

The State of the Inequitable Conduct Doctrine

**The Federal Circuit's Review of:
*Therasense, Inc. v. Becton, Dickinson and Co.***



Duty To Disclose Information Material To Patentability (Duty of Candor to PTO)

Current Rule 56:

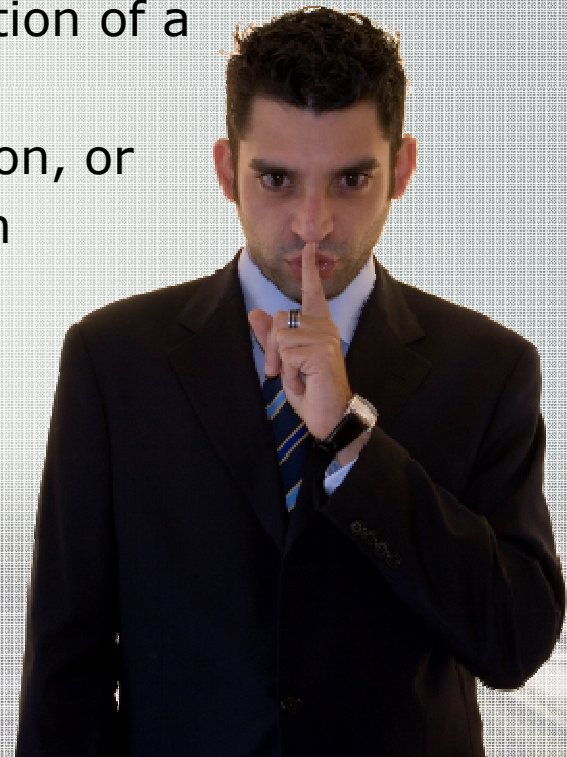
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
- 1) it establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
 - 2) it refutes, or is inconsistent with, a position the applicant takes in:
 - opposing an argument of unpatentability relied on by the Office, or
 - asserting an argument of patentability.

37 C.F.R. § 1.56(b) (2009)

The Doctrine of Inequitable Conduct: What is it?

Substantive Elements

1. An individual associated with the filing and prosecution of a patent application
 - a) Made an affirmative misrepresentation of a material fact, or
 - b) Failed to disclose material information, or
 - c) Submitted false material information
2. The individual did so with a specific intent to deceive the PTO



Undisputed Inequitable Conduct Formula

The Formula:

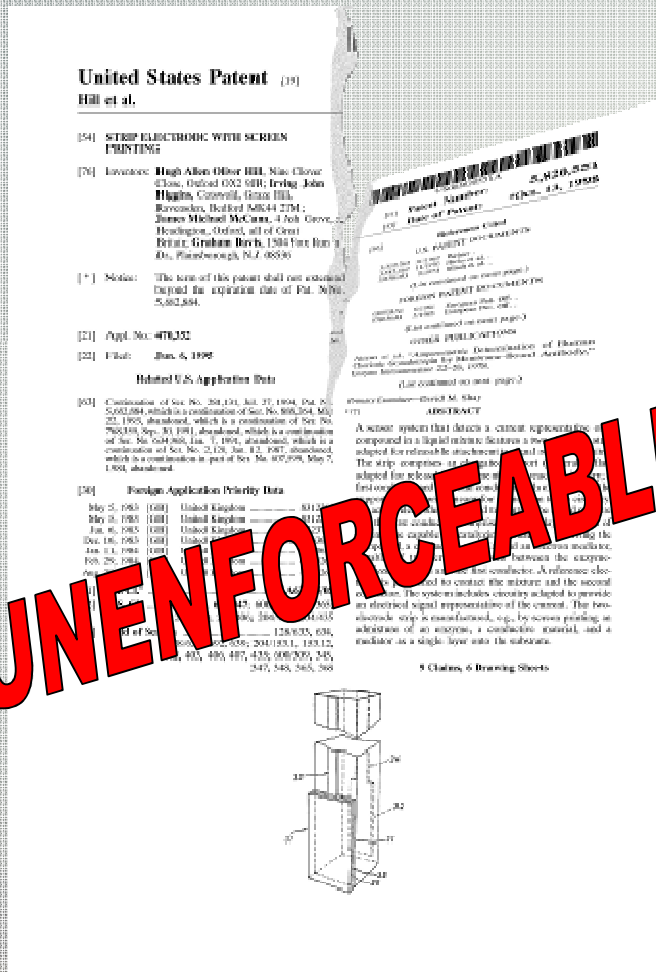
Materiality + Intent = Inequitable Conduct

The Burden: Clear and Convincing Evidence

Then Court must weigh the equities to determine whether patent applicant's conduct warrants finding patent unenforceable.



