Rethinking Patent Fraud Enforcement in a Reform Era

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RETHINKING PATENT FRAUD ENFORCEMENT IN A REFORM ERA

KALI MURRAY* AND DMITRIY VINAROV*

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“As a political matter, piecemeal legislation to address inequitable conduct is not realistic. A call for simply relieving patent attorneys and applicants from the consequences of ‘fraud’ and ‘inequitable conduct’ will hardly evoke sympathetic attention from busy legislators and committee staffs.”

INTRODUCTION

A key element of our patent system is the desire to prevent a patentee from benefiting from potentially fraudulent behavior during the patent application process. Policing patent fraud prevents a patentee from obtaining a significant monopoly, either through active

* Assistant Professor, Marquette University Law School. This Article is dedicated to Mary Jane Saunders and The Honorable Catherine Curtis Blake. I would like to thank Alison Julien for her invaluable editorial comments. I would also like to thank Barry Grossman of Foley & Lardner, LLP for his suggestion to conduct initial research on these issues.


malfeasance or passive complicity, by disclosing incorrect or inaccurate information to the United States Patent and Trademark Office ("USPTO"). Beyond this equitable basis, the existence of legal mechanisms that prevent patent fraud serves to uphold the fundamental basis of the "patent bargain," which rests on the full and accurate disclosure of all relevant information relating to the invention.\(^2\) Thus, the existence of policing mechanisms for fraud—in any form—is absolutely vital to uphold the transparency of any patent system.

A significant challenge exists, then, where, as in the United States, the policing mechanisms for fraud are deeply compromised by a jurisprudential standard that has created confusion for the patent community. We speak, of course, of the Court of Appeals for the Federal Circuit’s ("Federal Circuit") recent re-examination of the materiality standard for the doctrine of inequitable conduct in cases such as *eSpeed, Inc. v. BrokerTec USA, L.L.C.*,\(^3\) *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*,\(^4\) *Nilssen v. Osram Sylvania, Inc.*,\(^5\) and *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*\(^6\) The difficulty of policing fraud mechanisms arises from one particular jurisprudential choice: the Federal Circuit’s failure to adopt the current materiality standard outlined in Rule 1.56(b).\(^7\) This current standard replaced the earlier “reasonable examiner” standard, originally promulgated by USPTO in 1977.\(^8\) While the Federal Circuit has affirmed findings of materiality based upon the 1992 Rule 1.56 standard,\(^9\) it has declined to specifically address whether the 1992 Rule 1.56 standard replaced the 1977 “reasonable examiner” standard. Indeed, the Federal Circuit began to suggest that the sole standard should be the “reasonable examiner” standard.\(^10\) These varying approaches have created a

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3. 480 F.3d 1129, 1136-37 (Fed. Cir. 2007).
4. 487 F.3d 897, 901-27 (Fed. Cir. 2007).
5. 504 F.3d 1223, 1235 (Fed. Cir. 2007).
8. See Dayco Prods., Inc. v. Total Container, Inc., 329 F.3d 1358, 1363 (Fed. Cir. 2003) (noting that the USPTO “amended its rules to provide a different standard for materiality”).
9. See infra note 31 for a review of cases that apply this relevant standard.
10. See, e.g., *eSpeed*, 480 F.3d at 1136 (stating that, under the reasonable examiner standard, information is material when “a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent”) (internal quotations omitted); *McKesson Info.*, 487 F.3d at 908, 913 (stating that “[m]ateriality . . . embraces any
jurisprudential jumble that fails to offer significant certainty in assessing what standard will be applied to assess materiality during prosecution and enforcement of an issued patent.

The Federal Circuit’s jurisprudential choice has proven once again to be controversial prompting new scholarly solutions and new legislative proposals. The controversy is organizing itself along information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent,” and further stating that failure to disclose the Baker patent met the “reasonable examiner” materiality standard and should have been disclosed to the examiner because “[i]f the same art had been before the examiners and the claims are substantially similar, [that is] probably a pretty good indication that the reference would be pretty material”) (internal quotations omitted); Nilssen, 504 F.3d at 1235 (“The information is material if there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.”) In applying the “reasonable examiner” standard, the Federal Circuit stated that “[t]he fact that Nilssen had repeatedly cited or had cited to him the prior art references in question makes it highly likely that a reasonable examiner would have wanted to consider the information in the withheld patents in determining patentability.”) (internal quotations omitted); Pfizer, Inc., 518 F.3d at 1366 (stating that information is material for the purposes of an inequitable conduct determination if a reasonable examiner would have considered such prior art important in deciding whether to allow the parent application, and noting that, under the “reasonable examiner” standard, “a misstatement or omission may be material even if disclosure of that misstatement or omission would not have rendered the invention unpatentable”).

