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Inequitable Conduct: A Standard in Motion.

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Cover Page Footnote

I want to thank my family and friends for their love and support, especially my mom and dad whose enduring commitment to me made this all possible. Also many thanks are due to the Fordham IPLJ editorial board and staff as well as my mentor Ariella who is great with words.

Inequitable Conduct: A Standard in Motion

Benjamin Brown *

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INTRODUCTION

A great deal of criticism has been directed at the United States patent system due to spiraling patent litigation costs and the inconsistent quality of patents issued by the United States Patent and Trademark Office (the “Patent Office”).¹ The judicially

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¹ See FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, executive summary 4–5 & ch. 5 at 24–25 (2003) [hereinafter FTC report], available at <http://www.ftc.gov/opa/2003/10/>

created doctrine of inequitable conduct is one of the most highly criticized areas of this patent system and an area recently targeted for reform because its inherently subjective nature engenders significant litigation costs and deters patent applicants from being forthright and honest, thereby impacting patent quality.² While scholars and practitioners alike have engaged in numerous discussions about whether reforming the doctrine of inequitable conduct would lower litigation costs and improve patent quality, few have undertaken a statistical analysis to quantify the effect of any such reform.

This Comment will discuss the evolution of the inequitable conduct standard and will examine, using statistical analysis, the policy considerations and consequences of reforming this standard through legislation. Part I sets forth an explanation of how the inequitable conduct standard developed and analyzes how courts have been implementing this standard since its inception. Part II investigates the allure of pleading even a meritless inequitable conduct defense in an effort to avoid a finding of patent infringement and presents a statistical analysis of how courts adjudicate the defense. Part III reviews the current reform proposals and the policy implications of these proposals. Part IV examines the pending legislation designed to reform this standard and discusses the effect such legislation would have on patent litigation. Finally, the author endorses in the conclusion of the Comment his view that reform lies not in modifying the inequitable conduct standard but in modifying the procedural paradigm in which such claims are brought.

I. BACKGROUND

Inequitable conduct is a defense a party accused of patent infringement can raise during a patent litigation.³ The defense is invoked in litigation when there is evidence that a patent applicant

cpreport.htm; NAT'L ACAD. OF SCI., A PATENT SYSTEM FOR THE 21ST CENTURY 47, 70 (Stephen A. Merrill et al. eds., 2004) [hereinafter NAS study], available at <http://www.nap.edu/catalog/10976.html>.

² NAS study, *supra* note 1, at 7, 121–23.

³ See 6 DONALD S. CHISUM, CHISUM ON PATENTS § 19.03 (MB 2008).

breached a duty of candor and good faith to the Patent Office by engaging in behavior such as misrepresenting information or omitting information that might adversely impact the Patent Office's decision to grant a patent.⁴ If a court determines inequitable conduct occurred, the court can hold the patent unenforceable, meaning that the patent holder cannot enforce the patent rights on other parties even if the patent is valid and being infringed by these other parties.⁵

Whether inequitable conduct occurred is determined using proof of materiality and intent shown by clear and convincing evidence.⁶ Materiality, in turn, is established by using one of a number of judicially sanctioned tests,⁷ each of which evaluates whether affirmative misrepresentations or omissions of information should be considered material.⁸ In deciding whether information is "material," the courts typically utilize the "reasonable examiner" test because it is the broadest test and the one that most closely aligns with how business should be conducted with the Patent Office.⁹ This "reasonable examiner" test examines whether "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."¹⁰ In finding materiality pursuant to this test, the court determines whether a threshold level of materiality has been reached.¹¹ Though, information that is merely cumulative to what was already taken into account by the examiner is generally disregarded because it does not raise a new issue beyond what the examiner previously considered.¹²

⁴ *Id.*

⁵ *See* *Lummas Indus., Inc. v. D.M. & E. Corp.*, 862 F.2d 267, 274 (Fed. Cir. 1988).

⁶ *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

⁷ *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315–16 (Fed. Cir. 2006).

⁸ *See* *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998).

⁹ *Digital Control*, 437 F.3d at 1315–16.

¹⁰ *Id.* at 1315 (citing PTO Rules of Practice in Patent Cases, 37 C.F.R. § 1.56 (1977)).

¹¹ *Baxter Int'l*, 149 F.3d at 1327.

¹² *See* *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991) (citing *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440 (Fed. Cir. 1991)).

In addition to determining materiality, it is also the responsibility of the court to determine whether the evidence indicates that the patent applicant possessed a threshold level of intent to deceive or mislead the Patent Office.¹³ To make such a finding of intent—a subjective determination of the state of mind of the individual allegedly involved in the misconduct¹⁴—a court must find that the conduct, when viewed in light of all the evidence, including evidence of good faith, indicates sufficient culpability to warrant a finding that the patent applicant intended to deceive or mislead the Patent Office.¹⁵ Intent to deceive does not, however, need to be proven by direct evidence.¹⁶ Clear and convincing inferential evidence of the circumstances surrounding the alleged conduct is sufficient to prove intent to deceive.¹⁷ In the event the court finds that the threshold levels of materiality and intent have been established, the court must then balance such evidence.¹⁸ If the information is highly material, this balancing can result in a finding of inequitable conduct even when there is not much evidence of intent.¹⁹ Similarly, an inequitable conduct finding may occur when information is not very material, if there exists strong evidence of intent.²⁰

A. Court Involvement in the Standard of Inequitable Conduct

The doctrine of inequitable conduct arose from a series of Supreme Court cases ending in 1945.²¹ The series culminated with

¹³ *Baxter Int'l*, 149 F.3d at 1327.

¹⁴ NAS study, *supra* note 1, at 122.

¹⁵ *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988).

¹⁶ *Baxter Int'l*, 149 F.3d at 1329; *see also* *Hycor Corp. v. Schueter Co.*, 740 F.2d 1529, 1540 (Fed. Cir. 1984).

¹⁷ *Baxter Int'l*, 149 F.3d at 1329.

¹⁸ *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362–63 (Fed. Cir. 2003).

¹⁹ NAS study, *supra* note 1.

²⁰ *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984).

²¹ *Digital Control*, 437 F.3d at 1315; *see* *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944); *see also* *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244 (1933) (providing the doctrine of unclean hands for equity matters that the Supreme Court relies on in *Precision*, 324 U.S. at 819).

Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.,²² where the Supreme Court refused to enforce patents tainted with fraud.²³ Fashioning an inequitable conduct defense from the equitable doctrine of unclean hands, the *Precision* Court stated that applicants “have an uncompromising duty to report to [the Patent Office] all facts concerning possible fraud or inequitableness underlying the applications in issue.”²⁴ However, the *Precision* Court did not articulate any specific test or provide any guidance for future courts to help them determine when inequitable conduct would be deemed to have occurred (and, therefore, when a patent would be rendered unenforceable).²⁵ Following the *Precision* Court’s decision, the Patent Office created Rule 56, which imposes a duty of candor and good faith on every individual who is associated with the filing and prosecution of a patent application.²⁶

Not surprisingly, the inequitable conduct doctrine continued to develop through numerous court decisions following the Supreme Court’s *Precision* pronouncement and the Patent Office’s implementation of Rule 56.²⁷ As the doctrine evolved, different courts fashioned different tests to determine what constituted materiality, with some courts using an objective “but for” test, other courts using a subjective “but for” test, and yet other courts using a “but it may have” test.²⁸ Under the objective “but for” test, information is material if it would preclude a patent from being issued.²⁹ Courts apply this test by determining whether the information involved in the alleged misconduct would invalidate the patent if such information was considered.³⁰ The objective

²² *Precision*, 324 U.S. 806.

²³ *Id.* at 819.

²⁴ *Id.* at 818.

²⁵ *Id.* at 819.

²⁶ *Digital Control*, 437 F.3d at 1315.

²⁷ *Cf. id.*

²⁸ *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984); *see also* *Plastic Container Corp. v. Cont’l Plastics of Okla., Inc.*, 607 F.2d 885, 899 (10th Cir. 1984); *Norton v. Curtiss*, 433 F.2d 779, 795–96 (C.C.P.A. 1970); *In re* *Multidistrict Litig. Involving Frost Patent*, 398 F. Supp. 1353, 1368 (D. Del. 1980).

²⁹ *Digital Control*, 437 F.3d at 1315; *Gemveto Jewelry Co. v. Lambert Bros., Inc.*, 542 F. Supp. 933, 939–40 (S.D.N.Y. 1982).

³⁰ *In re Frost Patent*, 398 F. Supp. at 1368.

