

INEQUITABLE CONDUCT CLAIMS IN THE 21ST CENTURY: COMBATING THE PLAGUE

By Katherine Nolan-Stevaux

“[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”¹

In an *ex parte* patent prosecution system, patent validity depends on the quality of the information available to the examiner. Consequently, patent applicants are under a strict duty to disclose all relevant prior art materials of which they are aware.² The Federal Circuit has emphasized this duty by stating that “[t]he highest standards of honesty and candor on the part of applicants in presenting such facts to the office are thus necessary elements in a working patent system. We would go so far as to say they are essential.”³ In the United States, the duty to disclose is enforced during litigation through the affirmative defense of inequitable conduct.⁴ When asserted successfully, this defense prevents a patentee who knowingly withheld relevant prior art information from enforcing her patent rights.

In theory, the United States Patent and Trademark Office (PTO) ensures that issued patents do not claim knowledge in the public domain, and it does so by upholding the standards of novelty and nonobviousness.⁵ Unless the PTO can prove by a preponderance of the evidence that a claimed invention has been described previously, it must issue a patent on the invention.⁶ Consequently, an examiner’s access to relevant prior art strongly influences whether claims in a patent application will issue. In

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

2. 37 C.F.R. § 1.56 (2004).

3. *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1538 (Fed. Cir. 1984) (quoting *Norton v. Curtiss*, 433 F.2d 779, 794 (C.C.P.A. 1970)).

4. See generally Michael A. Weidinger, *Inequitable Pleading: Defendants’ Particular Burden in Patent Infringement Suits*, 62 GEO. WASH. L. REV. 1178 (1994).

5. See 35 U.S.C. §§ 102, 103 (2000).

6. The burden of showing non-patentability rests on the PTO. See *id.* § 102; *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). In addition, examiners must produce a prima facie case of obviousness, whereas applicants are not required to submit evidence of nonobviousness. See UNITED STATES PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2142, at 2100-128-29 (8th ed. 2001) [hereinafter MPEP], available at <http://www.uspto.gov/web/offices/pac/mpep/mpep.htm>. Furthermore, under 37 C.F.R. § 1.114(d) (2004), examiners cannot issue a truly final rejection since applicants may file an unlimited number of continuations.

many fields, applicants are better informed on the availability and relevance of prior art than are examiners.⁷ As a result, examiners are more likely to issue invalid patents because material references are not before them rather than because of an inability to understand available references.⁸

Improperly granted patents incur significant social and economic costs.⁹ The doctrine of inequitable conduct aims to remedy these ills by stripping patent rights from undeserving individuals post hoc. However, many legitimate patentees must defend their patents against frivolous allegations, creating a substantial strain on the courts and the patent system in general. The practice of asserting a defense of inequitable conduct, regardless of the merits of the defense in a given case, has reached the breaking point.

This Note recommends three conservative reforms to the implementation of inequitable conduct allegations aimed at reducing the number of frivolous allegations. These proposals are in line with particular reforms advocated by the National Academy of Sciences (NAS) and the Federal Trade Commission (FTC).¹⁰ Part I discusses the foundations of the doctrine of inequitable conduct and the current state of the law. Part II addresses the policy arguments underlying inequitable conduct and provides an empirical study on how district courts have applied the law in the past ten years. The Part shows that in summary judgment proceedings, 42% of the allegations of inequitable conduct were dismissed because they failed to raise genuine issues of material fact requiring disposition in trial, and in trials and post-trial motions, courts failed to find clear and convincing evidence of inequitable conduct 70% of the time. Thus, a substantial majority of inequitable conduct allegations fail to uncover clear and convincing evidence of wrongdoing. Based on these findings, Part III outlines four

7. See Jay P. Kesan & Marc Banik, *Patents as Incomplete Contracts: Aligning Incentives for R&D Investment with Incentives to Disclose Prior Art*, 2 WASH. U. J.L. & POL'Y 23, 32 (2000).

8. See David Hricik, *Aerial Boundaries: The Duty of Candor as a Limitation on the Duty of Patent Practitioners to Advocate for Maximum Patent Coverage*, 44 S. TEX. L. REV. 205, 220-21 (2002) (discussing how validity depends on disclosure and the problems stemming from this dependence).

9. See Hricik, *supra* note 8, at 222; Mark D. Janis, *Reforming Patent Validity Litigation: The "Dubious Preponderance"*, 19 BERKELEY TECH. L.J. 923, 923-24 (2004); Kesan & Banik, *supra* note 7, at 23-24, 32-33; Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1515-20 (2001).

10. FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003) [hereinafter FTC REPORT], available at <http://www.ftc.gov/opa/2003/10/cpreport.htm>; NAT'L ACAD. OF SCIS., A PATENT SYSTEM FOR THE 21ST CENTURY (Stephen A. Merrill et al. eds., 2004) [hereinafter NAS STUDY].

possible reforms to curb the number of unsubstantiated inequitable conduct charges: (1) eliminate the doctrine of inequitable conduct; (2) award attorneys' fees to patentees when there are no issues of material fact supporting the allegations; (3) lower the presumption of validity for prior art not examined during prosecution; and (4) encourage the submission of statements of relevance of prior art during prosecution. This Note discusses the insurmountable limitations associated with the first proposition and, therefore, only advocates the adoption of proposals two through four as a means of combating the inequitable conduct plague.

I. BACKGROUND

A. Origin of the Doctrine of Inequitable Conduct

Inequitable conduct is a judicially created patent law doctrine founded in the equitable doctrine of unclean hands.¹¹ In equity jurisprudence generally, a party seeking relief must not have unclean hands itself if it wishes the court to act in its behalf.¹² The Supreme Court appealed to this equitable doctrine and recognized a private right of action for inequitable conduct in the specific context of patent infringement in the landmark case *Keystone Driller Co. v. General Excavator Co.*¹³ In this case, the patentee (who assigned his rights to the plaintiff) learned of a prior, public use of his claimed inventions prior to initiating an infringement suit.¹⁴ He then prepared an affidavit for the prior user to sign in exchange for "valuable considerations," stating that his prior public use was merely an abandoned experiment.¹⁵ When the defendant deposed the prior user, the user failed to disclose the terms under which he had signed the affidavit.¹⁶ Although the Supreme Court did not explicitly state it, the patents were rendered effectively unenforceable by the patentee's conduct in suppressing prior art connected to the patents-in-suit.¹⁷

Although often termed "fraud on the [p]atent [o]ffice,"¹⁸ inequitable conduct encompasses behavior broader than common law fraud. Tradi-

11. *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244-45 (1933). All references to inequitable conduct in this Note refer to the doctrine in the context of patent law.

12. *See Wheeler v. Sage*, 68 U.S. 518, 530-31 (1863); *Bein v. Heath*, 47 U.S. 228, 247 (1848).

13. 290 U.S. at 246-47.

14. *Id.* at 243.

15. *Id.*

16. *Id.*

17. *Id.* at 247.