11. See, e.g., Chris Henry, Comment, Inequitable Conduct Inequitably Conferred: When Do Patent Applicants’ Actions Intend to Deceive?, 65 WASH. & LEE L. REV. 1159, 1162 (2008) (To establish an “intent to deceive in an inequitable conduct claim, in the absence of direct evidence of a subjective intent to deceive, an accused infringer should have to prove, by clear and convincing evidence, that a patentee acted objectively reckless—that the patentee acted in the face of what the person having ordinary skill in the art (the PHOSITA) would recognize as an objectively high likelihood that the patentee’s actions constituted either a failure to disclose material information, or a submission of false material information”); Elizabeth Peters, Note, Are We Living in a Material World?: An Analysis of the Federal Circuit’s Materiality Standard, 93 IOWA L. REV. 1519, 1577 (2008) (contending that the doctrine of inequitable conduct should be undertaken using a prima facie materiality standard); James Cronin, Why the Federal Circuit Should Use the Reasonable Examiner Standard, 50 ST. LOUIS U. L.J. 1327 (2006) (assessing the varying standards outlined by the Federal Circuit and arguing that the reasonable examiner standard should be applied in the inequitable conduct context).

familiar lines as everyone offers different ways of revising the materiality standard. One more stab at revising the materiality standard, at this point, may simply not work. In fact, instead of revising the materiality standard and the broader doctrine of inequitable conduct—of which the materiality standard is a key element—it might be time to revisit the implicit bargain represented by the entire doctrine of inequitable conduct.

This implicit bargain consists of three key assumptions. First, the doctrine of inequitable conduct itself rests in equity rather than an articulated statutory standard. Second, the doctrine of inequitable conduct presumes only a competitor (and not other interested third parties or the government) can effectively police the patent fraud. Third, the doctrine of inequitable conduct asserts the best way for a competitor to raise the issue of patent fraud is as a defense (and not through an independent private right of action). These assumptions, however, have posed difficult problems. The equitable nature of the doctrine causes significant institutional conflict between the USPTO and the Federal Circuit. Patent practitioners are still waiting for guidance about the “material information” every person associated with a patent application is expected to disclose. Equally profound, these assumptions may be increasingly out of sync with the type of patent reform contemplated by congressional reform. The movement from a first-to-invent system to a first-to-file system will involve a significant reshaping of the current system. The implicit bargain may have to be revisited in light of the new priorities of a revised patent system.

Unlike in 1988, when Harold Wegner wrote the words that preface this Article, “busy legislators” and “committee staffs” are finally paying attention to re-evaluating the current structure of patent law. With this reform in mind, this Article seeks to examine two issues. First, after reviewing the Federal Circuit’s latest jurisprudence in this area, this Article will examine why the doctrine of inequitable conduct remains a deeply compromised and ultimately unworkable standard. Second, this Article explores the way in which the patent fraud mechanisms can be


13. See infra Part I.A.
14. See infra Part I.B.
15. Id.
rewritten in light of current reform efforts. Any reform should begin with consciousness of two factors. First, the response to the existence of patent fraud is tightly correlated with the larger concerns of the relevant patent regime. Second, any enforcement should be cognizant of ameliorating institutional conflict between the USPTO and the Federal Circuit.

I. A COMPROMISED STANDARD: THE CURRENT DOCTRINE OF INEQUITABLE CONDUCT

Often, complaints related to the doctrine of inequitable conduct focus on the fact that “too” many “spurious” inequitable conduct claims are made within the course of litigation. The problem, however, may instead result from two key “compromises” that underlie how the doctrine is implemented. The first compromise—the equitable nature of the doctrine itself—may prompt significant institutional overreach on the part of the Federal Circuit. A court analyzing an accusation of inequitable conduct must often undertake its assessment of patentee behavior at a significant temporal remove from the administrative context in which the decision occurred. The Federal Circuit’s refusal to adopt any given standard of materiality, then, reflects its attempt to maintain the optimal institutional flexibility in assessing how an examiner would react to varying decisions made by both the patentee and examiner. Of course, the Federal Circuit’s attempt to maintain its institutional flexibility comes at a deep cost. The patentee is left with little guidance in understanding what kind of behavior will raise the specter of patent fraud. The USPTO’s interest in maintaining clear guidelines concerning the prosecution of the patent is undermined. The significant institutional power enjoyed by the Federal Circuit to undertake its equitable analysis is exacerbated by compromised administrative authority of the USPTO. A weakened administrative actor simply may not be able to muster a response to a strong centralized actor, such as the Federal Circuit.

The second compromise of the doctrine of inequitable conduct is perhaps, in the end, the most important and least understood compromise—the less than robust conception of the “public interest,” one of the deepest legacies of the Patent Act of 1952. In particular, funneling the “public interest” through claims made by competitors may

not be the optimal way of structuring assessment of fraudulent behavior. This Section considers each in turn.

A. Compromised Implementation: Institutional Conflict in the Assessment of Inequitable Conduct

Patent fraud enforcement in the modern era, as currently epitomized by the doctrine of inequitable conduct, can comfortably be analogized to a volcano: periods of stability punctuated by violent eruptions. The causes of these periodic eruptions are linked to the basic “DNA” of the doctrine of inequitable conduct. Initially, the doctrine of inequitable conduct is, at its core, an equitable determination. In its current form, the doctrine requires that a trial court first assess whether a patentee, acting with the intent to deceive, failed to disclose or misrepresented material information to the USPTO. It then weighs materiality and intent to determine whether the equities warrant a conclusion that inequitable conduct occurred. An equitable remedy, by its very

18. See Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1048 (Fed. Cir. 1995) (outlining the elements of the doctrine of inequitable conduct). The nondisclosure or misrepresentation must meet threshold levels of both materiality and intent. GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1273 (Fed. Cir. 2001) (assessing the required threshold intent within the context of an inequitable conduct assessment). A showing of materiality alone does not give rise to a presumption of an intent to deceive. Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867 (Fed. Cir. 1988); see also M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., 439 F.3d 1335, 1341 (Fed. Cir. 2006) (“[A] failure to disclose a prior art device to the [US]PTO, where the only evidence of intent is a lack of a good faith explanation for the nondisclosure, cannot constitute clear and convincing evidence sufficient to support a determination of culpable intent.”); Pfizer, Inc. v. Teva Pharms. USA, Inc., 518 F.3d 1353, 1367 (Fed. Cir. 2008) (applying the standard set out in Ferring to conclude that no inference of intent was possible in the face of a credible good faith explanation for the withholding). An inference of intent to deceive is generally appropriate, however, when (1) highly material information is withheld; (2) “the applicant knew of the information [and] . . . knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.” Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006); see also Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997) (“[A] patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead.”).