“but for” test is exemplified by *Walker Process Equipment v. Food Machinery & Chemical Corp.*,³¹ where the Supreme Court held a patent invalid because the applicant withheld prior public use information from the Patent Office.³² The Court reasoned that because prior public use is an absolute bar to patentability, the patent would not have been issued “but for” this withholding of information.³³

The subjective “but for” test focuses on whether the misrepresentation of information actually caused the examiner to approve a patent application that would not have otherwise been approved.³⁴ In order to find inequitable conduct under the subjective “but for” test, a court needs to consider the state of mind of the actual examiner who issued the patent.³⁵ In this regard, as the Sixth Circuit noted in *American Cyanamid Co. v. Federal Trade Commission*,³⁶ the ultimate questions are: (1) did the examiner receive all the information he requested; and (2) did the examiner rely on misleading information to issue the patent.³⁷ This subjective “but for” test is contrasted with the objective “but for” test, where the state of mind of the actual examiner is irrelevant and a court determination of invalidity is used to determine if information is material.³⁸

The third, the “but it may have” test, seeks to determine if the misrepresentation or omission might have reasonably affected the examiner’s decision on patentability during prosecution.³⁹ An example of this test can be seen in *SCM Corp. v. Radio Corp. of America*,⁴⁰ where a patent applicant conducted testing to distinguish the invention from the prior art,⁴¹ and then filed an

³¹ *Walker Process Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

³² *Id.* at 174.

³³ *Id.*

³⁴ *Digital Control*, 437 F.3d at 1315; *Gemveto Jewelry*, 542 F. Supp. at 939–40.

³⁵ James Cronin, Comment, *Inequitable Conduct and the Standard of Materiality*, 50 ST. LOUIS U. L.J. 1327, 1340 (2006).

³⁶ *American Cyanamid Co. v. Fed. Trade Comm’n*, 363 F.2d 757 (6th Cir. 1966).

³⁷ *Id.* at 778.

³⁸ *Digital Control*, 437 F.3d at 1315.

³⁹ *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984); see also *Digital Control*, 437 F.3d at 1315.

⁴⁰ *SCM Corp. v. Radio Corp. of Am.*, 318 F. Supp. 433 (S.D.N.Y. 1970).

⁴¹ *Id.* at 444.

affidavit showing only the test results that supported the application, omitting contradictory test results.⁴² In determining materiality, the *SCM* court focused on whether the withheld information was relevant, and reasoned that any inequitable conduct in the obtaining of a patent was enough to dissuade a court from enforcing the patent against infringers.⁴³ Thus, rather than look at the state of mind of the actual examiner, the court determines if the misrepresentation or omission might affect any examiner's decision on patentability of the patent application.⁴⁴

In 1977, the Patent Office amended Rule 56 to clarify the duty of candor and good faith.⁴⁵ The amended rule was expected to stabilize court decisions and aid people applicants in complying with the duty of candor and good faith.⁴⁶ This amended rule required applicants to disclose "material" information in their possession and went on to provide a definition of what information would be deemed material⁴⁷—a definition fashioned off of the Supreme Court's definition of materiality from a securities fraud case.⁴⁸ Following the Patent Office's amendment, the courts embraced as an appropriate starting point Rule 56's definition of materiality, with the Federal Circuit noting "that the pertinent inquiry is not whether a reasonable examiner would want to be aware of a particular thing, but whether, after he was aware of it, he would 'consider it important' in deciding whether to reject one or more claims."⁴⁹ While subsequent cases before the Federal Circuit continued to discuss all four of the materiality tests, the Rule 56 "reasonable examiner" test gradually became the sole test invoked by the court.⁵⁰

⁴² *Id.* at 446.

⁴³ *Id.* at 449.

⁴⁴ *Id.* at 445.

⁴⁵ *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006).

⁴⁶ *See Patent Examining and Appeal Procedures*, 42 Fed. Reg. 5588, 5588 (Jan. 28, 1977).

⁴⁷ *Id.* at 5589–90.

⁴⁸ *See TSC Indus., Inc. v. Northway*, 426 U.S. 438, 449 (1976).

⁴⁹ *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 n.2 (Fed. Cir. 1984).

⁵⁰ *Digital Control*, 437 F.3d at 1316.

In 1992, the Patent Office again amended Rule 56,⁵¹ creating “an arguably narrower standard of materiality.”⁵² This 1992 amendment—still in place today—provides:

[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.

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 consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.⁵³

Despite this 1992 amendment, it was not until 2006 that a court considered how the amended definition would impact a judicial determination of materiality, as the amendment by its terms applied only to applications pending or filed after March 16, 1992.⁵⁴ Although a few post-1992 cases utilized the new Rule 56 definition,⁵⁵ the 2006 Federal Circuit case of *Digital Control, Inc.*

⁵¹ Duty of Disclosure, 57 Fed. Reg. 2021, 2021 (Jan. 17, 1992).

⁵² *Digital Control*, 437 F.3d at 1314.

⁵³ PTO Rules of Practice in Patent Cases, 37 C.F.R. § 1.56(b) (2008).

⁵⁴ Duty of Disclosure, 57 Fed. Reg. 2021, 2021 (Jan. 17, 1992); *see also Digital Control*, 437 F.3d at 1316 (deciding that the court did not have to follow the 1992 rule change); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363–64 (Fed. Cir. 2003).

⁵⁵ *See Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1374 (Fed. Cir. 2000) (applying the new rule to a patent issuing on an application filed after 1992 without any discussion of whether the old standard should apply); *Molins PLC v.*

*v. Charles Machine Works*⁵⁶ was the first case to pronounce how the 1992 amendment would affect judicial decisions adjudging materiality.⁵⁷ In *Digital Control*, a three judge panel, which included the Chief Judge of the Federal Circuit, decided to continue using the 1977 “reasonable examiner” test, even though the materiality definition that supported the test no longer existed and had been superseded by the 1992 definition.⁵⁸ In supporting its decision, the court reasoned that the “reasonable examiner” definition in Rule 56 became the dominant materiality test invoked; it did not supplant or replace the case law precedent but rather provided another test of materiality.⁵⁹ Such rationale was surprising considering earlier judicial pronouncements indicating the court’s willingness to adhere to the definitions set forth by the Patent Office.⁶⁰

Other than as set forth above, neither the *Digital Control* decision nor subsequent Federal Circuit decisions explained why it chose to ignore the materiality definition set forth in the 1992 amendment and continue using the 1977 Rule 56 standard instead, a break from the Federal Circuit’s long tradition of deferring to the rules and regulations promulgated by the Patent Office. Such a break from tradition is particularly surprising considering the fact that the Patent Office amended Rule 56 “to present a clearer and more objective definition of what information the Office considers material to patentability,”⁶¹ suggesting that the Patent Office wanted to alter how the courts determined materiality. Perhaps the decision to ignore the 1992 amendment was a reaction to the 2005 patent reform bill pending in the House of Representatives, which would have severely restricted the materiality standard.⁶² After all, several months prior to the *Digital Control* decision, Judge Pauline

Textron, Inc., 48 F.3d 1172, 1179 n.8 (Fed. Cir. 1995) (observing that administrative rules are not retroactive, but that the case arose before the rule change, so the issue need not be addressed).

⁵⁶ *Digital Control*, 437 F.3d 1309.

⁵⁷ *Id.*

⁵⁸ *Id.* at 1316.

⁵⁹ *Id.*

⁶⁰ *Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1328 n.3 (Fed. Cir. 1998).

⁶¹ *Duty of Disclosure*, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992).

⁶² *See* H.R. 2795, 109th Cong. (2005).

Newman of the Federal Circuit called for Congress and industry to broadly examine the impact of the proposed reforms and understand the issues involved before moving forward with the legislation.⁶³

Alongside the debate over how materiality should be defined, beginning in 2003 the Federal Circuit began relaxing the intent standard.⁶⁴ In 1988, the Federal Circuit held in an en banc decision in *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*⁶⁵ that more than “gross negligence” must exist to justify a finding of intent to deceive.⁶⁶ *Kingsdown* marked a shift in the requirements for making a finding of inequitable conduct, where prior to the *Kingsdown* decision the Court was becoming increasingly concerned with how frequently inequitable conduct was being raised.⁶⁷ By rejecting the notion that intent could be inferred from an unknowing negligent act, the *Kingsdown* decision implied a certain level of knowledge was needed to prove intent to deceive, which was developed by subsequent decisions.⁶⁸ Historically the courts have allowed intent to be inferred from the facts and circumstances of the case due to the difficulty of proving an individual knowingly deceived the Patent Office.⁶⁹ To infer intent requires that the applicant knew of the information, the applicant knew or should have known of the materiality of the information, and the applicant has not provided a credible explanation for withholding or misrepresenting the information.⁷⁰ A “should-have-known” standard was developed to address

⁶³ Marius Meland, *Federal Judges Urge Caution on Patent Reform*, IP LAW 360, June 13, 2005, available at http://www.law360.com/registrations/user_registration?article_id=3559.

