

CONTROLLING THE “PLAGUE”: REFORMING THE DOCTRINE OF INEQUITABLE CONDUCT

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ABSTRACT

Following its characterization of inequitable conduct as a “plague” in 1988, the Federal Circuit took steps to narrow the defense, and the United States Patent and Trademark Office (PTO) amended its rules to more clearly define the duty of disclosure. However, proliferation of the defense has proved difficult to control. In recent years, the Federal Circuit has issued a number of decisions that expand the defense, leading one judge, in dissent, to recently proclaim that the court had “return[ed] to the ‘plague’ of encouraging unwarranted charges of inequitable conduct.” This recent expansion, in turn, has fueled a series of patent reform proposals. Reform of the inequitable conduct doctrine is necessary to rein in the assertion of inequitable conduct as a litigation tactic, and to stem a growing tide of inequitable conduct cases and establish an appropriate and sensible role for the doctrine within patent litigation. This Article advocates four reforms to the doctrine of inequitable conduct:

- Materiality should be explicitly linked to the PTO’s 1992 definition of materiality in its regulations;
- The standards for proving intent should be clearly defined;
- The step of “balancing” materiality and intent should be clarified and codified, making clear that even if thresholds of materiality and intent exist, the court retains equitable discretion to decline to find inequitable conduct;
- There should be a single, narrowed remedy. Only the claims directly affected by the inequitable conduct (rather than the entire patent) should be deemed unenforceable.

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I. INTRODUCTION

Twenty years ago, the Federal Circuit expressed its displeasure with the proliferation of inequitable conduct claims in patent litigation, famously calling it a “plague”:

[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client's interests adequately, perhaps. They get anywhere with the accusation in but a small percentage of the cases, but such charges are not inconsequential on that account.¹

Starting with the *Burlington* and *Kingsdown* decisions in 1988, the Federal Circuit took steps to narrow the defense, and the United States Patent and Trademark Office (PTO or USPTO) subsequently amended its rules to define more clearly the duty of disclosure. However, proliferation of the defense has proven difficult to control.

In recent years, the Federal Circuit has issued a number of decisions that have arguably expanded the defense, while also clouding its boundaries. For example, in one recent case, the trial court granted summary judgment of inequitable conduct on the basis that third-party experts who submitted declarations during prosecution failed to disclose material information when those declarations omitted past financial ties with the patentee.² The court held the experts had intended to deceive the PTO because they “should have known” that such financial ties were highly material, even without any suggestion that the scientific information they provided was inaccurate or misleading.³ The doctrine's expansion led one judge to proclaim in dissent that the court had “return[ed] to the ‘plague’ of encouraging unwarranted charges of inequitable conduct”⁴ This recent expansion has also fueled a series of patent reform proposals.⁵

This Article argues that reform of the inequitable conduct doctrine is necessary. Although there has been a recent, renewed trend toward its expan-

1. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988); *see also Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 n.15 (Fed. Cir. 1988) (citing *Burlington* and alluding to the “present proliferation of inequitable conduct charges”).

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

3. *Id.* at 1192.

4. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007) (Newman, J., dissenting).

5. The recent round of patent reform efforts was launched in 2003–2004 with the release of two major reports, one from the Federal Trade Commission and one from the National Academy of Sciences. FEDERAL TRADE COMMISSION, 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> [hereinafter FTC REPORT]; COMM. ON INTELLECTUAL PROP. RIGHTS IN THE KNOWLEDGE-BASED ECON., NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY (Stephen, A. Merrill, Richard C. Levin & Mark B. Myers eds., 2004) [hereinafter NAS REPORT].

sion, the rate at which inequitable conduct is found in Federal Circuit case law has remained somewhat below the level that existed just prior to *Burlington* and *Kingsdown*. Nonetheless, this Article argues that some critical clarifications and restrictions on the doctrine are necessary to rein in the assertion of inequitable conduct as a litigation tactic, to stem a growing tide of inequitable conduct cases, and to establish an appropriate and sensible role for the doctrine within patent litigation.

As one commentator noted twenty years ago, “[t]he strategic and technical advantages that the inequitable conduct defense offers the accused infringer make it almost too attractive to ignore.”⁶ One advantage is the possibility of a broad remedy—a finding of inequitable conduct will render the entire patent unenforceable, rather than just the particular affected claims. In certain cases, related patents may be held unenforceable as well. A second advantage is an asymmetrical discovery burden that exerts pressure on the boundaries of the attorney-client privilege, since most relevant documents will come from the files of the inventor and the patent attorney who prosecuted the patent, and those individuals will likely be subject to deposition. A third advantage is the opportunity that inequitable conduct provides to impugn the character of the inventor and her counsel, providing a counterbalance to the patentee’s likely narrative at trial of the inventor as an idealized genius.

With those advantages, together with an increasing murkiness in the elements and boundaries of the defense, it is little wonder that accused infringers look for any opportunity to inject the inequitable conduct defense into patent litigation, and are doing so with increasing frequency.

Under the basic doctrine, a *prima facie* claim of inequitable conduct comprises three elements:

1. an affirmative misrepresentation of material fact, a submission of false material information, or a failure to disclose material information;
2. an intent to deceive the Patent Office; and
3. an equitable evaluation, or “balancing,” of materiality and intent to determine whether the conduct is sufficiently culpable to warrant a finding of unenforceability.⁷

6. John F. Lynch, *An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct*, 16 AIPLA Q.J. 7, 8 (1988).

7. *E.g.*, *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir.

If these elements are satisfied, the entire patent is rendered unenforceable.⁸ The Federal Circuit has, however, been inconsistent and, recently, increasingly broad in how it articulates and applies those broad-brush elements.

To rectify the problems associated with the doctrine’s expansion and to reduce the tactical incentives to over-use the defense, this Article advocates four reforms to the doctrine of inequitable conduct:

1. Explicitly link the element of materiality to the definition of materiality in the 1992 revision of the PTO’s regulations.
2. Define clear standards for proving intent.
3. Clarify and codify the step of “balancing” materiality and intent, making clear that even if thresholds of materiality and intent exist, the court retains equitable discretion to decline to find inequitable conduct.
4. Create a single, narrowed remedy. Only the claims directly affected by the inequitable conduct (rather than the entire patent) should be deemed unenforceable.

Part II of this Article explains each of the *prima facie* elements of inequitable conduct. Part III examines the characterization of inequitable conduct claims as a “plague,” which connotes two key aspects: nuisance and prevalence. By analyzing data relating to the more than 300 Federal Circuit cases since 1982 that address inequitable conduct, together with selected data from the district court level, this article examines the trends in the case law, and identifies some benchmarks against which the “plague” characterization can be measured. Part IV critically examines a number of recent inequitable conduct cases from the Federal Circuit to identify several key problems leading to ambiguity and expansion of the doctrine. Part V evaluates several recent legislative reform proposals, identifying the strengths and weaknesses of each. Part VI sets out proposals for substantive reform.

II. BACKGROUND: THE LAW OF INEQUITABLE CONDUCT

Inequitable conduct is a judicially created defense to patent infringement,⁹ having its origins in the equitable doctrine of unclean hands.¹⁰ That is,

2006).

8. *Id.*

9. *Id.* at 1315.

10. See Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7

a patentee seeking to enforce its patent rights must not come before the court with unclean hands due to his intentional misleading of the PTO in order to obtain the patent.

Under modern doctrine, to prove that a patent is unenforceable due to inequitable conduct, a party must show that an inventor, an inventor’s attorney, or another person substantively involved with the application,¹¹ with intent to mislead or deceive the Patent Office, failed to disclose to the Patent Office material, non-cumulative information known to that person to be material, or submitted materially false information to the Patent Office during prosecution.¹² If the Court determines that the threshold levels of both materiality and intent were achieved, then the Court must balance materiality and intent, “with a greater showing of one factor allowing a lesser showing of the other.”¹³

The following Sections address the three elements of materiality, intent, and balancing in greater detail.

A. MATERIALITY

Although the case law concerning inequitable conduct has articulated a number of different standards for materiality,¹⁴ Rule 56 of the Rules of Practice in Patent Cases has long guided the determination of the materiality prong of the inequitable conduct inquiry.¹⁵ From 1977 until 1992, Rule 56 defined materiality in terms of a “reasonable examiner” test, and that was the dominant test throughout that period. In 1992, Rule 56 was amended to provide a more objective test of materiality. Although the 1992 version of Rule

HARV. J.L. & TECH. 37, 49–50 (1993); *see also* S. REP. NO. 110-259, at 59 (2008) (citing *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244 (1933)).

11. 37 C.F.R. § 1.56 (2008).

12. *Digital Control*, 437 F.3d at 1313; *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330–31 (Fed. Cir. 2004); 37 C.F.R. § 1.56.

13. *Digital Control*, 437 F.3d at 1313 (citing *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001)).

14. *See id.* at 1315.

15. 37 C.F.R. § 1.56. Rule 56, also characterized as the “duty of disclosure” requirement, is intended to improve the quality of examination and the validity of patents. *See* Rene D. Tegtmeyer, *The Patent and Trademark Office View of Inequitable Conduct or Attempted Fraud in the Patent and Trademark Office*, 16 AIPLA Q.J. 88, 88 (1988) (noting that Rule 56 is intended “to improve the quality of examination and the validity of patents”). *See also* *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362–63 (Fed. Cir. 1984) (describing four standards for determining materiality and holding that “[t]he PTO ‘standard’ [i.e., Rule 56] is an appropriate starting point for any discussion of materiality, for it appears to be the broadest, thus encompassing the others, and because that materiality boundary most closely aligns with how one ought to conduct business with the PTO”); Christopher A. Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 733 (2009).

56 is still in effect, the courts have apparently been reluctant to adopt this change, as explained in greater detail below.

When the Federal Circuit first declared a “plague” in 1988, the operative portion of the 1977 version of Rule 56 defined information as 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.”¹⁶ Perhaps unsurprisingly, the courts and the PTO provide differing accounts of the origin of the “reasonable examiner” standard. The Tenth Circuit (in a pre-Federal Circuit case) asserts that the PTO merely codified existing case law.¹⁷ According to the Federal Circuit, the 1977 version of Rule 56 was “a codification of earlier case law.”¹⁸ However, the PTO’s commentary from the 1977 enactment indicated that Rule 56 as a whole “codifies the existing Office policy on fraud and inequitable conduct, which is believed consistent with the prevailing case law in the federal courts. . . . [T]he section should have a stabilizing effect on future decisions in the Office, and may afford guidance to courts as well.”¹⁹ Additionally, the PTO’s commentary noted that the “reasonable examiner” definition of materiality was paraphrased from a Supreme Court decision relating to Securities and Exchange Commission rules, but that nonetheless the PTO believed it to be “consistent with the prevailing concept that has been applied by lower courts in recent patent cases.”²⁰

The PTO identified problems with the “reasonable examiner” standard, including that it was insufficiently objective, unworkable,²¹ and too impre-

16. 37 C.F.R. § 1.56 (1977).

17. *True Temper Corp. v. CF&I Steel Corp.*, 601 F.2d 495, 504 n.9 (10th Cir. 1979) (refusing to apply Rule 56 as alternative test for materiality because it “merely represented a codification of existing case law”); *see also Digital Control*, 437 F.3d at 1315.

18. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1551 (Fed. Cir. 1983) (citing *True Temper*, 601 F.2d 495).

19. Rules of Practice in Patent Cases, 42 Fed. Reg. 5588, 5589 (Jan. 28, 1977).

20. *Id. Contra Lynch*, *supra* note 6, at 13–15 (arguing that the 1977 version of Rule 56 was not based on existing inequitable conduct case law).

21. Duty of Disclosure and Practitioner Misconduct, 54 Fed. Reg. 11,334 (proposed Mar. 17, 1989) (“These proposed changes are considered desirable in view of the large amount of resources that are being devoted to duty of disclosure issues both within and outside the Office without significantly contributing to the reliability of the patents being issued.”).

cise.²² The PTO also characterized the standard as vague and not correlated to other areas of the patent law.²³

Accordingly, in 1989, the year after *Burlington* and *Kingsdown* declared a “plague” of inequitable conduct, the PTO proposed amendments to Rule 56 seeking to replace the reasonable examiner standard with a clearer and more objective set of guidelines.²⁴ In 1992, the PTO adopted a revised version of Rule 56, which largely remains in place today.²⁵ These revisions were intended to “specify more precisely the information” that should be disclosed to the PTO during prosecution.²⁶ Moreover, the determination what a reasonable examiner would have considered important is entirely a hypothetical determination left to the courts—testimony by actual examiners as to what they considered (or would have considered) important is prohibited.²⁷

The 1992 version of Rule 56 defines material information subject to the duty of disclosure as information that either (1) establishes (alone or in combination with other information) a *prima facie* case of unpatentability of a claim, or (2) refutes or is inconsistent with a position the applicant took in arguing for patentability or in opposing an argument of unpatentability relied on by the PTO.²⁸ Additionally, information is material only if it is not cumu-

22. E.g., Harry F. Manbeck, Jr., *Evolution and Future of New Rule 56 and the Duty of Candor: The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136, 139–40 (1992) (“[In 1990–1991] I concluded that existing Rule 56 was indeed too imprecise, and could, and probably was, leading to unjustifiable charges of inequitable conduct in litigation. It should be changed.”).

23. Duty of Disclosure, 56 Fed. Reg. 37,321, 37,322 (proposed Aug. 6, 1991) (codified at 37 C.F.R. § 1.56).

24. 56 Fed. Reg. at 37,321, 37,322.

25. See 56 Fed. Reg. at 37,321; Duty of Disclosure, 57 Fed. Reg. 2021 (Jan. 17, 1992).

26. 56 Fed. Reg. at 37,321.

27. 37 C.F.R. § 104.22 (2008) (prohibiting testimony by PTO employees without General Counsel’s approval); 37 C.F.R. § 104.23 (2008) (prohibiting expert or opinion testimony by PTO employees without General Counsel’s approval); U.S. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 1701 (8th ed., rev. 7, 2008) (prohibiting testimony and opinions concerning, *inter alia*, patent enforceability); *W. Elec. Co. v. Piezo Tech., Inc.*, 860 F.2d 428, 430, 433 (Fed. Cir. 1988) (reasonable examiner test “is an objective standard,” so testimony of examiners who examined patent-in-suit “is irrelevant to the issue of inequitable conduct”); *id.* at 431 (noting “the general rule . . . that a patent examiner cannot be compelled to testify regarding his ‘mental processes’ in reaching a decision on a patent application”).

28. 37 C.F.R. § 1.56(b) (1992). See also Rene D. Tegtmeyer, *Evolution and Future of New Rule 56 and the Duty of Candor: A Refocusing on Inequitable Conduct in New Rule 56*, 20 AIPLA Q.J. 191, 194 (1992) (noting that new Rule 56 “recognizes to some degree the unnecessary problems and expenses that are caused when questions of inequitable conduct arise in litigation based on allegedly withheld or misrepresented information not affecting patentability”).

lative of information that is already before the PTO as part of the patent application.²⁹

For a number of years after the adoption of the 1992 version of Rule 56, and as late as the *Purdue Pharma* decision on February 1, 2006, the Federal Circuit consistently held that the “reasonable examiner” test applied to patents prosecuted before 1992, and the new version of Rule 56 applied to applications pending or filed after the rule’s March 16, 1992 effective date.³⁰ These cases imply that the “reasonable examiner” test would gradually fade into irrelevance as the last of the pre-1992 patents expired.

However, on February 8, 2006, just a week after it decided *Purdue Pharma*, the Federal Circuit decided *Digital Control Inc. v. Charles Machine Works*,³¹ which breathed new life into the “reasonable examiner” test for patent applications pending or filed after March 16, 1992.³² *Digital Control* reached back to the 1984 *American Hoist* case,³³ decided four years before *Burlington* and *Kingsdown*, to revive a list of four historically accepted and judicially adopted standards of materiality.³⁴ The *Digital Control* court reasoned that the 1992 version of Rule 56 was “not intended to replace or supplant the ‘reasonable examiner’ standard,” and that the “reasonable examiner” standard should continue to exist as one of the tests for materiality.³⁵

Some uncertainty, however, remained. A week after *Digital Control*, the Federal Circuit decided *Ferring B.V. v. Barr Laboratories, Inc.*,³⁶ which reiterated

29. 37 C.F.R. § 1.56(b) (1992).

30. See *Purdue Pharma. L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006) (“Because all of the patent applications at issue in this case were pending on or filed after March 16, 1992, we look to the current version of Rule 56, rather than the pre-1992 version of the rule.”); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd.*, 394 F.3d 1348, 1352–53 (Fed. Cir. 2005) (“According to the PTO’s notice of final rulemaking, the rule change applied to all applications pending or filed after March 16, 1992.”) (citation omitted); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1364 (Fed. Cir. 2003) (“Since the time of the 1992 amendment we have continued to apply the reasonable examiner standard, *but only* as to cases that were prosecuted under the earlier version of Rule 56.”) (emphasis added) (citations omitted).

31. 437 F.3d 1309 (Fed. Cir. 2006).

32. *Digital Control* addressed the issue of inequitable conduct as it related to three patents: U.S. Patent No. 5,767,678; U.S. Patent No. 6,008,651; and U.S. Patent No. 6,232,780. *Id.* at 1310. Each of these patents was based on applications filed after March 16, 1992 but all three could be traced back to a common ancestor application that was filed on March 1, 1991. See U.S. Patent No. 5,767,678 (filed Oct. 9, 1996); U.S. Patent No. 6,008,651 (filed Sept. 18, 1998); U.S. Patent No. 6,232,780 (filed Mar. 3, 2000). Thus, each of these three patent applications was filed or pending after March 16, 1992.

33. *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984).

34. *Digital Control*, 437 F.3d at 1315.

35. *Id.* at 1316.

36. 437 F.3d 1181 (Fed. Cir. 2006).

the position that the pre-1992 version of Rule 56 applied to patents prosecuted before the amendment.³⁷ The implication in *Ferring* was that the 1992 version of Rule 56 should apply to patents prosecuted after the 1992 amendment. By 2008, any such uncertainty appears to have dissipated, when the Federal Circuit again endorsed the “reasonable examiner” test as the controlling standard.³⁸

B. INTENT

The intent prong of inequitable conduct has also posed significant challenges. There are virtually no cases in which there is direct evidence of intent, such as a smoking-gun document or flat-out witness admission that someone concealed information from the PTO for the purpose of misleading the examiner. Thus, courts have repeatedly stated that intent to deceive must often be proven by circumstantial evidence because direct evidence of intent is rarely, if ever, available.³⁹ But determining precisely what kind of evidence will suffice has been exceedingly difficult.

The *Kingsdown* and *Burlington* cases, decided at the height of the “plague,” each address the intent issue. In both cases, the district court granted summary judgment of unenforceability due to inequitable conduct based on actions that may fairly be characterized as sloppy or imprecise work by the patent lawyer during prosecution. As explained in more detail below, the prosecuting attorney in *Burlington* failed to perceive the distinction between two phrases he used interchangeably;⁴⁰ and in *Kingsdown*, the prosecuting attorney copied the wrong version of a claim into a continuation application.⁴¹

In *Burlington*, the Federal Circuit noted that “the nondisclosure of facts of which the applicant *should have known* the materiality may justify an inference of intent to mislead in appropriate cases.”⁴² The district court had granted

37. *Id.* at 1187 n.6 (“[W]e have continued to use the pre-1992 language regarding materiality for evaluating patents that were prosecuted before the amendment.”).

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

39. *E.g., Ferring*, 437 F.3d at 1191.