18. *See, e.g., Norton v. Curtiss*, 433 F.2d 779, 793 (C.C.P.A. 1970).

tionally, courts have employed the term "fraud" to describe conduct so reprehensible on its face that it formed the basis of an actionable wrong. Because severe penalties result when parties are found guilty of common law fraud, such a finding requires the presence of four factors: misrepresentation of a material fact; scienter, or knowledge or belief that the information is false; justifiable reliance upon the misrepresentation; and injury to the party deceived.¹⁹ In contrast, in an action at equity, fraud can be raised as an affirmative defense.²⁰ If a defendant's claim is held to be valid, a court will refuse to enforce any judgment in the plaintiff's favor. Inequitable conduct falls into this latter category of "fraud." Inequitable conduct encompasses affirmative acts (submission of false or misleading information to the PTO) as well as omission of material information, unlike common law fraud.²¹ Therefore, inequitable conduct has a broader reach than traditional common law fraud.

In 1945, the Supreme Court explicitly recognized inequitable conduct by a patent applicant as bar to enforcement of a patent in the case *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*²² The Court stated that:

[a] patent by its very nature is affected with a public interest. . . . The far reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.²³

Since *Precision Instrument*, the law has continually evolved, and with the creation of the Federal Circuit, has acquired more coherence in its application.²⁴ For example, many district courts agree that, when pled as an affirmative defense, allegations of inequitable conduct must be pled with particularity according to Federal Rules of Civil Procedure 9(b).²⁵

19. See, e.g., W. PROSSER & W. KEETON, LAW OF TORTS, §§ 105-110 (5th ed. 1984).

20. *Id.*

21. *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1559 (Fed. Cir. 1984).

22. 342 U.S. 806 (1945).

23. *Id.* at 816.

24. See Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J.L. & TECH. 37 (1993), for a history of the development of the doctrine.

25. FED. R. CIV. P. 9(b); see 6 DONALD S. CHISUM, CHISUM ON PATENTS § 19.03[6][b][iii] (2004) [hereinafter CHISUM ON PATENTS]. See *Chiron Corp. v. Abbott Labs.*, 31 U.S.P.Q.2d 1848, 1850 (N.D. Cal. 1994), for a discussion of the policy rationale behind applying FED. R. CIV. P. 9(b) to inequitable conduct.

B. Test for Inequitable Conduct

A finding of inequitable conduct is based on a two-step test: (1) whether the withheld information meets a threshold test of materiality and intent to mislead and (2) whether the applicant's conduct is so culpable, based on a balancing of the materiality and intent under the circumstances, that the patent should be rendered unenforceable.²⁶ Because materiality and intent are often intertwined, the necessary level of intent may decrease to support a finding of inequitable conduct if a reference is found to be highly material.²⁷ Furthermore, inequitable conduct requires clear and convincing evidence of the intentional failure to disclose material information²⁸ due to the presumption of validity that accompanies all issued patents.²⁹ Once a court finds that an applicant engaged in inequitable conduct during prosecution of a patent, the entire patent is invalidated. Inequitable conduct "goes to the patent right as a whole, independently of particular claims."³⁰ Therefore, even where the lack of candor and disclosure does not extend to all claims, a court will nonetheless hold the entire patent unenforceable.³¹

1. Materiality³²

The level of materiality required to support a finding of inequitable conduct is currently unclear. Prior to the establishment of the Federal Circuit, courts had employed at least three distinct standards of materiality: (1) an objective "but for" standard; (2) a subjective "but for" standard; and (3) a "but it may have" standard.³³ The Federal Circuit endorsed a fourth

26. *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1364 (Fed. Cir. 1984).

27. *Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 716 (Fed. Cir. 1981).

28. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

29. 35 U.S.C. § 282 (2000). "Clear and convincing evidence" lies between the "beyond a reasonable doubt" and the "preponderance of the evidence" standards. *Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988).

30. *In re Clark*, 522 F.2d 623, 625 (Fed. Cir. 1975).

31. See generally 6 CHISUM ON PATENTS, *supra* note 25, § 19.03[6][b][iii].

32. The majority of the analysis of inequitable conduct in this Note is restricted to the standards articulated by the Court of Appeals for the Federal Circuit. It should be noted that the previous standard of materiality appears to have been rooted in general fraud principles. See *Norton v. Curtiss*, 433 F.2d 779, 794 (C.C.P.A. 1970). Furthermore, inequitable conduct allegations rising in conjunction with antitrust allegations are beyond the scope of this Note.

33. See, e.g., *Plastic Container Corp. v. Cont'l Plastics of Okla., Inc.*, 607 F.2d 885, 899 (10th Cir. 1979); *Gemveto Jewelry Co. v. Lambert Bros.*, 542 F. Supp. 933, 939-40 (S.D.N.Y. 1982). The "but it may have" standard endorses an inquiry into whether the

standard, based on PTO Rule 1.56 (“Rule 56”).³⁴ In doing so, the court remarked that Rule 56 appears to encompass the other standards and that its definition of materiality closely aligns “with how one ought to conduct business with the PTO.”³⁵ Yet, the Federal Circuit noted that it did not intend to be bound by any one standard, given that materiality and intent are often interrelated.³⁶

Just as the applicable standard of materiality has evolved over time, the Rule 56 definition of materiality has also evolved. Rule 56 specifically deals with the duty of disclosure that applicants must uphold before the PTO. Prior to 1992, Rule 56 required disclosure of information material to the application “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.”³⁷ In 1992, the PTO amended Rule 56 to address criticisms concerning a perceived lack of certainty in the standard and to reduce the frequency at which defendants raised the inequitable conduct defense in litigation.³⁸ The new Rule 56 states:

Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any considera-

relevant facts “might reasonably have affected” a PTO examiner’s determination of patentability. *Gemveto Jewelry*, 542 F. Supp at 940.

34. *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362-63 (Fed. Cir. 1984). Prior to 1992, Rule 56(a) defined material information as that “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.” 37 C.F.R. § 1.56 (1991).

35. *Am. Hoist*, 725 F.2d at 1363.

36. *Id.*

37. 37 C.F.R. § 1.56(a) (1991).

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

tion is given to evidence which may be submitted in an attempt to establish a contrary conclusion or patentability.³⁹

The Federal Circuit has yet to determine whether the revision to Rule 56 promulgated by the PTO should apply in determining materiality. According to the Federal Circuit, the revised rule “was not intended to constitute a significant substantive break with the previous standard.”⁴⁰ The court consistently has applied the pre-1992 rule to cases in which the patents at issue were prosecuted prior to 1992.⁴¹ However, in some cases the court has applied both standards⁴² or has applied only the post-1992 version of Rule 56, leaving district courts unsure of which standard should apply.⁴³ Thus, although the Federal Circuit has centered its definition of materiality in Rule 56, the current standard is still in flux.

39. 37 C.F.R. § 1.56 (2004).

40. *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003).

41. *See, e.g.*, *CFMT, Inc. v. YieldUP Int'l Corp.*, 349 F.3d 1333, 1342-43 (Fed. Cir. 2003) (reversing finding of inequitable conduct on applications filed in 1985 and 1988 because statements at issue were not inaccurate and PTO examiner had not relied on those statements to find application was not obvious); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1231, 1234 (Fed. Cir. 2003) (finding inequitable conduct based on pre-1992 standard where patent in question was submitted to PTO in 1989); *Promega*, 323 F.3d at 1372 (remanding determination of inequitable conduct during prosecution of patent filed in 1987 for district court's determination whether the conduct amounted to inequitable conduct under the circumstances); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268 (Fed. Cir. 2001) (affirming district court's verdict of inequitable conduct during the prosecution of a patent filed in 1991); *Li Second Family Ltd. v. Toshiba Corp.*, 231 F.3d 1373 (Fed. Cir. 2000) (affirming finding of inequitable conduct for patents filed as continuations-in-part of applications filed in 1973 and 1977); *Elk Corp. v. Dallas v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 31 (Fed. Cir. 1999) (finding non-disclosure of prior art was material); *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1457 (Fed. Cir. 1984) (finding materiality is limited to claims not abandoned during prosecution); *Am. Hoist*, 725 F.2d at 1350 (refusing to limit materiality to Rule 56 alone).

