

2008-1511, -1512, -1513, -1514, -1595

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

THERASENSE, INC. (now known as Abbott Diabetes Care, Inc.)
and ABBOTT LABORATORIES,

Plaintiffs-Appellants,

v.

BECTON, DICKINSON AND COMPANY,
and NOVA BIOMEDICAL CORPORATION

Defendants-Appellees,

and

BAYER HEALTHCARE LLC,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California
in consolidated case nos. 04-CV-2123, 04-CV-3327, 04-CV-3732,
and 05-CV-3117, Judge William H. Alsup.

BRIEF OF *AMICI CURIAE*
INTELLECTUAL PROPERTY LAW PROFESSORS
CONCERNING EN BANC REVIEW OF INEQUITABLE CONDUCT
AND IN SUPPORT OF NEITHER PARTY

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I. IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici Curiae Intellectual Property Law Professors (“*Amici*”) are law professors who have an interest in the proper development and application of patent laws.¹ Although the legal positions taken by *amici* may, if adopted, affect the outcome of this case, *amici* do not expressly support either party. All parties have consented to the filing of this brief.

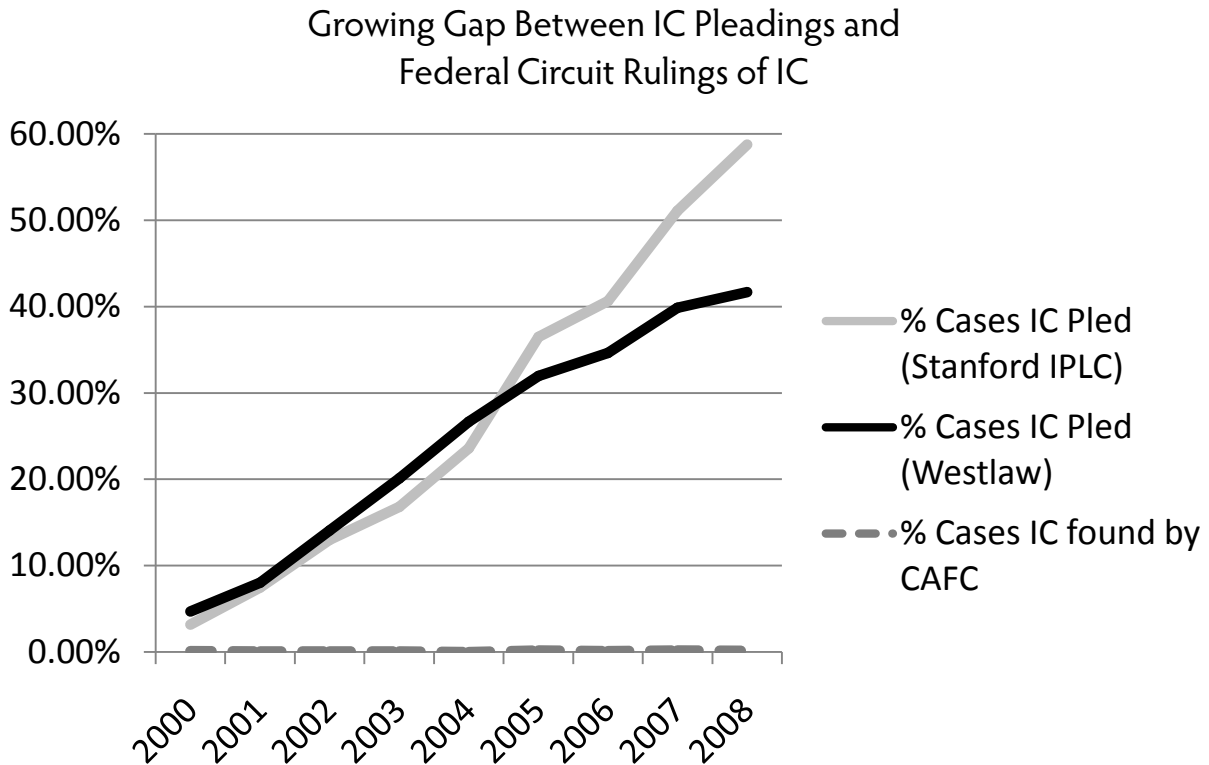
II. INTRODUCTION

Amici thank the Court for undertaking an en banc review of the inequitable conduct doctrine. The questions posed in the Court’s April 26, 2010 Order indicate that the Court is considering a thorough review of the doctrine. Such a review is important, and, increasingly, necessary. Uncertain and inconsistent rulings in recent years—combined with the strong remedy of whole-patent unenforceability—have incentivized accused infringers to plead the defense at an ever-increasing rate. The chart below, taken from a recent study,² shows that the number of responsive pleadings mentioning inequitable conduct and patents, measured as a percentage of all patent cases filed, has been steadily increasing.

¹ *Amici* have no stake in any of the parties to this litigation or the result of this case, other than an interest in seeking correct and consistent development of patent law jurisprudence. No part of this brief was authored by counsel for any party, person or organization besides *amici*. No party to the appeal or its counsel has contributed monetarily to this brief or its preparation.

² Christian Mammen, “Controlling the ‘Plague’: Reforming the Doctrine of Inequitable Conduct,” 24 BERKELEY TECH. L.J. 1329, 1360 (2010).

The chart shows data from two studies, one using data from Westlaw and the other using data from the Stanford IP Litigation Clearinghouse. The dashed line at the bottom of the graph represents the ratio of [cases in which this Court has found inequitable conduct to exist] to [all patent cases filed in the district courts].