⁶⁴ James E. Hanft & Stacey S. Kerns, *The Return of the Inequitable Conduct Plague*, 19 INTELL. PROP. & TECH. L.J. 1, 2 (2007). See generally Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003).

⁶⁵ *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988).

⁶⁶ *Id.* at 876.

⁶⁷ Cf. *id.*; *supra* text accompanying note 23 (discussing *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, in which the Supreme Court refused to enforce patents tainted with fraud).

⁶⁸ See Hanft & Kerns, *supra* note 64, at 1.

⁶⁹ *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005).

⁷⁰ *Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 397 (Fed. Cir. 1996).

situations when there is a disregard for warnings that material information existed or there is cultivation of ignorance to avoid actual knowledge.⁷¹ If there is no actual knowledge and no warnings about the existence of material information, no intent to deceive can be found.⁷² However, the Federal Circuit panel decisions have altered the knowledge requirement in the “should-have-known” standard and replaced the need for evidence with a positive inference of wrongdoing.⁷³

In the 2005 case *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*,⁷⁴ the Federal Circuit found inequitable conduct occurred when the inventor had no actual knowledge of the materiality of the information and had no warnings about the materiality of the information.⁷⁵ There, a Dutch inventor inadvertently wrote the final step of a process partially in the past tense, insinuating that he completed the step when, in fact, he had not.⁷⁶ Although there existed no evidence that the Dutch inventor or the prosecuting attorneys ever knew or suspected that there was a mistake in how the patent application was drafted,⁷⁷ the Court inferred intent, reasoning that the inventor was aware the final step had not been completed and charging the inventor with “knowledge of the law,” even though the Manual of Patent Examination Procedures (“MPEP”) is not law.⁷⁸ The court therefore used knowledge of law to impute that the inventor should have known of the materiality of the misrepresentation to find intent, in contrast to earlier precedent, which held no intent could be found where no knowledge or warnings about the materiality existed.⁷⁹

⁷¹ *FMC Corp. v. Hennessy Indus. Inc.*, 836 F.2d 521, 526 n.6 (Fed. Cir. 1987).

⁷² *Nordberg*, 82 F.3d at 397.

⁷³ *Ferring v. Barr*, 437 F.3d 1181, 1196 (Fed. Cir. 2006).

⁷⁴ *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347 (Fed. Cir. 2005).

⁷⁵ *Id.* at 1361.

⁷⁶ *Id.* at 1360–61.

⁷⁷ *Id.* at 1361.

⁷⁸ *Id.* The MPEP rules suggest that use of the past tense should be avoided. MPEP § 608.01(p)(II)(2007); see also *Novo Nordisk Pharm.*, 424 F.3d at 1361.

⁷⁹ See *Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 397 (Fed. Cir. 1996).

The Federal Circuit employed similar logic a couple of months later in *Ferring v. Barr*.⁸⁰ In that case, Ferring's patent application was rejected because of a prior art reference, but the rejection hinged on the determination of the word used in the prior art reference, and the inventors sought declarations to prove the meaning of this term was different.⁸¹ Although the Ferring inventors knew of the connections between the declarants and the patent applicant, and that the patent examiner had asked for non-inventor affidavits, he failed to notify the patent examiner that four of the five declarations came from scientists that had been employed or received funding from Ferring.⁸² In so doing, the court found intent to deceive, as Ferring "should have known" that omitting the connections between declarants and the patent applicant was material.⁸³ The problem with such rationale, however, is that the court had previously held that an individual cannot intend to deceive if there is no actual knowledge of the materiality of the omitted information,⁸⁴ and there was no evidence here that the Ferring inventors knew or avoided warnings that the connections were material.

The erosion of the intent standard continued with *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*⁸⁵ Here, Purdue's failure to disclose to the Patent Office that a "surprising discovery" regarding dosage range formulation was based on insight rather than experimental data, and the trial court found this to be highly material and inferred intent from this high materiality.⁸⁶ The Federal Circuit held that "[i]n a case such as this, when the materiality of the undisclosed information is relatively low, there is less basis for inferring intent from materiality alone."⁸⁷ Such rationale implied that if the court were to determine that information is moderately or highly material, intent could be

⁸⁰ *Ferring v. Barr*, 437 F.3d 1181 (Fed. Cir. 2006).

⁸¹ *Id.* at 1183–84.

⁸² *Id.* at 1184.

⁸³ *Id.* at 1191–92.

⁸⁴ *FMC Corp. v. Manitowac Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987).

⁸⁵ *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123 (Fed. Cir. 2006).

⁸⁶ *Id.* at 1134–35.

⁸⁷ *Id.*

inferred based on materiality alone.⁸⁸ This erosion continued with *Kao Corp. v. Unilever U.S., Inc.*,⁸⁹ in which the trial court found materiality but no intent to deceive.⁹⁰ In that case, inventors initially disclosed only some results to the examiner, presenting the previously omitted data a year later.⁹¹ Holding the omitted information material but finding no attempt to conceal the information, the trial court refrained from making a finding of intent to deceive.⁹² Although on appeal the Federal Circuit stated that it may have weighed the evidence differently given a blank slate, the court refused to second guess the district court's decision,⁹³ suggesting that it might well have affirmed a finding of inequitable conduct if the case had been decided differently.

While *Kingsdown* has not been explicitly overruled,⁹⁴ the post-2003 cases relaxing the intent standard indicate—especially when viewed alongside the Federal Circuit's decision to maintain the “reasonable examiner” test⁹⁵—the Federal Circuit's attempt to expand the scope of the inequitable conduct doctrine. Such expansion lies in sharp contrast to the limiting reform called for by the Patent Office and Legislature.

II. ANALYSIS OF INEQUITABLE CONDUCT ADJUDICATIONS

As briefly discussed earlier in this Comment, the advantages of raising the inequitable conduct defense can lead to an overpleading of the defense.⁹⁶ When an alleged patent infringer invokes the inequitable conduct defense, he stands the chance of having the patent rendered unenforceable against him,⁹⁷ even if he

⁸⁸ See Hanft & Kerns, *supra* note 64, at 4.

⁸⁹ *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963 (Fed. Cir. 2006).

⁹⁰ *Id.* at 972.

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1202 (Fed. Cir. 2006).

⁹⁵ See *Digital Control*, 437 F.3d at 1316; *supra* text accompanying note 50.

⁹⁶ See John F. Lynch, *An Argument For Eliminating The Defense of Patent Unenforceability Based on Inequitable Conduct*, 16 AIPLA Q.J. 7, 8 (1988).

⁹⁷ See NAS study, *supra* note 1, at 121.

in fact infringed the patent.⁹⁸ Perhaps almost as important, pleading inequitable conduct puts the patentee on the defensive and permits the alleged infringer to scrutinize the motives and conduct of the patent applicant, even providing him with access to documents protected by the attorney-client and work product privileges.⁹⁹ Although inequitable conduct typically needs to be pled with particularity,¹⁰⁰ often the accused infringer can seize upon inconsistencies uncovered through discovery in the produced documents to develop an adequate pleading.¹⁰¹

Due to the ease of pleading the inequitable defense doctrine and the strong advantages of doing so, it is important to quantitatively understand the role inequitable conduct plays in patent litigation. While it is difficult to quantify the number of times inequitable conduct is pled or how much discovery into inequitable conduct is permitted and completed, examining how patent disputes are ultimately adjudicated provides some insight into how the inequitable conduct defense is litigated and the extent to which pleading inequitable conduct affects the outcome of a case.

Table 1 below sets forth the total number of reported patent decisions between 2000 and 2007, alongside a breakdown of how many of these decisions involved inequitable conduct determinations.¹⁰²

⁹⁸ See CHISUM, *supra* note 3, § 19.03[5][d] (“[A] patent may be valid and yet be rendered unenforceable for misuse or inequitable conduct. Similarly, a valid patent may be (in the abstract) infringed . . . but there will be no liability to the patentee when the patent is unenforceable.” (quoting *Gardco Mfg., Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1213 (Fed. Cir. 1987)).

⁹⁹ Lynch, *supra* note 96, at 8.

¹⁰⁰ See CHISUM, *supra* note 3, § 19.03[6][b][ii].