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

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

42. *Burlington*, 849 F.2d at 1421 (emphasis added). The court also stated that, under 37 C.F.R. § 1.56(d), the PTO would not grant a patent when, inter alia, “the duty of disclosure was violated through bad faith or gross negligence.” *Id.*

The Federal Circuit noted in *Burlington* that, in addition to any adjudications of inequitable conduct that the courts might engage in, the Patent Office also had procedures for determining inequitable conduct. *See* U.S. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2010 (5th ed., rev. 7, 1986);

summary judgment of unenforceability based on the patent’s interchangeable usage of two phrases: one characterizing the invention as “impregnat[ion of] *individual fibers* in the yarn bundle,” and the other characterizing the invention as “impregnat[ion of] the *fiber bundles* and encapsulat[ion of] the individual fibers.”⁴³ The distinction allegedly made a difference as to whether the invention read onto two prior art patents. In response, the attorney who prosecuted the patents testified that he had not perceived a distinction between the two phrases, and that he had used one as “shorthand” for the other.⁴⁴ The Federal Circuit vacated the summary judgment and remanded, stating that it was error to reject the attorney’s explanation out of hand in favor of “a less plausible sinister interpretation.”⁴⁵ Although the Federal Circuit closed its opinion in *Burlington* with its now-famous paragraph about the “absolute plague” of inequitable conduct, it did not provide affirmative guidance on the standard of proof for intent, other than to note that failure to disclose information the party “should have known” to be material can form a basis for intent.

In *Kingsdown*, the Federal Circuit convened en banc to address whether “gross negligence” could support a finding of intent to deceive the Patent Office,⁴⁶ and concluded that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive;

id. § 2020.03 (“As soon as an issue of ‘fraud,’ ‘inequitable conduct’ or ‘violation of the duty of disclosure’ is identified in, or with regard to, an application, the application should be forwarded to the Office of the Assistant Commissioner for Patents.”).

Shortly thereafter, however, the PTO ceased making determinations of inequitable conduct. In revisions of the Manual of Patent Examining Procedure (MPEP) published between 1992 and 1995, sections 2010 and 2020 were deleted. Starting in 1995, the Patent Office explicitly stated its policy of not becoming involved in adjudicating issues of intent to deceive, due in part to its lack of expertise and resources to make the fact- and evidence-intensive assessments of intent. U.S. PATENT & TRADEMARK OFFICE, U.S. DEPT’ OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2010 (6th ed. Jan. 1995) (“The Office is not the best forum in which to determine whether there was an ‘intent to mislead’ Accordingly, the Office does not investigate and reject original or reissue applications under 37 C.F.R. [§] 1.56.”); *see also* Manbeck, *supra* note 22, at 139–140 (noting that the PTO disbanded the “fraud squad” in 1988); Tegtmeyer, *supra* note 28, at 193 (noting that 1992 version of Rule 56 confirms that PTO no longer investigates inequitable conduct issues).

43. *Burlington*, 849 F.2d at 1419 (emphasis added).

44. *Id.* at 1420.

45. *Id.* at 1421.

46. *See* 37 C.F.R. § 1.56(d) (1977) (“An application shall be stricken from the files if it is established by clear and convincing evidence that any fraud was practiced or attempted on the Office in connection with it or that there was any violation of the duty of disclosure through bad faith or *gross negligence*.”) (emphasis added); Rules of Practice in Patent Cases, 42 Fed. Reg. 5588, 5594 (Jan. 28, 1977).

the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to *require* a finding of intent to deceive.”⁴⁷ In so ruling, the Federal Circuit again reversed a grant of summary judgment of inequitable conduct, ruling that the district court’s finding of intent was clearly erroneous. During prosecution, the examiner rejected as indefinite the application’s claim 50. Following amendments to overcome the indefiniteness rejection, the examiner indicated that an amended claim 50 would be allowable.⁴⁸ Subsequently, a continuation application included the disallowed, pre-amendment version of claim 50, not the allowable, amended version.⁴⁹ Hollister, the accused infringer, alleged that this change was made with gross negligence or intentionally (e.g., in order to strengthen Kingsdown’s infringement claim against Hollister), and therefore constituted inequitable conduct. The Federal Circuit disagreed, ruling that this error was “insufficient to warrant a finding of an intent to deceive the PTO.”⁵⁰ The Federal Circuit emphasized that the error would have been an easy one to make.⁵¹ In fact, the prosecuting attorney testified that he was unaware of the error until Hollister raised it.⁵² The Federal Circuit also rejected Hollister’s contentions that intent should be inferred from Kingsdown’s actions, holding that there was nothing improper about trying to write otherwise patentable claims to cover a competitor’s known product,⁵³ and that Kingsdown’s failure to abandon its suit, or to file a disclaimer or reissue application, was irrelevant to the issue of intent.⁵⁴

The *Burlington* and *Kingsdown* opinions differed in at least one key respect in their treatment of how intent can be proven. *Burlington* held that intent can be shown if the applicant knew of the undisclosed prior art and “should have known” of its materiality. However, *Kingsdown* held that even gross negligence cannot alone support a finding of intent. At the time of *Burlington* and *Kingsdown*, the “should have known” test and gross negligence were related, as explained in the 1984 *J.P. Stevens* case. In *J.P. Stevens*, the Federal Circuit held that gross negligence is sufficient to prove intent, and that gross negligence is

47. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc) (emphasis added).

48. *Id.* at 874–875.

49. *Id.* at 869–71.

50. *Id.* at 873.

51. *Id.*

52. *Id.* at 872.

53. *Id.* at 874.

54. *Id.* at 875–76. It was in response to this last issue that the Federal Circuit invoked *Burlington*’s “plague” rhetoric, stating that “[a] requirement for disclaimer or reissue to avoid adverse inferences would merely encourage the present proliferation of inequitable conduct charges.” *Id.* at 876, 876 n.15.

shown where the applicant reasonably should have known of the materiality of the undisclosed information.⁵⁵

Consistent with *J.P. Stevens, Burlington* held that intent could be inferred from the nondisclosure of facts that the applicant should have known were material.⁵⁶ The en banc Federal Circuit in *Kingsdown* then ruled that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.”⁵⁷

Viewed through the prism of *J.P. Stevens*, it would have been reasonable to infer that *Kingsdown*’s holding also meant that intent could not be inferred under the “should have known” test. The Federal Circuit’s 1990 decision in *Hoffmann-La Roche v. Lemmon*⁵⁸ supports such an inference. In that case, the district court ruled that during prosecution of a reissue application the applicant was “grossly negligent since he should have known of the materiality of the withheld information. The intent to deceive can be inferred from this gross negligence.”⁵⁹ The Federal Circuit reversed because, under *Kingsdown*, gross negligence alone cannot support a finding of intent.⁶⁰

In the 2001 *Brasseler* case, the Federal Circuit provided an indication that *Kingsdown* had not definitively resolved the status of the “should have known” test, holding that gross negligence in the avoidance of learning the materiality of information can support a finding that the applicant should have known of the materiality of that information.⁶¹ The *Brasseler* ruling effectively inverted *J.P. Stevens*: The Federal Circuit used gross negligence to prove that the applicant should have known about the information’s materiality and therefore intended to deceive the examiner. In contrast, the Federal Circuit in *J.P. Stevens* used the “should have known” test to prove gross negligence to support an inference of intent to deceive.

55. *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984).

56. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1421 (Fed. Cir. 1988).

57. *Kingsdown*, 863 F.2d at 876.

58. *Hoffmann-La Roche Inc. v. Lemmon Co.*, 906 F.2d 684 (Fed. Cir. 1990).

59. *Id.* at 687 (citation omitted).

60. *Id.* at 688.

61. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001); *Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 397 (Fed. Cir. 1996) (“[A]n applicant who knew of the art or information cannot intentionally avoid learning of its materiality through gross negligence, i.e., it may be found that the applicant ‘should have known’ of that materiality.”) (citing *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)).

Finally, in 2006, the Federal Circuit revitalized *Burlington*’s “should have known” test, sidestepping *Kingsdown*’s prohibition on proving intent through gross negligence. In *Ferring*,⁶² the Federal Circuit held that in certain cases,

[S]ummary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or *should have known* of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.⁶³

C. BALANCING

The third prong of the inequitable conduct inquiry enters into consideration once minimum thresholds of both materiality and intent have been satisfied. In such cases, the materiality and intent are equitably “balanced” to determine whether the misconduct is sufficiently culpable to support a holding of unenforceability.⁶⁴

The term “balancing” can be somewhat confusing as a characterization of the manner in which the court evaluates materiality and intent. Typically, the term describes competing values, metaphorically arrayed at opposite ends of a simple lever, where the “weightier” value prevails over the lesser value. This ordinary conception might lead some to the conclusion that the balancing that is conducted for inequitable conduct has materiality and intent on opposite ends of the lever.

However, such a conception fails to account for the fact that a finding of inequitable conduct requires both materiality and intent, and that the existence of equally high amounts of both materiality and intent leads not to equipoise, but to a permissible finding of inequitable conduct. Moreover, a finding of high materiality and low intent on the one hand, and a finding of low materiality and high intent on the other hand, may both be sufficient to establish that there has been inequitable conduct. Under the simple-lever model, these alternative findings would lead to opposite or competing outcomes. A different depiction of the “balancing” test is therefore necessary.

In *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, the Federal Circuit provided a more detailed explanation of the manner in which materiality and in-

62. 437 F.3d 1181 (Fed. Cir. 2006).

63. *Id.* at 1191 (emphasis added). See also James E. Hanft & Stacey S. Kerns, *The Return of the Inequitable Conduct Plague: When “I Did Not Know” Unexpectedly Becomes “You Should Have Known”*, INTELL. PROP. & TECH. L.J., Feb. 2007, at 1, 3–4.

64. E.g., *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006); *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001).

tent are balanced.⁶⁵ First, the court must find by clear and convincing evidence that threshold levels of both materiality and intent independently exist.⁶⁶

If both thresholds have been met, the court can then engage in an equitable assessment, or balancing, of the merits to determine whether a finding of unenforceability is appropriate:

At this second stage, . . . the question is no longer whether materiality and/or intent to deceive were proven with evidence that is sufficiently clear and convincing. . . . [T]he district court must balance the *substance* of those now-proven facts and all the equities of the case to determine whether the severe penalty of unenforceability should be imposed.⁶⁷

The balancing process, as explained by *Star Scientific*, may be depicted as shown in Figure 1, below. The thresholds of materiality and intent are represented by the dashed lines. If either materiality or intent (or both) fall below those thresholds, there can be no inequitable conduct.⁶⁸ If both thresholds have been met, the court must then engage in discretionary balancing to determine whether the conduct warrants a finding of unenforceability. If the levels of materiality, intent, or both are low, the court may conclude that no inequitable conduct should be found, as shown by the striped area below and to the left of the solid curve. If the levels of materiality, intent, or both are high, the court may reach a finding of inequitable conduct, as shown by the area above and to the right of the solid curve. The solid curve approximately represents the continuum between the endpoints described by the Federal Circuit as “[t]he more material the omission or the misrepresentation, the lower [the] level of intent [is] required to establish inequitable conduct, and vice versa.”⁶⁹

65. 537 F.3d 1357, 1367 (Fed. Cir. 2008).

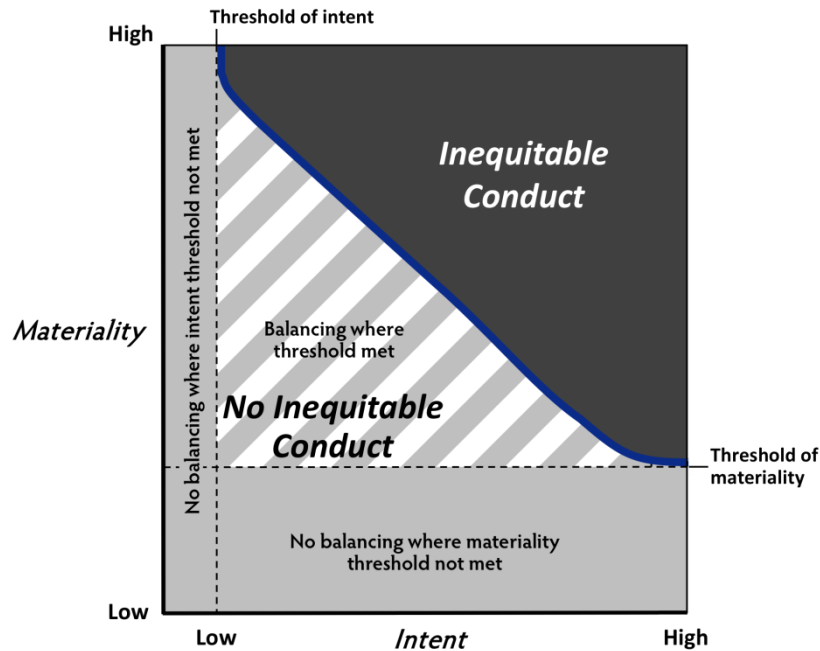
66. *Id.* at 1367.

67. *Id.*

68. *E.g.*, *Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 398 (Fed. Cir. 1996) (declining to balance materiality and intent because Telsmith failed to make threshold showing of intent).

69. *Star Scientific*, 537 F.3d at 1367 (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997)).

Figure 1: Balancing Materiality and Intent



Thus, as Figure 1 illustrates, not every finding of (greater-than-threshold) intentional withholding of (greater-than-threshold) material information requires a finding of inequitable conduct. There are, however, few reported cases in which a court has found both thresholds were satisfied, but nonetheless exercised its discretion at the balancing stage to refuse to find inequitable conduct.⁷⁰

III. IS INEQUITABLE CONDUCT A “PLAGUE”?

At the time of the *Burlington* and *Kingsdown* decisions, was there a “plague” of inequitable conduct claims? If so, does it exist today—either continuously since 1988, or after an interval of quiescence? The “plague” label suggests a thing that is both undesirable and prevalent. This Part addresses both of these concepts. Section A considers the circumstances under which the asser-

70. See, e.g., *Rentrop v. Spectranetics Corp.*, 550 F.3d 1112, 1120 (Fed. Cir. 2008); *Informatica Corp. v. Bus. Objects Data Integration, Inc.*, 489 F. Supp. 2d 1060, 1075 (N.D. Cal. 2007) (“[T]he Court determines that the very minimal showing of materiality, if any, balanced against at most a very weak inference of intent to withhold that prior art, weighs against a determination that [patentee] is culpable of inequitable conduct as to those products.”).

tion of inequitable conduct is undesirable. Section B evaluates the extent to which inequitable conduct is actually used in the case law.

A. UNDESIRABILITY OF INEQUITABLE CONDUCT AS A LITIGATION TACTIC

The suggestion that inequitable conduct is undesirable is inherently a subjective assessment. This undesirability assessment focuses on the extent to which the doctrine provides incentives to assert inequitable conduct merely for its value as a litigation tactic. For accused infringers, inequitable conduct has two principal values as a litigation tactic, particularly when liability issues (e.g., infringement, validity, and enforceability) are tried together in an unbifurcated jury trial.⁷¹

One incentive to assert the inequitable conduct defense is its effect of rendering the entire patent, and possibly any descendant patents,⁷² unenforceable. Under current doctrine the entire patent is unenforceable, even if inequitable conduct is proven as to just a single claim and the misrepresentation

71. Because inequitable conduct is an issue arising in equity, there is no Seventh Amendment right to jury trial. *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993). Nonetheless, the issue is frequently tried to a jury, either with the jury as the fact finder or, more frequently, with the jury acting in an advisory capacity for the court. *See, e.g.*, *Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V.*, 464 F.3d 1339 (Fed. Cir. 2006); *ISCO Int'l, Inc. v. Conductus, Inc.*, 123 F. App'x 974 (Fed. Cir. 2005); *Specialty Rental Tools & Supply, Inc. v. Boyd's Bit Serv., Inc.*, 84 F. App'x 90 (Fed. Cir. 2003); *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098 (Fed. Cir. 2003); *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728 (Fed. Cir. 2002); *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365 (Fed. Cir. 2001); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306 (Fed. Cir. 2000); *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 161 F.3d 688 (Fed. Cir. 1998); *Hupp v. Siroflex of Am., Inc.*, 122 F.3d 1456 (Fed. Cir. 1997); *Cargill, Inc. v. Sears Petroleum & Transp. Corp.*, 388 F. Supp. 2d 37, 62 (N.D.N.Y. 2005); *Echometer Co. v. Lufkin Indus., Inc.*, No. 7:00-CV-0101-N, 2004 U.S. Dist. LEXIS 30583, at *1–2 (N.D. Tex. Mar. 22, 2004); *ISCO Int'l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, 499–500 (D. Del. 2003); *Transclean Corp. v. Bridgewood Servs., Inc.*, 101 F. Supp. 2d 788, 792 (D. Minn. 2000). Due to the technical complexity of patent cases, together with the potential for certain issues to be case-dispositive, and the risk that evidence pertinent only to some issues will “infect” decision-making on other issues, courts have frequently experimented with various forms of bifurcation or phasing in patent jury trials. *Cf.* J. Howard T. Markey, *On Simplifying Patent Trials*, 116 F.R.D. 369 (1987). *But see* Rita Mankovich Irani, *The New Skirmish in Patent Cases: Who Goes First at Trial and with What Evidence?*, 17 AIPLA Q.J. 364 (1989).

72. The doctrine of declaring related patents unenforceable is known as infectious unenforceability. *Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884, 902 (N.D. Ill. 2006) (discussing doctrine of infectious unenforceability), *aff'd*, 504 F.3d 1223 (Fed. Cir. 2007). The requirements for infectious unenforceability are not clearly defined, but center on an “immediate and necessary relation” between the claims tainted by inequitable conduct and claims in related patents sought to be declared unenforceable through infectious unenforceability. *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 810–11 (Fed. Cir. 1990).

or omission does not impact the other claims of the patent.⁷³ Likewise, because of its capacity to take down the entire patent, the target claim for an inequitable conduct defense need not even be one of the claims that the plaintiff has asserted in its infringement action.

Additionally, an allegation of inequitable conduct introduces a pro-defendant narrative of human drama into a proceeding that a jury might otherwise find to be dry and technical. Infringement analysis requires comparing the accused products to the asserted claims on a limitation by limitation basis,⁷⁴ and invalidity analysis requires comparing the asserted claims to the prior art.⁷⁵ Patent owners frequently tell an invention story to introduce a spark of human drama in patent cases. In the archetypical invention story, the inventor is a kind of hero, toiling away in obscurity on a problem that most of her contemporaries thought could not be solved. The invention is conceived in a "Eureka!" moment that goes on to change the lives of millions of Americans. Inequitable conduct provides the accused infringer a counter-narrative with which to impugn the character of the inventor. The inequitable conduct narrative presents the inventor and the lawyer who prosecuted the patent application as scoundrels who lied, cheated, and misled the Patent Office to obtain issuance of the patent. The power of this counter-narrative provides accused infringers a strong incentive to tell it whenever possible.

The question of undesirability of inequitable conduct as a litigation tactic may thus be summarized in this fashion. The doctrine of inequitable conduct, as it currently stands, is overbroad. The standards for materiality, intent, and their equitable balancing are vaguely and inconsistently defined in the case law. The sole remedy, unenforceability of the entire patent, provides a complete victory to the accused infringer who successfully asserts the inequitable conduct defense in litigation. This combination of vague standards and a powerful remedy incentivizes accused infringers to assert the defense whenever possible, strategically choosing articulations of the standards that are most favorable to the particular facts of the case. Moreover, because inequitable conduct renders the entire patent unenforceable, a party has further incentives to allege the defense as to claims that it has not been accused of infringing.⁷⁶ Viewed from a perspective of valuing the integrity of the judicial

73. *Fox Indus., Inc. v. Structural Pres. Sys., Inc.*, 922 F.2d 801, 804 (Fed. Cir. 1990).

74. *E.g., In re Gabapentin Patent Litig.*, 503 F.3d 1254, 1259 (Fed. Cir. 2007).

75. *E.g., In re Crish*, 393 F.3d 1253, 1256 (Fed. Cir. 2004).