Although it is difficult to pinpoint the precise cause of this upward trend, *amici* suggest that it is due, at least in part, to the doctrinal uncertainty that has propagated over the past ten to fifteen years. Whatever the cause, *amici* suggest that providing higher thresholds and bright-line rules will help control the “plague” of unwarranted inequitable conduct allegations.

Consistent with their academic interest in the development of the doctrine, *amici's* responses to the Court's questions are guided by several core principles.

First, the affirmative defense of inequitable conduct is a judicially-created, equitable defense.

Second, the defense relates to the disclosure of information to the Patent Office to facilitate the effective and efficient examination of patents; accordingly, it is appropriate to defer to Patent Office characterizations of the information it wants to receive during prosecution.

Third, patent applicants and prosecuting attorneys (and others subject to the duty of disclosure) should have clear rules about the information they are required to disclose.

Fourth, patent applicants and prosecuting attorneys (and others subject to the duty of disclosure) should have a safe harbor if they act in good faith. And the burden of proof should remain with the party asserting the defense. Thus, the defense should only succeed when there is evidence of bad faith. However, that evidence may be circumstantial.

With these principles in mind, *Amici* turn to the Court's six questions.

III. QUESTIONS PRESENTED

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?

2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? ... If so, what is the appropriate standard for fraud or unclean hands?

3. What is the proper standard for materiality? What role should [PTO rules] play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?

4. Under what circumstances is it proper to infer intent from materiality?

5. Should the balancing inquiry (balancing materiality and intent) be abandoned?

6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

IV. BRIEF RESPONSES TO QUESTIONS PRESENTED

1. The materiality-intent-balancing framework for inequitable conduct should be modified, as discussed in further detail below. In particular, the court should employ an objective, patentability-related standard for materiality, such as the current version of PTO Rule 56. The standard for intent should place a renewed emphasis on the clear and convincing burden of proof, and should discard any attempt to use “gross negligence” or “should have known” as part of the standard for intent. For the sake of clarity, because it has often been ignored

(suggesting its unworkability), and because it is unnecessary given the proposed elevated threshold of materiality and requirement for specific intent to justify the remedy of unenforceability, the balancing step should be abandoned.

2. The sliding scales for intent and materiality should be replaced with a single, relatively high, threshold for each. Although the inequitable conduct defense has roots in both fraud and unclean hands, it would unnecessarily complicate and muddy matters to expressly link and reframe inequitable conduct in terms of either of those doctrines.

3. The proper test for materiality should be based on clearly ascertainable, bright-line rules. The “reasonable examiner” test is too subjective, is inadequately tied to determinable standards, and is not useful in providing advance notice of the standard of disclosure that is required. The Court should, in its exercise of equitable discretion, defer significantly to Patent Office rules identifying the kinds of information that are subject to the duty of disclosure. Although the but-for test for materiality is alluring, it may set the bar for materiality too high. Moreover, the but-for test provides only a post-hoc framework for assessing materiality (i.e., for determining after-the-fact whether information that was not disclosed should have been disclosed), which is of diminished utility in providing before-the-fact guidance to applicants and their attorneys during patent prosecution.

4. Materiality and intent are distinct concepts, and should require separate proofs. The willingness in current precedent to permit a dispositive inference of intent solely from a “high level” of materiality would become obsolete if the sliding-scale test for materiality is replaced with a single threshold. Moreover, to infer intent from materiality is tantamount to making a determination that the applicant “should have known” of the materiality. The “should have known” test is fraught with problems and should be abandoned.

5. If suitably high thresholds for proving materiality and intent are adopted, the balancing step should be abandoned. Under the current rubric, with sliding scales for both materiality and intent, the balancing step is necessary because there may be cases where both materiality and intent thresholds are minimally satisfied, but the conduct is insufficiently culpable to warrant a finding of unenforceability.

6. Amici express no views on the possible applicability of materiality or intent doctrines from other substantive-law contexts.

V. **ARGUMENT**

A. **Materiality**

The core dispute about the materiality standard focuses on a choice between the “reasonable examiner” standard and the more objective standard in the current

version of PTO Rule 56.³ The more complete usual statement of the “reasonable examiner” standard is that information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.⁴ Although the full statement has an implied focus on patentability-related information,⁵ this Court has applied the “reasonable examiner” standard to cover a broader range of information types, including false assertion of small-entity status,⁶ failure to disclose that some third-party experts had a past relationship with the applicant,⁷ and failure to disclose

³ Some might argue that the much more stringent “but-for” test for materiality should be adopted as the exclusive test for materiality. *See Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (describing various standards for materiality). *Amici* believe that to be a minority view, and do not address it here in detail.

⁴ This standard was codified in the 1977 version of PTO Rule 56. 37 C.F.R. § 1.56 (1977). There does not appear to be a clear consensus as to whether this rule originated with the PTO or in the courts. *See Mammen*, 24 BERKELEY TECH. L.J. at 1335.

⁵ *See, e.g., Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 972 (Fed. Cir. 2010) (“Information is material where a reasonable examiner would find it important to a determination of patentability.”).

⁶ *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1231 (Fed. Cir. 2007) (“[I]t is not beyond the authority of a district court to hold a patent unenforceable for inequitable conduct in misrepresenting one’s status as justifying small entity maintenance payments”).

