

Appeal Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595.

Before The  
United States Court of Appeals  
For the  
Federal Circuit

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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.

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**BRIEF OF AMICUS CURIAE**  
**UNIVERSITY OF KENTUCKY INTELLECTUAL PROPERTY LAW SOCIETY**  
**IN SUPPORT OF NEITHER PARTY.**

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CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 47.4, Charles Lee Thomason, counsel, for amicus The University of Kentucky Intellectual Property Law Association, certifies the following:

1. **The full name of every party or amicus represented by me is:**  
The University of Kentucky Intellectual Property Law Association
2. The name of the real party in interest represented by me is: none
3. All parent corporations and any publicly held companies that own 10 percent of more of the stock of the party or amicus curiae represented by me are:  
None.
4. The named of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:  
No others.

7/2/10  
Date:



Signature of counsel  
Charles Lee Thomason

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Interest of Amicus

The undersigned counsel for Amicus Curiae The University of Kentucky Intellectual Property Law Association respectfully submits this brief pursuant to Rule 29, FED. R. APP. PROC. The Order granting review en banc granted permission for the filing of amicus briefs.

No part of this brief was authored by counsel for any of the parties to the appeal. No person or entity, other than the amicus listed here, made any financial contribution to the preparation or submission of this amicus brief.

Amicus curiae The University of Kentucky Intellectual Property Law Association is a voluntary association of law students in the College of Law at the University of Kentucky, having an academic interest any change in the patent law.

The undersigned counsel is an Adjunct Professor of IP and Patent Law at The University of Kentucky College of Law, Lexington, KY.

## Statement of the Issues

The *en banc* order, 2010 WL 1655391 (Fed. Cir. April 26, 2010) enumerated the following questions for rehearing *en banc*:

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? *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds by Standard Oil Co. v. United States*, 429 U.S. 17 (1976); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933). If so, what is the appropriate standard for fraud or unclean hands?
3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office's 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? *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed.Cir.1988) (*en banc*).
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.

Restatement of the Issues.

Amicus urges the en banc court to consider the foregoing issues with due regard to the following Question:

Whether the paramount public "interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct"<sup>1</sup> is secured by requiring:

- (1) a "threshold level"<sup>2</sup> of clear and convincing evidence showing intent and materiality, that then,
- (2) is "balanced"<sup>3</sup> before
- (3) "discretion"<sup>4</sup> to declare a patent unenforceable is exercised.

Or whether that three-tiered assessment is too malleable or abstruse to protect the public interest in patents, as well as to serve the private interests of litigants.

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<sup>1</sup> *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816, 65 S.Ct. 993, 89 L.Ed. 1381, 65 U.S.P.Q. 133 (1944).

<sup>2</sup> A trial court must ask whether the evidence reaches that "threshold level" of materiality, and of culpable intent. *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1439 (Fed.Cir.1991).

<sup>3</sup> After a finding of threshold levels of materiality and intent, the trial court then "must weigh" those, *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 at 1178 (Fed. Cir. 1995), to "determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent," *Therasense, Inc. v. Becton, Dickinson and Co.*, 565 F.Supp.2d 1088, 1112 (N.D. Cal. 2008). The more material the information misrepresented or withheld by the applicant, the less evidence of intent will be required in order to find inequitable conduct. *N.V. Akzo v. E.I. DuPont de Nemours*, 810 F.2d 1148, 1153 (Fed.Cir.1987).

<sup>4</sup> A "district court must still balance the equities to determine whether the applicant's conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable. Thus, even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365, (Fed.Cir. 2008), cert. denied, *R.J. Reynolds Tobacco Co. v. Star Scientific, Inc.*, \_\_\_\_ U.S. \_\_\_, 129 S.Ct. 1595, 173 L.Ed.2d 678 (2009).

## Summary of the Argument

The three-tiered approach used to determine the defense of inequitable conduct has proven to be unworkable. In a sense, it conjugates the inequitable conduct problem into a different equation, which gets solved by the three-tiered approach, and then, that solution is converted into an answer to the original problem.

The three-tiered approach to declaring unenforceability, *vel non*, fundamentally measures only the litigants' private interests in a post-mortem assessment of whether, on a material matter, the infringer can show a threshold level of inference and circumstances that, clearly and convincingly, evidence a subjective bad intent that infected the actions of the applicant/patentee. The "balance" is too centered on the private interests of the litigants. The public interest in patents is left alongside the path, as the litigants search for clues and fragments that may bear on the "threshold levels" that the three-tiered approach considers.