76. *See Lynch, supra* note 6, at 8, 15–18 (summarizing tactical reasons to assert inequitable conduct in litigation).

process (and certainly from the perspective of patentee-plaintiffs⁷⁷), such a broad, litigation-strategy-motivated use of the inequitable conduct doctrine may indeed be undesirable.⁷⁸

This is not to say that the inequitable conduct defense is undesirable as a whole. Patentees who intentionally withhold information or make misleading statements to the Patent Office, with the intent to deceive the Patent Office, should be held accountable for that conduct when it is sufficiently egregious. Thus, it is not the defense itself that presents problems; rather, the boundaries of the doctrine as it has evolved have become vague and malleable, inviting the over-use of the inequitable conduct defense as a litigation tactic, even in cases where the factual basis for asserting the defense is weak.

77. The author of this Article claims no affiliation with either a pro-patentee or pro-defendant point of view. However, it is important to keep in mind that some of those who advocate for or against particular reform proposals do likely have a self-interested bias concerning the desirability or undesirability of a broad inequitable conduct doctrine.

78. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349–50 (Fed. Cir. 2008) (Rader, J., dissenting). Judge Rader wrote,

Although designed to facilitate USPTO examination, inequitable conduct has taken on a new life as a litigation tactic. The allegation of inequitable conduct opens new avenues of discovery; impugns the integrity of patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a case without the rigors of claim construction and other complex patent doctrines. This court has even observed a number of cases, such as this one, that arrive on appeal solely on the basis of inequitable conduct where the trial court has apparently elected to try this issue in advance of the issues of infringement and validity.

Id.; see also S. REP. NO. 110-259, at 3 (2008) (characterizing inequitable conduct’s defects as “troubling, plaintiff-focused litigation concerns”); *id.* at 3–4 n.11 (citing testimony from congressional hearings); *id.* at 33 n.156 (“The Committee heard some concerns that inequitable conduct is ‘over plead’ and a tool of harassment.”); *id.* at 59–62. The Committee Report noted,

[S]hifting standards [of inequitable conduct] . . . encourage improper challenges to patents . . . giv[ing] rise to significant litigation costs and uncertainty about patent rights The inequitable conduct defense today has become a convenient and frequently raised litigation tactic that is overpled and a quick route to taking down otherwise valid and commercially valuable patents The defense has proven to be irresistible for litigants—if proven, it allows an infringer to escape any liability for infringing a valid patent. This powerful incentive leads defendants to raise even the most questionable inequitable conduct challenges on the remote chance that they will prevail.

Id.; H.R. REP. NO. 110-314, at 21, 43 (2007) (explaining how inequitable conduct is over-used, leading to complexity, expense and uncertainty in patent litigation, with the burden falling disproportionately on the patent owner).

B. THE PREVALENCE OF INEQUITABLE CONDUCT

Having thus considered the undesirability of inequitable conduct as a litigation tactic, this Section examines empirical data in order to assess the prevalence of the inequitable conduct defense.⁷⁹

1. Methodology and Data

In particular, this Section analyzes data from the Federal Circuit cases decided between 1982 and 2008⁸⁰ that address inequitable conduct, together with selected data from the district courts.

The Federal Circuit has issued over 600 cases since 1983 that mention “inequitable conduct.”⁸¹ Over 300 of those cases substantively address, and contain a ruling on, an issue of inequitable conduct. In most cases, that ruling was made directly on the merits of a defense of inequitable conduct. Some-

79. Chief Judge Michel has called for the use of more empirical data, particularly in relation to Congress’ patent reform efforts. Paul R. Michel, Chief Judge, U.S. Court of Appeals for the Fed. Circuit, A Strong Patent System, As Prepared For Delivery to the Association of Corporate Patent Counsel 2 (Jan. 28, 2009), *available at* http://www.cafc.uscourts.gov/pdf/1-28-09_CJMACPC_Speech.pdf (referring to “claims . . . made in vague, general terms, devoid of statistics” and criticizing the absence of “comprehensive data about real cases”).

80. The data set for this analysis includes only Federal Circuit cases that use the phrase “inequitable conduct” (as identified by a Westlaw search of the CTAF database using the search term “inequitable conduct”) and that substantively address an issue of inequitable conduct (as identified by a manual review of the cases). See Shashank Upadhye, *Liar Liar Pants on Fire: Towards a Narrow Construction for Inequitable Conduct As Applied to the Prosecution of Medical Device and Drug Patent Applications*, 72 UMKC L. REV. 669, 727, 734 (2004) (providing a selective listing and categorization of cases). Additionally, there are a handful of early Federal Circuit cases that address an early iteration of the defense as “fraud on [or in] the Patent Office.” *Sun-Tek Indus., Inc. v. Kennedy Sky Lites, Inc.*, 848 F.2d 179 (Fed. Cir. 1988); *Concrete Unlimited Inc. v. Cementcraft, Inc.*, 776 F.2d 1537 (Fed. Cir. 1985); *USM Corp. v. SPS Tech., Inc.*, 770 F.2d 1035 (Fed. Cir. 1985); *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437 (Fed. Cir. 1984); *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529 (Fed. Cir. 1984); *Preemption Devices, Inc. v. Minn. Mining & Mfg. Co.*, 732 F.2d 903 (Fed. Cir. 1984); *Studiengesellschaft Kohle, M.B.H. v. Dart Indus., Inc.*, 726 F.2d 724 (Fed. Cir. 1984); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983); *Envtl. Designs, Ltd. v. Union Oil Co. of Calif.*, 713 F.2d 693 (Fed. Cir. 1983). However, because the doctrine of inequitable conduct is broader than fraud, see *J.P. Stevens & Co. v. LexTex Ltd., Inc.*, 747 F.2d 1553, 1559 (Fed. Cir. 1984), and because none of these cases found fraud to exist (i.e., they affirmed district court findings of no fraud, or vacated or reversed district court findings of fraud), they have not been included in the data set. In essence, the no-fraud rulings cannot necessarily be equated with no-inequitable-conduct rulings because conduct that is found to be short of the narrow definition of fraud could have nonetheless satisfied the elements of the more expansive definition of inequitable conduct.

81. Westlaw, CTAF Database (providing search results following search term “inequitable conduct”).

times, however, the ruling was made in the context of some other issue, such as a request for attorneys’ fees. The data set includes all rulings that substantively address inequitable conduct. Additionally, as an approximate measure of the Federal Circuit’s overall load of patent cases, this Section examines the number of reported cases in the Federal Circuit database in Westlaw that use the term “patent.”⁸²

Insofar as Federal Circuit decisions effectively represent the final terminus of the litigation cycle for inequitable conduct cases,⁸³ pleadings at the district court stage represent the initial terminus. However, with nearly 50,000 patent cases filed in the same 26-year period (1983–2008),⁸⁴ it was beyond the scope of this Article to manually compile and examine the pleadings in those cases. Accordingly, this Article compiled data concerning pleadings alleging inequitable conduct from two sources, Westlaw’s Federal Filings database (Westlaw) and the Stanford Intellectual Property Litigation Clearinghouse (IPLC).⁸⁵ These sources include data on the extent to which inequitable conduct is asserted in pleadings since the year 2000. The Westlaw search⁸⁶ identifies the number of answers or other responsive pleadings in Westlaw’s database of federal court filings⁸⁷ that include the terms “inequitable conduct”

82. Westlaw, CTAF Database (providing sources from search conducted on Oct. 12, 2009, using search terms “patent” and da(=yyyy)).

83. The Supreme Court has not heard a case involving inequitable conduct or related doctrines in over sixty years. The last such case was *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806 (1945).

84. See *infra* Table 2, col. A.

85. Stanford IP Litigation Clearinghouse, <http://lexmachina.stanford.edu> (last visited Feb. 25, 2009) (providing search results for an advanced search conducted on February 25, 2009. Search results restricted to patent cases, restricted to answers, using search term “inequitable conduct,” with a date restriction of cases docketed between 1/1/yyyy and 12/31/yyyy for 2000–2008).

86. Westlaw, FED-FILING-ALL Database (limiting Oct. 12, 2009 search to “Pleadings” and “Answers and Counterclaims,” and utilizing the search terms “inequitable conduct” & patent & da(=yyyy)). The number of documents resulting from this search may be somewhat over-inclusive as an indicator of the number of cases in which inequitable conduct is pled, to the extent multiple answers (e.g., amended pleadings or replies to counterclaims) allege inequitable conduct in same case. However, assuming the rate of multiple pleadings remains constant from year to year, the rate of change from year to year would not be impacted by any such over-inclusiveness. The data may also be somewhat under-inclusive, to the extent inequitable conduct is alleged in a complaint (e.g., unfair competition or declaratory relief claim) and inequitable conduct is not specifically mentioned in the answer.

87. Westlaw, FED-FILING-ALL Database. According to Westlaw’s online database summary, as of January 2009, this database provides coverage starting in 2000. As of October 2009, the same summary stated that the database provided coverage starting in 1995. Although searches for the years 1991–1999 provided non-zero results, those results cannot be compared with results from the IPSC. Those results have been presented in italics in Table

and “patent.” This search provides an approximation of the number of cases in which inequitable conduct is pled.

Data from both the Federal Circuit and district court searches are summarized below in Table 1. Table 1 also includes the number of patent cases filed⁸⁸ in U.S. District Courts each year.⁸⁹

1, but are not otherwise addressed in this Article.

88. U.S. Courts, Judicial Business of the United States Courts, www.uscourts.gov/judbususc/judbus.html (last visited Oct. 22, 2009) (hosting annual reports for 1993–2008). See also Patstats.com, Historical Filings, http://www.patstats.org/Historical_Filings_Patent_Suits_OtherSuits.doc (providing Administrative Office of U.S. Courts annual report statistics for 1983–2007). But see Amanda Bronstad, *Patent Infringement Filings Take a Nosedive*, NAT’L L.J., Jan. 19, 2009, available at <http://www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1202427537496> (citing data from Stanford IP Litigation Clearinghouse and indicating that only 2605 patent suits were filed in 2008).

89. It does not include, for example, patent infringement cases initiated in the ITC; however, the number of such cases, or investigations, is relatively minimal. For a list of all ITC Section 337 investigations, which number fewer than 700 instituted between 1976 and 2008, See Listing of U.S. International Trade Commission Section 337 Investigations, <http://info.usitc.gov/ouii/public/337inv.nsf/All?OpenView> (last visited Feb. 16, 2010). See also RUSSELL E. LEVINE, THE PRO’S AND CON’S OF PATENT LITIGATION BEFORE THE INTERNATIONAL TRADE COMMISSION 1 (2006), http://www.abanet.org/litigation/committees/intellectual/roundtables/1106_outline.pdf (stating that from 1995 to 2000, an average of 12 investigations were instituted annually, and that the number of investigations increased to 34 in 2006).

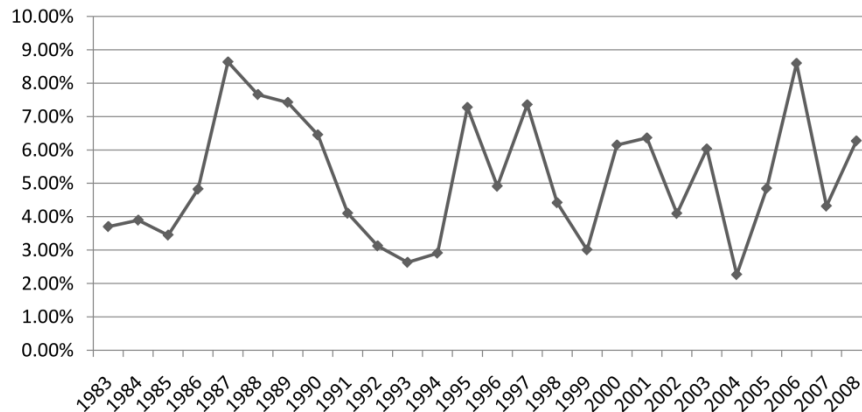
Table 1: Inequitable Conduct Data

Year	Patent Cases Filed	District Court: IC Pled		Federal Circuit:			
		West	IPSC	IC	No IC	DCT Vacated	All Patent Cases
1983	1017			1	3	0	108
1984	1057			3	3	0	154
1985	1155			2	4	1	203
1986	1105			2	9	0	228
1987	1129			5	14	0	220
1988	1226			0	15	3	235
1989	1155			1	12	4	229
1990	1238			4	10	0	217
1991	1171	2		1	5	2	195
1992	1474	2		1	5	0	192
1993	1553	5		3	2	0	190
1994	1617	3		1	2	2	172
1995	1723	10		4	10	2	220
1996	1840	7		4	7	0	224
1997	2112	17		4	14	2	272
1998	2218	33		1	10	0	249
1999	2318	40		1	7	0	266
2000	2484	110	75	3	11	1	244
2001	2520	200	186	2	16	0	283
2002	2700	362	335	2	8	2	293
2003	2814	565	473	2	13	2	282
2004	3075	759	671	0	4	2	265
2005	2720	827	944	5	6	3	289
2006	2830	926	1087	3	16	3	256
2007	2896	1148	1472	5	6	1	278
2008	2909	1157	1631	4	14	1	319

2. Preliminary Analysis of Federal Circuit Data

To test the proposition that the inequitable conduct allegations are growing, this Article first looked at the percentage of Federal Circuit cases per year that address inequitable conduct, regardless of the outcome the Federal Circuit reached on the inequitable conduct issue. This is illustrated in Figure 2.

Figure 2: Percentage of Federal Circuit Patent Cases Addressing Inequitable Conduct



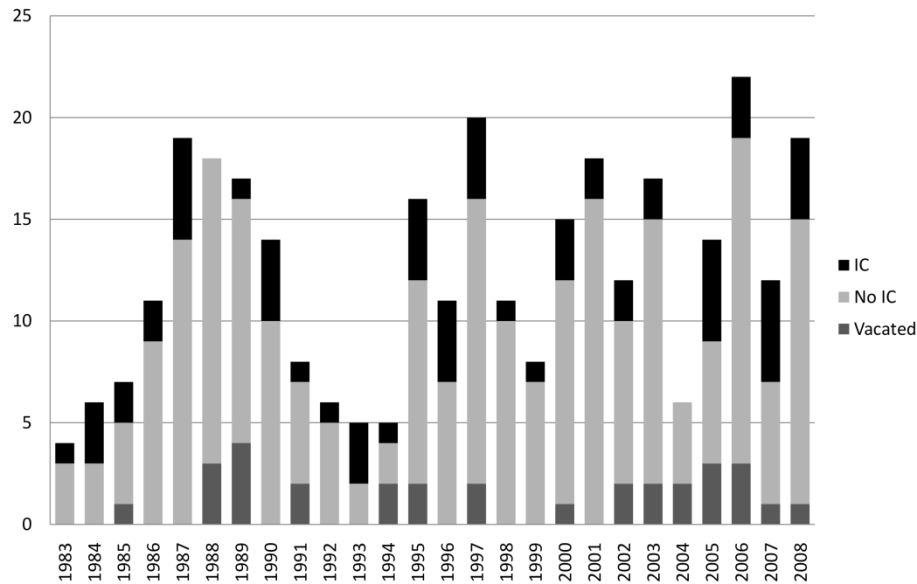
The total body of Federal Circuit inequitable conduct decisions shows a large spike in the number of cases in 1987, the year before *Kingsdown* and *Burlington* were decided, with a marked drop in the number of cases ruling on inequitable conduct during the period 1988 through 1994. Since then, the results at the Federal Circuit level have been mixed. Because the Federal Circuit's overall load of patent cases has fluctuated and generally increased over time, it would be reasonable to expect a corresponding variation in the absolute number of inequitable conduct rulings by the Federal Circuit. To account for this variation in the Federal Circuit's patent case load, the graph in Figure 2 provides a year-by-year detail of the percentage of Federal Circuit patent cases that address inequitable conduct (measured as the ratio of the number of Federal Circuit cases that address inequitable conduct to the number of Federal Circuit cases using the term "patent").

In 2006, the year of the *Ferring* and *Digital Control* decisions, the percentage of cases addressing inequitable conduct nearly reached the level seen in 1987. Otherwise, the wide fluctuation in the percentages since 1994 does not provide conclusive insights.

In addition to analyzing the overall frequency of all inequitable conduct rulings, it may be useful to assess how the Federal Circuit actually ruled on the inequitable conduct issue. This Article separates the rulings into three categories: "IC" when the Federal Circuit affirmatively ruled there was inequitable conduct, "No IC" when the Federal Circuit affirmatively ruled there was no inequitable conduct, and "Vacated" when the Federal Circuit vacated a district court ruling on inequitable conduct. The results of this analysis are

in Figure 3, which shows the absolute numbers (rather than percentages) of the various types of inequitable conduct rulings.

Figure 3: Federal Circuit Cases Addressing Inequitable Conduct



The graph in Figure 3 shows several noteworthy data points. In 1987, the year before *Kingsdown* and *Burlington*, the Federal Circuit found inequitable conduct to exist in five cases. Over the next several years, although the total count of inequitable conduct rulings remained relatively high, the number of “IC” cases dropped significantly. There was not another year with five “IC” rulings until 2005. This can be seen in Figure 4, which shows only the cases where the Federal Circuit found inequitable conduct.

Figure 4: Number of CAFC Cases Finding Inequitable Conduct

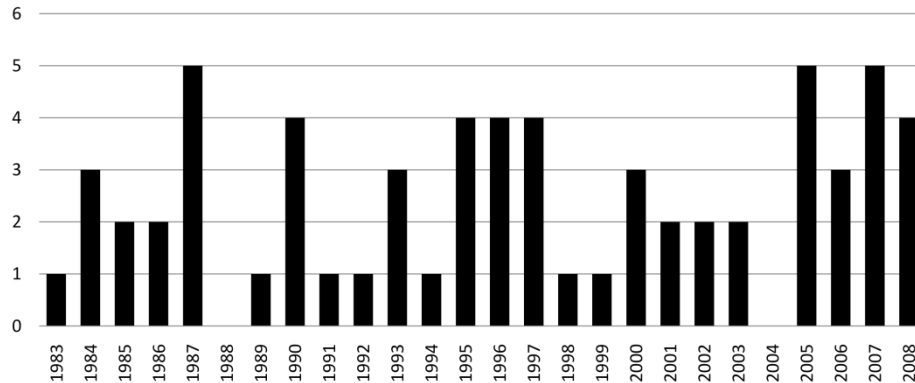


Figure 4 shows a cluster of three to five “IC” rulings per year over the past four years. This is above the average of just over 2.5 “IC” rulings per year. In absolute numbers, that sustained above-average trend is unmatched in the history of the Federal Circuit. But is it appropriate to declare the recent trend a “plague,” relative either to the 1987–1988 period, or to the overall 25-year pattern of inequitable conduct rulings? Given the overall growth in the Federal Circuit’s case load over that period, this conspicuous cluster may not be sufficiently decisive to warrant declaration of a “plague.”

3. *Further Analysis of Federal Circuit Data*

Several additional patterns emerge when the Federal Circuit data is examined more closely. Virtually all of the Federal Circuit’s findings of inequitable conduct affirm lower-court findings of inequitable conduct. Federal Circuit courts affirm lower court “No IC” rulings 92% of the time. By contrast, Federal Circuit courts affirm “IC” findings only 41% of the time. These patterns are illustrated in Figures 5 and 6.