⁷ *Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181, 1187 (Fed. Cir. 2006) (“[A] declarant’s prior relationships with the patent applicant may be material, [and] failure to disclose such relationships to the examiner may constitute inequitable conduct.”).

examiners' rejections of claims in co-pending applications even when the rejected claims are not "substantially similar."⁸

By contrast, the current version of Rule 56 is explicitly focused on patentability issues. It may be paraphrased as defining material information as that which establishes a prima facie case of unpatentability of a claim or refutes a position the applicant took in arguing for patentability before the PTO.⁹

There is a conflict of precedent about which of these standards to apply. For a number of years after the adoption of the 1992 version of Rule 56, and as late as the *Purdue Pharma* decision on February 1, 2006, this Court consistently held that the "reasonable examiner" test applied to patents prosecuted before 1992, and the new version of Rule 56 applied to applications pending or filed after the rule's March 16, 1992 effective date.¹⁰ These cases imply that the "reasonable examiner"

⁸ *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897, 919 (Fed. Cir. 2007) ("[A] showing of substantial similarity is *sufficient* to prove materiality. It does not necessarily follow, however, that a showing of substantial similarity is *necessary* to prove materiality. Indeed ... rejected claims in a co-pending application [need] not be substantially similar to be material.") (emphasis in original).

⁹ 37 C.F.R. §1.56(b) (1992).

¹⁰ *See Purdue Pharma. L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006) ("Because all of the patent applications at issue in this case were pending on or filed after March 16, 1992, we look to the current version of Rule 56, rather than the pre-1992 version of the rule."); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd.*, 394 F.3d 1348, 1352-53 (Fed. Cir. 2005) ("According to the PTO's notice of final rulemaking, the rule change applied to all applications pending or filed after March 16, 1992.") (citation omitted); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1364 (Fed. Cir. 2003) ("Since the time of

test would gradually fade into irrelevance as the last of the pre-1992 patents expired. However, on February 8, 2006, just a week after it decided *Purdue Pharma*, this Court decided *Digital Control Inc. v. Charles Machine Works*,¹¹ which breathed new life into the “reasonable examiner” test for patent applications pending or filed after March 16, 1992.¹² *Digital Control* reached back to the 1984 *American Hoist* case,¹³ decided four years before *Burlington and Kingsdown*, to revive a list of four historically accepted and judicially adopted standards of materiality.¹⁴ The *Digital Control* court reasoned that the 1992 version of Rule 56 was “not intended to replace or supplant the ‘reasonable examiner’ standard,” and that the “reasonable examiner” standard should continue to exist as one of the tests for materiality.¹⁵ Since *Digital Control*, this Court has cited the “reasonable

the 1992 amendment we have continued to apply the reasonable examiner standard, *but only* as to cases that were prosecuted under the earlier version of Rule 56.”) (emphasis added) (citations omitted).

¹¹ 437 F.3d 1309 (Fed. Cir. 2006).

¹² *Digital Control* addressed the issue of inequitable conduct as it related to three patents: U.S. Patent No. 5,767,678; U.S. Patent No. 6,008,651; and U.S. Patent No. 6,232,780. *Id.* at 1310. Each of these patents was based on applications filed after March 16, 1992 but all three could be traced back to a common ancestor application that was filed on March 1, 1991. *See* U.S. Patent No. 5,767,678; U.S. Patent No. 6,008,651; U.S. Patent No. 6,232,780. Thus, each of these three patent applications was filed or pending after March 16, 1992.

¹³ *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984).

¹⁴ *Digital Control*, 437 F.3d at 1315.

¹⁵ *Id.* at 1316.

examiner” standard in at least 25 cases¹⁶ and cited Rule 56 in at least 9 cases.¹⁷

Most of the cases that cite Rule 56 also mention the “reasonable examiner” standard.

Choosing between the reasonable examiner standard and the current version of Rule 56 makes a difference. There are at least two main distinctions between these two standards. First, and perhaps most importantly from a legal process perspective, the “reasonable examiner” standard does not provide objective, advance guidance to applicants in determining what they should disclose to the PTO when they are making such decisions during prosecution. Instead, it facilitates a subjective, hindsight assessment by the finder of fact.¹⁸ This is particularly true if a “but-for” standard of materiality is required, as whether the information was material will depend on hindsight evaluation of other information

¹⁶ Westlaw search conducted July 22, 2010 in CTAF database with search terms "reasonable examiner" /p "inequitable conduct" & da(>2/7/2006).

¹⁷ Westlaw search conducted July 22, 2010 in CTAF database with search terms "rule 56" /p "inequitable conduct" & da(>2/7/2006).

¹⁸ In fact, because the “reasonable examiner” inquiry is made without deference either to current PTO policy about what should be disclosed (*i.e.*, the current version of Rule 56), or to specific testimony by the actual examiner involved in the prosecution (which is prohibited by PTO policy under 37 C.F.R. § 104.22 (2008) (prohibiting testimony by PTO employees without General Counsel’s approval); 37 C.F.R. § 104.23 (2008) (prohibiting expert or opinion testimony by PTO employees without General Counsel’s approval); and MANUAL OF PATENT EXAMINING PROCEDURE § 1701 (8th ed., rev. 7, 2008) (prohibiting testimony and opinions concerning, inter alia, patent enforceability)), the “reasonable examiner” test is in reality an inquiry into what information the *finder of fact* determines a reasonable examiner would have wanted.

(potentially including information not before the PTO) regarding whether the claims would validly have issued but for a false statement or omission. By contrast, the current version of Rule 56 provides objective criteria that an applicant can apply at the time of whether-to-disclose decisions. In this sense, the 1992 version of Rule 56 may be said to be more self-sufficient in its application.

The second main difference between the two standards is the delta in their application. A number of the most controversial inequitable conduct cases in recent years involve facts that would not have resulted in a materiality finding under the current version of Rule 56, but which the courts found violative of the “reasonable examiner” standard. Arguably, this is true of the *Ferring*, *Nilssen*, and *McKesson* cases cited above.¹⁹ In other words, had the courts applied Rule 56 instead of the reasonable examiner test, the information in these cases would likely have been found to be not material.