¹⁰¹ See Lynch, *supra* note 96, at 15–16.

¹⁰² See Kevin Mack, Note, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147, 155 tbl.1 (2006) (citing University of Houston Law Center, U.S. Patent Litigation Statistics, <http://www.patstats.org> (last visited Mar. 1, 2006) (providing statistical analysis of patent cases involving inequitable conduct from the years 2000–05)); University of Houston Law Center, U.S. Patent Litigation Statistics, Cumulative Caselist, http://www.patstats.org/Cumulative_Caselist_thru_2Q08.xls (last visited Oct. 7, 2008) [hereinafter *Caselist*] (listing the patent cases decided from 2005 through the second quarter of 2008); University of Houston Law Center, U.S. Patent Litigation Statistics, Decisions for 2007, <http://www.patstats.org/2007%20full%20year.htm> (last visited Oct.

Table 1: Statistics Regarding Inequitable Conduct from 2000–07¹⁰³

Year	Number of Reported Patent Cases	Total Number of Times Inequitable Conduct was Addressed by the Court ¹⁰⁴	Number of Times Patentee Prevailed (No Inequitable Conduct Found)	Number of Times Alleged Infringer Prevailed (Inequitable Conduct Found)	Percentage of Reported Patent Cases in which the Court Ruled Upon an Inequitable Conduct Defense ¹⁰⁵
2000	104	20	15	5	19
2001	161	27	23	4	17
2002	234	37	26	11	16
2003	208	40	22	18	19
2004	127	44	29	15	35
2005	248	46	33	13	19
2006	359	49 (43)	37 (32)	12 (11)	14 (12)
2007	439	95 (65)	55 (45)	40 (20)	22 (15)

7, 2008) [hereinafter *2007 Decisions*] (detailing the decisions on patent cases for the year 2007); University of Houston Law Center, U.S. Patent Litigation Statistics, Decisions for 2006, <http://www.patstats.org/2006.htm> (last visited Oct. 7, 2008) [hereinafter *2006 Decisions*] (detailing the decisions on patent cases for the year 2006). The tables were compiled with the raw data provided by the University of Houston Law Center in addition to the data provided in Mack, *supra*.

¹⁰³ The numbers not in parentheses represent court decisions on inequitable conduct on a patent by patent basis, e.g., if a reported decision included two patents and the court decided inequitable conduct with respect to each patent this would be counted as two in the chart even though it is only in one case. The numbers in parentheses represent the number of cases decided, irrespective of the number of patents upon which the court rendered a decision.

¹⁰⁴ For each year, this figure is calculated by adding the number of times the patentee prevailed and the number of times the alleged infringer prevailed.

¹⁰⁵ For each year, this figure is calculated by dividing the total number of times inequitable conduct was addressed by the court by the number of reported patent cases. The percentage is rounded to the nearest whole number.

The above table shows that, between 2000 and 2007, courts addressed, on average, inequitable conduct in less than 20% of all reported patent cases.¹⁰⁶ This figure must be qualified, however, because it is almost impossible to ascertain the number of times inequitable conduct was pled, given that approximately 86% of patent cases settle¹⁰⁷ and are therefore not captured in these statistics. Interestingly, during 2006 and 2007, inequitable conduct was being addressed by the Court less frequently than the average for the time period of Table 1—in only 108 out of 798 cases—a mere 14% of the time.¹⁰⁸

It is equally important to observe that during the eight-year period reflected in Table 1, the alleged infringer prevailed against the patentee approximately one-third of the time with the court finding inequitable conduct was committed by the patentee.¹⁰⁹ When looking at the years 2006 to 2007, inequitable conduct was found in about 4% of all patent cases litigated—31 times out of 798 cases.¹¹⁰ While this figure does not take into account the number of times the defense was raised, it seems to indicate that there is not some massive failure of the system to reign in

¹⁰⁶ See Mack, *supra* note 102, at 156; *Caselist*, *supra* note 102; *2007 Decisions*, *supra* note 102; *2006 Decisions*, *supra* note 102.

¹⁰⁷ See University of Houston Law Center, U.S. Patent Litigation Statistics, Patent Case Dispositions, 2005 to 2007, [http://www.patstats.org/2005-2007_FY_PATENT_CASE_DISPOSITIONS_\(corrected\).doc](http://www.patstats.org/2005-2007_FY_PATENT_CASE_DISPOSITIONS_(corrected).doc) (last visited Oct. 7, 2008) (detailing patent case dispositions for the fiscal years 2005–07).

¹⁰⁸ See *Caselist*, *supra* note 102; *2007 Decisions*, *supra* note 102; *2006 Decisions*, *supra* note 102. The number 798 was obtained by totaling the number of cases reported from the second column and the number 108 was obtained by adding 43 and 65 from the third column. The numbers in parenthesis were used because they represent the number of cases rather than a determination on a per patent basis. Each percentage is rounded to the nearest whole number.

¹⁰⁹ During the years 2000 to 2007, out of the 358 times the Court ruled on inequitable conduct, the Court found there to be inequitable conduct by the patentee 118 times, or 33% of the time. See Mack, *supra* note 102, at 156; *Caselist*, *supra* note 102; *2007 Decisions*, *supra* note 102; *2006 Decisions*, *supra* note 102.

¹¹⁰ This figure was calculated by dividing the number of times the alleged infringer prevailed (from column 5) over the number of reported patent cases (from column 2) for the years 2006 and 2007. The percentage is rounded to the nearest whole number. See *Caselist*, *supra* note 102; *2007 Decisions*, *supra* note 102; *2006 Decisions*, *supra* note 102.

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misconduct and that there are a relatively small number of patents acquired through improper means.¹¹¹

Using the same data source as Table 1, Table 2 below breaks down how the courts have treated inequitable conduct cases between 2000 and 2006.¹¹²

Table 2: Breakdown of Decisions on Inequitable Conduct from 2000–06¹¹³

	Patentee Prevails	Alleged Infringer Prevails	% of Time Alleged Infringer Prevails ¹¹⁴
Appellate Affirmances	57	23	29
Appellate Reversals	14	3	18
Total Appellate Decisions ¹¹⁵	71	26	27

¹¹¹ It is difficult to say the actual number of “bad patents” that applicants have committed inequitable conduct during the procurement of the patent because only about 2% of patents are litigated, however it provides insight into the overall success rate of the inequitable conduct defense and the number of patents that are potentially acquired through improper means.

¹¹² The data for 2007 is now available. *See 2007 Decisions, supra* note 102. According to the 2007 data, the trial court, when ruling after a trial, found inequitable conduct 31% of the time, while the Federal Circuit, ruling on appeal, found inequitable conduct 75% of the time. *Id.* The percentages are rounded to the nearest whole number.

¹¹³ *See 2006 Decisions, supra* note 102; University of Houston Law Center, U.S. Patent Litigation Statistics, Decisions for 2005, <http://www.patstats.org/2005rev2.htm> (last visited Oct. 7, 2008) [hereinafter *2005 Decisions*] (detailing the decisions on patent cases for the year 2005); University of Houston Law Center, U.S. Patent Litigation Statistics, Decisions for 2000–04, <http://www.patstats.org/2000-04.htm> (last visited Oct. 7, 2008) [hereinafter *2000–04 Decisions*] (detailing the decisions on patent cases for the years 2000 to 2004).

¹¹⁴ For each category, this figure is calculated by dividing the number of times the alleged infringer prevails into the total number of decisions for each category, the sum of the number of times the alleged infringer prevails and the number of times the patentee prevails.

¹¹⁵ For each category, this figure is the sum of appellate affirmances and appellate reversals.

Trial Court Rulings After Trial	64	37	37
Trial Court Summary Judgment	50	15	23

It is interesting to note that during the aforementioned seven years, the Federal Circuit found inequitable conduct 27% of the time while the trial court, when ruling after a trial, found inequitable conduct 37% of the time.¹¹⁶ Such variance indicates that although the Federal Circuit has tended—particularly recently¹¹⁷—to use a broader standard of inequitable conduct than that proposed by the Patent Office and Legislature, it is still less willing than are the trial courts to find inequitable conduct and is not hesitant to reverse lower court findings of inequitable conduct, which it has done 82% of the time.¹¹⁸ What remains to be seen is whether—and the degree to which—the Federal Circuit’s recent trend of broadening the inequitable conduct standard will affect future decisions and the percentage of inequitable conduct findings it overrules.