Figure 5: Federal Circuit Dispositions of “No IC” Ruling by District Court

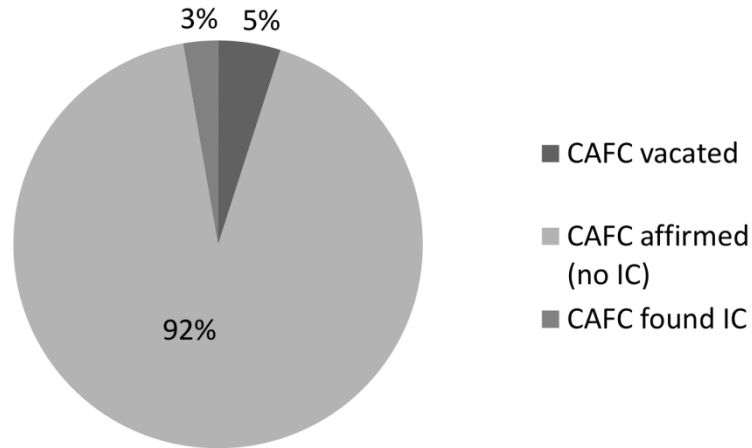
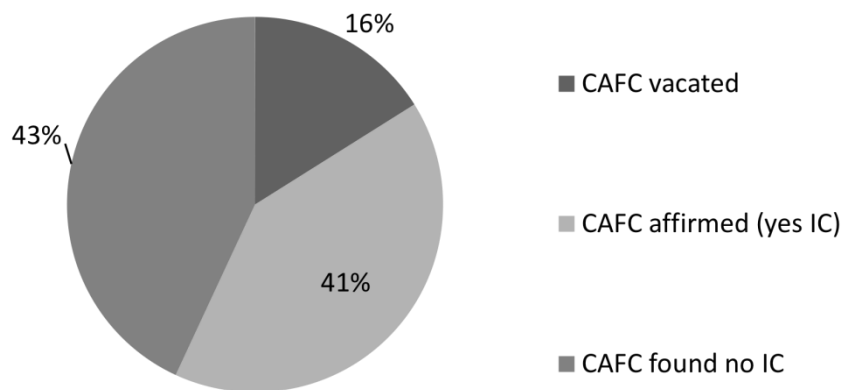


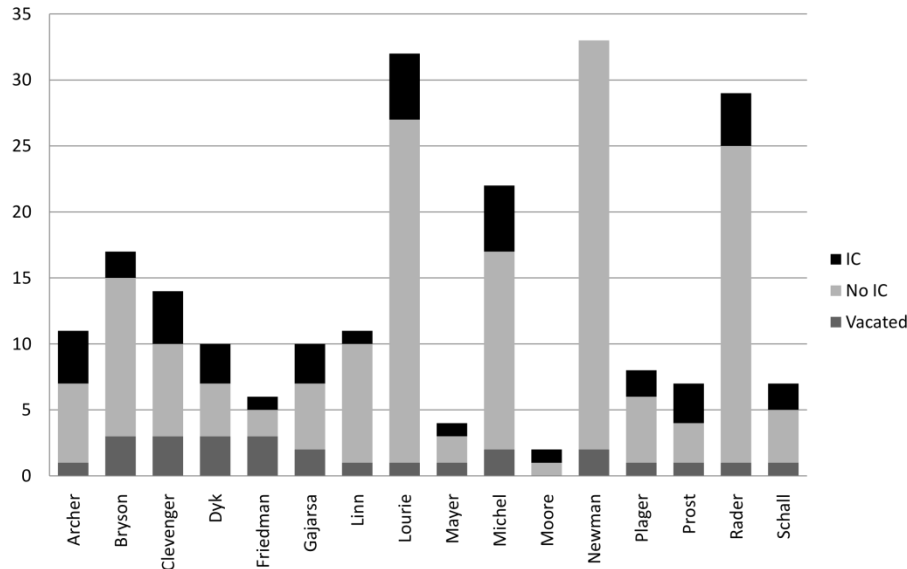
Figure 6: Dispositions of IC Findings by District Court



Another way to examine the Federal Circuit data is to consider whether the cases characterizing inequitable conduct as a “plague” reflect the perspectives of particular judges. In fact, not all judges are equally disposed to support or reject inequitable conduct claims. The next chart, Figure 7, identifies the number of majority opinions with inequitable conduct rulings written by each sitting judge on the Federal Circuit.⁹⁰

90. This chart has been limited to sitting judges, and has excluded former judges and judges from other courts who authored an opinion while sitting by designation on the Federal Circuit. *See* United States Court of Appeals for the Federal Circuit, Judicial Biographies, <http://www.cafc.uscourts.gov/judgbios.html> (last visited Oct. 22, 2009) (providing a list of the current and former judges of the Federal Circuit).

Figure 7: Authors of Majority Opinions Concerning Inequitable Conduct



The height of the bar for each judge correlates approximately with his or her tenure on the court. Thus, for example, Judges Newman (appointed 1984), Michel (appointed 1988), Rader (appointed 1989), and Lourie (appointed 1990) have the longest tenure.⁹¹ Perhaps the most striking feature of this graph is that, despite her long tenure and many opinions, Judge Newman has *never* written a majority opinion supporting a finding of inequitable conduct. When this fact is considered, it should come as no surprise that, although she did not originally coin the “plague” label, she is responsible for nine of the twelve subsequent characterizations of inequitable conduct as a “plague” in Federal Circuit opinions.⁹² Judges Lourie and Rader together are responsible for the remaining three opinions. The six most recent invoca-

91. One curious exception to this pattern appears to be Judge Mayer (appointed in 1987). Also, the pattern does not hold for the judges who have taken “senior” status (Judges Friedman, Archer, Plager and Clevenger).

92. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1196–97 (Fed. Cir. 2006), *cert. denied*, 549 U.S. 1015 (2006); *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1155 (Fed. Cir. 2003); *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003); *Ohio Cellular Prods. Corp. v. Adams USA, Inc.*, 175 F.3d 1343, 1355 (Fed. Cir. 1999); *Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1469 (Fed. Cir. 1998); *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1482 (Fed. Cir. 1998); *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1998); *Allied Colloids Inc. v. American Cyanamid Co.*, 64 F.3d 1570, 1578 (Fed. Cir. 1995).

tions of “plague” have appeared in dissenting opinions, five of which were written by Judge Newman.⁹³

4. *Analysis of District Court Data*

It appears that the patterns of inequitable conduct rulings at the Federal Circuit are not strongly indicative of a “plague.” While there is an identifiable cluster of inequitable conduct findings in the past several years, the overall pattern of the Federal Circuit is to affirm most findings of “No IC” and to vacate or reverse over half of the lower court findings of inequitable conduct that it addresses on appeal.

The data concerning the frequency with which inequitable conduct is pled in the district courts tells a different story. There has been a strong upward trend. Table 2 analyzes some of the data identified in Table 1.⁹⁴

93. *McKesson*, 487 F.3d at 926; *Ferring*, 437 F.3d at 1196–97; *Ulead*, 351 F.3d at 1155; *Hoffmann-La Roche*, 323 F.3d at 1372; *Ohio Cellular*, 175 F.3d at 1355.

94. Table 2 does not include data concerning district court adjudications of inequitable conduct. See Katherine Nolan-Stevaux, Note, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 163–64 (2005) (providing data on summary judgment and post-trial adjudications of inequitable conduct by district courts from 1995–2004); Patstats Home Page, <http://www.patstats.org/patstats2.html> (last visited Nov. 18, 2009) (compiling statistics on patent cases, including district court rulings on inequitable conduct).

Table 2: Selected Data from District Court Filings and Federal Circuit Outcomes

	A	B	C	D	E	F	G	H
	District Courts			Federal Circuit			IC @	IC @
Year	Patent Cases Filed	IC Pled	IC Pled ÷ Cases Filed	IC	No IC	DCT Vacated	CAFC ÷ IC Pled	CAFC ÷ Patent Cases Filed
1983	1017			1	3	0		0.10%
1984	1057			3	3	0		0.28%
1985	1155			2	4	1		0.17%
1986	1105			2	9	0		0.18%
1987	1129			5	14	0		0.44%
1988	1226			0	15	3		0.00%
1989	1155			1	12	4		0.09%
1990	1238			4	10	0		0.32%
1991	1171	2		1	5	2		0.09%
1992	1474	2		1	5	0		0.07%
1993	1553	5		3	2	0		0.19%
1994	1617	3		1	2	2		0.06%
1995	1723	10		4	10	2		0.23%
1996	1840	7		4	7	0		0.22%
1997	2112	17		4	14	2		0.19%
1998	2218	33		1	10	0		0.05%
1999	2318	40		1	7	0		0.04%
2000	2484	110	4%	3	11	1	2.73%	0.12%
2001	2520	200	8%	2	16	0	1.00%	0.08%
2002	2700	362	13%	2	8	2	0.55%	0.07%
2003	2814	565	20%	2	13	2	0.35%	0.07%
2004	3075	759	25%	0	4	2	0.00%	0.00%
2005	2720	827	30%	5	6	3	0.60%	0.18%
2006	2830	926	33%	3	16	3	0.32%	0.11%
2007	2896	1148	40%	5	6	1	0.44%	0.17%
2008	2909	1157	40%	4	14	1	0.35%	0.14%

Column A lists the number of patent cases filed in U.S. District Courts each year.

Column B identifies the number of answers or other responsive pleadings in Westlaw’s database of federal court filings that include the terms “inequitable conduct” and “patent.” This roughly approximates the number of cases in which inequitable conduct is pled. While Table 1 also includes simi-

lar data from the Stanford IP Litigation Clearinghouse, this Article elects to focus primarily on the Westlaw data, which shows a slightly less extreme (but still dramatic) trend at the district court level.

Column C calculates the number of cases in which inequitable conduct is pled (Column B) divided by the total number of patent cases filed (Column A). Although the Table presents this calculation as a percentage, it is appropriate to note that this calculation may not accurately represent a true percentage, for two reasons. First, the responsive pleadings asserting inequitable conduct may not have been filed in the same year as the case was filed. Second, the numbers of inequitable conduct pleadings may be both under-counted (i.e., pleadings not included in the database) and over-counted (i.e., multiple such pleadings in the same case). Nonetheless, since each of those reasons may fairly be expected to remain constant over time, this ratio does represent a useful depiction of the trend.

Columns D–F⁹⁵ contain the specific Federal Circuit data compiled by the author, as described above in connection with Table 1.

Column G calculates the number of Federal Circuit findings of inequitable conduct (Column D) divided by the number of cases in which inequitable conduct is pled at the district court level (Column B). Again, this ratio is expressed as a percentage, and represents an approximation of the percentage of patent cases in which inequitable conduct is pled that ultimately result in a ruling of inequitable conduct by the Federal Circuit.⁹⁶ This value could be considered an “ultimate success rate” for inequitable conduct allegations. However, it does not account for settled cases (in which the inequitable conduct defense may or may not have been a factor), cases in which the inequitable conduct defense was abandoned, and cases in which the district court ruled on inequitable conduct but either the issue was not appealed or the Federal Circuit did not address the issue on appeal.

Column G indicates that, over the past 7 years (2002–2008), a pleading of the inequitable conduct defense results in a Federal Circuit finding of inequitable conduct in only approximately 1 of 250 cases. Yet, as Column C indicates, it has been pled in about 3 of 10 cases during that same period, with a strong upward trend in the pleading frequency. This 75-fold differential,

95. Westlaw, CTAF Database (providing data compiled by author based on review of cases including phrase “inequitable conduct”). *Cf.* Patstats, <http://www.patstats.org/patstats2.html> (last visited Nov. 18, 2009) (offering various full-year statistics involving issues argued in patent cases, including inequitable conduct).

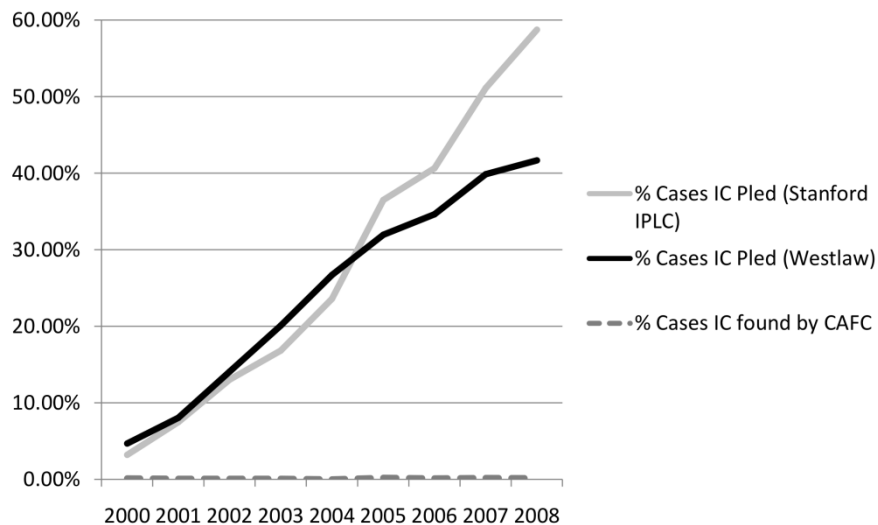
96. The pleadings and Federal Circuit rulings referred to in this ratio are almost certainly never from the same cases; it would be exceedingly rare for a case to proceed from pleading to Federal Circuit ruling within a single calendar year.

between pleading and ultimate success on appeal, supports the widely repeated belief that inequitable conduct is overpled and a “plague.”

Finally, Column H calculates the Federal Circuit’s findings of inequitable conduct (Column D) divided by the total number of patent cases filed in a particular year (Column A), and expresses this ratio as a percentage. With the same caveat noted above that the cases filed and cases decided on appeal within a single calendar year will not be the same cases, Column H approximates the percentage of patent cases filed that ultimately result in a Federal Circuit ruling of inequitable conduct, regardless of the frequency with which inequitable conduct is pled.

The arithmetic mean of Column H is 0.14% (or roughly 1 Federal Circuit finding of inequitable conduct per 700 patent cases filed in the district courts), with a standard deviation of 0.10%. Only a few years (1984, 1987, 1988, 1990, and 2004) fall more than one standard deviation away from the mean, suggesting that the rate at which the Federal Circuit ultimately finds inequitable conduct in patent cases is relatively stable over time, regardless of the frequency with which the defense is pled. Similarly, the 7-year average (2002–2008) 210-fold differential between Column H and Column C (which increased to more than 260-fold in 2007–2008) also supports the “plague” conclusion. Figure 8, below, depicts this growing gap in graphic form. Both the Westlaw and IPLC data are included for emphasis.

Figure 8: Growing Gap Between IC Pleadings and Federal Circuit Rulings of IC



It bears emphasizing that the calculations in Columns G and H cannot represent event-history (actual case-outcome) data. First, no effort has been made to track the history of particular cases by correlating specific filings and

pleadings with Federal Circuit rulings. Second, a case rarely, if ever, progresses from the filing of an answer in the district court to a final disposition by the Federal Circuit within a single year. Typically, two to five years might elapse between those two events in a particular case. In the absence of actual case-history, it would be arbitrary and potentially confusing to correlate appellate outcome data with case-filing data from an earlier year, rather than the same year. Additionally, there is a countervailing factor at play—the impact of recent Federal Circuit rulings on whether inequitable conduct is pled in new filings. That is, it may be appropriate to consider whether a particular Federal Circuit case or trend of cases signals, induces, or encourages parties to plead relatively more or fewer inequitable conduct allegations in subsequently-filed cases. Thus, in the absence of more detailed data about the actual procedural histories of cases or the impact of specific Federal Circuit rulings on subsequent pleadings, and to capture and reflect overall trends, Tables 1 and 2 and Figure 8 simply report the data in the year in which it was filed, and perform calculations on the data as it appears within a particular year.

5. *Conclusions*

To summarize: The overall volume of inequitable conduct cases at the Federal Circuit, both as a percentage of the Federal Circuit’s patent case load, and in terms of absolute numbers of cases finding inequitable conduct, has trended slightly upward in the past several years. But, particularly in light of the Federal Circuit’s pattern of affirming most “No IC” findings and vacating or reversing a majority of lower-court “IC” findings, this trend does not, by itself, appear to be a sufficiently dramatic change to warrant a declaration that a “plague” of inequitable conduct has returned. Among those judges who have expressed concern about inequitable conduct as a “plague,” Judge Newman stands out as particularly vocal on the issue. But are her protestations warranted? The statistical data is suggestive that the prevalence of inequitable conduct cases is expanding, especially at the pleading stage.

Another possible way to address this question is to review some of the Federal Circuit’s recent inequitable conduct decisions and their potential impact on the scope of the inequitable conduct doctrine. The implication may be that recent cases have expanded the doctrine, thus potentially expanding the incentives for accused infringers to allege inequitable conduct as a defense. The next Section of this Article analyzes several recent Federal Circuit inequitable conduct decisions.

IV. RECENT CASES

The Federal Circuit decided six cases during the period 2006–2008 that are of particular importance to the development of the inequitable conduct doctrine. As this Part explains, the *Ferring*, *Digital Control*, *McKesson*, *ESpeed*, *Star Scientific*, and *Praxair* cases have each contributed in important ways to the development of the inequitable conduct doctrine.

A. *FERRING*

*Ferring*⁹⁷ represents a return to the “should have known” standard of intent that was rebuked in *Kingsdown*. Like *Burlington* and *Kingsdown*, the appeal in the 2006 *Ferring* case arose from a district court’s grant of summary judgment of inequitable conduct. *Ferring*’s patent related to medicine administered “orally.”⁹⁸ During prosecution, the examiner considered prior art relating to “peroral” administration of the compound. The applicants argued that “oral” administration meant swallowing for absorption through the gastrointestinal tract, and that “peroral” meant absorption through the walls of the mouth. The examiner suggested that the applicants “obtain evidence from a ‘non-inventor’ ” to support this asserted distinction.⁹⁹ The applicants submitted four such declarations. However, the declarations did not disclose that *Ferring* had previously employed or granted funding to three of the four declarants.¹⁰⁰ The Federal Circuit held that these non-disclosed prior relationships were material information, particularly where the declarants’ neutrality was relevant to the credibility of their assertions.¹⁰¹ The Federal Circuit did not address the substantive truth or accuracy of the declarations, or the fact that one declarant apparently had no such prior relationship with *Ferring*.

Having determined that this omission was material, the Federal Circuit then turned to the intent prong. Although the court recited the rule that “materiality does not presume intent, which is a separate and essential component of inequitable conduct,”¹⁰² it then disregarded the rule and inferred intent from materiality. Specifically, the court announced a new rule stating that where the undisclosed information is highly material, summary judgment on the issue of intent is appropriate if “(1) the applicant knew of the informa-

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

98. *Id.* at 1184.

99. *Id.* at 1183–84.

100. The decision does not mention whether the fourth outside declarant, Miller, had any such connections. *Id.* at 1185.

101. *Id.* at 1188.

102. *Id.* at 1190–91 (quoting *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990)).

tion; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.”¹⁰³

Judge Newman filed a sharp and lengthy dissent, arguing that the majority decision in *Ferring* “resurrects the plague of the past, ignoring the *Kingsdown* requirements of clear and convincing evidence of a misrepresentation or omission material to patentability, made intentionally and for the purpose of deception.”¹⁰⁴ Judge Newman singled out the majority’s intent ruling, stating: “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.”¹⁰⁵

Implications: Although subsequent cases have given *Ferring* a broad scope, it may be interpreted quite narrowly as part of a line of cases including *Refac*¹⁰⁶ and *Paragon*.¹⁰⁷ The *Ferring* majority quotes *Refac* to suggest that factual affidavits present special cases of heightened scrutiny.¹⁰⁸ As *Refac* indicates, affidavits are “inherently material,” even if cumulative, precisely because they are “intended to be relied upon.”¹⁰⁹ This suggests that affidavits generally lie at the higher end of the continuum of materiality, particularly if there are indicia that the examiner actually relied on the contents of the affidavits.¹¹⁰ If so, then a relatively lower degree of intent may be required to support a finding of inequitable conduct arising out of an affidavit. *Ferring* stands for the proposition that the failure to disclose the existence of prior dealings or relationships between an affiant and a patent applicant is inexcusable, as the applicant or the affiant “should have known” that the existence of any such relationships would be pertinent. This use of the “should have known” standard in the summary judgment context comes perilously close to outright abrogation of the intent element of inequitable conduct. Whatever the doctrinal merit of this ruling, one pragmatic response to *Ferring* for patent prosecutors and inventors is to ensure that any affidavits submitted during prose-

103. *Id.* at 1191.

104. *Id.* at 1197.