But these two differences do not dictate a conclusion or compel an answer as to how materiality should be defined as part of the inequitable conduct defense. Presumably, the courts have plenary discretion over how to define materiality in that context because inequitable conduct is a judicially created defense.²⁰ Its roots

¹⁹ See *supra* notes 6-8.

²⁰ *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (“The inequitable conduct doctrine, a judicially created doctrine, was borne out of a series of Supreme Court cases in which the Court refused to enforce patents whereby the patentees had engaged in fraud in order to procure those

are in the equitable doctrine of unclean hands.²¹ The fact that the doctrine has judicial origins has important implications for separation-of-powers issues. Specifically, because inequitable conduct is a judicial doctrine, no statute is being interpreted, and no agency (*e.g.*, the PTO) is charged with interpreting or applying a statute in connection with inequitable conduct determinations. Therefore, strictly speaking, no *Chevron*²² deference is owed.²³

Although it is judicially created, the doctrine *does* pertain to the conduct of administrative proceedings within the PTO. In particular, the doctrine seeks to discourage the deceptive or misleading withholding of material information from (or making factual misrepresentations to) patent examiners. This notion is embodied in all of the tests for materiality enumerated in *Digital Control*.²⁴ For

patents.”) (citing *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); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933)).

²¹ See Robert J. Goldman, *Evolution of the Inequitable conduct Defense in Patent Litigation*, 7 HARV. J. L. & TECH. 37, 49-50 (1993); see also S. Rep. No. 110-259, at 59 (2008) (citing *Keystone Driller*).

²² *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

²³ *But see* Arti K. Rai, “Growing Pains in the Administrative State: The Patent Office’s Troubled Quest for Managerial Control,” 157 U. PA. L. REV. 2051, 2079 (2009) (“[B]ecause rulemaking in this arena is properly regarded as procedural, and there is little if anything in the patent statute that speaks directly to the question, it should be subject to Chevron deference. Indeed, even absent new rulemaking, litigants could argue that the Federal Circuit must defer to the single, relatively narrow standard of materiality articulated by the PTO in Rule 56.”) (footnotes omitted).

²⁴ See *Digital Control*, 437 F.3d at 1315.

example, the “but-for” test²⁵ requires a change to the proper outcome of the patent examination process; the “reasonable examiner” test inquires what information a hypothetical patent examiner would want to have; and the current version of Rule 56²⁶ is the PTO’s own regulation about what information should be disclosed to the examiner during prosecution. And there are many examples of this Court citing Rule 56 – both the 1977 and 1992 versions of the rule – as the standard to define materiality.²⁷

The connection between materiality and PTO policies and practices is important. One of the sources of criticism of the current incarnation of the inequitable conduct doctrine is that, as applied by the courts, the doctrine actually hampers effective and efficient examination of patent applications, by requiring over-disclosure of information.²⁸ Additionally, when the PTO adopted changes to

²⁵ *Id.*

²⁶ 37 C.F.R. § 1.56.

²⁷ *E.g.*, *Rothman v. Target Corp.*, 556 F.3d 1310, 1323 (Fed. Cir. 2009); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1337 (Fed. Cir. 2008); *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1179 n.8 (Fed. Cir. 1995); *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1398 (Fed. Cir. 1986); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362-1363 (Fed. Cir. 1984).

²⁸ *E.g.*, Matthew M. Peters, Legislative Update, “The Equitable Inequitable: Adding Proportionality and Predictability to Inequitable Conduct in the Patent Reform Act of 2008,” 19 DEPAUL J. ART, TECH. & INTELL. PROP. L. 77, 115 (Fall 2008) (“The significance of the [McKesson] decision in the context of the Act is that the unenforceability of the patents turned on the inner workings of the PTO

Rule 56 in 1992, discarding the “reasonable examiner” standard in favor of a more objective standard, the stated rationale was a desire to more closely align the rule with the information examiners need.²⁹

It therefore makes sense for this Court, in reconsidering the inequitable conduct doctrine, to adopt an attitude of deference to the PTO in determining what information it actually needs to conduct effective and efficient examinations. One way to achieve this would be for the inequitable conduct doctrine to expressly defer to the PTO’s definition of material information. Even if inequitable conduct

and the patentee’s duty to remind the office of information that it already had. While it may be possible for the court to define that duty and it may even be reasonable to force applicants to err on the side of over-disclosure, however the PTO is obviously in a better position to evaluate this kind of conduct because it is the agency in question.”).

²⁹ Duty of Disclosure and Practitioner Misconduct, 54 Fed. Reg. 11,334 (proposed Mar. 17, 1989) (“These proposed changes are considered desirable in view of the large amount of resources that are being devoted to duty of disclosure issues both within and outside the Office without significantly contributing to the reliability of the patents being issued.”); Rene D. Tegtmeier, “The Patent and Trademark Office View of Inequitable Conduct or Attempted Fraud in the Patent and Trademark Office,” 16 AIPLA Q.J. 88, 88 (1988) (noting that Rule 56 is intended “to improve the quality of examination and the validity of patents”); Harry F. Manbeck, Jr., “Evolution and Future of New Rule 56 and the Duty of Candor: The Evolution and Issue of New Rule 56,” 20 AIPLA Q.J. 136, 139-140 (1992) (“[In 1990-1991] I concluded that existing Rule 56 was indeed too imprecise, and could, and probably was, leading to unjustifiable charges of inequitable conduct in litigation. It should be changed.”); Rene D. Tegtmeier, “Evolution and Future of New Rule 56 and the Duty of Candor: A Refocusing on Inequitable Conduct in New Rule 56,” 20 AIPLA Q.J. 191, 194 (1992) (noting that new Rule 56 “recognizes to some degree the unnecessary problems and expenses that are caused when questions of inequitable conduct arise in litigation based on allegedly withheld or misrepresented information not affecting patentability.”).

