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The New Inequitable Conduct Standard in Patent Litigation

Asserting and Defending Inequitable Conduct Challenges After the Landmark Therasense Decision

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1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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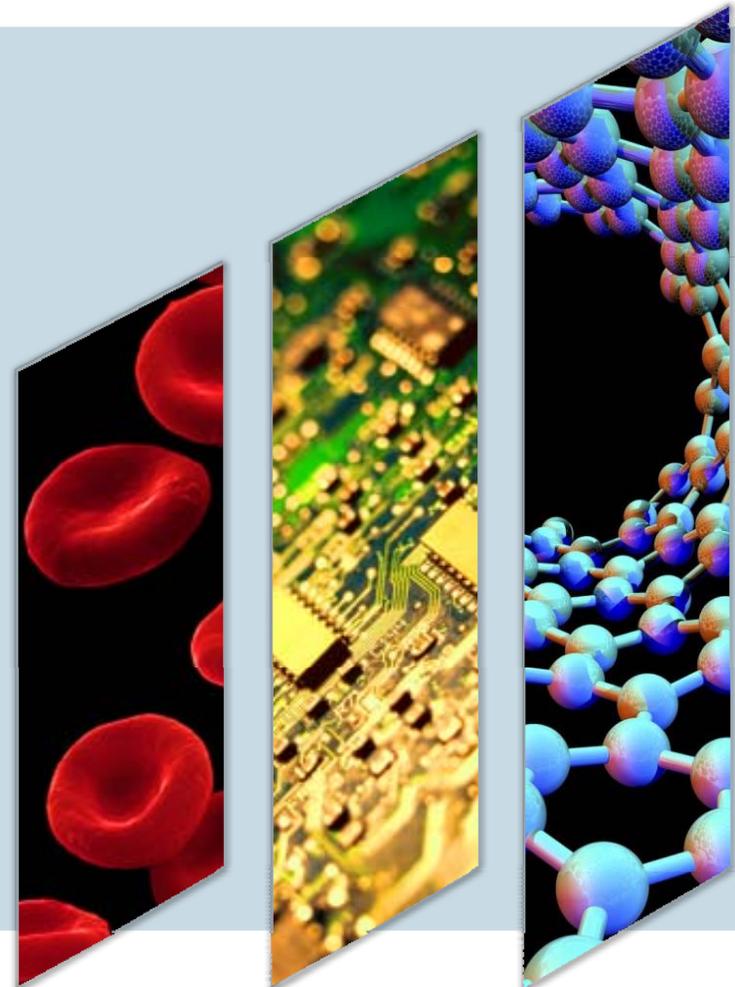
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Therasense, Inc. v. Becton, Dickinson & Co. (en banc)

July 26, 2011



History Of Inequitable Conduct Defense

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Inequitable Conduct – Overview

- **Omission or misrepresentation of material information with intent to deceive the PTO**
- **Renders the entire patent unenforceable**
 - **Sometimes even related patents too**
- **Also offers accused infringers their only realistic shot at attorneys' fees**

U.S. Supreme Court Unclean Hands Decisions

- **Keystone Driller (1933)**
- **Hazel-Atlas Glass (1944)**
- **Precision Instruments (1945)**

Early Patent Prosecution Practice

- **1950's and 1960's – Understanding that Patent Office would conduct a search**
- **1970 – Norton v. Curtis (CCPA)**
 - “highest standards of honesty and candor” are essential
 - Not an adversary proceeding.
- **1977 – Rule 56 Amended – “Duty of Candor” added**

1977-88

- Law and practice of inequitable conduct defense underwent “substantial development and change” and “inaugurated a whole new way of life”

In re Harita, 847 F.2d 801 (Fed. Cir. 1988) (Judge Rich).

- **Non-Disclosed Art**
 - Attorney Records
 - Inventor Records
- **Interpretation of Prior Art**
- **Jury Question?**
 - **Gardco (1987)**

Backlash

- **FMC Corp. (1987)**
 - Should not be a “magic incantation” to be asserted against every patentee
- **Burlington Indus. (1988)**
 - The “habit of charging inequitable conduct has become an absolute plague.”
- **Molins (1995)**
 - Unjustified accusations “should be condemned”

1988 - 2010

- **Trend to Rein In Use of Inequitable Conduct Defense**
- **Ebbs and Flows in Panel Decisions**
- **Role of Appellate Court Where Credibility An Issue**

Inequitable Conduct – Previous Standard

- **1) Threshold level of materiality**
- **2) Threshold level of intent**
- **3) Balance equities**
 - **Sliding scale: Strong showing of one prong (typically materiality) could make up for weaker evidence of the other**
 - **Clear and convincing evidence needed**