105. *Id.* at 1202; accord Lynn C. Tyler, *Kingsdown Fifteen Years Later: What Does it Take to Prove Inequitable Conduct?*, 13 FED. CIR. B.J. 267, 268–69 (2003) (arguing that courts should not infer intent solely from failure to disclose a known reference that is material).

106. *Refac Int’l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576 (Fed. Cir. 1996).

107. *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182 (Fed. Cir. 1993).

108. *Ferring*, 437 F.3d at 1189 n.9 (quoting *Refac*, 81 F.3d at 1583).

109. *Refac*, 81 F.3d at 1583.

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

cution scrupulously disclose all possible interests or relationships with the patent applicants.¹¹¹

B. *DIGITAL CONTROL*

In February 2006, the same month it decided *Ferring*, the Federal Circuit reaffirmed the vitality of the "reasonable examiner" test in *Digital Control v. Charles Machine Works*,¹¹² ruling that the test represented the broadest (and lowest) threshold of materiality in the doctrine of inequitable conduct. The Federal Circuit affirmed the district court's ruling that misstatements in the applicant's Rule 131 declaration (i.e., a declaration to establish an earlier invention date, in order to "swear behind" prior art) were material, but reversed summary judgment on the materiality of undisclosed prior art, holding that there were fact issues concerning the prior art's cumulativeness.¹¹³

On the issue of intent, the Federal Circuit held that the district court had intertwined its findings on the Rule 131 declaration and the undisclosed prior art, requiring remand to separate out the intent analysis.¹¹⁴

In reaching this ruling, the Federal Circuit summarized the history of the materiality prong, explaining that several standards for materiality had been applied throughout the history of the doctrine of inequitable conduct.¹¹⁵ After reviewing these various standards, the court ruled that the 1977 "reasonable examiner" test remained applicable, even as to patents prosecuted entirely after 1992.¹¹⁶ The court found that the 1992 standard did not supplant the "reasonable examiner" standard, and that it therefore remained viable as the broadest threshold level of materiality.¹¹⁷ This ruling effectively relegated to the sidelines the more objective definition of materiality introduced by the PTO's 1992 revision of Rule 56.

111. Senators Specter and Hatch have specifically criticized *Ferring* for finding "an applicant's failure to adequately disclose its relationship with an expert to be material even though the expert's views were accurate and true." S. REP. NO. 110-259, at 60 (2008) (noting additional views of Senators Specter and Hatch).

112. *Digital Control*, 437 F.3d 1309.

113. *Id.* at 1319, 1321–22.

114. *Id.* at 1321.

115. *Id.* at 1314–16.

116. *Id.* at 1316 ("[T]he 'reasonable examiner' standard and our case law interpreting that standard were not supplanted by the PTO's adoption of a new Rule 56."). Compare 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, 1557–64 (2008) (arguing for application of the 1992 Rule 56 standard of materiality), with James Cronin, *Inequitable Conduct and the Standard of Materiality: Why the Federal Circuit Should Use the Reasonable Patent Examiner Standard*, 50 ST. LOUIS U. L.J. 1327, 1328–29 (2006) (arguing for application of the reasonable examiner standard).

117. *Id.*

Judge Newman repeatedly has disapproved of this ruling. In *Ferring*, Judge Newman argued in dissent that “[t]he court in *Digital Control* holds, in contradiction of precedent, that it will hold practitioners to the standard of the pre-1992 version of Rule 56 for patents prosecuted after 1992, even though that standard no longer exists.”¹¹⁸

The enacting history accompanying the 1992 revisions, which refers to the “plague” of inequitable conduct claims as a motivation for the amendment, supports Judge Newman’s view.¹¹⁹ The 1992 amendments were intended to provide a clearer and more objective rule, which was less vague than the “reasonable examiner” standard.¹²⁰ The 1992 rule was proposed to ameliorate uncertainty in the “reasonable examiner” standard, with aspirations to minimize litigation while still providing the PTO the information it needed for efficient and effective examination.¹²¹ Former PTO Commissioner Gerald Mossinghoff has also opined that the 1992 version of Rule 56 should govern post-1992 patents.¹²²

Separation-of-Powers Issue: The debate between the majority and dissent in *Digital Control* exposes a deeper issue concerning separation of powers and the origins of the inequitable conduct doctrine. Under the majority’s approach, inequitable conduct is a judicially-created doctrine.¹²³ As such, no deference is owed to the PTO’s determinations of what information is material to patent prosecution. The *Digital Control* majority noted that the Federal Circuit has articulated several different tests for materiality, which corroborates this view.¹²⁴ However, the court has pervasively referred to PTO Rule 56 for

118. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1202 n.3 (Fed. Cir. 2006) (Newman, J., dissenting). *See also* *Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1384 (Fed. Cir. 2006) (Newman, J., dissenting).

119. Duty of Disclosure and Practitioner Misconduct, 54 Fed. Reg. 11,334 (proposed Mar. 17, 1989) (“These proposed changes are considered desirable in view of the large amount of resources that are being devoted to duty of disclosure issues both within and outside the Office without significantly contributing to the reliability of the patents being issued.”).

120. Duty of Disclosure, 56 Fed. Reg. 37,321, 37,322 (proposed Aug. 6, 1991) (to be codified at 37 C.F.R. § 1.56).

121. Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992).

122. Gerald S. Mossinghoff, The Duty of Candor and Good Faith to the United States Patent and Trademark Office, Remarks to the American Bar Association, Intellectual Property Law Section at the 17th Annual Intellectual Property Law Conference (Apr. 12, 2002) (transcript on file with Oblon, Spivak, McClelland, Maier & Neustadt, LLP), *available at* <http://www.oblon.com/media/index.php?id=44> (“My own view is that the courts should apply the version (or versions) of Rule 56 that was (were) in effect at the time the conduct objected to occurred.”).

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

124. *Id.*

the definition of materiality, most commonly using the “reasonable examiner” standard. If the PTO was the originator of the “reasonable examiner” standard, with the courts following suit, it would stand to reason that the courts would owe some deference to any PTO modifications of the standard.

In contrast, under the approach Judge Newman takes in dissent, the PTO ought to be vested with the determination of what information is material to patent examination. Because it conducts such examination, it is therefore entitled to deference, perhaps under a principle analogous to the rule stated by the Federal Circuit in *Garner*: “An agency’s interpretation of its own regulations is entitled to substantial deference and will be accepted unless it is plainly erroneous or inconsistent with the regulation.”¹²⁵ This analogy is imperfect, however, since the concept being interpreted is “materiality” as used in the judicially-created doctrine of inequitable conduct, not “materiality” as used in Rule 56. Moreover, the 1992 amendment is not, strictly speaking, an interpretation of the 1977 rule—though it could be argued that the 1992 amendments may be viewed as the PTO’s interpretation of what a reasonable examiner would want.

In ruling that the 1992 revision to Rule 56 did not supplant the “reasonable examiner” standard, the Federal Circuit disregarded its own precedents and the clearly articulated purpose in Rule 56’s enacting history. The effect of this ruling is that a standard that the PTO has criticized as “vague” could render patents unenforceable for failure to disclose information that the PTO’s own regulations would not require “for effective and efficient examination.”

Implications: Despite this unsettling revival of the “reasonable examiner” standard, the court in *Digital Control* also left two openings for advocates to narrow the scope of inequitable conduct. First, by describing a continuum among the various standards of materiality, the court made clear that the “reasonable examiner” standard occupies the broadest (and therefore lowest) threshold of materiality. Thus, in balancing materiality and intent, “the requisite finding of intent must be high” where only this low threshold of materiality has been met.¹²⁶ *Digital Control*’s quantification of materiality should provide an effective counterpoint to the invariable assertion in litigation that the nondisclosed information in that case is highly material (even if it merely satisfies the “reasonable examiner” threshold) and therefore requires only a low showing of intent. Second, although the Federal Circuit carefully pro-

125. In re *Garner*, 508 F.3d 1376, 1378–79 (Fed. Cir. 2007) (quoting *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1282 (Fed. Cir. 2005)).

126. *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315–16 (Fed. Cir. 2006).

tected its precedents interpreting the “reasonable examiner” standard, it did not rule that the “reasonable examiner” standard and the 1992 version of Rule 56 are substantively different standards. Therefore, a fair and persuasive argument is that the PTO, through the rulemaking process of the 1992 amendment to Rule 56, has defined what information a reasonable examiner (i.e., a PTO employee) would find important in determining patentability. If successful, this argument would establish that the “reasonable examiner” standard—even if not abrogated—is coextensive with the 1992 version of Rule 56.

C. *McKESSON*

In 2007, the Federal Circuit decided *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*¹²⁷ In *McKesson*, the Federal Circuit ruled that the same test for determining the materiality of prior art should apply to determining materiality of rejections in copending applications.¹²⁸ In other words, a rejection of claims in an inventor’s copending application may be material information, and failure to disclose such a rejection can be a basis for finding inequitable conduct.

The district court found U.S. Patent No. 4,857,716 to be unenforceable due to inequitable conduct, and the Federal Circuit affirmed.¹²⁹ *McKesson* involved three lines of patent applications, all prosecuted during approximately the same time period in 1986–1989:

- Application no. 06/862,278 (the ’278 application) led to continuation application no. 07/205,527, which led to U.S. Patent No. 4,857,716.
- The ’278 application also led to continuation-in-part application no. 07/078,195-a, which led to U.S. Patent No. 4,835,372.
- A separate application, no. 06/862,149 (the ’149 application), led to U.S. Patent No. 4,850,009.¹³⁰

Examiner Trafton examined the applications descending from the ’278 application,¹³¹ while Examiner Lev examined the ’149 application.¹³² The same attorney, Schumann, prosecuted all three lines of applications.¹³³ Dur-

127. 487 F.3d 897 (Fed. Cir. 2007).

128. *See id.* at 920–921 (evaluating materiality of examiner’s rejections under reasonable examiner test).

129. *Id.* at 902, 926.

130. *Id.* at 902–07.

131. *Id.* at 903–04, 906–07.

132. *Id.* at 904–06.

133. *Id.* at 902–07.

ing prosecution of the '149 application, Examiner Lev rejected claims on two occasions, and attorney Schumann did not disclose those rejections to Examiner Trafton in the '527 application.

The Federal Circuit affirmed the district court's ruling that attorney Schumann had committed three separate acts of inequitable conduct, including failing to tell Examiner Trafton about Examiner Lev's rejections of copending claims. The patentee argued, based on the *Dayco* case,¹³⁴ that there was no duty to disclose the rejection to Examiner Trafton because the rejected claims were not “substantially similar” to claims pending in the '527 application. In response, the Federal Circuit held that *Dayco* was not binding on the court's materiality inquiry:

Under *Dayco*, [materiality under the reasonable examiner] standard is satisfied in the rejected-claims setting if the rejected claims are substantially similar to the claims at issue. In other words, a showing of substantial similarity is *sufficient* to prove materiality. It does not necessarily follow, however, that a showing of substantial similarity is *necessary* to prove materiality.¹³⁵

This ruling strikes down the bright-line *Dayco* rule that the duty to disclose copending rejections exists only where the claims in the two applications are substantially similar (i.e., “could have conceivably served as the basis of a double patenting rejection”¹³⁶).

The *McKesson* court was also significantly deferential to the district court on the issue of intent, leading Judge Newman to argue in dissent that the “plague” had returned:

To avoid the inequity resulting from litigation-driven distortion of the complex procedures of patent prosecution, precedent firmly requires that the intent element of inequitable conduct must be established by clear and convincing evidence of deceptive intent—not of mistake, if there were such, but of culpable intent. . . . That standard was not met here. This court returns to the “plague” of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent.¹³⁷

134. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003) (holding that intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible).

135. *McKesson*, 487 F.3d at 919 (Fed. Cir. 2007) (emphasis added) (citation omitted).

136. *Dayco*, 329 F.3d at 1365 (quoting *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998)).

137. *McKesson*, 487 F.3d at 926–27 (citation omitted).

Implications: Particularly for large technology companies with many patent applications simultaneously pending before the PTO, the absence of a bright-line rule concerning materiality of rejections in copending applications could impose an enormous burden on both applicants and examiners. The applicants would have to assess whether each office action rejecting claims in any pending application is material to, and therefore must be disclosed in, every single other pending application being prosecuted by that company.

However, as with *Digital Control*, despite the apparent and worrisome broadening of the duty to disclose rejections in copending applications, the court’s ruling provides some clues about arguments that may limit the scope of the ruling. On the issue of intent, the court compared the *McKesson* facts favorably with those found in *Li Second Family LP v. Toshiba Corp.*,¹³⁸ in particular that “the applicant made statements to the examiner [i.e., Trafton] inconsistent with the other examiner’s [i.e., Lev’s] decisions.”¹³⁹ Thus, because Schumann argued to Examiner Trafton that the prior art did not disclose “3-node communication,” and Examiner Lev subsequently made a rejection in another application based in part on prior art that in fact disclosed 3-node communication, Schumann’s failure to disclose Lev’s rejection to Trafton supported an inference that Schumann intended to mislead the PTO via the nondisclosure of information that would have undermined the argument he had made to Trafton. The court’s analysis actually seems more germane to materiality, namely that the fact of having made statements to one examiner inconsistent with the other examiner’s rejection increases the materiality of that rejection to the other application. This interpretation offers a possible fallback bright-line rule.

Additionally, since the court analyzed three separate theories of inequitable conduct for the same patent, the ruling could be interpreted as either endorsing inequitable conduct-by-multiple-minor-transgressions¹⁴⁰ or, alternatively, as including dicta as to two of the three theories. The court tacitly acknowledged these possibilities when it concluded that “[i]t is not necessary to decide whether any one of the three nondisclosures, standing alone, would have been sufficient to justify a judgment of unenforceability.”¹⁴¹

138. 231 F.3d 1373 (Fed. Cir. 2000).

139. *McKesson*, 487 F.3d at 924.

140. See *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed. Cir. 2007) (endorsing a theory of inequitable conduct via a pattern of misconduct).

141. *McKesson*, 487 F.3d at 926.

D. *ESPEED*

In *eSpeed*,¹⁴² the Federal Circuit raised the possibility that disclosing *too much* information to the PTO could result in a finding of inequitable conduct, on the theory that the applicant “buried” material information among irrelevant information. The patent in suit related to a computerized system for trading government securities. Two sets of rules, referred to as the “new rules” and “old rules,” governed the process by which customers could increase their securities purchase volume.¹⁴³ The patentee had a prior art software program called the Super System.¹⁴⁴ During prosecution, three declarations were submitted to the examiner describing the Super System, but indicating that it did not include the “new rules.” Over one thousand pages of exhibits accompanied the declarations, including portions of the Super System source code. The source code submitted in those exhibits demonstrated that the Super System did in fact accommodate the “new rules,” contradicting the assertions made in the declarations. The applicant did not specifically point out these portions of the source code to the examiner.¹⁴⁵

Although the Federal Circuit affirmed the district court’s inequitable conduct ruling, the two courts differed in their approaches. In the *intent* portion of its inequitable conduct ruling, the district court ruled that submitting a “blizzard of paper” without pointing out the references to the “new rules” was “more consistent with an intent to hide than to disclose.”¹⁴⁶ In the *materiality* portion of its opinion, the Federal Circuit “agree[d] with the district court that the ‘blizzard of paper’ submitted to the PTO . . . left the examiner with the impression that the examiner did not need to conduct any further . . . investigation.”¹⁴⁷

Implications: The Federal Circuit’s shift of the “blizzard of paper” discussion from the analysis of intent to the analysis of materiality has led some to speculate that the Federal Circuit was signaling a revival of the doctrine of inequitable conduct by “burying.” In other words, even though an applicant actually submitted a material reference to the examiner, the applicant could nonetheless be found to have committed inequitable conduct by “burying” the reference in a “blizzard of paper” in an effort to prevent the examiner from duly considering it.

142. *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 480 F.3d 1129 (Fed. Cir. 2007).

143. *Id.* at 1131–32.

144. *Id.* at 1132.

145. *Id.* at 1132–33.

146. *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 417 F. Supp. 2d 580, 598 (D. Del. 2006).

147. *eSpeed*, 480 F.3d at 1137 (citing *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1377 (Fed. Cir. 2000)).

Although some historical support exists for the “burying” doctrine,¹⁴⁸ the Federal Circuit rejected that doctrine in *Molins PLC v. Textron, Inc.*¹⁴⁹ Instead of a revival of “burying,” the *eSpeed* ruling is better understood as a straightforward application of the holding in *Rohm & Haas*,¹⁵⁰ that a misstatement to the examiner cannot be “cured” simply by disclosing the correct information to the examiner without comment, and instead can be “cured” only by specifically identifying the misstatement and pointing out how the newly submitted information contradicts the prior misstatement. Moreover, by citing *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*,¹⁵¹ the court evinced some concern that, like references in foreign languages, the relevance of source code may not be readily accessible or apparent to an examiner without some additional explanation. Thus, an alternative explanation of *eSpeed* is that it requires source code submitted to the examiner to be treated like foreign language references, and is not an all-purpose revival of the “burying” doctrine.

E. *STAR SCIENTIFIC*

In *Star Scientific*,¹⁵² decided in August 2008, the Federal Circuit provided a renewed focus on a narrow and clearly defined articulation of the intent element. At the same time, though, it continued to support the “reasonable examiner” standard for materiality. The court reversed a district court finding of inequitable conduct as to two patents.¹⁵³ For one patent, the Federal Circuit ruled that the threshold of materiality was not met.¹⁵⁴ For the other patent, the court ruled that the threshold of intent was not satisfied.¹⁵⁵ The pa-

148. *E.g.*, Rules of Practice in Patent Cases, 42 Fed. Reg. 5588, 5590 (Jan. 28, 1977) (analogizing Rule 56 to a Supreme Court decision relating to the SEC, in which “[t]he Court noted that the standard of materiality should not be so low that . . . the fear of liability would cause management ‘simply to bury the shareholder in an avalanche of trivial information—a result that is hardly conducive to informed decision making.’”); U.S. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2002.03 (5th ed., rev. 3, 1986) (“[N]on-identification of an especially relevant passage buried in an otherwise less or non-relevant text could result in a holding of ‘violation of duty of disclosure.’”). *See also* Glenn E. Von Tersch, *Curing the Inequitable Conduct Plague in Patent Litigation*, 20 HASTINGS COMM. & ENT. L.J. 421, 430–31 (1998) (discussing “burying” issue); Upadhye, *supra* note 80, at 715–17.

149. 48 F.3d 1172, 1183–84 (Fed. Cir. 1995). *But see* Cotropia, *supra* note 15, at 768 (advocating expanding inequitable conduct to include intentional “burying”).

150. *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1572–73 (Fed. Cir. 1983).

151. 204 F.3d 1368, 1372, 1377 (Fed. Cir. 2000).

152. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008).

153. *Id.* at 1360.

154. *Id.* at 1370.

155. *Id.* at 1367–68.

tents in *Star Scientific* related to methods for curing tobacco that would reduce the amount of carcinogens known as tobacco specific nitrosamines (TSNAs) in the tobacco. The predominant method for tobacco-curing in the U.S. from the 1970s to the late 1990s involved burning fuel, typically propane, and blowing the hot exhaust gas directly on the tobacco. Tobacco cured in this manner had higher levels of TSNAs.¹⁵⁶

Williams, an inventor at Star, developed methods of reducing the level of TSNAs in cured tobacco and engaged attorney Delmendo to prosecute the patents.¹⁵⁷ Burton, a Star consultant, sent Delmendo a letter relating his observations about lower TSNA levels in Chinese tobacco, which was cured using an older (radiant-heat) method.¹⁵⁸ Additionally, Williams sent Delmendo data from two U.S. farms that still used the radiant-heat method (the “Jennings data” and the “Curran data”) and had reduced TSNA levels.¹⁵⁹ The Curran data was of a partially cured sample, and Williams’s associate finished curing it with a microwave oven.¹⁶⁰ Delmendo filed several patent applications for Williams.¹⁶¹ Thereafter, Delmendo was replaced as prosecution counsel by Rivard, an attorney from a different firm.¹⁶² In the application that ultimately issued as U.S. Patent No. 6,202,649 (the ’649 patent), Rivard filed a petition to make special, and included an Information Disclosure Statement (IDS) that did not disclose the Burton letter.¹⁶³ Rivard also filed a continuation application (which ultimately issued as U.S. Patent No. 6,425,401 (the ’401 patent)), and filed a petition to make special and IDS in that application, again without disclosing the Burton letter.¹⁶⁴ During prosecution, Rivard became aware of the Burton letter and the Curran data but ultimately did not disclose the letter or the data because he concluded that neither was material.¹⁶⁵

The district court held a bench trial on inequitable conduct, and ruled that both patents were unenforceable.¹⁶⁶ The Federal Circuit, in an opinion by Chief Judge Michel, provided an extended exposition of the elements of inequitable conduct, emphasizing—

156. *Id.* at 1361.