The statistics set forth in Table 2 also provide some insight into the number of times alleged patent infringers made meritless claims of inequitable conduct. For a patentee to prevail on a summary judgment motion, a court would need to find that the patentee did not—as a matter of law—commit inequitable conduct.¹¹⁹ As indicated in Table 2 above, the courts made such a

¹¹⁶ See *2006 Decisions*, *supra* note 102; *2005 Decisions*, *supra* note 113; *2000–04 Decisions*, *supra* note 113.

¹¹⁷ See *supra* text accompanying notes 64–93.

¹¹⁸ See *2006 Decisions*, *supra* note 102; *2005 Decisions*, *supra* note 113; *2000–04 Decisions*, *supra* note 113. The 2007 data is not dispositive on the subject, as only one decision was reversed by the Federal Circuit on appeal. However, that one reversal was in favor of the alleged infringer. See *2007 Decisions*, *supra* note 102.

¹¹⁹ See *CHISUM*, *supra* note 3, § 19.03[5][c] n.13 (citing *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993) (“While our precedent urges caution in the grant of summary judgment respecting a defense of inequitable conduct, summary judgment is not foreclosed. . . . [W]e must decide whether the evidence respecting culpable intent makes the fact reasonably inferable either way, or whether the evidence is so one-sided that the factual issue of intent may be decided as a matter of law.”); see also *FED. R. CIV. P. 56(c)* (“The judgment sought should be rendered if the

finding 77% of the time.¹²⁰ While this high figure appears to suggest an over-pleading of the inequitable conduct defense, the figure must be considered in the context of all adjudications because in a high percentage of cases the court does not decide the issue of inequitable conduct on summary judgment. When accounting for all court decisions during this period, only 19% (or one in five) inequitable conduct pleadings appear to be meritless, i.e., they were thrown out on summary judgment.¹²¹ This lower figure, though certainly indicating a prevalence of meritless claims of inequitable conduct, does not indicate an epidemic of over-pleading the defense.

The conundrum with eliminating the inequitable conduct standard (or moving to a “but for” standard) is that not all cases described had both validity and inequitable conduct determinations. In fact, during 2006–07, courts made both inequitable conduct and validity determinations in only 45% of cases where the court found inequitable conduct.¹²² Given the complexities of litigation, it is difficult to surmise why no validity determination was made in the remaining 55% of cases where inequitable conduct was found. What is clear, however, is that some percentage of those 55% of cases had a valid inequitable conduct defense, but not a strong enough invalidity defense to merit adjudication on the issue. This means that more

pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.”); *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006) (“In order to prevail at the summary judgment stage, the moving party must show that there are no genuine issues of material fact and that no reasonable jury could find against the moving party.”).

¹²⁰ This figure is obtained by taking the number of times the patentee prevailed on summary judgment (50) divided by the number of summary judgment decisions by the Court (65). See *2006 Decisions*, *supra* note 102; *2005 Decisions*, *supra* note 113; *2000–04 Decisions*, *supra* note 113.

¹²¹ This figure is obtained by taking the number of times the patentee prevailed on summary judgment (50) divided by the total number of appellate decisions (71+26), the total trial court decisions (64+37), and the total number of summary judgment decisions by the Court (50+15). See *2006 Decisions*, *supra* note 102; *2005 Decisions*, *supra* note 113; *2000–04 Decisions*, *supra* note 113.

¹²² This percentage is calculated by dividing the total number of cases where inequitable conduct was found (31) by the number of cases where the court found both inequitable conduct and the patent in question to be invalid (14). See *infra* Table 3.

questionable—and perhaps even reprehensible—actions would go unpunished if invalid claims were a prerequisite to pleading inequitable conduct because the court never reaches the inequitable conduct defense since the claims are determined to be valid despite the patentee’s actions.

Table 3 below sets forth court decisions where both inequitable conduct and validity were ruled upon for the 2006–07 period.

Table 3: Findings of Inequitable Conduct versus Validity Findings 2006–07¹²³

	Patent Found Valid	Patent Found Invalid	Total Cases
Inequitable conduct found	0	14	31
No Inequitable conduct found	32	10	77

This table is significant because one of the proposed reforms to the inequitable conduct standard is to make it a strict “but for” standard, meaning that inequitable conduct is only considered if one or more claims are found invalid.¹²⁴ By analyzing Court decisions where both invalidity and inequitable conduct were ruled upon, the impact of this type of standard can be understood. The first row of Table 3 shows that a patent was never found valid when inequitable conduct was deemed to have occurred. This demonstrates a high correlation between a finding of claim invalidity and inequitable conduct. Since the patent has wholly or partially been found invalid already, the “but for” standard may not translate into much punishment for the patentee, except if remaining valid claims are held unenforceable. This high correlation between invalidity and inequitable conduct provides some credence to eliminating the inequitable conduct defense all

¹²³ See 2007 Decisions, *supra* note 102; 2006 Decisions, *supra* note 102.

¹²⁴ This “but for” standard is similar to the judicial “but for” test described above. See *supra* text accompanying notes 27–33.

together, since if the patentee committed inequitable conduct, then the patent is probably invalid.

An examination of another data source compiled from 244 federal district court opinions involving inequitable conduct between 1995 and 2004¹²⁵ largely confirms the statistical results presented above. Of the 244 court opinions, 119 (approximately half) were summary judgment decisions.¹²⁶ Of these, the court declined approximately 50% of the time to grant summary judgment motions, finding that the allegations warranted a trial.¹²⁷ In the remaining 50% of the summary judgment motions the court ruled on the issue finding inequitable conduct in ten cases and no inequitable conduct in 50 cases (42% of the 119 summary judgment decisions).¹²⁸ In other words, between 1995 and 2004, 42% of all summary judgment motions alleging inequitable conduct appear to be the result of an over-pleading of the defense because there were no factual questions and the law did not support a finding of inequitable conduct. When those cases rejecting summary judgment are removed from the analysis, the 1995 to 2004 sample shows that 83% of summary judgment motions found no inequitable conduct, compared to 76% of the summary judgment motions between 2000 and 2006 discussed above.¹²⁹

In total, between 1995 and 2004, inequitable conduct was found 30% of the time (in 37 out of 125 cases).¹³⁰ When compared with the trial court decisions in Table 3 above in which

¹²⁵ Katherine Nolan-Stevaux, Note, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 160–61 (2005) (using the search terms “patent & ‘inequitable conduct’” in the Westlaw database of federal IP district court cases and excluding preliminary injunction motions).

¹²⁶ *Id.* at 161.

¹²⁷ *Id.* at 161 tbl.1.

¹²⁸ *Id.*

¹²⁹ Even more interesting is that 50 out of 244 district court decisions were seemingly without merit (about 20%). *See id.* This aligns with the data presented in *supra* Table 2, where 50 out of 263 decisions fell in the same category. *See supra* text accompanying note 120. While this is not a statistically significant comparison, it does show consistency in the numbers.

¹³⁰ Nolan-Stevaux, *supra* note 125, at 162.

inequitable conduct was found 37% of the time,¹³¹ it becomes clear that for over fourteen years, the trend of such cases is in favor of finding no inequitable conduct occurred.

Table 4 below sets forth court decisions where both inequitable conduct and validity were ruled upon between 1995 and 2004.¹³²

Table 4: District Court Findings of Inequitable Conduct versus Validity 1995–2004¹³³

	Patent Found Valid	Patent Found Invalid	Total Cases
Inequitable Conduct Found	2	16	47
No Inequitable Conduct Found	56	18	138

Interestingly, the data of Table 4 supports the same two observations drawn from the data of Table 3 above. First, patentees that commit inequitable conduct typically have patents that are invalid when the court decides both issues, and second, over half the time the court does not decide both inequitable conduct and validity of a patent. The first observation supports the conclusion that entirely eliminating inequitable conduct may not change who is punished any more than using a “but for” standard because a patentee that commits inequitable conduct usually has invalid patent claims. The second observation supports the conclusion that requiring invalid claims to plead inequitable

¹³¹ Again this is not statistically significant because the 1995 to 2004 data set did not consider later determinations by higher courts, while the 2000 to 2006 data set did consider appellate decisions.

¹³² *Id.* at 163. The data set presented in *supra* Table 4 is comparable to the data presented in *supra* Table 3. However, *supra* Table 4 represents a ten year period rather than a two year period, and it also considers only a sampling of district court opinions for that particular ten year timeframe.