19. Glaxo, 52 F.3d at 1048; see also Purdue Pharma L.P. v. Endo Pharms. Inc., 438 F.3d 1123, 1128 (Fed. Cir. 2006) (“Once threshold findings of materiality and intent are established, the trial court must weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred.”). The showing of intent can be proportionally less when balanced against high materiality. Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1381 (Fed. Cir. 2001). In the converse, low levels of materiality require demonstration of higher intent. Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1439 (Fed. Cir. 1991) (“The more material the omission, the less culpable the intent required,
nature, then, is a contextual determination that requires the court to assess the factual circumstances before it.\(^\text{20}\)

Moreover, this equitable remedy, through its requirement of materiality, necessarily depends on judicial assessment of complex administrative choices. Judicial fact-finders, thus, are confronted with a particularly acute dilemma: evaluating how an individual examiner may have reacted to a number of complex choices undertaken by the patent applicant. This position is not ideal position for any judge, and it is particularly problematic if the judge does not share the technical expertise of a patent examiner. This judicial assessment is made even more complex since the judge has to evaluate the patent applicant’s behavior long after that behavior actually occurred. The difficulty of this assessment, perhaps, explains why no less than four standards (along with the current standard articulated in Rule 1.56(b)) have been used to evaluate this choice.\(^\text{21}\)

These two basic elements of the “DNA,” which by themselves might be unobjectionable, together then operate to create significant conceptual uncertainty as to under what circumstances the doctrine will be triggered. This significant uncertainty inherent in the contours of the doctrine itself is exacerbated by the varying institutional responses of the two primary actors in the patent regime, the Federal Circuit and the USPTO.

The USPTO’s instinctual response has been to consistently seek to clarify the scope of the doctrine and its impact on practice before the

\(^{20}\) An equitable determination in the fraud context differs from a legal recovery in fraud in two key respects. First, in equity, the court could infer fraudulent intent from the nature of the transaction or its surrounding circumstances. Second, in equity, the court could only order that the tainted transaction could be wiped out, whereas in at law, the party impacted by fraud could repudiate the contract and then seek restitution. See Peter Rosenberg, The Assertion of a Fraud Upon the Patent Office as a Means of Defeating the Patent Monopoly, 7 J. PAT. OFF. SOC’Y 455, 458 n.11 (1968). The doctrine of inequitable conduct differs from common law fraud because it can lead to a declaration of patent fraud unenforceability and potential antitrust damages. FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1417 (Fed. Cir. 1987).

\(^{21}\) Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (noting that these tests included: (1) “the objective ‘but for’ standard, where the misrepresentation was so material that the patent should not have issued; [2] the subjective ‘but for’ test, where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so; . . . [3] the ‘but it may have’ standard, where the misrepresentation may have influenced the patent examiner in the course of prosecution[;]” and (4) the 1977 Rule 1.56 “reasonable examiner” standard).
agency. The USPTO has attempted various approaches: (1) outlined the affirmative duties of patent practitioners, both substantively and procedurally; (2) narrowed the scope of the materiality standard, once in 1977 and again in 1992; and (3) suggested that no relationship exists between the materiality standard and the subsequent application of the doctrine of inequitable conduct. Obviously, the USPTO is not a selfless actor in this particular dynamic. The agency may seek clarifying standards not because such standards are necessarily better, but rather because of its more direct accountability to a regulated community. Harry Manbeck, the Commissioner of Patents and Trademarks, in remarks upon passage of the revised materiality standard in 1992, stated, rather evocatively, that passage of such a standard was imperative because the agency would rather face a “sullen” regulated community, than a “mutinous” one.

By contrast, the Federal Circuit, since its inception in 1982, has sought to preserve its flexibility in assessing the equitable elements of inequitable conduct. In American Hoist & Derrick Co. v. Sowa & Sons, Inc., the Federal Circuit (in an opinion authored by Judge Giles Rich) stated that, while the standard issued by the USPTO was a logical starting point, “[t]here is no reason to be bound by any single standard, for the answer to any inquiry into fraud in the [US]PTO does not begin and end with materiality, nor can materiality be said to be unconnected to other considerations.” This statement neatly summarizes the institutional prerogatives at play in the Federal Circuit’s

22. The USPTO introduced the affirmative duty of candor and good faith in 1977. 37 C.F.R. § 1.56(a) (1977) (“A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application[,]”); Patent Examining and Appeal Procedures, 42 Fed. Reg. 5588, 5589 (Jan. 28, 1977) (publication of proposed rules related to the prosecution of the patent).

23. See 37 C.F.R. § 1.56(a) (2009) (outlining the current duty of candor and good faith).

24. See 37 C.F.R. § 1.56(a) (1977) (outlining the reasonable examiner standard); 37 C.F.R. § 1.56(b) (1992) (outlining the materiality standard).


28. 725 F.2d 1350, 1363 (Fed. Cir. 1984).
actions with its insistence on the flexibility needed to undertake a sufficiently equitable analysis.