157. *Id.*

158. *Id.* at 1361–62.

159. *Id.* at 1362.

160. *Id.*

161. *Id.* at 1361–62.

162. *Id.* at 1363.

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.* at 1365.

- The need for a threshold level of both materiality and intent;¹⁶⁷
- The court’s discretion to balance the equities and determine that there was no inequitable conduct, even if both thresholds have been met;¹⁶⁸
- The importance of strictly enforcing the clear and convincing burden of proof, since the penalty (“the loss of the entire patent even where every claim clearly meets every requirement of patentability”) is so severe;¹⁶⁹
- The separateness of materiality and intent, and of the proofs of these elements;¹⁷⁰
- When intent is inferred from circumstantial evidence, it must be “the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard;”¹⁷¹ and
- The reasonable examiner standard for determining materiality, and the immateriality of information that is cumulative of information already before the PTO.¹⁷²

Applying these principles, the Federal Circuit reversed, holding that the district court erred for two reasons in concluding that Williams and Star intended to deceive the PTO during prosecution of the ’649 patent. First, defendant R.J. Reynolds (RJR) failed to adduce evidence sufficient to infer intent, and could not carry its burden by relying on the absence of a credible explanation by Star.¹⁷³ Second, the district court clearly erred in finding that the Burton letter and Curran data were material to the prosecution of the ’401 patent, due to their cumulativeness with other information previously disclosed to the examiner.¹⁷⁴

167. *Id.*

168. *Id.* at 1365, 1367.

169. *Id.* at 1365–66 (noting that the doctrine had its origins in fraud but has subsequently become more broad, covering lesser wrongful conduct, without any expansion of remedies to include lesser penalties for less culpable conduct).

170. *Id.* at 1366.

171. *Id.* This articulation accords with the holding in *Kingsdown* that circumstantial evidence must indicate sufficient culpability to “require”—not merely permit—a finding of intent. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988).

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

173. *Id.* at 1365, 1368.

174. *Id.* at 1365, 1370.

Implications: The extensive exposition of the inequitable conduct doctrine in *Star Scientific*, together with the opinion’s admonitions about the severity of the penalty, the high burden of proof (particularly its comments about proof of intent), and the court’s discretion to deny inequitable conduct even where both thresholds have been met, appears to be an effort to limit the influence of various earlier cases that may have stated the standards more loosely. Perhaps inconsistently with that purpose, the opinion again elects the “reasonable examiner” standard as the test for materiality—without any mention of the 1992 version of Rule 56 and its less-malleable, more objective definition of materiality. Also, it bears noting that the opinion is not an en banc ruling and therefore lacks the precedential authority to override inconsistent panel decisions from the Federal Circuit. This limited influence became apparent a month later, when the Federal Circuit issued the *Praxair* decision.

F. *PRAXAIR*

In September 2008, a month after *Star Scientific*, the Federal Circuit decided *Praxair, Inc. v. ATMI, Inc.*,¹⁷⁵ in which it apparently applied a test for materiality even lower and more malleable than the “reasonable examiner” standard, and also reiterated the *Ferring* “should have known” test for intent. The district court ruled that “the level of materiality of the [restricted flow orifice (RFO)] art is sufficiently high so as to support an ultimate finding of inequitable conduct.”¹⁷⁶

The Federal Circuit affirmed the unenforceability of one patent-in-suit. To support its materiality determination, the Federal Circuit did not articulate any of the established standards, instead holding merely that the “overall degree of similarity between the omitted reference and the claimed invention” could be used to determine materiality.¹⁷⁷ On this standard, the nondisclosed art was material.¹⁷⁸ The Federal Circuit then declined to consider Praxair’s argument that the nondisclosed art was cumulative, concluding on a narrow reading of the record that Praxair had failed to raise the argument below.¹⁷⁹

As for intent, the Federal Circuit specifically recited *Ferring*’s ruling that intent can be proven when the applicant should have known of the materiality of known, material art. The court then combined *Ferring* with the holding

175. 543 F.3d 1306 (Fed. Cir. 2008). Judge Dyk, who was on the *Star Scientific* panel and did not dissent, wrote the *Praxair* decision. The differences between the legal standards applied in these two cases cannot therefore be explained away as reflecting the views of two entirely different panels of the Federal Circuit.

176. *Id.* at 1313.

177. *Id.* at 1314–15.

178. *Id.* at 1314.

179. *Id.* at 1315.

in *Critikon*¹⁸⁰ that an applicant who should have known of the materiality of nondisclosed art “can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent” a finding of intent.¹⁸¹ On that basis, the court rejected the prosecuting attorney’s testimony and attempted good faith explanation for not having disclosed the RFO art, affirming the finding of inequitable conduct.¹⁸²

Implications: *Star Scientific* arguably represented an effort by Chief Judge Michel to re-establish doctrinal and analytical rigor to inequitable conduct cases. A month after the *Star Scientific* opinion was issued, one of its panel members authored the *Praxair* opinion, which clearly embraces—and expands—the *Ferring* ruling as to intent, while ignoring the *Star Scientific* decision for both materiality and intent. The contrast between these two cases is strongly suggestive that, without some kind of authoritative restatement of the doctrine of inequitable conduct, various panels of the Federal Circuit will continue to offer up a smorgasbord of inequitable conduct rulings and doctrinal articulations to suit any taste.

These disparate rulings have wrought doctrinal uncertainty that will inexorably lead to over-assertion of the inequitable conduct defense. The implications of many of these cases that mere threshold levels of materiality and intent can regularly support determinations of unenforceability suggest that even if the statistical data does not clearly show a resurgent “plague” of inequitable conduct, at least at the Federal Circuit level, the combined enticements of a strong remedy and an uncertain (and perhaps expanding) legal standard mean the defense could grow even more popular.

It is unclear when the Federal Circuit will undertake another en banc review of the inequitable conduct doctrine—it has been over twenty years since *Kingsdown*. Therefore, perhaps, it is time to consider statutory reform of this judicially-created doctrine.

180. *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997).

181. *Praxair*, 543 F.3d at 1313–14.

182. *Id.* at 1317–18. Noting that a notice of allowability had already issued for the ‘609 patent at the time statements inconsistent with RFO art were made during prosecution of the ‘115 patent, the Federal Circuit reversed as to the ‘609 patent, finding neither materiality nor intent. *Id.* at 1318–19.

V. LEGISLATIVE PROPOSALS TO REFORM INEQUITABLE CONDUCT

In recent years, Congress has seen several proposals for legislative reform of the inequitable conduct doctrine.¹⁸³ The inequitable conduct provisions in these reform proposals have varied considerably in scope. In the 2007–2008 session of Congress, three patent reform bills were introduced, each of which included proposals to reform inequitable conduct.

Congress’ proposed reform measures in all three bills generally fall within one of four broad categories: (1) specifying the prima facie elements of inequitable conduct, specifically materiality and intent; (2) specifying the standard of pleading or proof in litigation in the courts; (3) changing the range of remedies available in the courts; and (4) providing a forum within the PTO (rather than the courts) for adjudication of inequitable conduct allegations. This Article argues that reform should focus only on the first and third items, clarifying the prima facie elements and reforming the remedy. The second item, standards of pleading¹⁸⁴ or proof, is unambiguously established; however, the Federal Circuit’s August 2009 ruling in *Exergen* may significantly increase the Rule 9(b) scrutiny given to inequitable conduct pleadings.¹⁸⁵ The fourth item, a new PTO forum, would cause unwarranted complexity, would

183. The current round of reform efforts started in earnest with the publication of the FTC and NAS reports in 2003 and 2004. *See supra* note 5. Patent reform legislation has been introduced into Congress more or less annually since 2005. Cotropia, *supra* note 15, at 737–41 (summarizing inequitable conduct reform proposals in 2005 and 2006 patent reform legislation); Kevin Mack, Note, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147, 156–61 (2006) (summarizing 2005 patent reform legislation).

184. A search of the Westlaw DCT database, conducted January 17, 2009, with the search terms (9(b) /s “inequitable conduct”) yielded 140 district court cases, dating mainly from 1988 to the present. *E.g.*, *Venetec Int’l, Inc. v. Nexus Medical, LLC*, 541 F. Supp. 2d 612 (D. Del. 2008); *Solarex Corp. v. Arco Solar, Inc.*, 121 F.R.D. 163 (E.D.N.Y. 1988). However, the Federal Circuit did not address the applicability of Rule 9(b) until 2003, when it indicated its applicability to inequitable conduct in dicta. *Ferguson Beauregard/Logic Controls, Division of Dover Resources, Inc. v. Mega Systems, LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003). In 2007, the Federal Circuit squarely ruled that Rule 9(b)’s heightened pleading standard governs inequitable conduct. *Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356–57 (Fed. Cir. 2007) (affirming dismissal of inequitable conduct pleading due to insufficient particularity). In August 2009, the Federal Circuit again held that Rule 9(b) governs pleadings of inequitable conduct, and also set forth greater detail concerning what Rule 9(b) requires. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326–29 (Fed. Cir. 2009). *But see* David Hricik, *Wrong About Everything: The Application by the District Courts of Rule 9(b) to Inequitable Conduct*, 86 MARQ. L. REV. 895 (2003) (arguing that Rule 9(b) should not apply to inequitable conduct).

185. *See supra* note 184.

increase administrative costs, and (as the MPEP acknowledges¹⁸⁶) would require the PTO to investigate allegations of intent to deceive, which lies outside its area of expertise.

The inequitable conduct provisions of each of the recent patent reform bills are discussed in detail below.

A. LEAHY BILL, SENATE BILL 1145

In April 2007, Senators Leahy, Hatch, and eight other senators introduced Senate Bill 1145 (the Leahy bill).¹⁸⁷ Versions of the Leahy bill had been introduced in several previous sessions of Congress.¹⁸⁸ The Senate Judiciary Committee Report supporting the Leahy bill acknowledges that earlier iterations of the bill did not include provisions relating to inequitable conduct,¹⁸⁹ but that three concerns prompted its inclusion: (1) the absence of a clear standard of materiality in the Federal Circuit,¹⁹⁰ (2) the collapse of the intent element into materiality,¹⁹¹ and (3) the courts’ lack of discretion in selecting a remedy.¹⁹²

To remedy these three problems, the Leahy bill proposed to add a new § 298 to the Patent Act. The Leahy bill’s proposed § 298 consists of five subsections. Subsection (a) would codify the *prima facie* elements of inequitable conduct and the requirement that inequitable conduct be proved by clear and convincing evidence; subsection (b) would define materiality using the “reasonable examiner” standard; subsection (c) would permit intent to be inferred, but prohibit proof of intent via “gross negligence” or materiality; subsection (d) would codify the requirement that inequitable conduct be pled with the particularity of Rule 9(b) of the Federal Rules of Civil Procedure;

186. See *supra* note 42 and accompanying text.

187. S. 1145, 110th Cong. (as reported in Senate, Apr. 18, 2007).

188. E.g., S. 3818, 109th Cong. (2006).

189. S. REP. NO. 110-259, at 32 (2008).

190. The Senate Report states,

First, the Federal Circuit has failed to establish one clear standard of materiality for inequitable conduct purposes. Having multiple materiality standards is hardly helpful to the district courts that are charged with making inequitable conduct determinations in the first instance, and patent holders are left with less than clear guidance about what they should disclose to the USPTO.

Id. The committee report specifically calls out *Digital Control* to illustrate the lack of a single clear standard. *Id.* at 32 n.151.

191. *Id.* (“Second, direct evidence of an intent to deceive is uncommon, so some courts collapse the issue of intent into the issue of materiality, so that intent to deceive is often inferred from materiality.”).

192. *Id.* (“Third, if inequitable conduct is found, judges have no discretion as to the remedy—no claim of the patent can ever be enforced against anyone.”).

and subsection (e) would create several new alternative remedies and grants the district court discretion to select one or more of those remedies.¹⁹³

The Leahy bill proposes no substantive changes to the clear and convincing standard and the requirement for particularized pleading in compliance with Rule 9(b) of the Federal Rules of Civil Procedure,¹⁹⁴ as those principles are well-established in the case law. The Judiciary Committee Report suggests a belief, however, that the heightened pleading requirement and “clear and convincing” proof standard are novel additions to the law of inequitable conduct that “presumably” will ameliorate “concerns that inequitable conduct is ‘over plead [sic].’”¹⁹⁵ Contrary to the Judiciary Committee’s optimism, it is difficult to conceive how codification of existing law will “ameliorate” existing problems.¹⁹⁶

Each of the three other provisions of the Leahy bill’s proposal for inequitable conduct requires more detailed discussion.

First, the Leahy bill would codify the definition of materiality using the vague and subjective “reasonable examiner” standard that was set forth in the 1977 version of PTO Rule 56,¹⁹⁷ and that the Federal Circuit continues to identify as the lowest threshold for materiality.¹⁹⁸ In selecting this standard, the Judiciary Committee noted that some cases “appear to emphasize improperly the first part of this definition (reasonably important to an examiner) without giving necessary consideration to the latter part of the definition (in deciding whether to allow the patent).”¹⁹⁹ This, the Committee believed, essentially reduced the materiality standard to a “relevancy standard.”²⁰⁰ The Committee expressed the hope that codification of the standard would force

193. *Id.* at 32–33 (summarizing proposed 35 U.S.C. § 298).

194. *See supra* note 184.

195. S. REP. NO. 110-259, at 33 n.156 (2008).

196. Anecdotally, however, the application of Rule 9(b) to inequitable conduct pleadings has been sporadic. Therefore, codification of the heightened pleading requirement may serve to increase its enforcement. In contrast with the un-elaborated Rule 9(b) pleading requirement proposed in the Leahy bill, the Federal Circuit has recently articulated in substantial detail what will be required to plead inequitable conduct under Rule 9(b). *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328–29 (Fed. Cir. 2009).

197. 37 C.F.R. § 1.56 (1977) (“[I]nformation is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”). The Leahy bill would also codify the requirement that material information be non-cumulative. S. 1145, 110th Cong. § 12 (as reported in Senate, Apr. 18, 2007) (proposing to enact 35 U.S.C. § 298(b)(2)). The non-cumulativeness requirement is a straightforward codification of existing law that has not attracted controversy.

198. *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314–16 (Fed. Cir. 2006).

199. S. REP. NO. 110-259, at 33 n.155 (citing *Nilssen*, *McKesson*, and *Ferring*).

200. *Id.*

courts to apply the entire definition,²⁰¹ thereby tightening the scope of materiality over that found in existing cases. In adopting this definition of materiality, the Committee specifically rejected a proposal by Senator Hatch that would have defined materiality in a manner more similar to the 1992 version of PTO Rule 56.²⁰² Senator Leahy proposed the “reasonable examiner” standard as a modification of Senator Hatch’s amendment, and Senator Leahy’s version prevailed.²⁰³ In response, Senators Specter and Hatch registered their disagreement.²⁰⁴ Senators Specter and Hatch stated that, under the “reasonable examiner” standard, “virtually any information can be characterized as ‘material.’”²⁰⁵ They cite *Nilssen*, *McKesson*, and *Ferring* as examples of this unacceptable result.²⁰⁶ Accordingly, they stated, “[w]e do not support the ambiguous language reported by the Committee” defining materiality under the “reasonable examiner” standard, adding that it “does not improve current law,” and calling the codification of that standard an “unworkable solution.”²⁰⁷ Specifically, they suggested that the “reasonable examiner” standard impedes the patent examination process by encouraging applicants to submit too much information to the examiner.²⁰⁸ Accordingly, they called for an “objective threshold” of materiality.²⁰⁹ However, they did not provide proposed language for a competing proposal, other than to suggest that materiality ought to be limited to “information that can affect the validity of a patent claim.”²¹⁰ In this respect, Senators Specter and Hatch seem to sympathize with the adoption of the 1992 version of Rule 56’s definition of materiality.²¹¹

Second, the Leahy bill’s proposed definition of intent states,

201. *Id.*

202. S. REP. NO. 110-259, at 40 (“Senator Hatch offered an amendment that would codify and raise the standard to prove inequitable conduct, including defining materiality as information that [if] considered would render a claim of the patent invalid.”). Compare this formulation with 37 C.F.R. § 1.56(b) (1992), which states,

[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.

203. S. REP. NO. 110-259, at 32, 40.

204. *Id.* at 59–62.

205. *Id.* at 60.

206. *Id.* at 60, nn. 9, 10.

207. *Id.* at 60–61.

208. *Id.* at 61.

209. *Id.*

210. *Id.*

211. See 37 C.F.R. § 1.56 (1992).

Intent to deceive the Office may be inferred under subsection (a), [which sets forth the prima facie elements of inequitable conduct,] but the inference may not be based solely on the gross negligence of the patent owner or its representative, or on the materiality of the information misrepresented or not disclosed.²¹²

While this language essentially tracks the ruling in *Kingsdown*, it also appears to be an attempt to legislatively overrule more recent cases such as *Ferring*²¹³ and *McKesson*.²¹⁴ However, this language does not propose to define what evidence may be used to prove intent, or what evidence would be sufficient to prove intent. Nor does this language address the “should have known” standard, or preclude all use of gross negligence or evidence of materiality to prove intent; rather, intent may not be “solely” based on such evidence. In short, although this definition would potentially override some of the more extreme cases, it would codify in statute many of the problems and ambiguities that are found in the current doctrine. Senators Specter and Hatch, by contrast, would draw a bright-line prohibition on the use of materiality as evidence of intent: “[W]e believe intent must be proven with independent evidence separate from and unrelated to the materiality of the information at issue.”²¹⁵ The addition of language to the same effect as *Star Scientific* would considerably improve this provision—if circumstantial evidence is used to prove intent, such intent must be the single most compelling inference from all the evidence (including evidence of good faith) to satisfy the clear and convincing burden of proof.

Third, the Leahy bill would empower the courts with the discretion to award one or more of a range of new remedies when inequitable conduct has been proven.²¹⁶ In addition to the traditional remedy of holding the entire patent unenforceable, the Leahy bill would permit courts to hold individual patent claims unenforceable, or to limit remedies to a reasonable royalty while denying equitable relief and lost profits damages.²¹⁷ The Leahy bill says nothing about the doctrine of infectious unenforceability. Nor does it say anything about the balancing element in the traditional inequitable conduct doc-

212. S. 1145, 110th Cong. § 12 (as reported in Senate, Apr. 18, 2007) (proposed 35 U.S.C. § 298(c)).

213. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (affirming summary judgment as to intent because applicant “should have known” of materiality of information).

214. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 924–25 (Fed. Cir. 2007) (inferring intent from fact of nondisclosure and representations concerning the prior art).