does not, technically speaking, entail judicial or agency interpretation of agency regulations,³⁰ it is similar enough in both substance and principle to cases where deference is given that the Court ought to give analogous deference to the PTO's definition of materiality. Accordingly, *amici* suggest that the Court define "material information" to be information that falls within the PTO's definition of that term (e.g., in Rule 56) that was in effect at the time the patent was being prosecuted. In any event, consistent with both the full statement of the "reasonable examiner" test, the enacting history and commentaries concerning the 1992 amendment (*see supra* note 29) and the express terms of the current version of Rule 56, material information should be defined in a way that clearly links it to patentability evaluations.

B. Intent

The intent element of inequitable conduct has long been a thorny and difficult problem. Indeed, it was the intent element that prompted this Court to convene en banc in *Kingsdown*.³¹

³⁰ *See In re Garner*, 508 F.3d 1376, 1378-1379 (Fed. Cir. 2007) ("An agency's interpretation of its own regulations is entitled to substantial deference and will be accepted unless it is plainly erroneous or inconsistent with the regulation.").

³¹ *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (holding en banc that "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive").

1. Cutting the Gordian Knot of “Gross Negligence” and “Should Have Known”

Over the years, the courts have applied various verbal formulations of the intent standard, sometimes including the terms “should have known” and “gross negligence.” Those terms should be expunged from the intent analysis.

It is widely accepted that direct evidence of intent to deceive the Patent Office is often difficult to find, and that circumstantial evidence must often be considered as the only evidence of intent.³² Indeed, scholars have noted the difficulty of judging the intent element, given the tensions between the judgmental moral stance of the doctrine, the natural instincts and motivations of inventors, and the duty-of-disclosure rules.³³

Before *Kingsdown*, the *J.P. Stevens* case permitted a showing of “gross negligence” to prove intent by circumstantial evidence, explaining, “Gross negligence is present when the actor, judged as a reasonable person in his position, **should have known of the materiality of a withheld reference.**”³⁴

³² *E.g.*, *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008).

³³ *E.g.*, Robin Feldman, “The Role of the Subconscious in Intellectual Property Law,” 2 HASTINGS SCI. & TECH. L. J. 1, 23 (2010).

³⁴ *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984) (emphasis added) (“Proof of deliberate scheming is not needed; gross negligence is sufficient.”).

In *Kingsdown*, this Court rejected the “gross negligence” standard, ruling en banc that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an intent to deceive.”³⁵ That should have been enough to dispose of gross negligence’s companion concept, the “should have known” test, although *Kingsdown* said nothing to affect proof of specific intent by circumstantial evidence.

It appeared for a time that “should have known” was in fact disposed of. In *Hoffmann-La Roche Inc. v. Lemmon Co.*,³⁶ this Court reversed a district court finding that the applicant intended to deceive the PTO because he was “grossly negligent since he should have known of the materiality of the withheld information.” Citing *Kingsdown*, this Court reversed the district court, reiterating the holding that gross negligence alone cannot support a finding of intent.³⁷

In 2001, this Court inverted *J.P. Stevens*’ relationship of “gross negligence” and “should have known,” holding that an applicant “cannot intentionally avoid learning of [withheld information’s] materiality, even through gross negligence; in such cases the district court may find that the applicant should have known of the

³⁵ *Kingsdown*, 863 F.2d at 876.

³⁶ *Hoffmann-La Roche Inc. v. Lemmon Co.*, 906 F.2d 684, 687-688 (Fed. Cir. 1990).

³⁷ 906 F.2d at 687 (quoting district court decision).

materiality of the information.”³⁸ *Ferring* reiterated the ascendance of the “should have known” test, affirming a grant of summary judgment of inequitable conduct where, *inter alia*, “the applicant knew or **should have known of the materiality of the information.**”³⁹ This is precisely the same formulation that the Court equated with “gross negligence” in *J.P. Stevens*.

In sum, there are two inconsistent lines of precedent on the intent issue: the *Kingsdown* line, which holds that “gross negligence” cannot prove intent; and the *Brasseler-Ferring* line, which holds that intent can be established where the applicant “should have known” of the materiality of withheld information. The two lines are in conflict because *J.P. Stevens* and *Brasseler* essentially equate the “gross negligence” and “should have known” standards.

Because of the ongoing confusion these two phrases have engendered, both terms should be eliminated from the intent inquiry.

2. Finding a Workable Standard

Instead, the Court should start with a renewed emphasis on the standard of proof. Inequitable conduct requires proof of each element by clear and convincing

³⁸ *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001).

³⁹ *Ferring B.V. v. Barr Labs, Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (emphasis added); *see also Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313 (Fed. Cir. 2008) (applying “should have known” test).

evidence.⁴⁰ As this Court has repeatedly noted, however, direct evidence of intent is often unavailable, indirect and circumstantial proof must be acceptable to prove intent.⁴¹

In *Star Scientific*,⁴² a panel of this Court articulated one way to meet the clear and convincing burden using circumstantial evidence, namely, that an intent to deceive must be the “single most reasonable inference able to be drawn from the evidence.”⁴³ This means that “a district court clearly errs in overlooking one inference in favor of an equally reasonable inference.”⁴⁴ Although *amici* submit that the “single most reasonable inference” test is an improvement and clarification over previous precedents, *amici* refrain from simply endorsing that test because it is not sufficient in all cases to satisfy the clear and convincing standard of proof. That is, it is possible to conceive of instances where intent to deceive the PTO is the single most reasonable inference from circumstantial evidence, yet that evidence (and the accompanying inference) still fall short of clear and convincing proof of deceptive intent.