Recent events illustrate the complex institutional conflict that undermines the effectiveness of our current patent fraud mechanism. Once again, the ongoing tension between the USPTO’s desire for clarity, and the Federal Circuit’s desire for flexibility, has prompted a crisis in the implementation of the current patent fraud mechanism. In 1992, the USPTO sought to clarify the duty to disclose material information by narrowing the scope of what could constitute material information. The text of the amended Rule 1.56(b) stated that:

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

(1) it establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) it refutes, or is inconsistent with, a position the applicant takes in:

(i) opposing an argument of unpatentability relied on by the Office, or

(ii) asserting an argument of patentability.

The Federal Circuit initially refined its materiality analysis in reaction to the amended Rule 1.56(b). Notably, in Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., the Federal Circuit stated, without reference to other standards, that the amended Rule 1.56(b) was the “starting point” of any inquiry under the doctrine of inequitable conduct, a standard subsequently adopted by several other cases.


30. 37 C.F.R. § 1.56(b).

31. 120 F.3d 1253, 1256 (Fed. Cir. 1997). See also Purdue Pharma L.P. v. Endo Pharms. Inc., 438 F.3d 1123, 1129 (Fed. Cir. 2006) (stating that “[i]n evaluating materiality, [the Federal Circuit] has consistently referred to the standard set forth in [USPTO] Rule 56,” and furthermore, “[b]ecause all of the patent applications at issue in this case were pending on or filed after March 16, 1992, we look to the current version of Rule 56, rather than the pre-1992 version of the rule”); Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1353 (Fed. Cir. 2005) (noting that in choosing which version of the rule to apply, the Federal Circuit gives “deference to the [USPTO’s] formulation at the time an application is being prosecuted before an examiner of the standard of conduct it expects to be followed in proceedings in the Office”).
The Federal Circuit, however, since Critikon has reasserted its prerogative to maintain institutional flexibility in two significant ways. Initially, the Federal Circuit has continued to assert its powers to use more than one materiality standard. In Digital Control, Inc. v. Charles Machine Works, the Federal Circuit reviewed whether a district court had erred by applying the “reasonable examiner” standard rather than the narrower amended rule issued by the USPTO in 1992. In holding that the district court had not erred in using the “reasonable examiner” standard, the Federal Circuit re-affirmed its prerogative to use multiple standards. The Court contended that the narrowly amended Rule 1.56 did not replace or supplant the case law precedent which allowed multiple standards, nor was the amended Rule 1.56 intended to replace the older reasonable examiner standard. The Federal Circuit’s holding in Digital Control indicates that its priority is that courts have all of the relevant tools to undertake their role in the equitable assessment that underlies the doctrine of inequitable conduct. Thus, it will tolerate the existence of multiple standards in an effort to preserve this flexibility.

Recently, however, the Federal Circuit has moved beyond simple tolerance of multiple standards to active encouragement of one particular standard: the reasonable examiner standard. The reasonable examiner standard is typically understood as the broadest available standard, thus giving a court the maximum flexibility to undertake the sliding scale of materiality and intent, at the heart of the inequitable conduct inquiry. In at least four cases, eSpeed, Inc. v. BrokerTec USA, L.L.C., McKesson Information Solutions, Inc. v. Bridge Medical, Inc.,

32. 437 F.3d 1309, 1316 (Fed. Cir. 2006).
33. Id.
34. Id. (citing 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992) (noting that the “[t]he rules do not define fraud or inequitable conduct which have elements both of materiality and of intent”).
35. The reasonable examiner standard was originally promulgated by the USPTO, which provides that materiality should be judged by whether “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(a) (1977); see also 42 Fed. Reg. 3732 (1976) (publication of proposed Rule 1.56); 42 Fed. Reg. 5580 (publication of issued rules).
36. See American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1363 (Fed. Cir. 1984) (The reasonable examiner was “an appropriate starting point for any discussion of materiality, for it appears to be the broadest, thus encompassing the others, and because that materiality boundary most closely aligns with how one ought to conduct business with the USPTO.”).
37. 480 F.3d 1129, 1136–37 (Fed. Cir. 2007).
38. 487 F.3d 897, 913 (Fed. Cir. 2007).
Nilssen v. Osram Sylvania, Inc.,39 and Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.,40 the Federal Circuit has re-asserted the primacy of the reasonable examiner standard.

The Federal Circuit first reasserted the primacy of the reasonable examiner standard in eSpeed.41 In eSpeed, the Federal Circuit used the “reasonable examiner” standard to affirm the district court’s findings of materiality. In justifying its application of the “reasonable examiner” standard, the Federal Circuit evaluated whether an applicant’s subsequent declarations that aimed to disclose and cure the earlier non-disclosure of certain facts would have been important to a “reasonable examiner” in deciding whether to allow the application to issue as a patent.42 The Federal Circuit’s holding in eSpeed foreshadowed a key trend in subsequent cases, namely, that its previous tolerance of multiple standards appears to have been replaced by the use of one sole standard.