215. S. REP. NO. 110-259, at 61.

216. S. 1145 § 12 (proposing to enact 35 U.S.C. § 298(e)).

217. *Id.*

trine. Although the Report of the Judiciary Committee does not say so, the introduction of a range of alternative remedies could be viewed as an alternative implementation of the balancing prong of the traditional inequitable conduct defense. So viewed, and considered with reference to Figure 1, the Leahy bill would actually expand the conduct for which an inequitable conduct remedy can be awarded, from the dark area above and to the right of the curve in Figure 1, to also include the striped area, between the curve and the dashed lines in the middle of the graph. That is, if the thresholds of materiality and intent are satisfied, the Leahy bill would appear to deem that sufficient for a finding of inequitable conduct, without the additional step of equitable balancing. The possibility of a lesser remedy may actually create *added* incentives for accused infringers to allege inequitable conduct on thin evidence, as infringers could still win a lesser remedy on such evidence, whereas infringers would get no remedy under current standards. So viewed, the expansion of conduct for which some remedy is available (particularly low-materiality, low-intent conduct) will likely *increase* the incentives of litigants to allege inequitable conduct—precisely the opposite of the bill’s intent. Senators Specter and Hatch recognized this possibility, questioning whether “expanding the range of available sanctions for inequitable conduct in the absence of other meaningful changes to the doctrine will encourage more, not less, inequitable conduct litigation.”²¹⁸

The Leahy bill was not approved in the Senate during the 110th Congress. A version of the Leahy bill was reintroduced in the 111th Congress.²¹⁹ However, as introduced and as reported in the Senate on April 2, 2009, it did not include provisions for inequitable conduct.²²⁰ Co-sponsor Senator Hatch has indicated a desire to include inequitable conduct provisions in the bill.²²¹

B. BERMAN BILL, HOUSE BILL 1908

Representative Berman introduced a version of the Leahy bill in the House of Representatives in April 2007.²²² The House approved the bill in September 2007. Because the inequitable conduct provisions are similar in structure to the Senate version of the bill, this Article discusses only the differences between the House and Senate versions. The Report of the House

218. S. REP. NO. 110-259, at 61.

219. S. 515, 111th Cong. (as introduced in Senate, Mar. 3, 2009).

220. *Id.*; S. 515, 111th Cong. (as reported in Senate, Apr. 2, 2009).

221. Press Release, Orrin Hatch, Senator, Senators Hatch, Leahy Introduce Patent Reform Act of 2009 (Mar. 3, 2009) (on file with author), *available at* http://hatch.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=ce28c6f0-1b78-be3e-e028-418ea18126e5.

222. H.R. 1908, 110th Cong. (2007).

Committee on the Judiciary stated that a desire to address “abusive” litigation practices motivated the reform of the inequitable conduct doctrine,²²³ specifically citing “overuse” of inequitable conduct.²²⁴ The specific defects in existing doctrine, as identified by the House committee report, include the proliferation of standards of materiality²²⁵ and the commingling of the materiality and intent prongs.²²⁶ Because these defects lead to improper overuse of the inequitable conduct defense and introduce uncertainty into patent litigation, the stated purpose of House Bill 1908 is “to provide an increased level of certainty to the defense.”²²⁷

The House version of the bill would add the substantive provisions of inequitable conduct as a new § 282(c) in the Patent Act.²²⁸ Each of the three main components discussed above is different in the House version.

Unlike the Senate version, the House version does not define “material information.”²²⁹ Instead, the House version would establish a “but for” test for causation: “in the absence of such deception, the Office, acting reasonably, would, on the record before it, have made a *prima facie* finding of unpatentability.”²³⁰ As the Federal Circuit noted in *Digital Control*, this “but-for” standard is the narrowest test for materiality among the various tests articulated by the courts.²³¹ It is worth noting that “material information” is not the only term of art that the House leaves undefined in this section. The House version uses, but fails to define the following terms: “duty of disclosure,” “person with a duty of disclosure,” and “*prima facie* finding of unpatentability.”²³² All three terms are defined in the current version of PTO Rule 56.²³³

223. H.R. REP. NO. 110-314, at 20 (2007).

224. *Id.* at 21.

225. *Id.* at 42 (citing *Digital Control v. Charles Mach. Works*, 437 F.3d 1309 [incorrectly identified as *Digital Control v. Merlin Technology*]).

226. *Id.* at 42–43. In this regard, however, the House committee report conflates two separate issues. The Senate Judiciary Committee also notes the problem with using materiality to prove intent. The balancing of materiality and intent, once both elements have been found to exist at a threshold level, is an aspect of the inequitable conduct doctrine that may be valuable independently of the identification of evidence that may be used to establish intent. See *supra* Figure 1.

227. *Id.* at 43, 85.

228. *Id.* at 18, 116–17.

229. *Id.* at 116–17 (proposing to enact 35 U.S.C. § 282(c)). Nor does it expressly require that the withheld information be non-cumulative.

230. *Id.* at 117 (proposing to enact 35 U.S.C. § 282(c)(1)(B)).

231. See *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314–16 (Fed. Cir. 2006).

232. See H.R. REP. NO. 110-314, at 116–17 (proposing to enact 35 U.S.C. § 282(c)).

233. 37 C.F.R. § 1.56 (2008). Rule 56 specifies that individuals having a duty of disclosure must “disclose to the Office all information known to that individual to be material to

Ordinarily, in matters of statutory interpretation where an administrative agency (here, the PTO) has a substantive connection to the statute (here, the Patent Act), it would be reasonable to infer that Congress intended the PTO’s definitions of those terms to govern, and perhaps that is a reasonable way to interpret the statute. However, because the bill largely failed to discuss the current version of Rule 56, and because the Federal Circuit in *Digital Control* essentially overrode any expectation that the 1992 version of Rule 56 would supplant judicial definitions of materiality,²³⁴ it may not be reasonable to expect that the courts would interpret the House version of the bill in accordance with Rule 56, unless expressly directed by Congress to do so.

Concerning intent, the House version mirrors the Senate version in requiring that the facts used to prove intent be “beyond” those used to prove materiality, apparently without prohibiting such facts as a component of the evidence of intent.²³⁵ The House version does not adopt the Senate version’s disavowal of “gross negligence” as a method of proving intent, but instead provides an affirmative definition of how to satisfy the intent standard, requiring “conscious or deliberate behavior.”²³⁶

Third, the House version provides a similar menu of remedies for inequitable conduct.²³⁷ The option to hold the entire patent unenforceable is the same. The House version would more narrowly limit the discretion to hold individual claims unenforceable, limiting the discretion to the claims-in-suit or the claims in which the inequitable conduct occurred.²³⁸ The House ver-

patentability as defined in this section.” 37 C.F.R. § 1.56(a). Individuals having a “duty of disclosure” are enumerated in Rule 56(c). 37 C.F.R. § 1.56(c). Rule 56 defines material information as information that

is not cumulative to information already of record or being made of record in the application, and [that either] establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or . . . refutes, or is inconsistent with, a position the applicant takes in: opposing an argument of unpatentability relied on by the Office, or [a]sserting an argument of patentability.

37 C.F.R. § 1.56(b). A “prima facie case of unpatentability” exists “when the information compels a conclusion that a claim is unpatentable . . . giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to [rebuttal evidence submitted to establish patentability].” *Id.*

234. See *supra* Section IV.B.

235. H.R. REP. NO. 110-314, at 117 (proposing to enact 35 U.S.C. § 282(c)(2)).

236. *Id.* (“Facts support an inference of intent if they show circumstances that indicate conscious or deliberate behavior on the part of the patentee, its agents, or another person with a duty of disclosure to the Office, to not disclose material information or to submit materially false information.”).

237. *Id.* at 117 (proposing to enact 35 U.S.C. § 282(c)(3)).

238. As a practical matter, this distinction between the House and Senate versions may not make much difference.

sion would permit the court merely to deny equitable relief, and would not deprive the patentee of the option to seek lost-profits damages.²³⁹

Fourth, in contrast to the silence of the Senate version, the House version expressly addresses infectious unenforceability, and would authorize the court to hold claims of a related patent unenforceable.²⁴⁰

Finally, the House version includes a short section requiring the court to refer inequitable conduct findings involving patent attorneys to the PTO for “appropriate disciplinary action.”²⁴¹

A version of the Berman bill was reintroduced by Congressman Conyers in the 111th Congress.²⁴² However, as introduced, the 2009 version of the House bill did not include provisions for inequitable conduct.²⁴³

C. KYL BILL, SENATE BILL 3600

In September 2008, Senator Kyl introduced Senate Bill 3600, a patent reform bill intended to compete with Senate Bill 1145, the Leahy bill. Like Senator Leahy’s bill, the Kyl proposal includes provisions on inequitable conduct. But the Kyl bill takes a significantly different approach. To handle inequitable conduct, the Kyl bill would create a new judicial procedure and two new administrative forums within the PTO. Courts would be prohibited from addressing inequitable conduct in patent litigation (or other litigation), except to pass on a threshold motion that would trigger the commencement of administrative proceedings. A reissue proceeding would address the impact of possible inequitable conduct on the patent itself, and the perpetrators of the inequitable conduct would be subjected to a separate disciplinary proceeding.

The Kyl bill’s inequitable conduct reform provisions are found in section 11. They would add two new sections to the Patent Act: § 298, titled “Inequitable Conduct”; and § 299, titled “Civil sanctions for misconduct before the Office.”

Section 298(a) starts with a claim to statutorily occupy the field of inequitable conduct: “Except as provided under this section or section 299, a patent shall not be held invalid or unenforceable based upon misconduct before the Office.”²⁴⁴ This is an evident effort to preempt the Federal Circuit’s

239. H.R. REP. NO. 110-314, at 117–18.

240. *Id.* at 117

241. *Id.* (proposing to enact 35 U.S.C. § 282(c)(4)).

242. H.R. 1260, 111th Cong. (as introduced in Congress, Mar. 3, 2009).

243. *Id.*

244. Patent Reform Act of 2008, S. 3600, 110th Cong. § 11 (2008) (as introduced in Senate, Sept. 25, 2008) (proposing to enact 35 U.S.C. § 298(a), first sentence).

position that inequitable conduct, as a judicially created doctrine, exists independently of Patent Office regulations.²⁴⁵ Section 298(a) continues by eliminating any claim or defense of inequitable conduct in civil litigation: “Nothing in this section shall be construed to create a cause of action or a defense in a civil action.”²⁴⁶ Thus, § 298(a) wipes the slate clean. With this bill, there would be neither a judicially-created doctrine of inequitable conduct nor a claim or defense of inequitable conduct in civil litigation.

Curiously, then, the first part of § 298(b) establishes motion practice in a civil action as a gating event to further inequitable conduct proceedings before the PTO.²⁴⁷ But if, under § 298(a), there is no claim or defense of inequitable conduct that may be asserted in a civil action, it is not clear whether a court in a civil action could have subject-matter jurisdiction to entertain such a motion. Moreover, § 298(b) contains no suggestions or limitations on the nature of civil action in which such a motion could be brought. This omission implies that such a motion could be brought in any civil action, not just patent infringement actions and related actions for declaratory relief. Indeed, unless the patent issue arises as part of a well-pled complaint, the federal courts’ exclusive jurisdiction over patent cases²⁴⁸ would not necessarily preclude such a motion from being brought in a state court action.²⁴⁹

Assuming a court in a civil action has jurisdiction to entertain such a motion, the Kyl bill provides a starkly different process. First, in ruling on the motion, the court would be required to make its findings only by a preponderance of the evidence²⁵⁰ rather than the clear and convincing evidence required under the current doctrine.²⁵¹

The *prima facie* elements to be found by the court bear a passing resemblance to the current judicially-created doctrine of inequitable conduct, as well as Rule 56.²⁵² But the bill contains important differences. In this regard,

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

246. S. 3600, at § 11 (proposing to enact 35 U.S.C. § 298(a), second sentence).

247. *Id.* (proposing to enact § 298(b)(1)(A)) (“If a court in a civil action, upon motion of a party to the action . . .”).

248. 28 U.S.C. § 1338 (2006) (stating that federal district courts have exclusive jurisdiction for patent cases).

249. *See, e.g.,* *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002); *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800 (1988).

250. S. 3600, at § 11 (proposing to enact 35 U.S.C. § 298(b)(1)(A)) (instructing the court to order the patent to be made the subject of a reissue application if it finds the applicant “more likely than not . . . intentionally deceived the Office . . .”).

251. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

252. 37 C.F.R. § 1.56 (2008).

the Kyl bill appears to have drawn inspiration from the PTO’s Code of Professional Responsibility.²⁵³ In particular, that code provides that a “practitioner” shall not “[k]nowingly giv[e] false or misleading information or knowingly participat[e] in a material way in giving false or misleading information, to . . . [t]he Office or any employee of the Office.”²⁵⁴ The Kyl bill would require proof that “a person who participated in a matter or proceeding before the Office knowingly and intentionally deceived the Office by concealing material information or by submitting false material information in such matter or proceeding”²⁵⁵

The differences between the Kyl bill and existing doctrine include the following. First, this provision reaches a broader range of people than practitioners covered by 37 C.F.R. § 10.23 and people identified in Rule 56(c) as owing a duty of disclosure to the Patent Office.²⁵⁶ Second, in contrast with the case law’s requirement that the person accused of inequitable conduct act with intent to deceive the Patent Office, the Kyl bill parallels 37 C.F.R. § 10.23 and requires that the person act “knowingly and intentionally.”²⁵⁷ Third, the existing doctrine requires only intent to deceive, while the Kyl bill imposes the additional requirement that the Patent Office in fact was deceived.²⁵⁸ Fourth, Rule 56 imposes a duty of disclosure, such that a mere failure to disclose material information is sufficient to satisfy the materiality prong;²⁵⁹ by contrast, the Kyl bill requires “concealing” material information. Fifth, there is no requirement that materiality and intent be balanced; apparently under the Kyl bill (as with the Leahy bill), if both materiality and intent are satisfied at a threshold level, the burden of proof has been met. Finally, the district court’s discretion is constrained—if it makes the pertinent find-

253. *See, e.g.*, 37 C.F.R. § 10.23 (2008); 37 C.F.R. § 11.18(b)–(c) (2008); U.S. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 410 (8th ed., rev. 7, 2008).

254. 37 C.F.R. § 10.23(c)(2)(ii).

255. S. 3600, at § 11 (proposing to enact 35 U.S.C. § 298(b)(1)(A)).

256. *See* 37 C.F.R. § 1.56(c); 37 C.F.R. § 10.23.

257. *See* 37 C.F.R. § 10.23(d) (defining knowledge to include “reckless indifference,” “half-truths,” and “concealment of material facts”).

258. In view of the prohibition on examiner testimony, *supra* note 27, proof of actual deception (other than evidence found in the prosecution history) would be difficult or impossible.

259. 37 C.F.R. § 1.56(b).

ings, it “shall” order the commencement of a reissue proceeding,²⁶⁰ and the district court’s ruling “shall not be subject to appellate review.”²⁶¹

There are also some ways in which this part of the Kyl bill is clearly narrower than existing doctrine. For instance, building on the proposition that a claim of inequitable conduct must be pled with particularity,²⁶² the Kyl bill requires an explanation as to how the withheld information would invalidate one or more claims of the patent, but does not require any particularity in the motion’s allegations of materiality, nondisclosure, intent to deceive, and actual deception of the Patent Office. Relatedly, proposed § 298(b)(1)(B) defines materiality narrowly in relation to patentability. It incorporates portions of Rule 56, requiring that the material be noncumulative and not already of record.²⁶³ And it is limited to information that establishes nonpatentability or refutes an argument that an applicant made in support of patentability of a patent claim. This is narrower than the current law because it largely tracks the 1992 version of Rule 56,²⁶⁴ abrogating the 1977 “reasonable examiner” standard that the Federal Circuit re-endorsed in *Digital Control*, and it is limited to issues of patentability, abrogating such recent cases as *Ferring*,²⁶⁵ *McKesson*,²⁶⁶ *Nilssen*,²⁶⁷ and even *Star Scientific*.²⁶⁸

With regard to the Kyl bill’s proposed use of a reissue proceeding to determine the impact of inequitable conduct on the patent itself, the bill limits the impact of the reissue proceeding on pending litigation. Once the reissue

260. The enforcement mechanism is in proposed section 298(b)(5). If the patentee fails to “seek reissue within 2 months of the court’s order, the court shall enter judgment that the patent is unenforceable.” S. 3600, at § 11.

261. *Id.* (proposing to enact 35 U.S.C. § 298(b)(1)(A)).

262. FED. R. CIV. P. 9(b); *Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007) (citing *Ferguson Beauregard/Logic Controls, Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003)).

263. 37 C.F.R. § 1.56(b).

264. The Kyl bill’s wording closely tracks Rule 56, but with some key omissions. While Rule 56 permits the analysis of unpatentability to be made with reference to the omitted information alone or in combination with other information of record in the application, the Kyl bill requires that that the omitted information—apparently alone—establishes unpatentability. Compare 37 C.F.R. § 1.56(b)(1), with S. 3600, at § 11 (proposing to enact 35 U.S.C. § 298(b)(1)(B)). This is, essentially, the difference between the materiality of omitted information for purposes of § 103 obviousness and § 102 anticipation. Also, the Kyl bill omits from its definition of materiality information that is inconsistent with arguments the applicant made in asserting patentability. Compare 37 C.F.R. § 1.56(b)(2)(ii), with S.3600, at § 11 (proposing to enact 35 U.S.C. § 298(b)(1)(B)).

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

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

267. *Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884 (N.D. Ill. 2006), *aff’d*, 504 F.3d 1223 (Fed. Cir. 2007).

268. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008).

proceeding has commenced, the court may not stay the civil action due to the pendency of the reissue, unless and until the Patent Office rejects one or more claims as to which allegations of infringement are still-pending and the court determines that such a stay would be in the interests of justice.²⁶⁹

Under proposed § 298(d), the patentee may file a reissue application, omitting one or more claims. This would allow the patentee to “scrub” the offending claim out of the patent.

This procedure will potentially burden the PTO with a new caseload of many hundreds (at least) of additional reissue petitions each year.²⁷⁰ The current caseload is about one thousand reissue petitions filed each year.²⁷¹ Therefore, assuming that the number of inequitable conduct-inspired reissue proceedings parallels the number of district court cases in which inequitable conduct is pled (see Table 1), the Kyl proposal could result in a doubling of the reissue caseload. With the existing caseload, the average time to first action of all patent applications²⁷² is 25.3 months, and the average time to final resolution is 31.9 months.²⁷³ Yet the Kyl bill would require a first action within three months of the filing for the reissue application,²⁷⁴ and completion of the reissue proceeding within one year of the initial notification date (i.e., 15 months from commencement).²⁷⁵ In light of estimates that the PTO’s reissue case load may double, it is unrealistic to expect the PTO to cut its time to first action by 88% (from 25.3 months to 3 months) and its average pendency by more than 50% (from 31.9 months to 15 months) without dedicating massive additional examination resources to inequitable conduct-prompted reissue proceedings.

If at least one claim comes out of the reissue proceeding,²⁷⁶ “no further sanctions may be imposed against the patentee,”²⁷⁷ except criminal, antitrust, and PTO-imposed sanctions, as described in proposed § 298(h). That is, a district court can hold a patent-in-suit unenforceable only if the patentee fails to initiate reissue proceedings within two months of the court’s order to do

269. S. 3600, at § 11 (proposing to enact 35 U.S.C. § 298(b)(4)).

270. See *supra* Table 1.

271. UNITED STATES PATENT AND TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2007, at 110 (2007) (table 2).

272. PTO statistics on reissue applications alone are not available.

273. UNITED STATES PATENT AND TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2007, at ii (2007).

274. S. 3600, at § 11 (proposing to enact 35 U.S.C. § 298(e)(1)).

275. *Id.* (proposing to enact 35 U.S.C. § 298(e)(3)).

276. The procedural details of the Kyl bill’s proposed reissue proceeding are not addressed here and are not compared in this Article with preexisting reissue procedures.

277. S. 3600, at § 11 (proposing to enact 35 U.S.C. § 298(g)).

so, and cannot otherwise impose any sanction or remedy for inequitable conduct.²⁷⁸ As noted below, however, one of the sanctions under the new proposed § 299 is a determination that one or more patent claims is unenforceable;²⁷⁹ it is unclear whether a successful reissue petition will override this potential sanction.