¹³³ See Nolan-Stevaux, *supra* note 125, at 125–63. Note the difference in totals between *supra* Table 4 and the 244 total cases Nolan-Stevaux considered is due to the fact that the courts declined to grant summary judgment in a portion of the cases and so no decision was made. See Nolan-Stevaux, *supra* note 125, at 161–63.

conduct may severely restrict the number of times inequitable conduct is found by the court.¹³⁴ This is shown in Table 4 by the courts only deciding about 38% of the time to determine validity when a finding of inequitable conduct occurred.¹³⁵ In rationalizing these two observations, it is important to consider that although those that commit inequitable conduct typically also have invalid claims, this conclusion might not hold true if the courts considered invalidity in all cases where inequitable conduct was found to occur.

While the above data seems to indicate that inequitable conduct is plead more often than needed, it does not appear to be a “plague”¹³⁶ or “appearing in nearly every patent suit”¹³⁷ as was previously thought. It is possible that relaxing the intent element of the inequitable conduct standard could provide a greater incentive to raise the defense more often, but it is extremely difficult to know how the courts would react. Currently, the Federal Circuit is more likely to reverse or find no inequitable conduct despite the anecdotal evidence suggesting otherwise. The statistical data also confirms that a policy determination needs to be made about what kind of behaviors should be discouraged and the practical costs of litigating such a standard.

III. POLICY RATIONALES FOR REFORMING THE INEQUITABLE CONDUCT STANDARD

Calls to reform the inequitable conduct standard were spearheaded by reports from the Federal Trade Commission (the “FTC”) in 2003 and the National Academy of Sciences (the “NAS”) in 2004.¹³⁸ The FTC report suggested that applicants submit statements of relevance regarding their prior art references to point the patent examiners to the best pieces of prior art, though

¹³⁴ See Nolan-Stevaux, *supra* note 125, at 163.

¹³⁵ This figure is obtained by dividing the number of times a validity determination was made (18) by the total of cases where inequitable conduct was found (47). See *supra* Table 4.

¹³⁶ Burlington Indus. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988).

¹³⁷ Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1454 (Fed. Cir. 1984).

¹³⁸ FTC report, *supra* note 1; NAS study, *supra* note 1.

the report simultaneously acknowledged its concern that such a requirement might create “dubious allegations” of inequitable conduct because it could lead to accusations of misrepresenting the importance of pieces of prior art.¹³⁹ The NAS report recommended eliminating the inequitable conduct doctrine or, at the very least, making legislative changes to its implementation.¹⁴⁰ Such suggested changes included not inferring intent from materiality of information, providing de novo review of inequitable conduct charges on appeal, awarding attorney’s fees to a prevailing patentee, and/or referring misconduct to the Patent Office for re-examination and disciplinary action.¹⁴¹ While the NAS recommendations appear drastic, the report deemed such sweeping changes necessary, as the NAS found the subjective nature of inequitable conduct to be among the chief factors increasing the cost of litigation and decreasing the predictability of patent infringement litigation.¹⁴²

In addition to the FTC and NAS reports, the House of Representatives and the Senate held hearings on the topic of patent reform.¹⁴³ The hearings garnered speakers and submissions from a diverse and knowledgeable field. This Article have analyzes below portions of these hearings¹⁴⁴ to illustrate some of the main positions and policy rationales taken by various constituents regarding inequitable conduct.

The Intellectual Property Owners Association (the “IPO”) took a position contrary to the NAS report, questioning whether any

¹³⁹ See FTC report, *supra* note 1, at 12–13.

¹⁴⁰ See NAS study, *supra* note 1, at 123.

¹⁴¹ *Id.*

¹⁴² See NAS study, *supra* note 1, at 117.

¹⁴³ See *Patent Reform: The Future of American Innovation: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) [hereinafter *Senate Hearings*], available at <http://judiciary.senate.gov/hearings>; *Amendment in the Nature of a Substitute to H.R. 2795 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 109th Cong. (2005) [hereinafter *Amendment*]; *Committee Print Regarding Patent Quality Improvement: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 109th Cong. (2005) [hereinafter *Committee Print Hearings*].

¹⁴⁴ See *infra* text accompanying notes 145–69.

legislative reforms were necessary.¹⁴⁵ The IPO did not support any legislative changes that would narrow the inequitable conduct standard or reduce the amount of prior art submitted to the Patent Office, but was instead interested only in legislation that would make patent applicants more comfortable submitting to the Patent Office explanations and opinions regarding prior art, thereby increasing the quality of patents issued by the Patent Office.¹⁴⁶ The Business Software Alliance (“BSA”) also expressed concern with any changes that would increase the threshold for a finding of inequitable conduct, as a patent applicant’s incentive to be open and honest with the Patent Office would be undermined if bad acts were not being punished in litigation.¹⁴⁷ The BSA therefore suggested that patent litigation cases be bifurcated and inequitable conduct not be adjudicated until after liability for infringement had been ruled upon,¹⁴⁸ since additional litigation may be avoided if the alleged infringer prevailed on other counts (such as invalidity) or if the dispute was settled.

Barr Laboratories, a generic drug company, was very concerned with the Legislature’s proposed adoption of a “but for” standard of materiality and the requirement that all misconduct be committed knowingly.¹⁴⁹ Barr maintained that this would establish a “nearly impossible-to-meet standard for proving a violation of the duty of candor,”¹⁵⁰ pointing in support of its assertion to a series of Federal Circuit cases acknowledging that direct evidence of a knowing intent to deceive rarely exists.¹⁵¹ Barr further pointed out that the adoption of a “but for” standard would change at least four recent decisions relating to pharmaceuticals from a finding of patent unenforceability to a finding of infringement.¹⁵²

¹⁴⁵ See *Committee Print Hearings, supra* note 143, at 13 (statement of J. Jeffrey Hawley, Legal Division Vice President and Director, Legal Staff, Eastman Kodak Co.).

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 24 (statement of Richard J. Lutton, Jr., Chief Patent Counsel, Apple Inc.).

¹⁴⁸ *Id.*

¹⁴⁹ *Amendment, supra* note 143, at 224 (letter to the Honorable Lamar Smith from Christine J. Siwik on behalf of Barr Laboratories, Inc.).

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.* at 224–25.

The American Bar Association's IP Law Section (hereinafter the "Section") rallied against any dilution of the "duty of candor and good faith" standard because the *ex parte* nature of the patent application process mandated a strong standard to ensure good faith dealings between the patent applicant and the examiner.¹⁵³ However, the Section, along with the biotech company Genentech, supported reforms that would affirmatively encourage more meaningful and valuable disclosures to patent examiners.¹⁵⁴ To this end, both the Section and Genentech endorsed a legislative reform proposal that would allow inequitable conduct to be pled only when a patent claim was found invalid and the alleged misconduct was causally related to the invalid claim—that is, the Section and Genentech also supported implementing a "but for" standard.¹⁵⁵ In support of its position, the Section noted that a "but for" standard is applied in other types of fraud cases, and that in such cases, misrepresentations or omissions are only material when they would affect the outcome of the case.¹⁵⁶ The Section wanted the same standard applied in inequitable conduct cases, since misrepresentations or omissions by the patent applicant that do not affect the outcome of the case, even if reprehensible, do not inflict harm on the accused infringer because these misrepresentations or omissions do not change the patentability of the subject matter.¹⁵⁷ The Section also proposed eliminating the "all or nothing" aspect for a successful holding of inequitable conduct, in which a court punishes a patentee by finding the whole patent unenforceable—even if the misconduct only relates to a portion of the claims.¹⁵⁸ Instead, the Section favored assessing a penalty that is in proportion to the seriousness of the offense,¹⁵⁹ which could reduce the incentives to raise the defense in borderline cases.

Both the Section and Jon Dudas, the Patent Office's Director, noted in the legislative hearings that the current inequitable

¹⁵³ *Committee Print Hearings*, *supra* note 143, at 47 (statement of William L. LaFuze, Chair, Section of Intellectual Property Law, American Bar Association).

¹⁵⁴ *Id.* at 49.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 86 (attachment IPL Section NRC Response).

¹⁵⁸ *Id.* at 87.