Only the litigants' private interests are integrated into the three-tiered approach, when used to adjudicate whether an accused infringer has dug up threshold levels of admissible inference and circumstances regarding nondisclosures to the USPTO.

The three-tiered approach conflicts with Supreme Court precedent on the “unenforceability” defense, as codified in the 1952 Patent Act.

A fair and objective determination of the inequitable conduct defense is highly important, since the “exclusive” rights granted by a patent rest on presumptions of full disclosure and due examination, and too, since the defense is pursued in most infringement suits.

## ARGUMENT

### STATUTORY PROVISIONS INVOLVED

Every patent is granted under the authority of Article 1, Section 8, clause 8 of the U.S. Constitution, which provides authority:

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

The present matter is a defense to patent infringement, as set forth in the 1952 Patent Act, 35 U.S.C. § 282, which provides, in relevant part:

“The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded: (1) ... absence of liability for infringement or unenforceability.”

A predecessor statute, the Consolidated Patent Act of 1870 set forth as a defense that “for the purpose of deceiving the public the description and specification filed by the patentee in the patent office was made to contain less than the whole truth relative to his invention or discovery.”

#### Proceedings Below.

In the case at bar, the prior rulings regard what meaning that an applicant, the prior art , the experts, and the judges could assign to an element described as “preferred,” or “optional,” or “required.”

## A.

The Defense of Unenforceability  
for “fraud or other inequitable conduct.”

### 1. The Objective Standards for Intent to Deceive.

Based on “fraud or other inequitable conduct,” a patent was declared unenforceable in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1944). After that 1944 decision, the 1952 Patent Act codified the “unenforceability” defense in 35 U.S.C. §282(1). That statutory term – unenforceability – has grown out, into a three-tier assay of inequitable conduct: threshold levels of proof, weighing and summing the levels, then balancing the equities. Different standards of review apply to the tiers. Overall, district courts and litigants struggle with this elaborate approach.

*Precision* began as an infringement suit, between competitors, which were parties to licenses that had settled a dispute over patents obtained by deceit.<sup>5</sup> A “trial on the sole issue of Automotive’s inequitable conduct” had adjudged the “private interests of the litigants”

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<sup>5</sup> “In conformity with these agreements, the Larson application was duly assigned to Automotive ...and the Larson patent was issued to Automotive. Both Snap-On and Precision operated under the interference settlement agreements ...[later], Precision began to furnish, and Snap-On began to sell, a modified wrench ...[which] is the wrench which is here charged with infringement.” *Automotive Maintenance Machinery Co. v. Precision Instrument Mfg. Co.*, 143 F.2d 332, 62 U.S.P.Q. 226 (7<sup>th</sup> Cir. 1944). “Thus the suit arose which is now before us.” *Precision, supra*, 324 U.S., at 814.

in those patents. *Id.*, at 815. However, the overarching concern that “brought the case” up to the Supreme Court, was “the public importance of the issues involved,” *id.*, because all “patent rights are ‘issues of great importance to the public.’” *Id.*, at 811.

Elemental to the “unenforceability” defense sustained in *Precision* were the beliefs and knowledge of those associated with patent that issued to Automotive and the Larson application that preceded issuance. The eventual assignee of the patent had “reason to believe” that the applicant had misrepresented the date of and background of the invention claimed. *Id.* at 815. Fidler, the assignee’s in-house attorney had sought opinions from outside counsel, which were equivocal on whether the patent was valid or enforceable. That step by Fidler was deemed “indicative of his belief” that deceit was used to obtain the patent. The assignee’s defense was that it “did not have positive and conclusive knowledge” of the deceit. *Id.* at 816-17.

Thus, in *Precision* the intent element of the defense was sustained upon a “reason to believe,” corroborated with proof that was objectively “indicative of” a belief, that accurate information was not disclosed to the patent examiner. Objective proof that indicated those grounds for

unenforceability was not rebutted, i.e., it was “not excused by reasonable doubts” of those associated with obtaining the granted patent.