Previous Standard: Materiality

- **Possible tests:**

- 1) **Objective “but for”**

- 2) **Subjective “but it may have”**

- 3) **Old Rule 56 (“reasonable examiner”)**

- 4) **Current Rule 56 (adopted in 1992)**

- Establishes prima facie case of unpatentability or
- Inconsistent with applicants’ positions

- **Any one may be sufficient. Digital Control (2006)**

Materiality Standard (Pre-Therasense)

- **“Important to Reasonable Examiner” Most Important**
- **Cumulative Art**
- **Examiner Knew Or Learned Of Otherwise**
- **Late Disclosure**
- **Co-Pending Applications**
- **Litigation Events and Documents**
- **Interest of Affiants**

Previous Standard: Intent

- **Kingsdown (1988) (en banc)**
 - **Gross negligence not enough; requires a finding of “intent to deceive”**
- **Consider Evidence Of Good Faith**
- **Circumstantial Evidence**
- **Materiality Of Reference**

Previous Standard: Intent

- **Significant split among different CAFC panels.**
 - **Ferring (2006)**: Summary judgment of inequitable conduct based on failure to disclose highly material art when applicant
 - (1) knew of the information
 - (2) “knew or *should have known* of the materiality,” and
 - (3) *failed to provide a “credible explanation”* for withholding
 - **Star Scientific (2008)**: Intent requires a “deliberate decision to withhold a *known* material reference.”
 - May be inferred from circumstantial evidence only when the requisite intent is the “*single most reasonable*” inference.

Balancing

- **American Hoist (1984) – Balance degree of materiality and intent**
- **J.P. Stevens (1984) – Must meet thresholds for both**



The New Inequitable Conduct Standard - Materiality

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Factual Background – Therasense patent in suit

- Technology for measuring glucose in blood samples, application in 1981 in the US '338 patent
- Related application for disposable electrode strip for glucose sensor, filed in 1983 – ultimately became '551 patent-in-suit, after:
 - 14 years of prosecution without issuing
 - Patent issued when new counsel for applicant asserted a new point of novelty of a sensor *without* a protective membrane
 - Prior '338 patent contained language suggesting that membranes were “optional.”
- Patent issued after applicant provided argument and extrinsic evidence that one of skill in the art would have believed protective membrane essential.

Inconsistent Argument/Evidence

- Opposition proceeding in European counterpart to prior art '338 patent.
- Applicant argued to EPO that the '338 patent was distinguishable because the use of a protective membrane was “optional” (1981)
- Inconsistent with argument made to obtain allowance of '551 (priority date -1983) that its novelty was based on test strip ability to be used without protective membrane.
- Arguments to European Office not disclosed to USPTO

District Court Decision

Therasense, 565 F.Supp 1088

- Court used PTO Rule 56 standard of materiality requires disclosure of information material to patentability, if: It refutes, or is inconsistent with, a position the applicant takes in (i) opposing an argument of unpatentability relied on by the office
- Applicant argued to EPO that 1981 patent was distinguishable because a protective membrane was “optional” (prior art to ‘551)
- Applicant argued to PTO that one of skill in the art in 1983 would not have believed a sensor could be used without a protective membrane.
- Failure to disclose EPO argument was material non-disclosure – Inequitable Conduct, precluded enforcement

Majority view of Problem with Materiality Standard

- Using Patent Office Standard for materiality leads to too much disclosure
- Causes more important references to be buried
- Sliding scale between intent and materiality conflates the analysis and burdens the PTO and courts with inequitable conduct charges
- Leads to burdened courts, strains PTO resources, and impaired patent quality
- Tampering with “intent” prong alone has not solved the problem.

New Standard for Materiality

- *Therasense* majority (6-5) announces new materiality standard
- Materiality is a separate element; no sliding scale test
- Materiality required to establish inequitable conduct is “but-for” materiality.
 - Prior Art is material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.
 - Congruent with validity determination
 - Inequitable conduct possible even if claim not invalidated due to lower evidentiary standard at PTO.

Exception for egregious conduct

- Affirmative acts of egregious misconduct are material.
 - An unmistakably false affidavit
 - *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983)
 - A patentee unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes it will affect the issuance of the patent.
 - But must be egregious: “unwillingness to extinguish the statutory presumption of validity where the patentee made a misrepresentation that did not affect issuance of patent.