The Doctrine of Inequitable Conduct: Purpose and Result



The purpose of the Doctrine of Inequitable Conduct is to render patents that were obtained in an improper manner unenforceable.

“Atomic Bomb”

- Inequitable conduct is the “atomic bomb” of patent infringement defenses
 - Not just claim involved with the inequitable conduct
 - Not just asserted claims
 - Every claim in patent
 - Can reach to every claim in related patent
 - Can wipe out an entire portfolio
 - Almost impossible to cure
 - No re-issue

Pre-*Therasense* law

- Varying standards exist leading to uncertainty and expense
- *Therasense* provides opportunity for Federal Circuit to review standards and give direction



What's Clear?

Lying or Concealing
a Very Material Reference
with Specific Intent to Deceive is

WRONG



The Rest – Not so Clear.

Intent Ranges from Negligence,
to Gross Negligence,
to Specific Intent to Deceive



Materiality?

Federal Circuit Uses "Reasonable Examiner" Test

- Based on Old Rule 56 (1977-1991)
- Required disclosure of any information a reasonable examiner "would find important in deciding whether to reject one or more claims"
- NO specific guidance on what a reasonable examiner would consider important



Another materiality test

Current Rule 56 (1992-present)

- Information is material in establishing a prima facie case of unpatentability, or
- Refutes or is inconsistent with a position the applicant takes regarding patentability before the USPTO



Then comes the “Sliding Scale”

- After finding intent and materiality, the Court placed them together on a “sliding scale”
 - A reduced showing of intent could be offset by a strong showing of materiality
 - A reduced showing of materiality could be offset by a strong showing of intent

The Old Federal Circuit Standards Backfired

- According to *Therasense*:
 - “The Court embraced these reduced standards for intent and materiality to foster full disclosure to the PTO.”
 - “This new focus on encouraging disclosure has had numerous unforeseen and unintended consequences.”
 - “Most prominently, inequitable conduct has become a significant litigation strategy.”

The State of the Inequitable Conduct Doctrine

“The habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”

-- *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 n.15 (Fed. Cir. 1988) (quoting *Burlington Indust., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)).



Still a Plague in 2010

- Study estimated that 80% of patent cases included allegations of inequitable conduct.

Implications of Inequitable Conduct Doctrine



- Severe consequences:
Entire patent – not a claim
- No statute of limitations
- Hinders innovation and business
- Increased litigation expense
- Bury the examiner strategy. Slows process and hinders effective review.

PTO gets buried with prior art

RESULT: Over-disclosure

“The inevitable result of this ‘cite everything, say nothing’ practice forced upon applicants . . . is that examiners are frequently overwhelmed with irrelevant references, making the most relevant prior art that much more difficult to identify. The productivity of the examiners declines, the whole patenting process slows down, and the pendency periods continue to rise.”



-- Brief of Intellectual Property Owners Association as Amicus Curiae Supporting Neither Party, *Therasense, Inc. v. Becton, Dickinson and Co.*, 374 Fed. Appx. 35 (Fed. Cir. 2010), (No. 2008-1511), 2010 WL 3229934 at *8

USPTO DOES NOT SUPPORT THIS TEST

Federal Circuit Tees it Up in *Therasense*

- “Recognizing the problems created by the expansion and overuse of the inequitable conduct doctrine, this court granted Abbot’s petition for rehearing *en banc*”
- “This Court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”