## 2. The Public Interest in Patents Is Served By Objective Tests.

The issuance of a patent monopoly “concerns the public interest as well as the private interests of the litigants.” *Precision*, at 811. The public interest in the patenting process “demands that all facts relevant” to the granting or refusing of a patent monopoly be disclosed.

In litigation, the idea that a patentee need present nothing to ‘defend the patent,’ which has a presumption of enforceability, is an anachronism. The public interest is better served when an objective assessment is made, early on, of whether the applicant had disclosed the most relevant art and information, and had an objectively lawful purpose not to disclose information known to the applicant.<sup>6</sup> Issuance of a patent should not negate the duty all applicants have to make proper disclosure, and it does not negate the public interest in the transparency of the USPTO’s examination of what was submitted by the applicant.

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<sup>6</sup> Cf. “After a patent has issued, validity is determined objectively based on prior art and the other requirements of patentability.” *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1329 (Fed. Cir. 2004), *aff’d after remand*, 432 F.3d 1356 Fed. Cir. 2005).

An evaluation of the disclosures and reasons for nondisclosure, using objective standards, more effectively “averts an injury to the public” interest in the patent system than use of the three-tiered test.

3. The 1952 Patent Act codified the Unenforceability Defense Standards of Proof From *Precision*.

In every case interpreting the laws governing patents, the starting point should be the statute and its legislative history.

Following the 1944 decision in *Precision*, the 1952 Patent Act codified the “unenforceability” defense. The statutory defense of “unenforceability” presumably is consonant the standards in *Precision*.

The present, three-tiered form of analysis conflicts with, or diverges expansively from *Precision*. En banc review should determine whether the interests of the public in patents, which *Precision* instructs must be protected, are served by or are subservient to the three-tier standard developed in the caselaw of this Court.

A test for judging inequitable conduct might be crafted, now, as if the current case were being reviewed based only on the 1952 Act and the decisional standards from *Precision*.

The present statute, enacted as part of the 1952 Patent Act, codified the defense of “unenforceability,” in 35 U.S.C. §282(1). The

statutory proscriptions prior to the 1952 Act indicate how the defense, originally requiring rigidly proven, subjective fraud, has developed into “unenforceability,” arising from the conduct assailed in *Precision*.

The Patent Act of 1790 enabled an action to “repeal” an issued patent which “was obtained surreptitiously by, or upon false suggestion.” The action to repeal was eliminated, and the 1836 Patent Act gave accused infringers a defense, in suits at law, that patents were improperly obtained. For suits pleaded in equity, the 1836 statute constrained efforts to have patents declared unenforceable, as in *Providence Rubber v. Goodyear*, 76 U.S. 788 (1869) and *Mowry v. Whitney*, 81 U.S. 434 (1871).

The public interest was the measure of the defense in the Consolidated Patent Act of 1870. It required proof that “for the purpose of deceiving the public the description and specification filed by the patentee in the patent office was made to contain less than the whole truth relative to his invention or discovery.”

When interpreting the 1870 Act provision on the applicant’s “purpose” to deceive “the public,” it was held “not sufficient that the specification contains less than the whole truth, but the omission must have been made with intent to deceive the public.” *Celluloid*

*Manufacturing Co. v. Russell*, 37 F. 676 (Cir. Ct. N.Y. 1889) (“the proof fails to show that the omission referred to was made with a fraudulent intent”). The “public interest demands that the true facts shall be shown as against the original patent, which has been secured by the patentee from the patent office, upon representations that it covers a valuable invention.” *New Departure Bell Co. v. Corbin*, 88 F. 901 (Cir. Ct. Conn. 1898).

The 1870 Act was interpreted not to allow a broad-based or “general defence” against any sort of “fraud or deceit,” but rather, it enumerated specific “acts of fraud which the infringer may rely upon as a defence to a suit against him founded upon that instrument.” *United States v. Bell Telephone Co.*, 128 U.S. 315, 371-72, 9 S.Ct. 90, 32 L.Ed. 450 (1888). *Precision* later allowed a general defense, which “is ‘not bound by formula’.” *Supra*, at 815. The 1952 Act codified that, presumably.

In the decades after *Precision*, the courts have become “bound by” a formulaic, three-tier standard, which results in varied and inconsistent conclusions about inequitable conduct. The complexity and uncertain contours of all that might be relevant to the three-tiered test has added needless costs and difficulties at the pleading, case management, discovery and disclosure stages. The impact may hit hardest when the

claims are construed, and the interpreted terms become the lexicon for assessing materiality under the three-tier test.