Court rejects PTO standard

- Contends changes to PTO materiality standard created uncertainty
 - Fraud standard (1949 -1977)
 - Reasonable examiner (1977-1992)
 - Refutes or is inconsistent with position taken by applicant regarding patentability (1993-present)
- Federal Circuit: tying materiality to PTO standard led to uncertainty and inconsistency due to changes.
- Reliance on the current PTO standard led to abuse of inequitable conduct standard

The materiality of Dissent

- Court divided 6-5 on standard of materiality.
- Bryson, Gajarsa, Dyk, and Prost
 - Rule 56 materiality should apply
 - Agree with majority that conduct must be willful
- O'Malley
 - Concurred on tightening of intent standard
 - Rejects both tests of materiality in favor of a flexible standard within discretion of district court.
 - Any willful act which rightfully can be said to transgress equitable standards of conduct

Dissenters' Argument to Supreme Court

- Restriction of inequitable conduct is inconsistent with Supreme Court precedent
 - *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933)(a false affidavit and other steps to avoid disclosure of possible invalidating prior art)
 - *Hazel-Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238 (1944)(misconduct before the PTO in submitting an article drafted by patentee's lawyers praising invention)
 - *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806 (1945)(false statement of applicant re dates of conception rendered patent unenforceable and misconduct need to preclude the "unclean litigant" need not be otherwise actionable)

Dissent focuses on Supreme Court policy favoring disclosure

- “By reason of the nature of an application for patent, the relationship of attorneys to the Patent Office requires the highest degree of candor and good faith. In its relation to applicants, the Office ... must rely upon their integrity and deal with them in a spirit of trust and confidence.
 - *Kingsdown v. Dorsey*, 338 U.S. 318 (1949)

Principles of Inequitable Conduct (Dissent)

- Public has interest in seeing that patent monopolies spring from backgrounds free of fraud and inequitable conduct
- Policy should encourage patent applicant's "uncompromising duty" of candor to report all facts underlying applications
- PTO must be able to make its judgments on the basis of sufficient evidence
- Intentional failure to disclose that an application is tainted by fraud is sufficient to justify not enforcing the patent
- Misconduct need not be actionable fraud; a willful act that violates the PTO standard for equitable dealing.

Effects of Decision

- Not surprisingly, tightened standard is leading to rejection of inequitable conduct claims.
 - *Fred Hutchinson Cancer Research Center v. BioPet Vet Lab, Inc.*, 2011 WL 2551002 (E.D.Va 2011)
 - *Generac Power Systems Inc. v. Kohler Co.*, 2011 WL 2648596 (E.D. Wisc. 2011)
- But, inequitable conduct not co-extensive with invalidity because of lower evidentiary standard at PTO.
 - *American Calcar Inc. v. American Honda Motor Co., Inc.*, 2011 WL 2519503 C.A.Fed. (Cal.) (June 27, 2011)
 - Court must consider whether clear and convincing evidence shows that a reference is material under the preponderance of the evidence standard
 - Consider *Microsoft v. i4i Ltd. Partnership*, 131 S.Ct. 2238 (June 9, 2011)

New Standard: Intent

- **Clear and convincing showing that applicant:**
 - (1) knew of the reference,
 - (2) knew that it was material, and
 - (3) made a deliberate decision to withhold it.
- Can be inferred from indirect evidence only if the required intent is the **only reasonable inference**.
- Can't rely on lack of good faith explanation. Patentee need not justify withholding unless defendant makes out a threshold showing.
- No “sliding scale” – can't rely on high materiality.



Transactional Prosecution Issues Post *Therasense*

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Areas of Concern

Information Disclosure Statements

Arguments and Representations

Declarations

Inventorship

Filing Particulars



Information Disclosure Statements

Everyone involved with the application has a duty to report information

What information should be reported or disclosed?

How should the information be treated in the disclosure?

Where does it end?

Who makes that decision?



The Practical Battle

Examiner

Inventor(s)

Applicant/Assignee

Attorney of Record



Cited Information

1. Information discovered
2. Information reviewed
3. Filing information disclosure statement
4. Examiner review (and consideration?)
5. Examiner push back



Practical Example

Freedom to Practice/Operate Analysis

Usually 10-500 (or more) references

Green Light/Yellow Light categorization

Maybe some in-depth analysis of some references

What gets cited?

Who makes that decision?

Does chart make it over to prosecution counsel?



Inventorship

Constant problems adequately explaining inventorship

Understanding of inventorship changes

Due diligence on inventorship changes/deletions

Claims amendments and cancellations

What happens to people who are removed as inventors?



Arguments & Representations

- Ignorance v. deception
- Understanding the references
- Reviewing critically with inventors and technical team
- Hiding the ball
- Declarations – leading the “witness”



Filing Particulars

- Small Entity v. Large Entity
- Best Mode
- Priority documents



The Related Applications Problem

- Related logically by priority or direct link
- Related by subject matter – same client
- Related by subject matter – different client
- Subject matter conflicts of interest



Thank you!!

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