¹⁵⁹ *Id.*

conduct standard perversely affects the patent application process by causing patent applicants to over-submit prior art references and under-disclose the relevance of prior art references.¹⁶⁰ Many patent applicants submit massive amounts of prior art references in Information Disclosure Statements (“IDS”) to avoid any later inequitable conduct allegations that they omitted any material information, but in so doing bury relevant references among those having little or no significance.¹⁶¹ At the same time, patent applicants avoid making any statements regarding prior art out of fear that any statements regarding the substance of prior art will become the basis for a later claim of misrepresentation.¹⁶² In some cases, patent applicants will avoid searching and/or gaining knowledge of possible prior art information in a desire to avoid committing inequitable conduct, however this means the Patent Office is deprived of possibly relevant prior art.¹⁶³ A 2005 review undertaken by the Patent Office found that over one-half of patent applications contained either no submitted references or over 20 submitted references.¹⁶⁴ As recognized by the Section and Mr. Dudas, a doctrine that encourages over-submission and under-disclosure does little to assure the Patent Office’s accurate and complete review of patent applications and leads only to inconsistent examination, especially in the fast-paced technology areas.¹⁶⁵

As a result of the Patent Office’s concerns outlined above, Mr. Dudas urged Congress to amend the doctrines of inequitable conduct and unenforceability to ensure that patent applicants are not discouraged from sharing relevant information with the Patent Office.¹⁶⁶ To this end, Mr. Dudas suggested that a court’s finding of intent be wholly separated from a finding of materiality, and that intent not be found without proof that a patent applicant made a

¹⁶⁰ *Senate Hearings, supra* note 143 (testimony of Honorable Jon W. Dudas Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office); *Committee Print Hearings, supra* note 143, at 48.

¹⁶¹ *Senate Hearings, supra* note 143; *Committee Print Hearings, supra* note 143, at 48.

¹⁶² *Senate Hearings, supra* note 143; *Committee Print Hearings, supra* note 143, at 48.

¹⁶³ *See Senate Hearings, supra* note 143.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*; *Committee Print Hearings, supra* note 143, at 49.

¹⁶⁶ *Senate Hearings, supra* note 143.

knowing misrepresentation with intent to deceive.¹⁶⁷ With respect to defining materiality, Mr. Dudas proposed that Congress limit the courts to using only the Patent Office's definition of materiality, as set forth in its Rule 56 1992 amendment.¹⁶⁸ This last proposal, of course, signaled the Patent Office's disapproval of the Federal Circuit's decision in *Digital Control* to not defer to the Patent Office's rulemaking authority.

Although, as illustrated above, different industry groups proposed different types of legislative reform, all shared the general consensus that patent applicants should have a robust duty of candor and good faith to increase the quality of patents issued and many considered the current inequitable conduct standard ripe for reform due to its inherent uncertainty, perverse barriers to patent examination, and high litigation costs.¹⁶⁹ The question that each of these groups struggled with—and came up with different answers to—was how to encourage patent applicants to be more forthcoming with the Patent Office, while ensuring an effective enforcement mechanism for those who engaged in misconduct. Part IV examines Congress's ongoing struggle to strike the appropriate balance between these two objectives.

IV. THE PATENT REFORM ACT

Following the substantial reports by the FTC and the NAS, on June 8, 2005, Congressman Lamar S. Smith introduced into the House of Representatives the Patent Reform Act of 2005.¹⁷⁰ This bill proposed many of the recommendations suggested by the FTC and NAS, and sought to resolve the dilemma of the inequitable conduct standard by codifying a duty of candor and good faith¹⁷¹ and increasing the burden for proving inequitable conduct by implementing an objective “but for” standard.¹⁷²

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ H.R. 2795, 109th Cong. (2005).

¹⁷¹ *See id.* § 5(a).

¹⁷² *See id.*

Most importantly, the 2005 bill eliminated the judicial equitable conduct defense and granted solely to the Patent Office the power to investigate inequitable conduct, mandating that courts defer to the Patent Office's judgment.¹⁷³ To find inequitable conduct, the Patent Office needed to show, with clear and convincing evidence, that:

- (1) the individual failed to disclose information or misrepresented information;
- (2) the information not disclosed was material or, in the case of a misrepresentation, the misrepresentation was material;
- (3) the individual had knowledge of the materiality of the information not disclosed or, in the case of a misrepresentation, of the misrepresentation and materiality of the misrepresentation; and
- (4) the individual had the intent to deceive or mislead.¹⁷⁴

This standard would have completely overhauled the then-existing intent element by requiring that the patent applicant have actual knowledge of the materiality of the information not disclosed or misrepresented. Also, rather than permitting an inference of intent, the Patent Office could not make a finding of inequitable conduct without direct proof of the patent applicant's intent to deceive or mislead.

It is vital to note that the 2005 bill would not have even permitted the alleged infringer to plead inequitable conduct until one or more claims were found invalid and the alleged infringer needed to show how the alleged misconduct resulted in an invalid claim. The bill further restricted the alleged infringer's pleading of inequitable conduct by requiring a showing that the alleged fraud was attributable to the patent owner¹⁷⁵ (that is the patent owner had engaged in or directed the patent attorney or agent to engage in the misconduct). While the purpose of this requirement was likely to

¹⁷³ *See id.*

¹⁷⁴ *Id.*

¹⁷⁵ *See id.*

encourage patent agents and attorneys to engage in more meaningful discourse regarding prior art with the Patent Office, its practical effect was to essentially eliminate the inequitable conduct defense, as alleged infringers would find it virtually impossible to prove that the patent owner was perpetrating the misconduct.

The 2005 bill was never passed into law. Instead, House Bill 1908 was introduced into the House of Representatives the following year, and an amended version of this bill was ultimately passed as the Patent Reform Act of 2007 (the “2007 Act”).¹⁷⁶ Although numerous aspects of this amended bill mirrored the proposed 2005 bill, House Bill 1908 proposed a radically different inequitable conduct standard. The 2007 Act codified the inequitable conduct defense and required the patent challenger to prove inequitable conduct by “clear and convincing evidence” that material information was misrepresented or omitted with the intent to mislead or deceive the patent examiner.¹⁷⁷ The Act went on to provide that information is material if:

- (i) a reasonable examiner would have made a prima facie finding of unpatentability, or maintained a finding of unpatentability, of one or more of the patent claims based on the information, and the information is not cumulative to information already of record or previously considered by the Office; or
- (ii) information that is otherwise material refutes or is inconsistent with a position the applicant takes in opposing a rejection of the claim or in asserting an argument of patentability.¹⁷⁸

Apart from materiality, the 2007 Act required separate proof of intent and to prove

specific facts beyond materiality of the information misrepresented or not disclosed must be proven that establish the intent of the person to mislead or deceive the examiner by the actions of the person.

¹⁷⁶ H.R. 1908, 110th Cong. (2007).

¹⁷⁷ *Id.* § 12(b)(4).

¹⁷⁸ *Id.*

Facts support an intent to mislead or deceive if they *show circumstances that indicate conscious or deliberate behavior on the part of the person to not disclose material information or to submit false material information* in order to mislead or deceive the examiner.¹⁷⁹

The materiality component of the 2007 Act is somewhat similar to the definition set forth in the Patent Office's Rule 56 and that the Federal Circuit rejected in *Digital Control*.¹⁸⁰ However, the 2007 Act's proposed materiality standard differs significantly from Rule 56 in one important regard. By providing that information is material if a reasonable patent examiner would have "maintained a finding of unpatentability,"¹⁸¹ the 2007 Act broadens Rule 56 to include situations such as when a misstatement is made in a declaration and the examiner removes the rejection because of the declaration. In so doing, the 2007 Act creates a materiality standard that is more akin to the reasonable examiner standard¹⁸² than to the Rule 56 standard, thereby keeping the standard relatively in line with current case law precedent.

In sharp contrast, the intent component of the 2007 Act differs markedly from current judicial precedent. As discussed in detail above, pursuant to current case law, after threshold levels of materiality and intent have been shown, a court will balance the evidence of materiality and intent to determine whether the facts support a finding of inequitable conduct.¹⁸³ By separating intent from materiality, the 2007 Act would not permit the courts to engage in any such balancing. Instead, the patent challenger would need to prove "specific facts beyond materiality of the information misrepresented or not disclosed"¹⁸⁴ to support a finding of intent. Such facts would need to show circumstances indicating the applicant's conscious or deliberate omission or misrepresentation

¹⁷⁹ *Id.* (emphasis added).

¹⁸⁰ *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315–16 (Fed. Cir. 2006).

¹⁸¹ H.R. 1908 § 12(b)(4).

¹⁸² *See infra* text accompanying notes 192–201.

¹⁸³ *Baxter Int'l Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1996).

¹⁸⁴ H.R. 1908 § 12(b)(4).

of material information,¹⁸⁵ such as an applicant's disregard for warnings that material information exists or a cultivation of ignorance to avoid actual knowledge.