#### 4. The Morphology of the Three-Tiered Assessment.

Unenforceability, formerly called ‘fraud on the Patent Office,’<sup>7</sup> derives from equity and common law fraud, and grounds its power to declare instruments void and unenforceable upon proof of materiality and intention.<sup>8</sup> Those concepts are elemental to the equitable defense, but very malleable when applied retrospectively to patent prosecution.

Courts may differ on the character and degrees of materiality, or the scope and targets of the intention. The measure may be qualitative – e.g., ‘levels’ of materiality – and too, some seek quantitative standards, such as Rule 1.56 or what could cause a ‘reasonable examiner’ to grant or deny a patent<sup>9</sup>, what would have been material to the hypothetical person of ordinary skill in the art to which the invention pertains.

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<sup>7</sup> See Miller, *Fraud on the PTO*, 58 JPOS 271 (1976).

<sup>8</sup> “Story’s Equity …stated: ‘Where the party intentionally, or by design, misrepresents a material fact, or produces a false impression, in order to mislead another, or to entrap or cheat him, or to obtain an undue advantage of him; in every such case there is a positive fraud, in the truest sense of the terms; there is an evil act, with an evil intent; *dolum malum, ad circumveniendum*,” and the “misrepresentation must be of something material, constituting an inducement, or motive to the act, or omission of the other, and by which he is actually misled to his injury.” Quoted in *Smith vs. Richards*, 38 U.S. 26, 13 Pet. 26, 10 L.Ed. 42 (1839). Petitioner argued in *Talbot v. Jansen*, 3 U.S. 133, 146, 3 Dall. 133, 1 L.Ed. 540 (1795) that “in matters of *meum et tuum*, the rule is clear, that fraud vitiates everything, and the fraud may be collected from circumstances.”

<sup>9</sup> *Therasense Inc. V. Becton, Dickinson and Co.*, 565 F. Supp. 2d 1088, 1111 (N.D. Cal. 2008) (a “reasonable examiner” standard).

The notion of a self-defining “threshold level” of materiality is quicksilver in the hands of some district judges and due diligence attorneys.<sup>10</sup> Similarly, an “intent to act inequitably”<sup>11</sup> is hardly self-defining. Intent is assessed using qualitative inferences of deceitfulness or good faith.<sup>12</sup> Also, courts differ on whether the key proof is specific intent to deceive an examiner about a material point, or is it as broad as subjective knowledge about undisclosed, material information<sup>13</sup>, or even just a generalized lack of candor about what ‘might’ be material.<sup>14</sup>

## 5. Paring the Tiers Down to An Objective Test.

Threshold levels of materiality, inference and circumstances of someone’s subjective bad intent, evidenced clearly and convincingly, bear on the litigants’ private interests. Those private interests have little more than an oblique relation to the public interest in issued patents that

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<sup>10</sup> As recently as *Dayco Prods., Inc. v Total Containment, Inc.*, 329 F.3d 1358, 1364 (Fed. Cir. 2003), the Federal Circuit had “not decided whether the standard for materiality in inequitable conduct case is governed by equitable principles or by the Patent Office’s rules.”

<sup>11</sup> *Halliburton Co. v. Schlumberger Technology Corp.*, 925 F.2d 1435, 1442 (Fed. Cir. 1991).

<sup>12</sup> Allowing inferences dependent “upon the totality of the circumstances, including the nature and level of culpability of the conduct and the absence or presence of affirmative evidence of good faith.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1562 (Fed. Cir. 1989).

<sup>13</sup> See, *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 526 (Fed.Cir.1987) noting that the high materiality of undisclosed information might provoke an “inference” of intent so strong that “subjective good faith” might not overcome it.

<sup>14</sup> The “must know, or should have known, of the materiality of the reference” standard has been used to infer intent. *M. Eagles Tool Whse., Inc. v. Fisher Tooling Co.*, 439 F.3d 1335 (Fed. Cir. 2006).

are unenforceable. An "underlying policy of the patent system" asks whether inventions have enough "worth to the public" to "outweigh the restrictive effect of the limited patent monopoly." *Bilski v. Kappos*, \_\_\_ U.S. \_\_\_, 2010 WL 2555192 (June 28, 2010), J. Breyer, concurring, and quoting from, *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

During the prosecution of the application, the burden is on the applicant to act in an objectively lawful manner. Evidence about the applicant's reasoning for nondisclosures is considered under the three-tiered approach, but mainly at the rebuttal phase.