42. *See, e.g.*, *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003) (finding information not material under either standard).

43. *See, e.g.*, *Paragon Podiatry Lab. v. KLM Labs., Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 2003) (discussing prima facie case of unpatentability without explicitly mentioning the post-1992 rule); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997) (overturning district court's decision on inequitable conduct where failure to disclose prior art patent was material to examiner's decision that Critikon's patent disclosed novel mechanism).

2. *Intent to Deceive*

Inequitable conduct also requires proof of intent to deceive, although such intent need not be shown directly.⁴⁴ Initially, a finding of gross negligence supported the requisite intent to deceive.⁴⁵ Thus, applicants who purposefully neglected their duty to disclose risked the unenforceability of their patents. Beginning in 1987, with *FMC Corp. v. Manitowoc Co.*,⁴⁶ the Federal Circuit retreated from this position, stating that gross negligence alone did not mandate a finding of intent to deceive. In 1988, in *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*,⁴⁷ the Federal Circuit *en banc* held that a finding of gross negligence did not justify an inference of intent to deceive. Rather, the Federal Circuit held that "all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive."⁴⁸ Thus, under the current standard, intent to deceive must be supported by clear and convincing evidence, although direct evidence of this intent is not required.

Since *Kingsdown*, cases dealing with intent can be categorized in three ways: those in which there is a clear intent to deceive, those in which high degree of materiality justifies a lower standard of intent, and those in which a court finds no intent. Although cases of clear intent to deceive are rare, *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*⁴⁹ illustrates the high water mark of such cases. The Federal Circuit, under the abuse of discretion standard, upheld the district court's finding of intent to deceive where an attorney knew that an article he failed to disclose would have shown that the invention in a patent application was not enabled, yet still wrote broad claims to cover the invention. Because the attorney was aware of the duty to disclose and failed to credibly justify his failure to do so, he had the requisite intent to deceive.⁵⁰

44. *Hycor Corp. v. Schueter Co.*, 740 F.2d 1529, 1539 (Fed. Cir. 1984); see Goldman, *supra* note 24, at 76-85 (outlining the evolution of the Federal Circuit's position on the requisite level of intent required to find inequitable conduct).

45. *In re Jerabek*, 789 F.2d 886, 891 (Fed. Cir. 1986); *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1553 (Fed. Cir. 1984); *Hycor*, 740 F.2d at 1540 (ruling that deliberate scheming not required to find intent); *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984); *Orthopedic Equip. Co. v. All Orthopedic Appliances*, 707 F.2d 1376, 1383 (Fed. Cir. 1983).

46. 835 F.2d 1411, 1415 n.9 (Fed. Cir. 1987).

47. 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc*).

48. *Id.* (citations omitted). For a detailed discussion of the intent to deceive standard post-*Kingsdown*, see Lynn C. Tyler, *Kingsdown Fifteen Years Later: What Does It Take to Prove Inequitable Conduct?*, 13 FED. CIR. B.J. 267 (2003).

49. 326 F.3d 1226 (Fed. Cir. 2003).

50. *Id.* at 1239-41.

Frequently, a withheld reference is highly material and therefore a lesser level of intent is sufficient to support a finding of inequitable conduct. In *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*,⁵¹ the Federal Circuit found that the plaintiff, Semiconductor Energy, had the requisite intent to justify a finding of inequitable conduct. The inventor, a Semiconductor Energy employee, submitted a Japanese language version of a material prior art reference in its entirety, but only a partial, one-page translation that failed to disclose all of the elements of the full-length patent.⁵² In addition, the plaintiff indicated that the reference in question was relevant only to one of the claims in the plaintiff's patent application, yet clear and convincing evidence demonstrated otherwise.⁵³ Thus, the Federal Circuit found that the district court's finding of intent by inference was not clearly erroneous.⁵⁴

II. DISCUSSION

Since the creation of the Federal Circuit, various parties have asserted that inequitable conduct charges have risen to plague proportions.⁵⁵ Between 1988 and 2001, the number of terminated patent lawsuits doubled from approximately 1,200 to 2,400 per year. This dramatic increase primarily was due to an increase in the number of patents issued, because the relative rate of litigation did not increase.⁵⁶ However, given that the absolute number of patent suits has increased, once again, inequitable conduct has come under the microscope.⁵⁷ Recently, both the NAS and the FTC released reports containing proposals for reform of the patent system, including reforms that alter the inequitable conduct doctrine.⁵⁸

51. 204 F.3d 1368 (Fed. Cir. 2000).

52. *Id.* at 1377-78.

53. *Id.*

54. *Id.* at 1383.

55. See *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988); Donald S. Chisum, *Best Mode Concealment and Inequitable Conduct in Patent Procurement: A Nutshell, a Review of Recent Federal Circuit Cases and a Plea for Modest Reform*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 277 (1997); Donald S. Chisum, *Patent Law and the Presumption of Moral Regularity: A Critical Review of Recent Federal Circuit Decisions on Inequitable Conduct and Willful Infringement*, 69 J. PAT. & TRADEMARK OFF. SOC'Y 27 (1987); Laurence H. Pretty, *Inequitable Conduct in the PTO—Is the "Plague" Entering Remission?*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 46 (1989); Note, *Can Intellectual Property Law Regulate Behavior? A "Modest Proposal" for Weakening Unclean Hands*, 113 HARV. L. REV. 1503 (2000); see also 6 CHISUM ON PATENTS, *supra* note 25, § 19.03[5][b] n.7.

56. See NAS STUDY, *supra* note 10, ch. 1, at 32.

57. See generally FTC REPORT, *supra* note 10; NAS STUDY, *supra* note 10.

58. NAS REPORT, *supra* note 10, at 5-8; see FTC REPORT, *supra* note 10, Executive Summary at 8-10, 13-14.

Any reforms of inequitable conduct must take into consideration both the policy rationales underlying the doctrine as well as the problems that exist with the current system. Consistent with these requirements, the following sections first address the rationales underlying inequitable conduct and then present the results of an empirical study examining district court cases in the past ten years in which inequitable conduct was a decisive issue.

A. Policy Rationales for Inequitable Conduct

The doctrine of inequitable conduct can be viewed as a mechanism both to promote innovation through the duty to disclose and to deter patent applicants from hiding valuable information in order to obtain a patent.