Federal Circuit Tees it Up in *Therasense*



Five Questions for Review

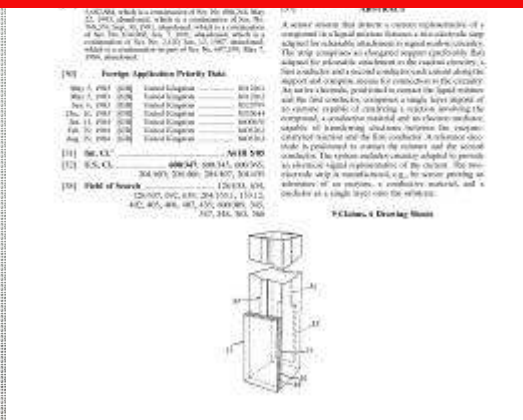
1. Should the materiality-intent-balancing test be altered or should there be a new test established?
2. If so, how should the test be altered or should the test be replaced?
3. What should the materiality standard be? Should the USPTO define the new term of materiality?
4. When is it proper to infer intent from materiality?
5. Should courts continue to balance materiality and intent?

Therasense Facts

USPTO

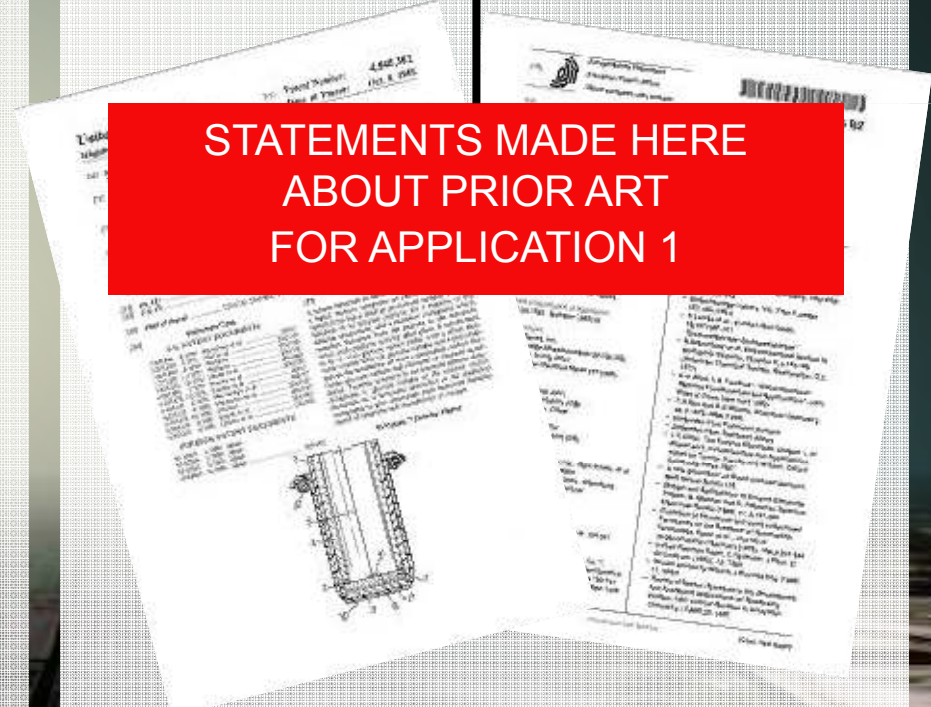


PRIOR STATEMENTS NOT DISCLOSED HERE IN APPLICATION 2 PROSECUTION



Patent at Issue: US 5,820,551

EPO



STATEMENTS MADE HERE ABOUT PRIOR ART FOR APPLICATION 1

Prior Art: US 4,545,382 & EP 78,636B2

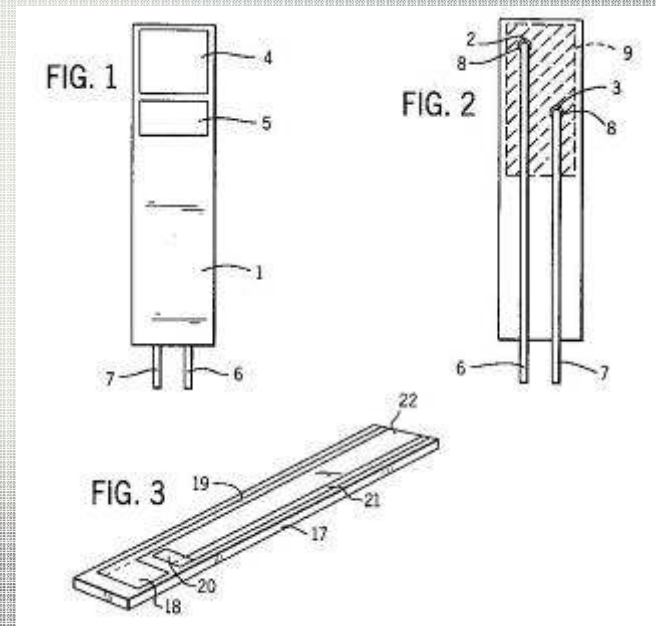
Therasense, Inc. v. Becton, Dickinson and Co. The Facts

The Technology:

Devices utilizing electrochemical sensors for measuring human glucose levels

Alleged Misconduct:

Withholding of statements made to the European Patent Office (EPO) during a prior application process concerning the same prior art that was at issue before the USPTO for the patent-in-suit.



Therasense, Inc. v. Becton, Dickinson and Co.

The Facts

1996

- Work was brought in house at Abbot Laboratories for the '551 patent application family after a 12 year pendency in the US.
- Up to this point, 12 rejections had been issued by the USPTO Examiner, most involving objections over the '382 and '636 prior art.
- Despite amending the proposed claims several times and submitting declarations by persons of ordinary skill in the art, the application had yet to overcome the Examiner's rejections.

November 1997

- New arguments presented to the Examiner by Abbott in-house counsel
- The new argument centered around disclosure in the specification of a sensor for use in whole blood without any protective membrane.

'382 patent disclosure of membraneless sensors:

"Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules."

Therasense, Inc. v. Becton, Dickinson and Co.

The Facts

What was Withheld?

In an EPO opposition to the '636 patent in the mid 1990's, the applicant claimed the **membrane** in that earlier invention was ***optional***.



The **same** element was later claimed as ***required*** before the USPTO.