A burden shifting approach, which first asks a patent applicant to explain how the nondisclosure served an objectively lawful purpose, would differ considerably from burdening a private litigant, unrelated to the applicant/patentee, with proving convincing inferences of subjective bad intent. The objective lawful purpose standard protects the public interest, as contrasted with an adversarial inquiry into an applicant's subjective bad intent that is keyed to the private litigants' self-interests.

It is not unfair to ask a patentee to go forward with showing that the application was prosecuted in an objectively lawful manner. The applicant/patentee's duty to be candid and to prosecute an application in

an objectively lawful manner should not evaporate once a patent issues and it enjoys a presumption of validity.

Think of the numbers of pretrial disputes, and the cost, due to contentiousness over an applicant/patentee opening up its files and producing evidence relevant to why and how it disclosed or did not disclose information.

The three-tiered approach is an unworkable construct of moving parts, which has outlived any utility. It is too expensive and uncertain for the litigants, and it does not serve the public interest.<sup>15</sup> The real world experience runs a spectrum from patentees unhappy about the uncertain enforceability of issued patents, across agencies and IP associations upset about the fallout from and costs of a three-tier approach to the inequitable conduct defense, to legislators desiring reform of the ‘subjective’ aspects but unable to achieve consensus, and as well to innovators who feel unjustly accused of infringing patents underserving of enforcement. None of these can be called ‘happy’ about the three-tier approach, or about how it is handled and adjudicated.

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<sup>15</sup> *Edward Katzinger Co. v. Chicago Metallic Mfg. Co.*, 329 U.S. 394, 399, 67 S.Ct. 416, (1947) (Court’s “solicitude for the interest of the public fostered by freedom from invalid patents ... , which has been manifest by the line of decisions,” at 402). “Inequitable conduct is an offense against the PTO and the public.” *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1383 (Fed. Cir. 1998).

The answer to the first *en banc* question is that the “materiality-intent-balancing framework for inequitable conduct” should be replaced, and at a minimum modified to place the public interests in patents as a paramount consideration.

## CONCLUSION

“This matter does not concern only private parties. There are issues of great moment to the public in a patent suit.”<sup>16</sup> The “paramount” interest of the public<sup>17</sup> has been subordinated, and primacy given to a three-tier assay of private litigants’ presentations of inferential facts and after-the-events circumstantial proofs.

Evaluating inequitable conduct based on objectively lawful standards, and uniform legal standards, serves the public interest. The three-tier approach is imbued with indefinite points of law, malleable standards of proof, and near-standardless discretion. Outcomes may be based on what judge or judges a litigant draws.

The three-tier approach makes patents more susceptible to the inequitable conduct being alleged, or at least, it exposes patentees to added costs for discovery and disposition of the defense. It can be shown that the materiality and intent elements are largely dependent on

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<sup>16</sup> *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 246 (1944), overruled on other grounds in *Standard Oil Co. v. United States*, 429 U.S. 17, 18 (1976).

<sup>17</sup> “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.” *Precision Instr. Mfg., supra* at 816, quoted in, *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 343 (1971) and in, *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965).

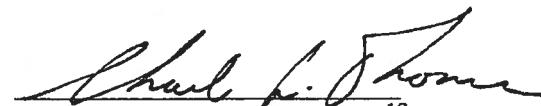
claim interpretation, which usually is addressed well into the case, and long after the application process has ended. The unintended, but pernicious effects of an elaborate, multivariate inquiry are its costs, uncertainty, and non-uniformity.

An objectively lawful purpose standard is consistent with the *Precision* case and the 1952 Act passed shortly after that decision. The applicant/patentee's objectively lawful purpose could be assessed early on, and before claim construction. The public interest is in objectively lawful prosecution and due examination of patents.

Respectfully submitted,

7/4/10

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## Certificate of Service

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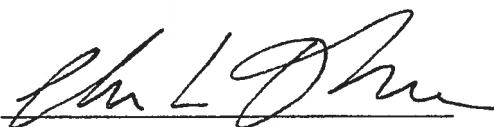
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Certificate of Compliance

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B).

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