1. Duty to Disclose

The United States, unlike most jurisdictions, imposes a duty to disclose upon all parties to a patent application.⁵⁹ Because the United States does not have a formal opposition proceeding during which an applicant's competitors may submit relevant prior art before a patent issues, the PTO depends upon examiners and applicants to cover the full scope of the prior art.⁶⁰ Although patent filings have increased, the number of examiners per thousand patents has decreased by approximately twenty percent since around 1999.⁶¹ Given Congress' reluctance to increase the number of examiners, the duty of disclosure is crucial. Since the burden is on the PTO to prove by a preponderance of the evidence that the claimed invention was not in the prior art and, once issued, the patent is presumed valid, there is a strong policy rationale to ensure that the PTO has access to all necessary information needed to deny patents to undeserving applicants. Studies estimate that between 83% to 97% of patents filed are issued by the PTO, justifying fears over the existence of "bad" patents.⁶² With such

59. See Hricik, *supra* note 8, at 231.

60. The duty to disclose is discharged only when all material information known to the applicant was cited by or submitted to the PTO, as dictated by 37 C.F.R. §§ 1.97(b)-(d), 1.98 (2004). For details on submission of the information disclosure statement (IDS), see Todd L. Juneau & Jill K. MacAlpine, *Protecting Patents from the Beginning: The Importance of Information Disclosure Statements During Patent Prosecution*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 577 (2000).

61. NAS STUDY, *supra* note 10, at 51.

62. See *id.* at 53 (describing studies done by two different groups on two different data sets attempting to correct for the presence of continuing applications, which differ with the PTO's own data which claims a lower percentage of continuances).

a high rate of patent issuance, it is very likely that improperly granted patents do issue.⁶³

Improperly granted patents impose additional transaction costs on potential deal-making parties because they must evaluate patent portfolios to assess the validity of patents that have undergone PTO review.⁶⁴ Due to the relative ease of obtaining patents coupled with the potential of winning large damage awards in infringement litigation, rent-seeking entrepreneurs may establish speculative patent acquisition and enforcement enterprises, hoping to collect license fees on questionable patents.⁶⁵ Furthermore, patentees, when doubtful that their patents will be upheld, generally set low license fees. Lured by such low license fees, potential infringers choose to license questionable patents rather than challenge their validity. Consequently, low license fees enable a patentee to collect rent despite the invalidity of her patent.⁶⁶ In addition, invalid patents that result in litigation impose costs on accused infringers who are forced to defend their activities.⁶⁷

Furthermore, improperly granted patents stifle innovation. First, patents on items in the public domain—or slight modifications thereof—result in the removal of objects from the public domain, conferring market power on the patent holder who may resort to litigation to enforce his patent rights. Granting patents for such inventions that do not meet the novelty, utility, and nonobviousness standards unjustly rewards patentees at the expense of the public, who will pay higher prices for products due to the opportunity to exclude others from buying, making, or selling a product based on the patented technology.⁶⁸ Second, such “bad” patents may

63. See Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 589-91 (1999).

64. See Hricik, *supra* note 8, at 222. Such costs are not limited to invalid patents, however, and can constitute hidden costs in many industries. See, e.g., NAS STUDY, *supra* note 10; Bronwyn H. Hall & Rosemary Ham Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry*, 32 RAND J. ECON. 101, 107-11 (2001).

65. See Hricik, *supra* note 8, at 222. For an example of one such rent-seeking entrepreneur, see Susan Hansen, *Lawyer Brings Lemelson's Lucrative IP Career to an End*, RECORDER, May 5, 2004 (describing how Lemelson used his patent portfolio to intimidate other companies to settle rather than face litigation despite the widely held view that his patents were invalid).

66. See Hricik, *supra* note 8, at 222.

67. See Lemley, *supra* note 9, at 1530-31 (stating that because attorneys' fees are awarded only in exceptional cases, as a practical matter, accused infringers usually get fees if they can prove that a suit was filed in bad faith despite the fact that 35 U.S.C. § 285 only applies to a “prevailing party”).

68. NAS STUDY, *supra* note 10, at 46.

encourage infringement, consequently raising transaction costs, and possibly discouraging investment because of potential investors' doubts about the validity of target patents.⁶⁹ Competitors may choose to design around the "bad" patent easily, but some fields are more resistant to such activities because of the subject matter or the economics involved.⁷⁰ In some fields, companies may avoid the time-consuming activity of challenging bad patents in order to preserve time-sensitive research opportunities.⁷¹ Third, firms may seek to expand their patent portfolios, not necessarily to exploit the patents themselves, but to create a bigger arsenal for asserting patents against competitors in infringement counterclaims.⁷² Such a strategy not only costs competitors additional legal fees, but also potential future innovation, as researchers will be diverted from innovative activity to aid in defending against infringement claims.⁷³

In order to avoid such "bad" patents and their concomitant social costs, examiners must have access to the most relevant prior art. The best source of such prior art is the applicant or her attorney. Although patent examiners are specialists within various scientific domains and have ready access to a database of issued patents, they lack comparable access to non-patent prior art.⁷⁴ As a result, examiners are more likely to compare the claims in an application against issued patents rather than against other prior art. For fields of rapid innovation, examiners will likely lack access to the most relevant information.⁷⁵ Unlike examiners, applicants are experts in their respective fields with the most up-to-date information. Furthermore, applicants' attorneys are acquainted with prior art from multiple clients.⁷⁶ Thus, the robust duty to disclose aims to provide examiners with information

69. See *Merges*, *supra* note 63, at 593-94.

70. See FTC REPORT, *supra* note 10, ch. 2, at 21-22. Where patented technology must conform to an industry or consumer standard, competitors may find it economically impossible to design around a particular patent. For biotechnology, six months of time diverted to design around a patent may take that particular opportunity off the table. *Id.* ch. 3, at 21-22. Furthermore, since patent litigation in this field may cost a party up to five to seven million dollars, litigation costs may exceed the potential revenue of the technology in question, were it to be developed further. *Id.*

71. See *id.* ch. 3, at 21-22 (discussing that in the field of biotechnology, by the time a court has determined the validity of a particular patent, the research opportunity has passed).

72. See *id.* ch. 2, at 30-32.

73. See *id.* (Greenhall's comments). Note that such a strategy is effective only against companies involved in innovation and does nothing to prevent firms that do not produce products from threatening infringement or demanding royalties or licenses.

74. Furthermore, patent examiners are also pressed for time.

75. See FTC REPORT, *supra* note 10, ch. 5, at 7.

76. Generally speaking—of course, this assertion is not true of, say, in-house attorneys.

they may lack, in order to ensure that issued patents are deserving of their presumption of validity.

However, although the duty to disclose aims to address the problems inherent in an *ex parte* system, it does not go far enough. Because the duty to disclose does not impose a duty to search for material information,⁷⁷ applicants may choose to ignore potentially relevant sources in order to increase the chances of their own patents issuing. In addition, by limiting the duty of candor to the applicant and her attorney, prior art known by others in an applicant's laboratory or research group need not be revealed. The PTO neither investigates nor rejects applications for failure to disclose information known by those other than the applicant or attorney.⁷⁸ Therefore, reforms should aim to eliminate the negative incentives produced under the current system.

2. *Deterrence Mechanism*

In addition to assuring that patents are worthy of the presumption of validity, the doctrine of inequitable conduct punishes those who seek to improperly profit from the system. Analogizing to criminal prosecution, compliance with Rule 56 requires both enforcement and a penalty for violation of the duty to disclose. Our society views with distaste bad-faith procurement of material goods, and patents are no different from other forms of wealth since they grant the right to prevent others from making, using, or selling a product based on patented knowledge.⁷⁹ Failure to comply with the duty to disclose exposes the patentee to charges of inequitable conduct if her patent is litigated. However, given that only approximately two percent of patents are ever litigated,⁸⁰ the patent applicant might expect her lack of full disclosure to go unnoticed. Consequently, the patent applicant has both the motive to avoid full disclosure or a full search of the prior art as well as the opportunity—she has more information about prior art than the PTO—to behave strategically. Accordingly, to deter such opportunistic behavior, courts impose large penalties, including unenforceability of the patent in suit and fee-shifting, for violation of the duty to disclose.⁸¹ Viewed from this vantage point, inequitable conduct also func-

77. See MPEP, *supra* note 6, § 2001.06, at 2000-05 (limiting the duty to disclose to the information inventors “are aware of”).