At least three subsequent cases have applied the rule announced in eSpeed. First, in McKesson, the Federal Circuit applied the “reasonable examiner” standard to affirm the district court’s findings with respect to materiality of the undisclosed competitor’s patent during prosecution of the application.43 The Federal Circuit’s definition of materiality in McKesson parallels its earlier language in Digital Control in that the court may judge the materiality of information withheld during prosecution by the “reasonable examiner” standard.44 Second, in Nilssen, the Federal Circuit applied the “reasonable examiner” standard to affirm the district court’s findings that the references withheld by the applicant were material.45 Finally, in Pfizer, Inc., the Federal Circuit

39. 504 F.3d 1223, 1245 (Fed. Cir. 2007).
40. 518 F.3d 1353, 1365–66 (Fed. Cir. 2008).
41. 480 F.3d at 1138–39 (stating that under the reasonable examiner standard, information is material when “a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent”).
42. Id.
43. McKesson, 487 F.3d at 913.
44. See Digital Control Inc., 437 F.3d at 1316 (“[B]ecause a party alleging inequitable conduct need only prove a ‘threshold level’ of materiality in order to proceed to the second ‘balancing’ portion of the inequitable conduct inquiry, and because the [US]PTO’s ‘reasonable examiner’ standard was broader than the other three standards, the [US]PTO standard gradually became the sole standard invoked by this court.”).
45. Nilssen, 504 F.3d at 1235. In applying the “reasonable examiner” standard, the Federal Circuit stated that “the fact that Nilssen had repeatedly cited or had cited to him the prior art references in question makes it highly likely that a reasonable examiner would have wanted to consider the information in the withheld patents in determining patentability.” Id. In Nilssen, the Federal Circuit’s definition of materiality parallels its earlier language in
applied the “reasonable examiner” standard to affirm the district court’s decision that references not disclosed by the applicant during prosecution of patents at issue were not material since the applicant did not intend to deceive the USPTO by failing to disclose the references.\textsuperscript{46} This recent precedent shows the Federal Circuit acting at the zenith of its institutional prerogative to interpret the contours of the doctrine of inequitable conduct.

The Federal Circuit’s institutional desire to maintain maximum flexibility in its assessment of inequitable conduct, however, distorts other major goals of the patent regime, such as the transparency over what constitutes misconduct before the USPTO. The Federal Circuit’s assertion of its institutional power is further amplified by the USPTO’s corresponding institutional weakness. The USPTO’s use of notice and comment rulemaking to enact many of its clarifying standards may not be within the scope of its enumerated duties under Section 2 of the Patent Act, which only permits the USPTO to undertake procedural rulemakings that govern the conduct of the proceedings before the Office.\textsuperscript{47} Indeed, R. Carl Moy, writing during the passage of the 1992 amendments of Rule 1.56, concluded that it “appears that new Rule [1.]56, when viewed as an attempt to correct the law of inequitable conduct, is outside the APA [Administrative Procedure Act]. It is neither a substantive, interpretive, nor procedural rule, nor is it a statement of policy.”\textsuperscript{48} Moy’s conclusion, in many respects, has been confirmed by the Federal Circuit’s recent decision in \textit{Tafas v. Doll}, in which the court held that Section 2 of the Patent Act does not vest the USPTO with any substantive rulemaking powers.\textsuperscript{49} Thus, the USPTO,

\textit{Honeywell} with respect to the definition of what constitutes the material information. \textit{See} Honeywell Int’l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982, 1000 (Fed. Cir. 2007) (“Information is material ‘if there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.’”) (quoting Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1440 (Fed. Cir. 1991) (quoting 37 C.F.R. § 1.56 (1989))).

\textsuperscript{46} \textit{Pfizer, Inc.}, 518 F.3d at 1366.

\textsuperscript{47} 35 U.S.C. § 2(b)(2)(A) (2006) (USPTO “may establish regulations, not inconsistent with law, which . . . shall govern the conduct of proceedings in the Office”).

\textsuperscript{48} R. Carl Moy, \textit{The Effect of New Rule 56 on the Law of Inequitable Conduct}, 74 J. PAT. & TRADEMARK OFF. SOC’Y 257, 276 (1992). Interestingly, Caspar W. Ooms, the then Commissioner of Patents, at the time of the passage of the Administrative Procedure Act (“APA”), also noted that the practice of “striking an application” for fraud before the issuance was potentially unreviewable behavior under the APA. Caspar W. Ooms, \textit{The United States Patent Office and the Administrative Procedure Act}, 38 TRADEMARK BULL. 149, 156 (1947).

\textsuperscript{49} \textit{Tafas v. Doll}, 559 F.3d 1345, 1352–53 (Fed. Cir. 2009).
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when it seeks, periodically, to clarify patent fraud enforcement mechanisms, is operating at its weakest institutional power. This inequity in institutional power will continue to provide the Federal Circuit with a disproportionate impact on the contours of the current patent fraud mechanism, with the attendant negative effect on the transparency of the overall patent regime.

B. Compromised Authority of the Public Interest

The institutional conflict between the Federal Circuit and the USPTO is a visible sign of the decline of the compromised standard of inequitable conduct; less visible is the doctrine’s failure to effectively provide a robust vision of public participation in policing patent fraud. This particular problem is less visible because the “public interest” purpose behind the provision of a patent fraud mechanism has always been stated in clear and certain terms. As the Supreme Court stated in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*

[t]he possession and assertion of patent rights are “issues of great moment to the public.” *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 246 [(1947)]. See also *Mercoid Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661, 665 [(1944)]; *Morton Salt Co. v. Suppiger Co.*, [314 U.S. 488, 492-94 (1942)]; *United States v. Masonite Corp.*, 316 U.S. 265, 278 [(1942)]. A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the “Progress of Science and useful Arts.” At the same time, a patent is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.