The earlier statements to the EPO indicating that the element was optional were withheld.

Therasense, Inc. v. Becton, Dickinson and Co.

The Facts

Findings

- Omissions = Intentional Acts of Deception
- Withheld EPO statements inconsistent with statements made before the USPTO.
- Abbott in violation of USPTO Rule 1.56(b)(2) = Patent Unenforceable



Abbott Requests Reversal

- Statements to EPO are immaterial attorney argument
- Statements to EPO not inconsistent with statements to the USPTO
- Statements to the USPTO made upon reasonable argument lacking any intent to deceive

Therasense: The Decision – Tally

- 7-4 decision
- Majority Opinion - written by Chief Judge Rader, joined by 6 other Judges (Newman, Lourie, Linn, Moore, Reyna, and O'Malley (in part))
- Concurrence – O'Malley
- Dissent – Bryson, joined by 3 Judges (Gajarsa, Dyk, and Prost)

What Were You Thinking? The Intent Standard

- Negligence? NO
- Gross Negligence? NO
- Specific Intent to Deceive? YES



Evidence of Intent

- Confession
- Conduct viewed in light of all the evidence
- Must be the “single most reasonable inference to be drawn from the evidence”
- 2 inferences possible? Fails to meet clear and convincing evidence standard



Federal Circuit in *Therasense*



- Confirm specific intent
- Discredit any and all panel decisions which contain “knew or should have known” intent standard
- Focus evidentiary review on time conduct occurred. No hindsight.

Therasense: Proving Intent

- “A district court may infer intent from indirect and circumstantial evidence”
 - Begg the question: What could this evidence be?
 - See Concurrence and Dissent, notes 1 – materiality *can* be a factor in showing intent to deceive
- “[T]o meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence.”
- “[T]he evidence ‘must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.’”

Therasense: Proving Intent

- “[W]hen there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.”
- “The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.”
 - This is because the accused infringer bears the burden of proof and must therefore first “prove a threshold level of intent to deceive by clear and convincing evidence.”

Therasense: The Decision on Materiality

Federal Circuit Adopts Strict But-For Test



“In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it,” the court said.