78. See *id.* § 2010, at 2000-11-12 (explaining that courts are a better forum through which such claims can be decided and stating that such PTO determinations would increase costs without commensurate increases in patent quality).

79. See Paul M. Janicke, *Do We Really Need So Many Mental and Emotional States in United States Patent Law?*, 8 TEX. INTELL. PROP. L.J. 279, 292 (2000).

80. See Lemley, *supra* note 9, at 1501.

81. See Shubha Ghosh & Jay Kesan, *What Do Patents Purchase? In Search of Optimal Ignorance in the Patent Office*, 40 Hous. L. Rev. 1219, 1236-37 (2004); Michael J.

tions as a penalty default to discourage applicants from playing strategic games. Patent applicants may avoid penalties by disclosing all material prior art of which they are aware at the outset.⁸²

Thus, the doctrine of inequitable conduct simultaneously serves to ensure that issued patents are valid and that applicants abide by the rules of the system or else face a large penalty. Any reforms to this system should strive to balance these two underlying policy goals.

B. Is There Really a Plague?

As discussed in the previous section, inequitable conduct before the PTO leads to the improper issuance of patents. Common consensus holds that a “plague” of inequitable conduct existed in the 1980s, and one recent dissenting opinion by Judge Newman suggests that the plague is upon us once again.⁸³ Yet no one has attempted to evaluate such claims before asserting that the system must be fixed.

Because enforcement of inequitable conduct is limited to litigation, any evaluation of the existence of a plague must focus on the charges brought in litigation.⁸⁴ A plague of inequitable conduct exists where parties with valid patents frequently are forced to defend against frivolous claims of inequitable conduct. Where such claims are not frivolous—where inequitable conduct allegations are successful—all parties in the system are rewarded: the patent is declared unenforceable and the perpetrator is penalized for her actions. Thus, parties are no longer forced to design around or license a “bad” patent or leave the particular field of research occupied by the patent. Accordingly, only if a preponderance of inequitable conduct charges fail would a plague truly exist.

In order to determine if we are in the midst of a plague, I analyzed inequitable conduct claims over the past ten years. Two hundred forty-four

Meurer, *Controlling Opportunistic and Anti-Competitive Intellectual Property Litigation*, 44 B.C. L. REV. 509, 535-38 (2003) (explaining how fee-shifting deters undesired behavior).

82. See Clarissa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 668-70 (2002) (discussing inequitable conduct as a penalty linked to inadequate disclosure in prosecution); R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of Festo*, 151 U. PA. L. REV. 159, 212-15 (2002) (explaining penalty rules in the context of prosecution history estoppel).

83. *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003) (Newman, J., dissenting) (arguing that the plague is upon the system again); see *Cargill, Inc. v. Sears Petroleum & Transp. Corp.*, 334 F. Supp. 2d 197, 230 (N.D.N.Y. 2004).

84. Although it is likely that decisions to seek a patent or to initiate infringement litigation may be influenced by suspicions of inequitable conduct, it is difficult to document the frequency of such decisions. Consequently, a better measure of whether such a plague exists is the use of inequitable conduct charges in litigation.

court opinions were issued between January 1, 1995 and December 31, 2004, in which allegations of inequitable conduct were decided in either summary judgment motions or following a bench trial (including post-trial motions for reconsideration or for a new trial).⁸⁵

During the ten years, courts issued 119 summary judgment decisions in which they addressed the issue of inequitable conduct (Table 1).⁸⁶

Table 1. Summary Judgment Decisions Addressing Inequitable Conduct from 1995-2004⁸⁷

| | Declined to grant summary judgment on inequitable conduct | Granted summary judgment, found no inequitable conduct | Granted summary judgment, found inequitable conduct |
|------------------|---|--|---|
| Summary Judgment | 50% (59) | 42% (50) | 8% (10) |

In half of all motions for summary judgment (when not declared moot based on other findings), district courts rejected inequitable conduct claims, because allegations surviving to the summary judgment stage raised enough of an inference to warrant proceeding to trial. Such data suggest that inequitable conduct during patent prosecution may be a significant problem. If inequitable conduct occurs regularly during prosecution, then Justice Newman's fear of a plague of unsubstantiated allegations is false. However, courts found that there were no genuine issues of material fact in 42% of the summary judgment motions on inequitable conduct and granted summary judgment for patentees. From this data, it appears that parties frequently allege inequitable conduct where courts find no evidence of it. Thus, patent holders are often forced to defend against charges without merit, supporting the idea of a plague of frivolous charges. In only 8% of cases did courts grant summary judgment for the defendant, indica-

85. My sample was generated using the search terms "patent & 'inequitable conduct'" and searching the database of Federal IP District Court Cases on Westlaw. I excluded motions for a preliminary injunction, because such cases focus on the likelihood of success. In 2002, approximately 2500 patent cases were terminated, which includes judgments, dismissals, settlements, and transfers. NAS STUDY, *supra* note 10, ch. 2, at 32, fig. 2-3. Thus, inequitable conduct allegations are a small percentage of all cases terminated each year.

86. The data included in this set represent cases in which defendants, asserting inequitable conduct as a defense to infringement, sought summary judgment on a finding of inequitable conduct; cases in which plaintiffs alleged inequitable conduct by defendant in the context of a declaratory judgment; and cases in which plaintiffs sought a finding of no inequitable conduct.

87. The numbers in parentheses represent the number of cases in each category out of a total of 119.

tive of the rare circumstances in which patentees blatantly engaged in inequitable conduct.⁸⁸ Overall, the summary judgment data suggest that defendants in patent infringement suits may allege inequitable conduct too routinely without adequate factual support for such allegations. However, without knowing the ultimate outcome of the cases in which these summary judgment motions were raised, it is difficult to make a definitive determination of whether inequitable conduct allegations constitute a plague.⁸⁹

In order to address this issue, I examined district court decisions in which allegations of inequitable conduct were decided. From January 1, 1995, until December 31, 2004, 125 such cases were decided (Table 2).

**Table 2. District Court Decisions Finding Inequitable Conduct
Post-Trial from 1995-2004**

| | Found inequitable conduct | Failed to find inequitable conduct |
|--------------------------|---------------------------|------------------------------------|
| District Court Decisions | 30% (37) | 70% (88) |

Seventy percent of the time, courts failed to find that the information withheld by applicants during prosecution met the requisite standard of materiality and intent. Assuming that summary judgment motions claiming inequitable conduct were filed prior to trial in these cases, courts likely found that defendants alleged sufficient material facts of inequitable conduct to warrant a trial on this issue.⁹⁰ Therefore, it is unlikely that these claims of inequitable conduct were without any basis in fact. In only 30% of cases did courts find inequitable conduct during prosecution of the patent(s)-in-suit, indicating that a substantial minority of commercially important patents are obtained by failing to uphold the duty to disclose.

In general, where courts ruled on both the validity and enforceability of patents, courts generally held that valid patents also were not unen-

88. *See Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (“A summary judgment that a reputable attorney has been guilty of inequitable conduct, over his denials, ought to be, and can properly be, rare indeed.”).