Even these clear words, however, mask significant uncertainties

50. 324 U.S. 806, 815–16 (1945); see also *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1947) (contending that patent rights are “issues of great moment to the public”).

51. 324 U.S. at 815–16.
associated with the status of the “public interest,” as vindicated by patent fraud enforcement mechanisms. First, the doctrine of inequitable conduct—like many of the doctrines mentioned by the Supreme Court in *Precision Instrument* (such as the doctrine of “patent misuse”)—was never fully incorporated into the current patent regime. Second, *Precision Instrument* never mentions a key question in terms of defining the public interest: the party that is in the best position to enforce that public interest. As stated by Michael Waterstone (referencing various civil rights statutes), “[e]ven the most far-reaching and thoughtfully drafted statutes need to be enforced to have any real impact.”

A key compromise associated with the doctrine of inequitable conduct is a deeply constrained view of who is to enforce the doctrine, a view which is consistent with the overall goals of the Patent Act of 1952, but which currently has significant limits for the present state of patent fraud enforcement.

The current patent administrative regime (as most aptly embodied by the Patent Act of 1952) never fully incorporated a number of doctrines, such as patent misuse, inequitable conduct and antitrust exceptions. For instance, key limits were placed on the defense of patent misuse in Section 271(d).

Equally evident, however, is that the doctrine of inequitable conduct itself was not easily incorporated into the Patent Act of 1952. The first three drafts of the Patent Act did not contain explicit references to the doctrine at all. Indeed, it is unclear

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No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement . . .

*Id.* A key additional aspect of patent fraud enforcement contemplated by the 1952 Act was its ability to use disclaimers to avoid error from inadvertent mistakes. Karl Lutz, *The Patent Act of 1952*, 35 *J. PAT. OFF. SOC’Y* 155, 161 (1953).

55. The first draft only protected those defenses actually enumerated in the statute itself. See *House Bill to Revise Title 35, H.R. 9133, 81st Cong. § 242* (1951).

In any action for infringement the defendant, in addition to absence of infringement
whether the equitable defenses were to be included in the scope of the act. For instance, in May 1952, in its assessment of a draft of section 282, the House Report Subcommittee on Patents, Trademarks and Copyrights of the Committee stated that “[t]he defenses to a suit for infringement are stated in general terms, changing the language in the present statute, but not materially the substance.”

This statement is a fairly crucial one, as the previous Patent Act had only prohibited filing a specification that contained false information and making a false claim of inventorship. Thus, it was unclear whether the broader remedy associated with the defense of inequitable conduct was available, and indeed, the key provision adding the defense of unenforceability was not added until June 1952, a month before the passage of the Patent Act in July 1952. The difficult passage of Section 282 indicates the continuing difficulty of outlining appropriate fraudulent patent enforcement consistent with the Patent Act of 1952.

Moreover, the doctrine of inequitable conduct, as enacted, contained considerable limits on who could enforce it. Section 282 permits a claim of inequitable conduct to be raised only as a defense. This limitation or absence of liability for infringement may plead as a defense the invalidity of the patent or any claim thereof on any ground specified in chapter 2 of this title as a condition of patentability, or for failure to comply with the requirements of Section 112 or 201 of this title; or any fact or act made a defense by this title.

Id. The second draft divided the remedy of a civil action and the presumption of validity into two different sections. House Bill to Revise Title 35, H.R. 3070, 82nd Cong. 1st Sess. §§ 241, 242 (1951). The defenses were included in Section 242, but failed as in the previous draft to mention any potential equitable defenses. Id. § 242 (1)–(4). Subsequent drafts reflected this division. See House Bill to Revise Title 35, H.R. 7794, 82nd Cong. 2nd Sess. §§ 281, 282 (1952).


57. Section 4920 outlined two defenses related to potential fraudulent behavior: (1) filing a specification with false information; and (2) making a claim that contained inventorship. Patent Act of 1897, Ch. 391, § 4920, 29 Stat. 692–94 (1897).

58. P.J. Frederico, one of the primary authors of the Patent Act of 1952, stated that the term of “unenforceability” “was added by amendment in the Senate for greater clarity.” P.J. Frederico, Commentary on the New Patent Act, 75 J. PAT. & TRADEMARK OFF. SOC‘Y 161, 215 (1993) (reprint); see also Symbol Techs., Inc. v. Lemelson Med. Techs., Inc., 277 F.3d 1361, 1366 (Fed. Cir. 2002) (referring to commentary of P.J. Frederico in assessment of the inclusion of Section 282(1)).

59. The Senate Bill amended the House Bill version of Section 282(1) to state the following: “[t]he following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded . . . (1) [n]oninfringement, absence of liability for infringement, or unenforceability.” Senate Bill to Revise Title 35, H.R. 7794, 82d Cong. § 282(1) (2nd Sess. 1952)(amending Section 282 to add defense of unenforceability).

reflects two key elements that significantly compromise the use of the doctrine of inequitable conduct. Initially, the contours of the doctrine itself are not outlined in the text of the Patent Act. This, in large part, results from the doctrine’s origins as a response to the government’s failure to pursue its ability to cancel a patent in light of the patentee’s potentially fraudulent behavior (a capacity first discussed in United States v. American Bell Telephone Co.).

Thus, the doctrine of inequitable conduct itself was always in some respect a “stop-gap” equitable measure that sought to correct the government’s failure to effectively police fraudulent behavior.