⁴⁰ *E.g.*, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co*, 537 F.3d 1357, 1366 (Fed. Cir. 2008); *Kingsdown*, 863 F.2d at 872 (“materiality and intent[] must be proven by clear and convincing evidence”).

⁴¹ *E.g.*, *Ferring*, 437 F.3d at 1191.

⁴² *Star Scientific*, 537 F.3d at 1366.

⁴³ *Id.*

⁴⁴ *Id.* at 1367 (quoting *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008)).

In considering the evidence pertinent to intent, the Court should specify that, when direct proof of an intent to deceive the PTO is not available, deceptive intent can be proven circumstantially by proving the following by clear and convincing evidence that the following occurred during prosecution:

- Knowledge of the information (e.g., a prior art reference);
- Knowledge of the materiality⁴⁵ and (in the case of affirmative false statements) falsity of the information;
- Knowledge (in the case of omissions) of the obligation to supply the information; and
- A deliberate decision to withhold or (in the case of affirmative false statements) provide the information.⁴⁶

Even if each of these is proven by clear and convincing evidence, the totality of the evidence may show that deceptive intent is nonetheless not the single most reasonable inference. For example, current doctrine further allows a party accused

⁴⁵ For present purposes, *amici* express no views on the level of granularity at which the knowledge exists. See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329-1330 (Fed. Cir. 2009) (to satisfy Rule 9(b), inequitable conduct pleading must identify specific claim limitations to which information is allegedly material, and must also identify specific information within reference that is allegedly material).

⁴⁶ See *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995) (“In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference”); *Star Scientific*, 537 F.3d at 1366 (“Thus, the fact that information later found material was not disclosed cannot, by itself, satisfy the deceptive intent element of inequitable conduct.”).

of inequitable conduct to come forward with evidence of good faith in order to combat a charge that information was withheld with intent to deceive.⁴⁷

Under the current scheme, however, where “should have known” is often all it takes for the accused infringer to establish a prima facie case of deceptive intent, applicants and prosecuting attorneys must—essentially as a matter of course—come up with an explanation for why the information was not disclosed. Worse still, courts sometimes look to the person accused of inequitable conduct to prove *lack* of deceptive intent.⁴⁸ Often, particularly given the volume of patent prosecutions typically handled by prosecuting attorneys over a period of years, as well as the complexity of coordinating international prosecution, this may not be something they specifically recall, but is instead something they reconstruct from a mixture of documents, memories and conversations. Then, to the extent these reconstruction efforts, which are effectively mandatory under the current scheme’s requirement to come forward with a good faith explanation, ring hollow, that hollowness can be interpreted by the fact-finder as a lack of credibility, which in turn is used to support the inference of intent. In this manner, persons accused of inequitable conduct are often placed in the Catch-22 position of having to

⁴⁷ *Star Scientific*, 537 F.3d at 1368.

⁴⁸ *E.g.*, *M Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.*, 439 F.3d 1325, 1341 (Fed. Cir. 2006) (“When the absence of a good faith explanation is the only evidence of intent, however, that evidence alone does not constitute clear and convincing evidence warranting an inference of intent”).

affirmatively disprove their own bad intentions and be judged culpable on the perceived non-credibility of those proofs.

The solution to this conundrum lies in a returned focus on the burdens of proof and production. The party asserting inequitable conduct has the burden to prove it by clean and convincing evidence. If a prima facie case of intent can be easily proven using the “should have known” standard, then not only is the burden of production shifted to the patentee,⁴⁹ but so too, in effect, is the burden of proof, in the sense that it becomes incumbent upon the patentee to provide a complete and coherent narrative about the non-disclosure, and failure to do so will support a finding of intent. It should be a corollary of adopting a higher threshold for proving intent that the patentee should be permitted, but not required (*de jure* or *de facto*), to provide evidence of good faith. In other words, the burden of proving intent should remain with the party asserting the defense. Nevertheless, district courts *may* properly hold (after making specific factual findings based on credibility determinations when persons accused of inequitable conduct choose to testify), that the totality of circumstances warrant the conclusion at the clear and convincing standard of proof that material false statements or omissions were done with intent to deceive the PTO (*e.g.*, that intent is the single most reasonable

⁴⁹ Here, we use “patentee” to refer generically to the person accused of inequitable conduct, as well as to the party defending against a charge of inequitable conduct, to the extent those two differ.