89. One additional complication arises when parties choose to settle rather than to proceed to trial after losing summary judgment on the issue of inequitable conduct: one cannot determine the role played by inequitable conduct in such cases.

90. However, only eleven summary judgment decisions included in Table 1 are represented in the data of Table 2. This may mean that the parties in a majority of cases in the Table 2 data set did not file summary judgment motions on inequitable conduct. Another explanation is that a majority of the cases in which genuine issues of material fact were found in Table 1 proceeded to settlement or licensing agreements and, therefore, are not represented in the second data set in Table 2.

forceable due to inequitable conduct (Table 3). Out of the thirty-seven cases in which courts found inequitable conduct, courts determined the validity of the patents-in-suit in only nineteen cases.⁹¹ Out of the eighty-eight cases in which courts did not find inequitable conduct, they determined the validity of the patents-in-suit in seventy-five cases.⁹²

Table 3. Validity of Patents With Respect to Findings of Inequitable Conduct

| | Patent(s) Valid | Patent(s) Invalid |
|---|-----------------|-------------------|
| Inequitable conduct found and validity ruled upon (18 total) ⁹³ | 11% (2) | 89% (16) |
| No inequitable conduct found and validity ruled upon (74 total) ⁹⁴ | 75% (56) | 25% (18) |

The most striking finding is that where courts find inequitable conduct, they generally also find that claims at issue in the patents are invalid. Indeed, in 89% of cases, courts found patents both unenforceable and invalid. However, given the paucity of such cases in the current data set, it is difficult to determine whether such a correlation would apply more broadly. Nevertheless, these data suggest that the material information that applicants withhold from the PTO during prosecution would prevent a patent from issuing. In contrast, where courts find no inequitable conduct, the patents-in-suit are more likely than not to be found valid, even in light of the additional prior art at issue in the inequitable conduct allegations.

Combining the findings of Tables 1 and 2 demonstrates that courts fail to find inequitable conduct 75% of the time (Table 4).

91. However, in one of these cases involving two patents-in-suit, one patent was held to be valid and the other invalid, although both were determined to be unenforceable. This case was not included in the data in Table 3.

92. However, in one of these cases which involved two patents-in-suit, the court declared one patent valid and other invalid, and both enforceable. This case was not included in the data in Table 3.

93. *Supra* note 91.

94. *Supra* note 92.

Table 4. Percentage of Total Decisions in Which Inequitable Conduct Is Found⁹⁵

| | No Inequitable Conduct Found | Inequitable Conduct Found |
|------------------------------|------------------------------|---------------------------|
| Summary Judgment Decisions | 50 cases | 10 cases |
| Trial & Post-trial Decisions | 88 cases | 37 cases |
| TOTAL | 75% (138 cases) | 25% (47 cases) |

These empirical data suggest that the patent system often enables potentially infringing parties to attack valid patents by alleging inequitable conduct where none exists. Therefore, reforms should be implemented to decrease the prevalence of such unwarranted attacks. In light of these findings, Part III evaluates several proposals bearing on inequitable conduct.

III. REFORMING THE SYSTEM

Many in the patent community believe that the patent system needs strengthening, although the interested parties have yet to reach consensus on the necessary reforms.⁹⁶ Any reforms to the doctrine of inequitable conduct should take into consideration how parties in litigation employ the doctrine. Although inequitable conduct likely influences both the decision of inventive enterprises to seek patents and their behavior in asserting those patents against alleged infringers, such behavior is difficult to study since most parties are unlikely to indicate that their patents are likely unenforceable. Accordingly, this Note addresses only those behaviors that can be measured.

Reforms should be implemented to strengthen the inequitable conduct doctrine based on policy rationales, while lessening the doctrine's effect on patentees who are unjustly forced to defend against it. Specifically, such proposals should decrease the number of unsubstantiated inequitable conduct charges and should encourage applicants to submit all relevant prior art references. This Part outlines four such proposals, based on the FTC and NAS Reports, taking into consideration the empirical data from Part II. The first proposal, and one that the NAS recommends, calls for the elimination of the doctrine of inequitable conduct.⁹⁷ Such a proposal may make sense in light of the data in Table 3, which shows that most patents declared unenforceable are also declared invalid. However, as discussed

95. Note that this table excludes summary judgment decisions in which genuine issues of material fact pertaining to inequitable conduct existed (i.e., column one of Table 1).

96. See, e.g., FTC REPORT, *supra* note 10; NAS STUDY, *supra* note 10, at 1.

97. NAS STUDY, *supra* note 10, at 123.

below, the rare cases in which a valid patent was declared unenforceable indicate the problems with such a reform. The second proposal, also heralded by the NAS, suggests that attorneys' fees be awarded to a prevailing patentee when courts determine that allegations against which they were forced to defend lacked merit.⁹⁸ The third proposal suggests that the presumption of validity should attach only to prior art analyzed by the examiner. In the final proposal, which the FTC recommends, patent applicants are required to provide brief statements of relevance for each prior art reference when requested to do so by an examiner.⁹⁹ This Note rejects the first reform because it fails to recognize the benefits provided by the inequitable conduct doctrine, but recommends the implementation of the last three reforms as the most efficient at reducing the number of frivolous allegations of inequitable conduct.

A. Eliminating Inequitable Conduct

At first glance, based on the findings outlined in Table 3, the simplest proposal for reforming abuses of the inequitable conduct doctrine would be to eliminate the doctrine entirely. In 89% of cases, where district courts found inequitable conduct, they also found that the patents in question were invalid. Thus, even in the absence of the inequitable conduct doctrine, such patents would still be invalidated. Furthermore, patent holders are improperly "taxed" for no valid reason because they are forced to incur additional costs beyond those involved in asserting infringement and defending against invalidity 75% of the time, where their patents are judged to be both valid and enforceable.¹⁰⁰ In the corporate setting, these patent holders incur both the direct costs of deposing their own researchers regarding what prior art they knew and when they knew of it and the indirect costs of reduced future invention because researchers must stop their work to focus on the issues involved in litigation (not to mention the reduced funds for research and development). Eliminating inequitable conduct would eliminate these costs. Although this proposal might seem extreme, the NAS made this very recommendation.

However, this reform ignores two crucial benefits arising from the inequitable conduct doctrine, namely, the deterrence effects for bad actors and the quality control effects on all patents.¹⁰¹ First, *Purdue Pharma v.*

98. *Id.*

99. FTC REPORT, *supra* note 10, Executive Summary, at 13.

100. *Supra* Table 3 at p.17.

101. See *Edited & Excerpted Transcript of the Symposium on Ideas Into Action: Implementing Reform of the Patent System*, 19 BERKELEY TECH. L.J. 1053, 1118 (stating Professor Lemley's fears of what may transpire if the inequitable conduct defense is eliminated).

Endo Pharmaceuticals,¹⁰² in which the patent was found valid but unenforceable due to inequitable conduct, demonstrates the necessity of the deterrence value of inequitable conduct. Second, the policy rationales underlying inequitable conduct are important enough to warrant only minor modifications to the doctrine, rather than its entire eradication.