This intent standard would likely lead to different Federal Circuit case outcomes. For example, in *Novo Nordisk Pharmaceuticals*,¹⁸⁶ the court inferred intent to deceive when a Dutch inventor wrote in the past tense.¹⁸⁷ Under the 2007 Act's proposed intent standard, however, the court could not have found intent to deceive, as there existed no facts showing the inventor's conscious or deliberate attempt to write the final step in the wrong tense. In this way, then, the proposed intent standard set forth in the 2007 Act is a more objective determination than the standard currently utilized by the courts, and is a determination that will force the courts to find "conscious or deliberate behavior" without relying on materiality.¹⁸⁸

In another sharp deviation from current judicial precedent, the 2007 Act rejects the Federal Circuit's current "all or nothing" remedy of patent unenforceability in the event inequitable conduct is found, in favor of a number of potential remedies for inequitable conduct, depending on the particular circumstances of a case. These remedies include: (1) denying an injunction and allowing only a reasonable royalty for damages; (2) "[h]olding the claims-in-suit, or the claims involved in the inequitable conduct, unenforceable[; (3)] [h]olding the patent unenforceable[;] and/or [(4)] holding the claims of a related patent unenforceable."¹⁸⁹ A court's imposition of a variety of different remedies depending upon the factual situation presented to it could eliminate some of the advantages of pleading inequitable conduct, because for borderline cases of inequitable conduct, the alleged infringer could prevail on the defense, yet still be liable for infringement and owe a reasonable royalty to the patentee. In another instance, the court might hold only the claims that issued due to the misconduct unenforceable, which leaves other claims of the patent enforceable

¹⁸⁵ *Id.*

¹⁸⁶ *Novo Nordisk Pharm. Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347 (Fed. Cir. 2005).

¹⁸⁷ *Id.* at 1359–60.

¹⁸⁸ H.R. 1908 § 12(b)(4).

¹⁸⁹ *Id.*

against the infringer. Although not all or nothing remedies, each would still serve the equitable function of punishing the patentee who committed the inequitable conduct and would provide judges with an arguably easier way of deciding borderline cases and meting out appropriate punishment.

Important to note is that the pending Senate version of the Patent Reform Bill, Senate Bill 1145, also has a section addressing inequitable conduct.¹⁹⁰ The Senate's version of the bill provides for nearly identical remedies as does the House of Representative's bill, with the only difference being that the Senate version does not permit a court to hold claims of a related patent unenforceable.¹⁹¹ The inequitable standard proposed by the Senate's bill, however, differs markedly from the standard proposed in the House of Representative's bill. Unlike House Bill 1908, Senate Bill 1145 largely codifies the existing judicial inequitable conduct standard. Under the Senate's version of the 2007 Act, information is material 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."¹⁹² These materiality requirements are a codification of the reasonable examiner standard currently employed by the courts coupled with the judicially oft-used doctrine of not allowing cumulative information to be considered.¹⁹³ Given that the House bill provides an objective materiality test that is somewhat close in scope, the final law, if passed, will likely be very similar to the current House and Senate proposals.

The Senate's version of the bill also appears to codify the *Kingsdown* standard of intent¹⁹⁴ by permitting intent to be inferred so long as it is "not . . . based solely on the gross negligence of the patent owner or its representative, or on the materiality of the

¹⁹⁰ S. 1145, 110th Cong. § 12 (2007).

¹⁹¹ *Id.*; H.R. 1908 § 12(b)(4).

¹⁹² S. 1145 § 12.

¹⁹³ See *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991).

¹⁹⁴ *Kingsdown Med. Consultants v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988); see *supra* text accompanying note 68.

information misrepresented or not disclosed.”¹⁹⁵ In so doing, Senate Bill 1145 adopts the *Kingsdown* standard of intent and implies a knowledge requirement. Although the Senate’s version of the bill also separates the materiality determination from the intent determination, it does not require proof that the misrepresentation was knowing.¹⁹⁶ In this way, then, the Senate’s version of the 2007 Act provides a broader test for finding intent than House Bill 1908, but one that would still likely curtail the Federal Circuit’s current trend of relaxing the intent standard.

Despite the differences that exist between the Senate and House of Representatives versions of the 2007 Act, both represent a radical shift away from the severely narrowed inequitable conduct standard that was proposed in the 2005 bill.¹⁹⁷ At the same time, however, both versions of the 2007 Act propose a variety of remedies intended to punish those who have engaged in inequitable conduct.¹⁹⁸ By proposing a broader standard along with a host of potential remedies, it appears that the most recent versions of the 2007 Act have attempted to strike a compromise that would remove some of the incentives of over-pleading inequitable conduct, especially in questionable borderline cases, without severely narrowing the inequitable conduct standard.

CONCLUSION

As the statistics presented in this article make clear, inequitable conduct is not a plague upon the courts but, rather, a defense that is pled in a mere 20% of patent infringement cases.¹⁹⁹ That said, and as indicated by the fact that courts dismiss inequitable conduct claims on summary judgment 50% of the time,²⁰⁰ inequitable conduct remains an over-pled defense. Such over-pleading, as discussed earlier, stems from the ease by which an alleged patent

¹⁹⁵ S. 1145 § 12.

¹⁹⁶ *Cf. id.*

¹⁹⁷ H.R. 2795, 109th Cong. § 5(a) (2005).

¹⁹⁸ *See* H.R. 1908, 110th Cong. § 12(b) (2007); S. 1145 § 12.

¹⁹⁹ *See supra* Table 1. This percentage is only counting those cases that go to trial or where the issue is decided on summary judgment.

²⁰⁰ *See supra* Table 2 and corresponding description.

infringer can raise the defense and the immense rewards of successfully doing so (namely, avoiding a patent infringement finding).²⁰¹

In an effort to curb the number of meritless claims of inequitable conduct brought by alleged patent infringers, industry groups and the legislature have spent a great deal of time and effort proposing ways to reform the inequitable conduct standard. The ultimate problem with all of the proposals to date, however, is that they seek to adjust the standard by which inequitable conduct claims are adjudged instead of removing the incentives of pleading the defense. In this way, although each of the proposed reforms may ultimately make it more difficult for an alleged patent infringer to prevail on an inequitable conduct claim, the alleged infringer remains free—and it remains in the alleged infringer’s best interest—to make such a pleading. Perhaps, then, the solution lies not in modifying the inequitable conduct standard but in modifying the procedural paradigm in which such claims are brought. That is, perhaps the simplest and yet most prudent approach to bringing about needed reform would be to leave the inequitable standard as it is currently applied by the courts and simply award attorneys’ fees, in whole or in part, whenever an alleged patent infringer loses an inequitable conduct summary judgment motion. Such a legislative provision would significantly reduce meritless claims of inequitable conduct without mandating that the courts apply a standard that they did not choose.

Interestingly, existing patent law already provides for the award of attorneys’ fees in “exceptional cases,”²⁰² though such fees are rarely awarded in cases involving inequitable conduct. Although an inequitable conduct case before the Patent Office qualifies as an “exceptional case,”²⁰³ a prevailing party must show an egregious case of misconduct with clear and convincing evidence to be entitled to attorneys’ fees²⁰⁴—a burden that is rarely met.²⁰⁵ While district courts have, between 1995 and 2004,

²⁰¹ See *supra* text accompanying notes 96–101.

²⁰² 35 U.S.C. § 285 (2006).

²⁰³ *Id.*

²⁰⁴ Nolan-Stevaux, *supra* note 125, at 168.

²⁰⁵ *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 712–13 (Fed. Cir. 1983).

awarded attorneys' fees approximately 40% of the time in summary judgment decisions against patent holders, no courts during this time have awarded attorneys' fees following a summary judgment decision denying an alleged infringer's claim of inequitable conduct.²⁰⁶ In this way, then, while courts arguably have the power to curtail frivolous inequitable conduct claims by imposing attorneys' fees, they have so far refrained from doing so,²⁰⁷ likely because they do not view spurious allegations of inequitable conduct as "exceptional" cases permitting the award of attorneys' fees.

The answer therefore appears to lie in amending Section 285 to provide that a party claiming inequitable conduct must pay for opposing counsel's attorneys' fees in the event such party's claim is dismissed upon a summary judgment motion. Such legislative reform would remove an alleged patent infringer's incentive to file a meritless claim of inequitable conduct. In so doing, the reform would reduce litigation costs and increase patent quality without usurping the judiciary's role and changing the inequitable conduct doctrine when, in fact, no such change is needed.

²⁰⁶ Nolan-Stevaux, *supra* note 125, at 168.

²⁰⁷ See *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 831 (Fed. Cir. 1992) (finding litigation may merit award of attorney fees); *Bayer Aktiengesellschaft v. Duphar Int'l Research B.V.*, 738 F.2d 1237, 1242-43 (Fed. Cir. 1984) (awarding fees for a frivolous position advanced by a party).