Perhaps the doctrine was never meant to be the only way in which one could undertake to police fraud. This equitable basis attaches significant uncertainty to the doctrine, which is intensified by the failure to include even a basic statutory text that outlines the primary elements of the defense. Additionally, the doctrine itself, by being a defense to an action, could be brought by only one set of parties: the patent’s competitors. The limits placed on standing reflect the narrow bilateral conversation—between the patentee and its competitors—at the heart of the Patent Act. This narrows, considerably, the circumstances in which a claim of inequitable conduct is even brought: the patentee must have first raised a claim under Section 281, and then the competitor raises the issue of inequitable conduct as an affirmative defense. Thus, a potentially broad public interest is funneled through the narrowest potential range of advocates.

II. RETHinking THE PATENT FRAUD COMPROMISE

Our current patent fraud enforcement mechanism, the doctrine of inequitable conduct, is deeply compromised because it fosters unhealthy institutional conflict between the two primary actors of the patent regime, as well as depends on, in large part, a limited range of enforcers, the patentee’s private competitors. What, then, are the alternatives? The remarkable ferment over the current patent reform offers the

61. 128 U.S. 315 (1888).
62. Kali N. Murray, Rules for Radicals: A Politics of Patent Law, 14 J. INTELL. PROP. L. 63, 79–80 (2006) (discussing bilateral standing compromise outlined by Section 281). Notably, the legislative history of the Act suggests that Section 281 and Section 282 were seen as linked. Section 281 outlined the broad power retained by the patentee to initiate suit while Section 282 granted it a strong presumption of validity and limited the ways in which the patent could be challenged. See supra note 55 (outlining legislative history of these two provisions).
63. Murray, supra note 62.
opportunity to fundamentally reconsider the “DNA” of any new patent fraud mechanism. This Section considers the larger principles that should be used to determine the alternatives.

Two principles may be necessary as we consider a “re-write” of our current patent fraud mechanisms. First, patent fraud enforcement mechanisms are necessarily linked to the larger values of their respective patent regimes. For example, the Patent Acts of 1790 and 1793, which promoted a system without significant examination of patents, both contained cancellation proceedings that allowed repeal of a patent obtained “surreptitiously by, or upon false suggestion.” The availability of a strong cancellation proceeding necessarily prevented fraudulent behavior that could arise in a system with little or weak examination of the respective patent application. Likewise, the Patent Act of 1952 proceeded with a basic theoretical perspective that a patent regime worked most effectively with a constrained set of public values. The textual philosophy of the Patent Act of 1952 reflects a key choice: a patent system achieves the maximum public value by strongly protecting the rights of the patentee. This premise is most clearly stated by Giles Rich in his summary of the major innovations of the Patent Act: “[p]rogress is most effectively promoted by protecting those who enrich the art as well as those who improve it.” Thus, the text of the act provided that an issued patent has a strong presumption of validity, the patentee has sole power to initiate a claim of patent infringement, and patent fraud enforcement was a task largely undertaken by a patentee’s competitors.

While this model has recently shown signs of significant strains—strains often seen most acutely in the compromised doctrine of inequitable conduct—the crafting of the Patent Act of 1952 appears in contrast to much current patent reform. Congress is contemplating both major theoretical shifts (such as a first-to-file system) and major procedural shifts (such as a post-grant proceeding). Yet, these suggested changes are not often linked to any broader theoretical discussion about the “progress” that is being served by these important

changes. Such a clarification might help to answer the key questions that any discussion of patent fraud mechanisms is likely to raise, such as what is the best allocation between public and private interests in a patent system, or who is in the best position to enforce the important public goals of the system.

Indeed, Congress is moving toward a patent system with a much different point of view than that of the Patent Act of 1952. This perspective seems to view “the public interest” in substantially different ways than the Patent Act of 1952. The public interest is not being simply demarcated by providing the patentee with the strongest ownership rights. Rather the public interest is being demarcated as allowing for the issuance of only those patents that can withstand the strongest scrutiny (thus preserving a stronger public domain). This perspective is seen most clearly by the inclusion of post-grant opposition proceedings in which an issued patent is subject to any number of challenges by a potentially unlimited range of interested third parties. This move suggests that different types of patent fraud mechanisms are necessary. Varying enforcement mechanisms are potentially available. First, the statute could define materiality, thus limiting a need to resort to varying administrative and judicial definitions. Second, the statute could contain an expanded civil remedy that would allow a broader range of interested parties to make a claim that the patentee had acted in a fraudulent manner. Finally, additional criminal remedies could be included to reinforce that fraudulent behavior should not be undertaken.

Notably, the Canadian Patent Act contains each of these three elements. Section 53(1) defines materiality: “[a] patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue . . . and the omission or addition is wilfully [sic] made for the purpose of misleading.” Section 60(1) allows an independent private right of action to be brought to declare a patent void for fraudulent behavior on the part of the patent owner: any “patent or any claim in a patent may be declared invalid or void by the Federal Court at the instance of the Attorney General of Canada or at the instance of any interested person.” Finally, Section 76 outlines criminal remedies that result in a fine against and/or imprisonment of any person who

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68. Id. § 60(1).
makes a false representation or produces or tenders a document that contains false remedies.\textsuperscript{69} Reading these three provisions together, Canada’s Patent Act makes very clear the significant compromises made in our current patent fraud enforcement regime. Our current patent fraud enforcement mechanism lacks a clear standard of materiality, lacks any ability to effectively structure third-party participation mechanisms beyond competitors, and lacks any additional disincentives from committing fraudulent acts. A real question, then, has to be whether our continual attempts to tinker around the edges of the compromised doctrine of inequitable conduct can accomplish any fundamental good.