Therasense: The Decision But-For Materiality – Preponderance Std.

"This court holds that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction," the Federal Circuit said.

Therasense: The Decision

But-For Materiality – Preponderance Std.

- Must there be a finding of invalidity for a reference to be held material?
 - If invalidated in light of deliberately withheld reference, the reference is necessarily material because invalidity is under clear and convincing standard
 - But for inequitable conduct, standard is (1) preponderance of evidence and (2) claims get broadest reasonable construction
- Litigation implications: Findings of inequitable conduct may, as a practical matter, be limited to instances where a court or jury first makes an invalidity finding based on a withheld reference.

Therasense: Materiality

The “Egregious Misconduct” Exception

- Exception to but-for materiality for “cases of affirmative egregious misconduct”
 - Example: “filing an unmistakably false affidavit”
 - But an affidavit that fails to disclose prior art references cannot fall within the exception.
 - Reasoning: “patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent”
 - Implications: What if an affidavit is false by omission, such as was (arguably) the case in *Therasense*?
 - Why isn’t false attorney argument in an office action just as bad? Is it that it is not “manufactured”? Apparently.

Therasense: The Decision

Rejection of PTO Rule 56 Standard



"This court declines to adopt the current version of Rule 56 in defining inequitable conduct because reliance on this standard has resulted in the very problems this court sought to address by taking this case en banc," the court said.

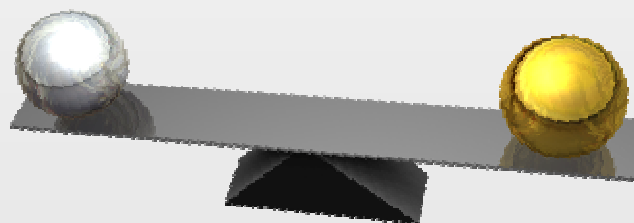
Therasense Decision: Rejects Rule 56 Standard Materiality as Overly Broad

2 prongs of the standard:

- Information is material in establishing a prima facie case of unpatentability, or
 - Refutes or is inconsistent with a position the applicant takes regarding patentability before the USPTO
- Prong 1 “overly broad” because it does not account for any arguments by the patentee to refute the prima facie case of unpatentability.
 - Prong 2 encompasses “anything marginally relevant” because any time a patentee says her invention is non-obvious, anything bearing any relation to non-obviousness could be material.

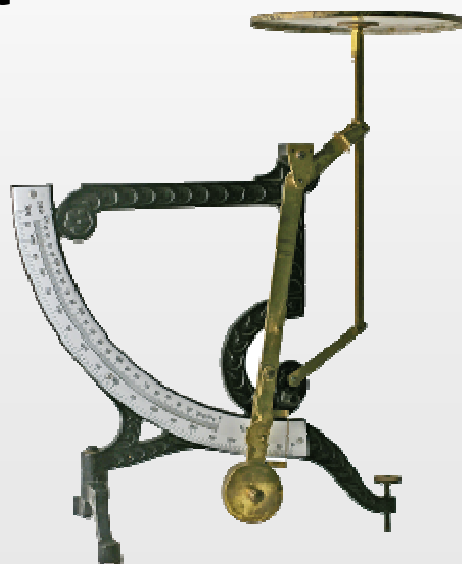
Should We Balance Materiality & Intent?

- Test has historically been a balancing test
- Question: Should it be?
- Agreement: Yes. Balance the factors, BUT independent findings of clear and convincing proof establishing both materiality and intent must take place.
- Balance goal = Equity



Sliding Scale Approach?

- Dilutes proof required for two elements
- Subjective approach yields inconsistent and unpredictable results
- Clear and convincing evidence standard for both elements is lost



Therasense: No More Sliding Scale

- The Federal Circuit made clear that intent and materiality are separate requirements, which courts must consider independently.
- The ruling said district courts should refrain from using a sliding scale, where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa to determine whether a patent holder engaged in misconduct.
- “Moreover, a district court may not infer intent solely from materiality.”