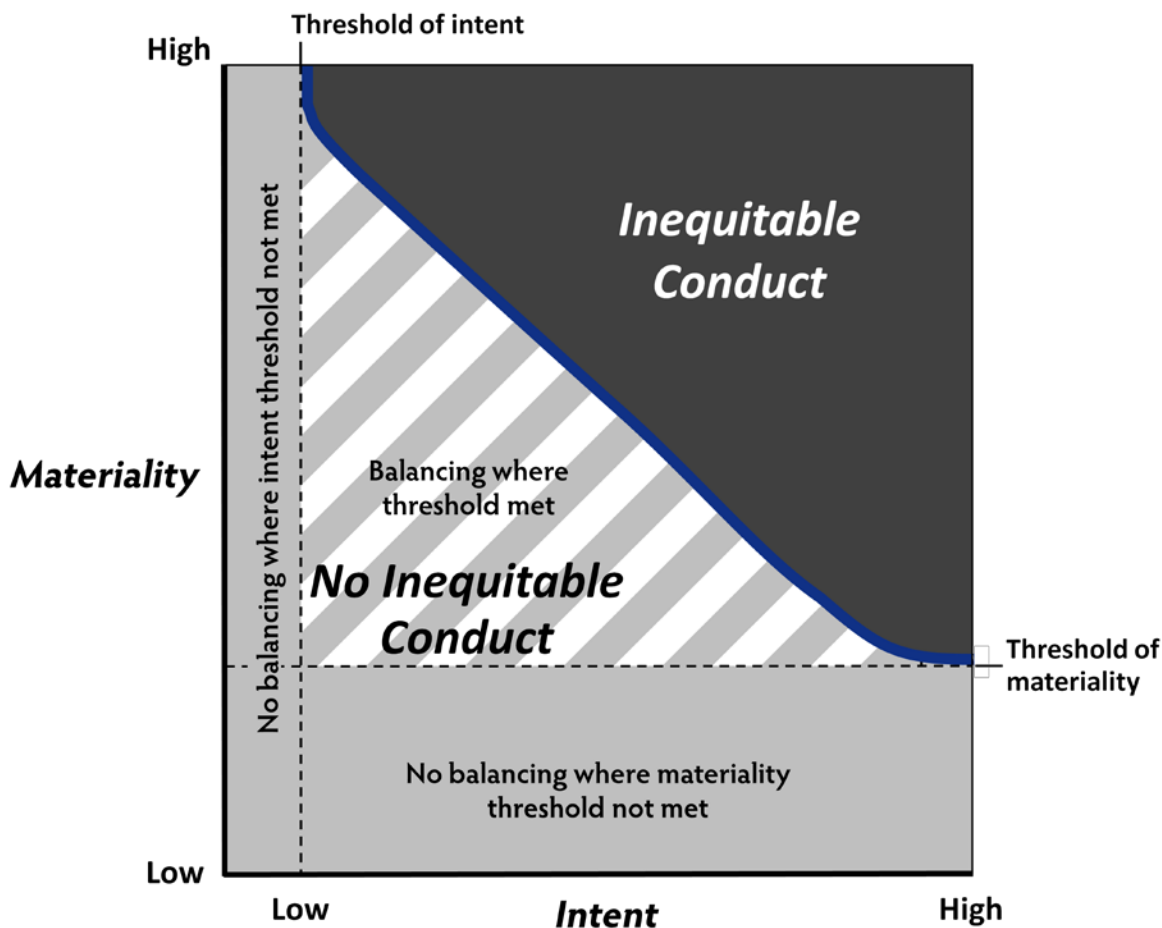
inference from that evidence), and any such findings should be carefully reviewed by the Court of Appeals.

C. Balancing and Remedies

The balancing step, as it exists in current doctrine, has been recognized as serving an important function to permit courts to exercise some equitable discretion.⁵⁰ As it is traditionally articulated, the balancing step first requires a finding by clear and convincing evidence that there is both a threshold level of materiality and a threshold level of intent. Once those thresholds are satisfied, then the court is permitted to balance materiality and intent to determine whether, under the facts and circumstances of that case, the conduct warrants a finding of unenforceability.⁵¹ This can be depicted graphically. In the chart below, the solid gray area below and to the left of the dashed lines represents areas where either or both thresholds of materiality and intent are not met. The gray striped area represents the zone where, although both thresholds have been met, courts exercise discretion to decline to find inequitable conduct. The black area in the upper right represents findings of inequitable conduct.

⁵⁰ *E.g., Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1383 (Fed. Cir. 1998) (referring to balancing as within the “sound exercise of [court’s] discretion”).

⁵¹ *Star Scientific*, 537 F.3d at 1367.



In practice, though, it is relatively rare for a court to find that both thresholds have been met, but that the case does not warrant a finding of unenforceability.⁵² Thus, with only a few exceptions, essentially the entire space represented by the striped area and the black area in the graph above are areas where courts will find unenforceability.

This can result in troubling findings of unenforceability on minimal determinations of both materiality and intent. Particularly troubling are cases that

⁵² See, e.g., *Rentrop v. Spectranetics Corp.*, 550 F.3d 1112, 1120 (Fed. Cir. 2008); *Informatica Corp. v. Bus. Objects Data Integration, Inc.*, 489 F.Supp.2d 1060, 1075 (N.D. Cal. 2007).

often involve a bare combination of the “reasonable examiner” threshold for materiality, and the “should have known” test for intent. If the balancing test were actually applied as it is stated, more of this sort of case would likely result in findings of no inequitable conduct.

This result supports one of two conclusions: either the balancing step needs to be more consistently applied and enforced, or it needs to be discarded as ineffectual. Although some *amici* have previously advocated retention and improved enforcement of the balancing test,⁵³ *amici* now believe that, on the whole, considering the need for bright-line rules, and in view of past experience with the sporadic application of balancing, it is preferable to abandon the balancing step—provided both the materiality and intent thresholds are increased sufficiently.

