost exclusively serves to bolster intent findings and affirmances in certain cases. Thus, it exacerbates the problem of lax application of the intent standard.

Furthermore, balancing materiality and intent is not a necessary facet of a regime committed to drawing only the most reasonable inferences and fully crediting plausible good faith explanations. Materiality and intent should be entirely separate threshold inquiries, and remain independent of one another throughout the analysis.

Finally, de-coupling the materiality and intent prongs would not undermine the essential equitable nature of the inequitable conduct doctrine. Trial courts should continue to be authorized to use their discretion to evaluate the quality and quantity of the evidence of each to determine, on particular facts, whether a determination that inequitable conduct has occurred is warranted. Even under current law, such a determination does not necessarily follow from findings that material information was withheld or misrepresented with deceptive intent.¹⁰¹ But in appropriate circumstances, where materiality and intent are independently established by clear and convincing evidence, the inherent equitable authority of the federal courts to deny relief to those who enter the court with unclean hands should be preserved and respected.

E. Trial judges should be permitted to tailor the remedy to the circumstances.

The one-size-fits-all remedy of total unenforceability deprives the courts of the ability to tailor the “punishment” to the offense. Recent reform proposals would expand the possible remedies for inequitable conduct. For example, a recent legislative initiative would have authorized courts to impose “[one] or more of” several potential

¹⁰¹ See, e.g., *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A.*, 464 F.3d 1339, 1347 (Fed. Cir. 2006). In *Kemin Foods*, the jury, acting in an advisory capacity, had found that the president of the owner of one of the patents-in-suit had withheld a reference with intent to deceive the USPTO. The Federal Circuit, though, affirmed the district court’s determination that the patent was not unenforceable, on the ground that the reference “was not highly material and that the showing of deceptive intent was not compelling.” According to the court, “[e]ven when a court finds that the patentee failed to disclose material information to the [USPTO] and acted with deceptive intent, the court retains discretion to decide whether the patentee’s conduct is sufficiently culpable to render the patent unenforceable.”

remedies, including “[h]old[ing] the patent unenforceable,” “hold[ing] [one] or more claims of the patent unenforceable,” and “order[ing] that the patentee is not entitled to equitable relief and that the sole and exclusive remedy for infringement of the patent shall be a reasonable royalty.”¹⁰² Such flexibility would appropriately reflect the reality that some misconduct is more egregious and deleterious than other misconduct. And giving the courts the power to sanction misbehaving patentees without necessarily wiping out all of the claims of the patent at issue, would lessen the incentives for frivolous assertions of inequitable conduct, or at least undermine the leverage of those accused infringers who seek to take advantage of the distorting effects of inequitable conduct allegations in litigation.

Authorizing courts to select from a menu of potential sanctions would, of course, add its own complexity and expense to the litigation of inequitable conduct allegations. But if such flexibility were adopted in combination with other reforms, such as those discussed above, the result should be a reduction, overall, in the frequency and burdens of litigating the issue.

F. Patentees who prevail on the issue of inequitable conduct could be awarded attorney fees.

Finally, as a further deterrent to frivolous or nuisance prosecution misconduct allegations, it may make sense to implement a fee-shifting provision in favor of patentees who prevail on the issue, for example, an automatic award of inequitable conduct-related attorney fees to a plaintiff who prevails on inequitable conduct, regardless of whether the patentee wins on infringement and validity.

V. CONCLUSION

To the extent that calls to eliminate the inequitable conduct doctrine or strip the courts of the authority to adjudicate such allegations stem from dissatisfaction with aspects of the Federal Circuit’s jurisprudence, the appropriate solution is to hone the doctrine, by congressional dictate if necessary. Abrogation would be appropriate, on the other hand, if there were a consensus that the doctrine serves no purpose. Given that the primary impetus behind calls for elimination of the doctrine is the former, the patent system is best served by efforts aimed at achieving a well-designed, well-implemented inequitable conduct doctrine.

¹⁰² S. 1145, 110th Cong. (1st Sess. 2007).