Therasense: Remand to Apply But-For Standard

- On remand, apply but-for materiality standard
 - Would patent have issued if Abbott had disclosed the EPO briefs?
- Intent: Lower court improperly found intent to deceive based on the absence of a good faith explanation for failing to disclose the EPO briefs
 - Improper application of “should have known” negligence standard for intent

Therasense Decision: The Dissent

- Agrees on intent element – specific intent
- Agrees as to no sliding scale
- Disagrees on materiality
 - Advocates PTO Rule 56 as the standard for materiality



USPTO Argues Current Rule 56 Test

- Duty of disclosure to USPTO
- USPTO knows what information is necessary
- Rule 56 provides clear guidance in determining what to submit to USPTO

“But For” Test =
License to lie with impunity



Therasense Decision: The Dissent PTO Rule 56 - Reasons

- PTO is in the best position to know what material examiners need to conduct effective and efficient examinations
 - PTO advocated a Rule 56 standard coupled with a specific intent requirement
- The but-for standard “will not provide appropriate incentives” to comply with PTO’s disclosure requirements.
 - Question – is the but-for standard an invitation or incentive to not comply with PTO Rule 56?
 - “little incentive” to comply because IC will mostly only apply where the claims are invalid in any event
 - E.g., why disclose prior use?

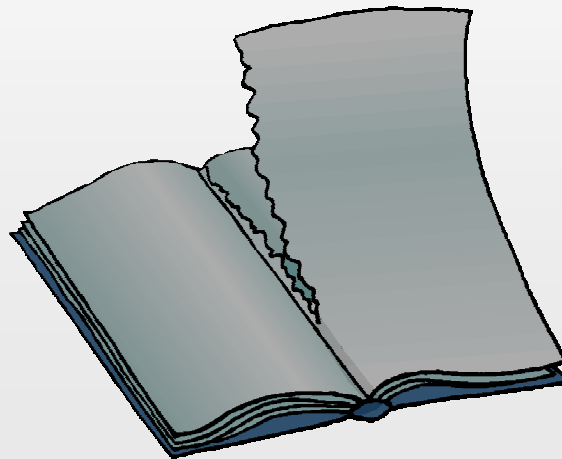
Therasense Decision: The Dissent Problems with But-For

- “There is little to lose by following a course of deceit”
- “An open door may tempt a saint”
- “[A] regime that ensures that a dishonest but potentially profitable course of action can be pursued with essentially no marginal added risk is an unwise regime no matter how virtuous its subjects.”



Therasense Decision: Does it Abolish Inequitable Conduct?

- The dissent says the majority “comes close to abolishing it altogether”.
- “Draconian”
- “Not a tweak”, but a “fundamental change”



Therasense Decision: The Dissent Where Do We Draw the Line Now?

- Majority says that “but for” test does not apply to “affirmative acts of egregious misconduct”
- But what about non-disclosure of prior art?
 - Majority says that cannot be egregious misconduct. This case shows that non-disclosure may be just as bad as affirmative misrepresentations
- Upshot: “The distinction between ‘affirmative acts’ and ‘nondisclosure’ is thus apt to become fertile ground for litigation in the future”
 - so too is the issue of what is “egregious”
 - see Dissent note 3 for this discussion

Therasense Decision: What's Left of the Inequitable Conduct Doctrine?

- Not much!
- Affirmative misrepresentations, that cause the patent not to issue, that intentionally were withheld to deceive the Patent Office – not inequitable conduct
- Patentee need not provide an explanation for non-disclosure
- No sliding scale
- Clear and convincing evidence



What Incentives Remain to Disclose?

- Ethical obligations to Patent Office and Bar
- Threat of discipline? Not really – 5 year SOL
- Threat of exceptional case finding, leading to an award of fees
- Threat that entire patent is unenforceable, not just specific claim(s) that are invalidated by the prior art

Issued Patent with Inequitable Conduct Issue

- Supplemental Examination under 35 USC 257 (America Invents Act)
 - Request supplemental examination to consider, reconsider, or correct information believed to be relevant to the patent
 - Address Inequitable Conduct issues including failure to meet Duty of Disclosure
 - Prior Art

We welcome your questions or comments
regarding the presentation.

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