In *Endo Pharmaceuticals*, the plaintiff, Purdue Pharma (“Purdue”), claimed a formulation of controlled-release oxycodone that controlled pain in 90% of patients.¹⁰³ The specification of the patents-in-suit claimed that such a result had been “surprisingly discovered.”¹⁰⁴ Although the district court held that the patents covering the formulation were valid, *Endo Pharmaceuticals* (“Endo”) contended that Purdue misrepresented the material fact that it “surprisingly discovered” that the controlled range at which oxycodone was effective was less than in other formulations.¹⁰⁵ During trial, Dr. Kaiko, the inventor, admitted that he had “no scientific proof” at the time he filed the application that the invention exhibited a reduced dosage range.¹⁰⁶ Purdue was unable to demonstrate any basis for Dr. Kaiko’s “insight.”¹⁰⁷ The district court found that any reasonable examiner would have concluded that Purdue’s lack of scientific proof that the claimed invention provided analgesic relief at a reduced dosage was material.¹⁰⁸ Furthermore, the district court found that Purdue had the intent to deceive. Dr. Kaiko admitted at trial that there were “no set of procedures and methods” in place prior, during, or subsequent to the prosecution of the patents-in-suit to determine that oxycodone was a stronger analgesic as claimed.¹⁰⁹ An internal memo written by Dr. Kaiko stated that “[w]hile the theoretical argument may be relatively strong using available data, it may be difficult to demonstrate these claims within the context of efficacy studies. Thus, any acceptance of a priority program for controlled-release oxycodone should not assume that all these claims can be demonstrated.”¹¹⁰ Given that the “surprising discovery” was essential to the issuance of the patents-in-suit and that Purdue was unable to prove at trial that it had reduced the invention to practice, the district court found that the material misrepresentations were serious enough to warrant rendering the patents-in-suit unenforceable.

102. 70 U.S.P.Q.2d 1185 (S.D.N.Y. 2004).

103. *Id.* at 1194.

104. *Id.*

105. *Id.* at 1204.

106. *Id.*

107. *Id.* at 1205.

108. *Id.*

109. *Id.* at 1206-07.

110. *Id.* at 1207.

Absent the doctrine of inequitable conduct, Purdue's patents would still be valid as none of the information discussed at trial would qualify as prior art references. From a policy perspective, the monopoly right should be granted only to deserving parties. Particularly when dealing with pharmaceuticals, public interest demands access to generic formulations when the patents covering brand-name drugs expire.¹¹¹ In addition, given the reliance of the PTO examiner on the applicant's duty to disclose and the duty of candor, allowing applicants to get around prior art by using past-tense in prophetic examples undermines the patent system and undermines faith in the presumption of validity.

Second, any proposal to eliminate inequitable conduct ignores the benefits provided to patent holders and inventors everywhere when inequitable conduct allegations succeed and lead to the unenforceability of a patent. Viewing the prevalence of inequitable conduct charges solely as a plague deserving of eradication ignores the cost of improperly granted patents to participants in the system. For example, few would allege that a plague of frivolous lack of enablement charges exists, despite the high rate at which such charges are brought.¹¹² Like the duty to disclose and the related doctrine of inequitable conduct, the enablement standard ensures that applicants before the PTO adequately disclose their invention to the public in exchange for the right to exclude others from making or using the invention during the life of the patent. Both requirements enable PTO examiners to ensure that patents deserve to be issued with a presumption of validity because they are useful, novel, and nonobvious over prior inventions. The cost of "bad" patents issuing through failure to disclose is borne by other innovators who are forced to pay questionable license fees in order to continue their work, to design around "bad" patents, or, depending on the nature of the field, to abandon a particular field of study. Thus, when substantial numbers of inequitable conduct charges succeed, the worry of a possible plague is outweighed by the value to innovators and society as a whole.

B. Reforming the Award of Attorneys' Fees

The expense incurred by patent holders defending against unsubstantiated inequitable conduct charges is one significant problem with the inequitable conduct doctrine. The so-called plague consists of the approximately 42% of inequitable conduct allegations which fail to raise issues of material fact in summary judgment motions (Table 1) and the approxi-

111. See FTC REPORT, *supra* note 10, ch. 3, at 11 n.51.

112. In contrast to enablement allegations, the NAS Study specifically advocates for reforming the best mode requirement to reduce the subjective elements of litigation. See NAS STUDY, *supra* note 10, at 7, 120-21.

mately 70% of cases in which courts fail to find inequitable conduct (Table 2). If prevailing patentees were awarded fees incurred by defending against frivolous inequitable conduct claims, the plague effectively could be neutralized.¹¹³

Currently, attorneys' fees are awarded to a prevailing party only in exceptional cases and at the court's discretion under § 285 of the patent statute.¹¹⁴ Although inequitable conduct before the PTO constitutes an "exceptional case,"¹¹⁵ courts rarely award attorneys' fees in this context, because the prevailing party must demonstrate an exceptionally obvious case of inequitable conduct through clear and convincing specific evidence.¹¹⁶ In the past ten years, in those cases where inequitable conduct was so clear as to warrant summary judgment against patent holders, parties prevailing on these claims received attorneys' fees only 40% of the time. In contrast, in the forty-three summary judgment decisions from the same time period where courts found no genuine issues of material fact in support of inequitable conduct claims, no district court awarded attorneys' fees to a prevailing patentee.¹¹⁷ Thus, courts view inequitable conduct as a worse offense than wrongly claiming that the adverse party engaged in inequitable conduct.

However, frivolous inequitable conduct charges should be viewed equal to inequitable conduct itself. Awarding fees to prevailing patentees faced with charges of inequitable conduct fits within the definition of bad faith or borderline conduct already used in determining the presence of exceptional circumstances in awarding fees under § 285.¹¹⁸ Because inequitable conduct is an affirmative defense akin to fraud, allegations must be supported by particularized facts in the complaint; thus, alleged infringers generally amend their original complaint, after at least some discovery has begun, to allege inequitable conduct. Therefore, parties wishing to allege inequitable conduct already have a reasonable idea about the success of

113. Such a proposal would be the reverse of the bounties described and advocated in Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667 (2003). However, the basic premise is similar: socially undesirable actions should be punished.

114. 35 U.S.C. § 285 (2000).

115. *Id.*; see also *Hoffman-LaRoche, Inc. v. Invamed Inc.*, 213 F.3d 1359, 1365 (Fed. Cir. 2000).

116. *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 712-13 (Fed. Cir. 1983).

117. In two cases, fees were awarded, but in neither of these cases did the court cite the unfounded claim of inequitable conduct to support the awards.

118. See *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 831 (Fed. Cir. 1992) (holding that litigation itself may warrant award of fees); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1537 (Fed. Cir. 1987) (requiring bad faith as basis for awarding fees); *Bayer Aktiengesellschaft v. Duphar Int'l Research B.V.*, 738 F.2d 1237, 1242 (Fed. Cir. 1984) (awarding fees where position taken by party in litigation was frivolous).

the merits of their claim. Where the proponents have yet to find evidence that could reasonably support the materiality and intent requirements, such claims should be discouraged. Therefore, encouraging courts to award § 285 fees when the proponent of inequitable conduct charges fails to raise an issue of genuine material fact would discourage frivolous allegations.

Furthermore, awarding fees to prevailing patentees encourages applicants to fulfill their duty to disclose. Although at first glance, it may seem unlikely that the behavior of patentees will change by sanctioning those who raise unsubstantiated allegations of inequitable conduct, such an award will ensure that those who do comply with the duty to disclose are not penalized through litigation expenses incurred in their defense. Parties fulfilling their duty will be less likely to face charges of inequitable conduct, and where such allegations fail to raise genuine material issues, they will be compensated for any expenses incurred in defending against such charges.