Section 299(a) instructs the PTO to develop a new administrative disciplinary procedure covering "parties to a matter or proceeding before the Office" that may have engaged in inequitable conduct.²⁸⁰ This procedure appears to be an attempt to implement a practice that the PTO abandoned in the late 1980s due, at least in part, to the PTO's lack of expertise in determining intent.²⁸¹ The administrative procedure in § 299 consists of several steps.

First, the PTO determines that probable cause exists if "[one] or more individuals or parties engaged in misconduct consisting of intentionally deceptive conduct of a material nature in connection with a matter or proceeding before the Office."²⁸² This determination is unreviewable.²⁸³ The test for probable cause is different from and potentially much broader than the test proposed in § 298: the intent to deceive need not be directed at deceiving the PTO; the test could include conduct other than a failure to disclose material information or a misrepresentation of material information; and the language "material nature" does not track "material information," the term defined in § 298.

Second, there must be notice and an opportunity for a hearing, resulting in a determination within one year of the probable cause finding.²⁸⁴ If the PTO finds misconduct, it may levy a civil penalty of up to \$150,000 for each act of misconduct and up to \$1 million for a "pattern of misconduct." To put these amounts in perspective, consider the fact that the typical patent application costs only \$8,500 to \$15,500 to prosecute, including filing fees and the fees of the prosecuting attorney.²⁸⁵ Thus, under the Kyl bill, the penalty imposed on a prosecuting attorney for a first offense could be as much as ten to twenty times the fee that lawyer earned for prosecuting the patent. Particularly in the absence of a clear, applicationally self-sufficient standard of conduct,

278. *Id.* (proposing to enact 35 U.S.C. § 298(b)(5)).

279. *Id.* at § 11 (proposing to enact 35 U.S.C. § 299(b)(3)(C)(iii)(I)).

280. *Id.* (proposing to enact 35 U.S.C. § 298(a)).

281. *See supra* note 42.

282. S. 3600, at § 11 (proposing to enact 35 U.S.C. § 299(b)(1)).

283. *Id.*

284. *Id.* (proposing to enact 35 U.S.C. § 299(b)(2)).

285. Oversight Hearing on the United States Patent and Trademark Office: Hearing Before the H. Subcomm. on Courts, the Internet, and Intellectual Property, Comm. on the Judiciary, 110th Cong. (2008) (statement of Alan J. Kasper, First Vice President, AIPLA).

many patent prosecutors could find this peril to be a prohibitive risk. But the Kyl bill provides even more possible fines. If the misconduct is deemed “exceptional” and was practiced by or at the behest of a real party in interest in a patent application, the penalty may include a determination that one or more claims is unenforceable and an additional penalty of up to \$10 million may be assessed.²⁸⁶ Also, anyone found to have engaged in misconduct can be held jointly and severally liable.²⁸⁷ The Attorney General is authorized to file collection actions to recover penalties in the Eastern District of Virginia.²⁸⁸

In connection with both the probable cause phase and the determination phase, the PTO is empowered to gather whatever evidence it “determines pertinent” that is in the possession of “any person.”²⁸⁹ This new, general power of investigation would be a significant expansion of the powers of, and burdens on, the PTO.

The Kyl bill does not specify the standard of proof required to establish such misconduct in the new administrative proceeding. It does, however, provide a right of appeal directly to the Federal Circuit.²⁹⁰ Determinations of misconduct are reviewed for substantial evidence and legal correctness.²⁹¹ Sanctions are reviewed for abuse of discretion.²⁹²

The Kyl bill was not approved in the Senate during the 110th Congress. A version of the Kyl bill was reintroduced in the 111th Congress.²⁹³ It includes only the civil sanctions provisions for inequitable conduct (proposed § 299) that were included in the 2008 version of the Kyl bill.²⁹⁴

VI. REFORM PROPOSALS

This Article advocates four key reforms²⁹⁵ to the doctrine of inequitable conduct:

286. S. 3600, at § 11 (proposing to enact 35 U.S.C. § 299(b)(3)(C)).

287. *Id.*

288. *Id.* (proposing to enact 35 U.S.C. § 299(b)(3)(F)(i)).

289. *Id.* (proposing to enact 35 U.S.C. § 299(c)(2)(A)).

290. *Id.* (proposing to enact 35 U.S.C. § 299(d)(1)).

291. *Id.* (proposing to enact 35 U.S.C. § 299(d)(4)).

292. *Id.*

293. Patent Reform Act of 2009, S. 610, 111th Cong. (as introduced in Senate, Mar. 17, 2009).

294. *Id.* at § 11 (proposing to enact 35 U.S.C. § 299).

295. Others have proposed alternative reforms. *See* Cotropia, *supra* note 15, at 43–57 (advocating (1) a broad definition of materiality, (2) requiring proof of intent to be separate from materiality, (3) discouraging “burying,” and (4) a narrower remedy); Lisa A. Dolak, Inequitable Conduct: A Flawed Doctrine Worth Saving at 7–12 (Sept. 23, 2008) (unpublished manuscript, on file with the author), *available at* http://works.bepress.com/lisa_dolak/4/ (advocating (1) adopting the PTO standard of materiality, (2) tighter standards for proof of

1. Materiality should be explicitly linked to the PTO’s 1992 definition of materiality in its regulations.
2. The standard for proving intent should be clearly defined.
3. The step of “balancing” materiality and intent should be clarified and codified, making clear that even if thresholds of materiality and intent exist, the court retains equitable discretion to decline to find inequitable conduct.
4. There should be a single, narrowed remedy. Only claims directly affected by the inequitable conduct (rather than the entire patent) should be deemed unenforceable.

First, concerning both materiality and intent, any codification should make clear that, for any particular allegedly wrongful act during prosecution, a single, clear, and objective (i.e., applicationally self-sufficient) standard should apply. The Federal Circuit’s two February 2006 decisions in *Digital Control* and *Ferring* have contributed to an unsettled status quo, providing multiple, subjective, and varying standards for both the materiality and intent prongs of the inequitable conduct analysis. A single, clear standard is necessary for both.

For materiality, the 1992 version of Rule 56²⁹⁶ would suffice. It is more objective than the subjective and malleable “reasonable examiner” standard. However, in deference to the PTO’s presumptive expertise concerning the information that it needs to conduct effective and efficient examination, it would be appropriate for a patent reform statute to codify deference to the PTO’s then-existing definition of materiality, consistent with former PTO Commissioner Gerald Mossinghoff’s view.²⁹⁷

For intent, *Ferring* and its progeny should be overruled. A standard that both affirmatively states what evidence of intent is sufficient and prohibits certain methods of proving intent should replace it. Specifically:

intent, including abrogation of *Ferring* and adoption of *Star Scientific*, (3) abandoning of the balancing step, (4) judicial discretion to fashion remedies, and (5) awarding attorney fees to patentees who successfully defend against claims of inequitable conduct).

296. 37 C.F.R. § 1.56 (1992).

297. Gerald S. Mossinghoff, The Duty of Candor and Good Faith to the United States Patent and Trademark Office, Remarks to the American Bar Association, Intellectual Property Law Section at the 17th Annual Intellectual Property Law Conference (Apr. 12, 2002) (transcript on file with Oblon, Spivak, McClelland, Maier & Neustadt, LLP), available at <http://www.oblon.com/media/index.php?id=44> (“My own view is that the courts should apply the version (or versions) of Rule 56 that was (were) in effect at the time the conduct objected to occurred.”).

1. Defendants should not be permitted to prove intent from materiality;
2. The concepts of “gross negligence” and “should have known” should be abrogated from the intent determination; and
3. Circumstantial evidence should continue to be permissible in proving intent. But if circumstantial evidence is used to satisfy the clear-and-convincing burden of proof, an intent to deceive the PTO must be the *single most reasonable* inference,²⁹⁸ not merely a permissible or plausible inference.

Even with improved and clarified standards of materiality and intent, it will be important to stay true to the doctrine’s equitable roots and retain some degree of judicial discretion, so the balancing step—as articulated most recently in *Star Scientific*²⁹⁹—should be retained.

Finally, the remedy for inequitable conduct should be harmonized with the law of invalidity, such that unenforceability is determined on a claim-by-claim basis, and only as to patent claims for which there is a justiciable case or controversy. Under current rules, inequitable conduct relating to a single patent claim—even a claim that is not asserted in a patent infringement suit—can produce the draconian result that renders unenforceable the entire patent (and, via the doctrine of infectious unenforceability, downstream patents as well). This creates significant incentives to “roll the dice” by asserting an inequitable conduct claim, spawning satellite litigation on non-asserted claims. The proposed narrower remedy would strike a more appropriate balance. It would limit overbroad incentives for accused infringers to allege inequitable conduct while still providing consequences for inappropriate conduct during prosecution. Even this narrowed remedy would be broader than the remedy for invalidity, since material information—under either the “reasonable examiner” standard or the 1992 version of Rule 56—is defined more broadly than information that could ultimately result in a finding of invalidity of a claim. For example, the 1992 version of Rule 56 defines materiality to include information that would tend to show a *prima facie* case of unpatentability *without regard to rebuttal evidence*.³⁰⁰ Empowering the courts with a discretionary range of remedies should not be embraced, because such discretion

298. *Supra* note 171 and accompanying text.

299. *Supra* note 168 and accompanying text.

300. Thus, for example, withheld material information may not result in invalidity, once appropriate rebuttal evidence is considered, but could result in unenforceability due to inequitable conduct if the withholding was done with the intent to deceive the PTO.

merely increase incentives for litigants to assert weak claims of inequitable conduct, hoping that the weak claim will produce at least a limited remedy.³⁰¹

These specific reforms could be achieved with the same verbal economy as the inequitable conduct provisions in Senate Bill 1145, the Leahy Bill, as shown in the table below.

Leahy Bill	This Article's Proposal
a) IN GENERAL.—A party advancing the proposition that a patent should be cancelled or held unenforceable due to inequitable conduct in connection with a matter or proceeding before the United States Patent and Trademark Office shall prove independently by clear and convincing evidence that material information was misrepresented or omitted from the patent application of such patent with the intention of deceiving the Office.	(a) IN GENERAL.—A party advancing the proposition that one or more claims of a patent should be cancelled or held unenforceable due to inequitable conduct in connection with a matter or proceeding before the United States Patent and Trademark Office shall prove independently by clear and convincing evidence that a person subject to the duty of disclosure in connection with such matter or proceeding violated the duty of disclosure with the intention of deceiving the Office.
(b) MATERIALITY.—Information shall be considered material for purposes of subsection (a) if— (1) a reasonable patent examiner would consider such information important in deciding whether to allow the patent application; and (2) such information is not cumulative to information already of record in the application.	(b) DUTY OF DISCLOSURE.—For the purposes of this section, the Director shall be authorized to promulgate regulations defining the duty of disclosure. The duty of disclosure governing an allegation of inequitable conduct shall be that which was in effect at the time the alleged inequitable conduct occurred.
(c) INTENT.—Intent to deceive the Office may be inferred under subsection (a), but the inference may not be based solely on the gross negligence of the patent owner or its representative, or on the materiality of the information misrepresented or not disclosed.	(c) INTENT.—Intent to deceive the Office may be proven under subsection (a) by direct or circumstantial evidence. Circumstantial evidence may be found to constitute clear and convincing evidence of an intent to deceive the Office only if an intent to deceive is the single most reasonable inference from all the evidence, including any evidence of good faith. Any such inference may not be based solely on: (a) the gross negligence of the person alleged to have violated the duty of disclosure; (b) the materiality, or degree of materiality, of the information misrepresented or not disclosed; or

³⁰¹ See *supra* note 216–18 and accompanying text.

	(c) a finding that the person alleged to have violated the duty of disclosure “should have known” of the materiality of the information misrepresented or not disclosed.
(d) PLEADING.—In actions involving allegations of inequitable conduct before the Office, the party asserting the defense or claim shall comply with the pleading requirements set forth under Federal Rules of Civil Procedure 9(b).	
	(d) EQUITABLE BALANCING.—If both a violation of the duty of disclosure and intent to deceive the Office are proven by clear and convincing evidence, the court shall undertake an equitable determination whether, in view of all the facts, a finding of inequitable conduct is warranted.
(e) REMEDIES.—If the court finds both that material information was misrepresented to, or withheld from, the Office and an intent to deceive, after balancing the equities, the court, using its discretion, shall impose 1 or more of the following remedies as it deems appropriate: (1) Hold the patent unenforceable. (2) Hold 1 or more claims of the patent unenforceable. (3) Order 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.	(e) REMEDY.—If the court makes a finding of inequitable conduct, it shall hold unenforceable those claims of the patent to which the information misrepresented or not disclosed is material.
	(f) PLEADING.—In actions involving allegations of inequitable conduct before the Office, the party asserting the defense or claim shall comply with the pleading requirements set forth under Federal Rules of Civil Procedure 9(b).

VII. CONCLUSION

In the late 1980s, measured by the number of cases and the deleterious effects of improper use of the defense, there was a plague of inequitable conduct allegations in patent litigation. In response, the Federal Circuit implemented several reforms in the *Kingsdown* case, and the PTO issued an amended Rule 56. Over the following two decades, the prevalence of inequitable conduct rulings in the Federal Circuit ebbed and flowed, and a number of doctrinal ambiguities persisted. Then, in 2006, with its rulings in *Digital Control* and *Ferring*, the Federal Circuit rolled back the reforms of the late

1980s and early 1990s. Subsequent decisions have further muddled the doctrine, with inconsistent and expansive application of the doctrine’s general principles. These doctrinal problems invite tactical use and abuse of the doctrine in future cases—which may be viewed as one form of expanding the “plague.”

In fact, litigants at the district court level have asserted the defense of inequitable conduct in an ever-increasing proportion of patent cases. The wide and growing disparity between the frequency with which inequitable conduct is pled, on the one hand, and the percentage of all patent cases that ultimately result in a Federal Circuit ruling of inequitable conduct, on the other, is further indicative of a spreading “plague.”

Reform is needed. Congress has proposed a number of different statutory revisions. Each of the patent reform bills introduced during the 110th Congress had several good ideas and several ideas that lacked historical context, were insufficient to implement true reform, or, worse, would likely be counterproductive against the stated purpose of reining in abuse of the inequitable conduct defense.

Patent reform legislation was again introduced early in the 111th Congress.³⁰² However, initial versions of the legislation did not include provisions for inequitable conduct reform.³⁰³ Between April 2, 2009 and October 5, 2009, the Patent Reform Act of 2009 showed little progress in Congress. However, on October 5, 2009, Commerce Secretary Locke sent Senators Leahy and Sessions a letter providing the Obama Administration’s views on patent reform,³⁰⁴ which may signal a resumption in legislative activity.

In the absence of legislative reform, judicial reform of inequitable conduct is also possible. However, there is no prospect for Supreme Court action on the horizon. The Court denied certiorari in 2006 in *Ferring*,³⁰⁵ and did so again in 2009 in *Aventis v. Amphastar*.³⁰⁶ In January 2009, patentee Aventis petitioned the Supreme Court for a writ of certiorari³⁰⁷ from the Federal Cir-

302. S. 515, 111th Cong. (as introduced in Senate, Mar. 3, 2009); H.R. 1260, 111th Cong. (as introduced in Congress, Mar. 3, 2009); S. 610, 111th Cong. (as introduced in Senate, Mar. 17, 2009).

303. *Id.* The sole exception is that the 2009 Kyl bill, S. 610, § 299, includes provisions for civil sanctions for misconduct before the PTO.

304. Letter from Gary Locke, Sec’y, Dep’t of Commerce, to Patrick Leahy, Chairman, and Jeff Sessions, Ranking Member, Comm. on the Judiciary U.S. Senate (Oct. 5, 2009) (on file with the U.S. Dep’t of Commerce), available at <http://judiciary.senate.gov/resources/documents/111thCongress/upload/100509LockeToLeahySessions.pdf>.

305. *Ferring B.V. v. Barr Labs., Inc.*, 549 U.S. 1015 (2006).

306. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 129 S. Ct. 2053 (2009).

307. Petition for Writ of Certiorari, *Aventis*, 129 S. Ct. 2053 (No. 08-937) (arguing for

cuit’s decision in *Aventis v. Amphastar*, in which the patent on Aventis’ \$2 billion-per-year drug was held unenforceable due to an omission in a non-inventor expert’s declaration. With echoes of *Ferring*, the expert was deemed to have made this omission intentionally because he should have known of the materiality of the omitted information.³⁰⁸ Aventis concluded its petition for certiorari with a plea for reform:

This issue will not benefit from further percolation in the circuits. The split in the lower courts and within the Federal Circuit itself is deep and mature, and the Federal Circuit has exhibited a steadfast unwillingness to revisit the issue en banc. Four decades of confusion are enough. The question presented is ripe—indeed overdue—for this Court’s review.³⁰⁹

Nonetheless, the Supreme Court denied certiorari.

Absent action by Congress or the Supreme Court, it remains possible that the Federal Circuit will implement doctrinal reform. Given the proliferation of panel decisions from the Federal Circuit, it would take an en banc decision to reform the substantive doctrine. However, assuming the Federal Circuit is actively looking for a suitable inequitable conduct case to take en banc,³¹⁰ it is unclear when that might happen; in late 2008, for example, the Federal Circuit declined a rehearing en banc in *Star Scientific*.³¹¹

In this context, the Federal Circuit’s August 2009 decision concerning the Rule 9(b) pleading standard in *Exergen v. Wal-Mart*³¹² hints at an interesting possible avenue for reform. The decision goes significantly farther than prior cases in the degree of specificity required to plead inequitable conduct. For example, an inequitable conduct pleading must now name the specific individual(s) alleged to have committed inequitable conduct, identify the specific claim limitations affected, identify the specific passages in the withheld reference that are alleged to be material, establish that those passages are not cu-

reform of the intent element of inequitable conduct, abolition of the “sliding scale between intent and materiality,” and for a broader discretionary range of remedies).

308. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1344–49 (Fed. Cir. 2008); Petition for Writ of Certiorari, *Aventis*, 129 S. Ct. 2053 (No. 08-937).

309. *Id.* at *30.

310. Chief Judge Michel has called upon practitioners to be “more strategic and more imaginative” in submitting *en banc* petitions to the Federal Circuit on important issues. Chief Judge Paul R. Michel, Remarks at Harvard Law School Conference on Intellectual Property Law 7 (Sept. 9, 2008) (transcript on file with author), available at http://www.cafc.uscourts.gov/CJM_Speech_Harv_LS_Conf_9-08.pdf.

311. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1357 (Fed. Cir. 2008), *reh’g en banc denied*, 2008 U.S. App. LEXIS 25385 (Fed. Cir., Oct. 22, 2008).

312. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009).

mulative of all the other references that were cited to the examiner, and plead facts from which a specific intent to deceive the examiner is reasonable (i.e., is plausible and flows logically from the facts alleged).³¹³

This degree of required specificity will doubtless chill some proportion of strategically-pled inequitable conduct claims, and time will tell how effective a strengthened Rule 9(b) requirement is at controlling the “plague” of inequitable conduct.

Ultimately, however, the success of a heightened pleading standard in reining in allegations of inequitable conduct will depend on the contours of the underlying doctrine. Consider, for example, the lesser impact of a heightened pleading standard on the intent element if, instead of the *Star Scientific* requirement that intent be the single most reasonable inference, the prevailing standard was *Ferring’s* should-have-known test. Put another way, if the bar for proving inequitable conduct is low, requiring the elements to be pled with specificity does not raise the bar of proof. If, however, the substantive bar is higher (and clearly articulated), then a stringent Rule 9(b) standard will weed out the strategically-asserted claims of inequitable conduct that seek to capitalize on lax pleading standards and doctrinal confusion. Therefore, although *Exergen* can be expected to cause a reduction in the prevalence of inequitable conduct in patent litigation, substantive reform of the kind outlined in this Article will be required to truly control the “plague.”

313. *Id.* at 1326–28.