Second, any patent fraud mechanism should seek to lessen the institutional competition between the two primary actors within the current patent regime. The key conflict between the USPTO and the Federal Circuit is a significant one that undermines the clarity of the current regime. Thus, any suggested patent reform mechanisms should seek to lessen that particular conflict and find a healthy institutional balance between the two major parties.

While current patent reform has not shown any distinctive appreciation of the first principle, it appears that some appreciation exists for the second one. Congress has considered substantive patent reform during the 109\textsuperscript{th} Congress, the 110\textsuperscript{th} Congress, and the 111\textsuperscript{th} Congress, and although not all of the bills have included provisions related to patent fraud mechanisms,\textsuperscript{70} a number of them included major revisions of the patent fraud mechanism. Some bills have only tinkered around the edges of the doctrine. For instance, H.R. 1908, as passed by the House of Representatives in July 2008, maintained the defense of inequitable conduct, referenced both USPTO standards (the reasonable examiner and objective standards) as necessary for the overall materiality analysis, and limited the type of relief available depending on a finding of equitable relief.\textsuperscript{71}

Other versions of the bills, however, have sought to substantively rebalance the institutional conflict between the USPTO and the trial courts over patent fraud determinations. For instance, proposed Section 5 of H.R. 2795 outlined a dual enforcement mechanism in which

\textsuperscript{69} Id. § 76.


the USPTO or court could determine whether a person subject to a duty of good faith and candor, knowingly and with the intent to deceive, failed to disclose or misrepresented material information. Notably, however, under Section 5, the court would be limited to assessing a claim related to unenforceability, only where (1) the validity of one or more claims in the patent was at issue; (2) the court had previously entered a judgment in the action that a claim in the patent is invalid; (3) the motion to amend the pleadings was brought by a party to the action adverse to the patent owner within three months after a judgment was entered by the court invalidating the claim; and (4) the motion outlined a number of substantive grounds for its claims.

In this regard, Senator John Kyl has been a particular innovator, offering interesting solutions that seek to effectively re-balance the institutional relationships between the USPTO and the Federal Circuit. In 2008, he submitted a version of the Patent Reform Act of 2008. That act would have required that, upon a finding that more likely than not a patentee concealed material information or submitted false material information, a judge could initiate a separate reissue application proceeding under Section 251. During that proceeding, the USPTO would make an assessment of the relevant misconduct and, if a finding of patent fraud was found, issue a variety of civil sanctions. In 2009, Senator Kyl submitted another version of the Patent Reform Act of 2009, which eliminated the reissue procedure, but once again proposed that the Director of the USPTO conduct a proceeding that would assess whether intentionally deceptive behavior had occurred in proceedings before the Office. The various suggestions outlined by these bills suggest a considerable awareness that one of the primary flaws of the current standard is the failure to accurately balance the institutional competition between the USPTO and the Federal Circuit. For instance, Senator Kyl's suggestions would remove private parties' ability to raise the defense of inequitable conduct, but at the same time would increase the USPTO's power to consider stronger remedies against potential misconduct.

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73. Id.
75. Id. § 298(b).
76. Id. § 299(b)(3).
78. Id. § 299(c)(3)(A)–(C).
Thus, current patent reform is correctly experimenting with revising the institutional balance between the USPTO and the Federal Circuit in undertaking patent fraud enforcement. Unfortunately, however, early efforts to strengthen the rule-making power of the USPTO seem largely abandoned in current drafts of the bills.\textsuperscript{79} Indeed, more curious aspects of recent bills have been the expansion of the powers of the USPTO, in a number of key respects, such as the ability to undertake post-grant proceedings,\textsuperscript{80} as well as policing patent fraud, without a corresponding increase in its ability to undertake substantive rule-making under Section 2 of the Patent Act. Institutional re-balancing within the context of patent fraud reform would be fruitless if the current contours of USPTO authority remain static.

CONCLUSION

Congress’s basic refusal to consider new patent enforcement doctrines demonstrates that Congress continues to attempt to engraft remnants of the former system onto its new animal. These consistent attempts demonstrate that instead of understanding its actions as a profound re-working of the basic “DNA,” our current patent regime reinforces how much farther Congress and the patent community may need to go in articulating what its actual goals are for reform. This Article contends, in the end, that instead of asking once again, what type of materiality standard is necessary, the patent community needs to ask itself a larger question: what kind of patent system do we want to have? Answering that question may help us to avoid the current compromises that have deeply wounded application of our current patent fraud mechanism, the doctrine of inequitable conduct.

\\textsuperscript{79} Compare S. 3818, 109th Cong. § 6(e)(5) ("[T]he Director may promulgate such rules, regulations, and orders as the Director determines appropriate to carry out the provisions of this title or any other law applicable to the United States Patent and Trademark Office or that the Director determines necessary to govern the operation and organization of the Office.") with H.R 1260, 111th Cong. § 11(a) ("[T]he Director shall have authority to set or adjust by rule any fee established or charged by the Office under sections 41 and 376 of title 35, United States Code or under section 31 of the Trademark Act of 1946 (15 U.S.C. 1113) for the filing or processing of any submission to, and for all other services performed by or materials furnished by, the Office, provided that such fee amounts are set to reasonably compensate the Office for the services performed.").

\textsuperscript{80} See, e.g., H.R. 1260, § 32 (outlining post-grant proceedings); S. 515, § 32 (same).