Given that the awarding of attorney's fees would be at the discretion of the court, one may wonder how this policy would change the current state of affairs. However, awarding fees for frivolous allegations of inequitable conduct would give judges a lever by which they can change the behavior of the parties before the court. In cases in which a judge found that it was a difficult call whether patentee's belief that a non-disclosed reference was withheld in good faith as cumulative to other disclosures, such fees should not be awarded. But, for cases in which there are insufficient material facts alleged to defeat a motion for summary judgment by the patentee, courts would likely award fees and rightly so. For the duty to disclose to function properly, patentees must have faith that they will not be forced to defend, at great cost, such frivolous assaults. Moreover, as outlined in Part III.D below, applicants may be asked to give a brief statement of relevance of all submitted references, and must further state whether other references exist but are believed to be cumulative. Thus, overall, awarding attorneys' fees under § 285 to prevailing patent holders would penalize parties who are unjustified in charging inequitable conduct and would extend relief to patent holders who fulfill their duty to disclose during prosecution.

C. Reforming the Presumption of Validity

As mentioned in Part II.A, the duty to disclose supplements the information before a PTO examiner to ensure that every patent issued is worthy of the presumption of validity. Because of this connection, the FTC report recommends lowering the presumption of validity given to an issued patent in order to make it easier to challenge improperly granted patents.¹¹⁹

119. FTC REPORT, *supra* note 10, Executive Summary, at 8-10.

Currently, the presumption of validity applies regardless of whether the PTO examined the prior art asserted by a challenger.¹²⁰ Most participants in the patent system agree that PTO examiners are overworked and unable to properly evaluate patents; consequently, many believe that a lesser degree of deference to the PTO is warranted. Accordingly, a lesser presumption of validity should attach to their work.¹²¹ The FTC Report recommends changing the burden of proof standard from clear and convincing to preponderance of the evidence in light of the fact that such a high standard makes improperly granted patents difficult to overturn.¹²²

Such a recommendation ignores the function of the standard of validity to society as a whole. As Mark Janis has written,¹²³ the presumption of validity has both expressive and instrumental functions. The words of the standard may be changed without affecting the underlying symbolic message that attaches to the presumption of validity. Even were one to succeed in changing both the words and the underlying message, the cure may be more painful than the problem it was designed to solve if it leaves society believing that patents are less valuable.¹²⁴ For example, the standard and the presumption are thought to be compelling to both judges and juries¹²⁵ and may encourage innovation overall. Given such considerations, the FTC Report's recommendation seems extreme, especially in the context of inequitable conduct.

However, a limited change to the presumption that issued patents are valid would be appropriate to address one particular concern, namely, that the presumption should not apply when an examiner has not reviewed relevant prior art. In such cases, for such unexamined prior art, the presumption should be based on a preponderance of the evidence. Thus, where a challenger asserts that a patent is invalid due to anticipation based on prior not before the PTO, she would only need to prove such a claim based on the preponderance of the evidence. A lower presumption of validity applicable to prior art not before an examiner would encourage applicants to fulfill their duty to disclose: the more prior art disclosed, the fewer possible references that would be subject to the lower preponderance of evidence burden of proof standard. Simultaneously, such a change might give applicants an incentive to search for prior art, despite the lack of such a requirement in the duty of disclosure.¹²⁶

120. See *Am. Hoist v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1981).

121. See Lemley, *supra* note 9, at 1528-29.

122. FTC REPORT, *supra* note 10, ch. 5, at 28.

123. See Janis, *supra* note 9, at 925.

124. See *id.* at 927.

125. See FTC REPORT, *supra* note 10, ch. 5, at 27.

126. See 37 C.F.R. § 1.56 (2004).

Under such a system, the patent and all the prior art examined during its prosecution would issue with a presumption of validity and could be defeated only by clear and convincing evidence from a challenger. However, only for unexamined prior art, the presumption of validity would be lessened to a preponderance of the evidence standard. Limiting the lower standard to non-examined prior art would lessen any fears that patents would be presumed to be less worthy, as more relevant art will be considered by the PTO under the new presumption. Consequently, the weakening of the standard in those select cases would not likely change the overall perception of the value of patents. However, if applicants continue to flood the examiner with prior art that she does not have time to examine, then such a change might not have any effect, which leads to the fourth proposed reform discussed below.

D. Providing Statements of Relevance

In general, participants in the FTC hearings felt that patent applicants substantially fulfill their duty to disclose, and rather than withholding prior art, the typical patent applicant floods the examiner with references.¹²⁷ If the presumption of validity is to retain its meaning, inventors must have confidence that examiners are competent and capable of analyzing all submitted references. By recommending that applicants submit statements of relevance, describing how each prior art reference is relevant to the invention in the application upon the request of an examiner, an examiner would be able to meaningfully analyze applications during a finite time frame, reducing opportunity for error and increasing the efficiency of the examination.¹²⁸ Although some participants in the FTC hearings feared that statements of relevance would increase allegations of inequitable conduct, because most allegations of inequitable conduct center on the failure to disclose information, it seems unlikely that such concerns would be borne out in practice.¹²⁹ Any increased costs incurred by such a reform would likely outweigh the current costs incurred by defending against frivolous claims of inequitable conduct. Furthermore, submission of brief statements would decrease the likelihood that material references would

127. FTC REPORT, *supra* note 10, ch. 5, at 11 n.73-n.74.

128. See Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 770, 773-75 (2002) (advocating for an expanded disclosure system with explanations of how the claims differ from the prior art and attaching the presumption of validity only to disclosed prior art).

129. See FTC REPORT, *supra* 10, ch. 5, at 11-13. While applicants would still be open to the charge that they mischaracterized the relevance of the reference, once the examiner notes that she has read the reference, it is much more difficult for a challenger to successfully allege inequitable conduct, due to the presumed ability of the examiner to understand the information before her.

get buried in the flood of submitted references, as examiners would be most likely to request statements of relevance in such cases. Statements of relevance are already required for submissions of foreign-language prior art references;¹³⁰ thus, where the benefits are substantial, applicants already provide explanations. Given that the two FTC reforms examined here would likely increase the ability of the examiner to efficiently analyze prior art reference and would provide incentives to make sure that examiners obtain all relevant references, issued patents would deserve the clear and convincing presumption of validity and the latter two reforms will make them more resistant to defeat on grounds of invalidity.

IV. CONCLUSION

The plague of inequitable conduct lies not in the number of charges brought each year, but in the number of unwarranted charges. When such charges are successful, inventive entities are encouraged in their work and are free to pursue inventive activity unfettered by worries about the effects of “bad” patents. In the past ten years, over 40% of motions for summary judgment on inequitable conduct failed to allege sufficient facts to proceed to the trial stage and, at trial, 70% of allegations of inequitable conducts failed. Thus, patentees are subjected to numerous frivolous inequitable conduct charges, and the application of the doctrine should be reformed to address this problem. The three proposals outlined in this Note seek to promote the efficiency of both the prosecution and litigation systems in the United States by rewarding the inventor who fulfills her duty to disclose and simultaneously dissuading unsubstantiated allegations of inequitable conduct.

130. 37 C.F.R. § 1.98(a)(3)(i) (2004).