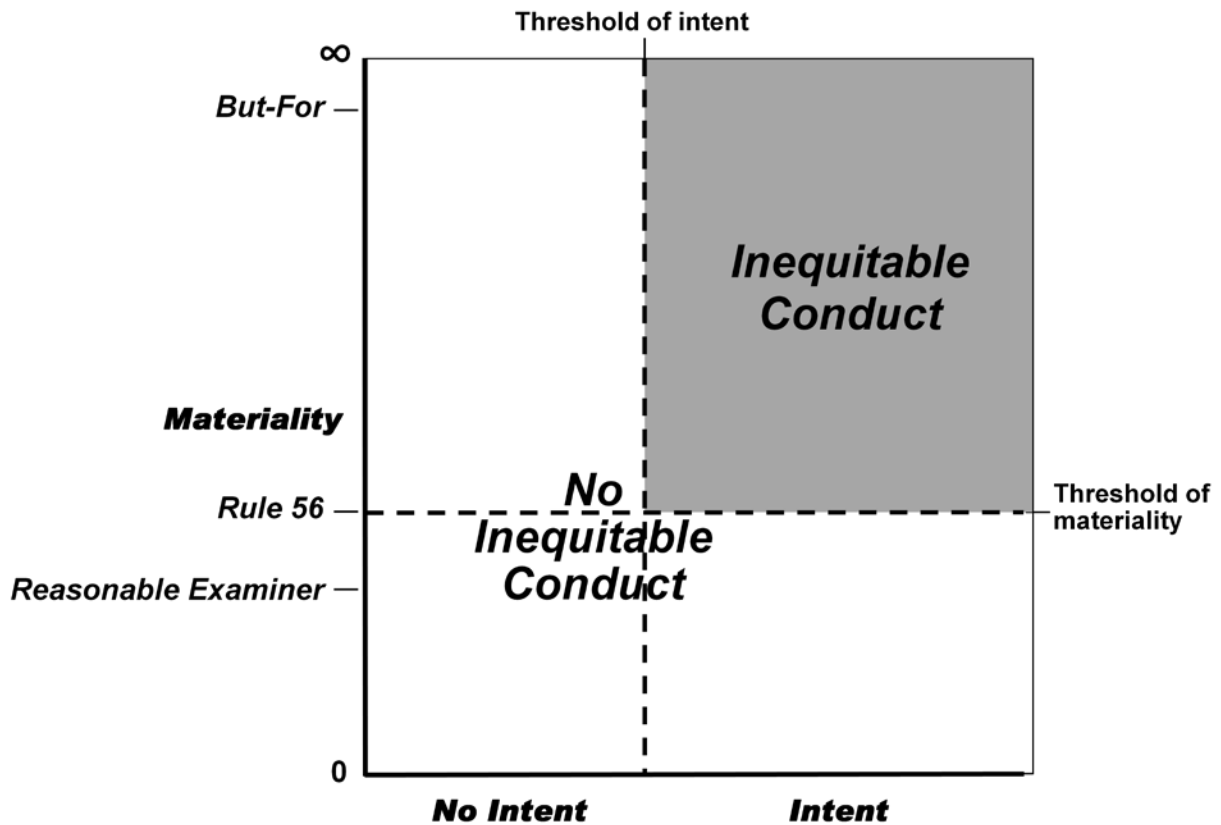
Amici do not favor permitting a range of remedies. *Amici* are concerned that doing so would actually *increase* the use of the inequitable conduct defense, by encouraging accused infringers with weak claims of inequitable conduct to “roll the dice” on getting something out of the defense.

VI. CONCLUSION AND RECOMMENDATIONS

Amici submit that the current materiality-intent-balancing framework should be modified. First, the Court should defer to the PTO’s definition of materiality, as currently stated in Rule 56, and in any event should limit materiality to information

⁵³ *E.g.*, Mammen, “Controlling the Plague,” 24 BERKELEY TECH. L.J. at 1391-1392.

that affects patentability. Second, the Court should renew its emphasis on the clear and convincing standard of proof for intent. One way of satisfying this standard, in some cases, is the *Star Scientific* “single most reasonable inference” test, with the further clarification that the burden of proof never shifts to the patentee to prove his or her own good faith. Third, with both thresholds clearly stated—and raised from their current levels—the balancing step should be abandoned, in favor of a bright-line rule. The graphical depiction of inequitable conduct would be modified to appear as follows:



With these changes and clarifications, *amici* submit that the doctrine will be simpler to apply, and (combined with the pleading standard articulated in *Exergen*⁵⁴) will result in fewer unwarranted allegations of inequitable conduct, thereby increasing both efficiency and justice. The inequitable conduct doctrine need not be a catch-all equitable defense in patent cases; limiting inequitable conduct to the circumstances outlined in this brief will not deprive courts of their equitable powers to impose less-draconian remedies for conduct falling within the scope of other equitable defenses.

Dated: July 30, 2010

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⁵⁴ 575 F.3d at 1325-1331.

PROOF OF SERVICE

I hereby certify that the Brief of *Amici Curiae* Nine Intellectual Property Law Professors in Support of En Banc Review of Inequitable Conduct was served upon principal counsel for Therasense, Inc.; Abbott Laboratories; Becton, Dickinson and Company; Nova Biomedical Corporation; and Bayer Healthcare LLC, and on counsel for *amici curiae* American Bar Association, Bruce A. Lehman, David C. Hricik, Dolby Laboratories, Inc., GEO Foundation, Ltd., International Intellectual Property Institute, Ole K. Nilssen, Verizon Communications, Inc. and Washington Legal Foundation on July 30, 2010 by forwarding two copies each via U.S. Mail, addressed to:

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Dated this 30th day of July, 2010.

By: _____
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CERTIFICATE OF COMPLIANCE

In accordance with Federal Rule of Appellate Procedure 32(a)(7)(C), the undersigned certifies that this brief complies with the applicable type-volume limitations. Exclusive of the portions exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b), this brief contains 6312 words. This certificate was prepared in reliance on the word count of the word-processing system (Microsoft Word 2007) used to prepare the brief.

The undersigned further certifies that this brief, which was prepared in the 14-point Times New Roman font of Microsoft Word 2007, complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (a)(6).

July 30, 2010

Christian E. Mammen