Inequitable Conduct After *Therasense*

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Overview

• Inequitable conduct origins
• Pre-Therasense “sliding scale”
• Therasense
• Post-Therasense survey
• Practical practice tips
What is Inequitable Conduct?

• **A defense to patent infringement**
  - Renders every claim of a patent unenforceable
  - **Infectious Unenforceability** – Every patent in chain may be held unenforceable

• **Based in policy – reflected in 37 CFR 1.56 (a)**
  - “A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability.”
  - “no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted”
Supreme Court Trilogy

- Plaintiff must come to court with “clean hands”
  
  *Keystone Driller Co.* 290 U.S. 240 (1933)
  Patentee paid prior user to sign false declaration, and to keep use secret

  *Hazel-Atlas Glass Co.*, 322 U.S. 238 (1944)
  Patentee’s attorney writes article praising invention, had it published by expert, PTO grants patent based on article

  *Precision Instrument Mfg. Co.*, 324 U.S. 806 (1945)
  Patentee makes false declaration regarding conception and reduction to practice dates to get behind competitor’s application; competitor becomes complicit in the fraud and purchases patent for enforcement
Pre-Therasense Sliding Scale

Courts begin to weigh materiality against intent

Higher materiality/
More likely to infer intent

Lower materiality/
More intent evidence needed
Inequitable Conduct Pre-**Therasense**

**McKesson Information Solutions Inc. v. Bridge Medical Inc.,** 487 F.3d 897 (Fed. Cir. 2007)

- High burden on patent prosecutors to disclose prosecution documents they may come in contact with

- Patentee failed to disclose:
  - Prior art cited by examiner in a related patent
  - The fact that broad claims were rejected in a related patent
  - The fact that a related patent was allowed
Inequitable Conduct Pre-Therasense

Satisfying Disclosure Obligations Pre-Therasense

- Sliding scale means a court will make a determination on the relevance of a reference (with ample time to analyze and assess that relevance) and then consider the rationale for failing to cite

- Conflict with larger volume patent practice realities and timing requirements for having information considered

- When materiality is found, lack of a good explanation for withholding may result in a finding of intent → concerns that inadvertent failure to disclose something could unwittingly result in a viable inequitable conduct claim
# Inequitable Conduct Pre-Therasense

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<thead>
<tr>
<th>Proving Inequitable Conduct</th>
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<td><strong>Materiality</strong></td>
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<td>Examples:</td>
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<td>• references that disclose claimed elements, or combinations of claimed elements not cumulative to other references</td>
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Facts:

- **Patent-in-Suit:** The ‘551 patent covers disposable test strips measuring blood glucose levels for diabetics.

- **Patentee failed disclose statements negating patentee’s non-obvious position in view of a commonly-owned patent (“the ‘382 patent”):**
  - **Before the PTO:** The ‘382 patent *required* the tested blood to contain protective membranes; the ‘551 patent did not.
  - **Brief Submitted to EPO:** filed during prosecution of the ‘382 patent counterpart before the European Patent Office (“EPO”), stating that use of blood with protective membranes was *optional.*
District Court:

- “This Court is well aware that inequitable conduct has become a knee-jerk and often-abused response by those accused of patent infringement. Judges ought to view such defenses with skepticism.”

- The district court still found inequitable conduct because defendants should have known about the brief and failed to offer a good-faith explanation for the omission.
En Banc Federal Circuit (1/2):

• “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.”

• Rejected the sliding scale approach that previously allowed strong evidence of materiality to compensate for weak evidence of intent to deceive (and vice-versa).

• Court must “weigh the equities” to determine whether the inequitable conduct warrants the unenforceability remedy
**Therasense v Becton** 649 F.3d 1276 (Fed. Cir. 2011)

*En Banc* Federal Circuit (2/2):

- The Federal Circuit remanded the case to the district court to determine whether defendants’ failure to disclose the ‘382 statements was material under the new test.

- Two pathways for proving inequitable conduct:
  - Clear and convincing proof of
    1. intentional misconduct (intent) and
    2. that the misconduct is a “but-for” cause of the patent issuing (materiality).
  - “Egregious affirmative acts of misconduct” - Intentional affirmative misstatements that go beyond attorney argument (Supreme Court Trilogy)
### Therasense Inequitable Conduct Standard

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| **Materiality**            | • Undisclosed information has to be “but for” material  
|                            | • Exception: egregious misconduct (Supreme Court Trilogy) |
| **Specific Intent**        | • Knowledge of the information  
|                            | • Knowledge that the information was material  
|                            | • Deliberately decided to withhold the information |
| **No Sliding Scale**       | • A court can no longer infer intent to deceive from non-disclosure of a reference solely because that reference was known and material |
**Post-Therasense: Non-art issues**

**Powell v. Home Depot, 663 F.3d 1221 (Fed. Cir. 2011) (No Inequitable Conduct)**

**Facts:**

- Powell's technology relates to a guard for a circular saw on an arm.
- Powell provided several prototypes to Home Depot for the company to use in its in-store saws. Rather than having Powell manufacture the guards, Home Depot turned to another company.
- During prosecution, Powell had filed a Petition to Make Special on grounds that he was obligated to manufacture and supply devices embodying the claims sought.
- Powell never informed the PTO that he no longer qualified for the Special designation after negotiation with Home Depot terminated.

**Federal Circuit Holding:** Materiality prong not met
Post-Therasense: Non-art issues

Outside the Box Innovations, 695 F.3d 1285 (Fed. Cir. 2012) (No Inequitable Conduct)

Facts:
- Outside the Box brought a declaratory judgment suit against Travel Caddy.
- Two Allegations of Inequitable Conduct:
  - Issue #1: Travel Caddy’s failure to disclose litigation of parent patent
  - Issue #2: Travel Caddy’s distributor was a potential patent licensee (small entity)
- The district court found the patent to be unenforceable
Post-Therasense: Non-art issues

*Outside the Box Innovations*, 695 F.3d 1285 (Fed. Cir. 2012) (No Inequitable Conduct)

**Federal Circuit:** Federal Circuit reversed and vacated due to lack of evidence on which to base deceptive intent.

- Nothing material was provided in the litigation;
- No validity issues were involved in the litigation;
- Good faith error in claiming small entity status (confusion over license vs. distribution agreement)
Post-Therasense: Uncited art issues

*Aventis Pharma v. Hospira*, 675 F.3d 1324 (Fed. Cir. 2012) (Finding of Inequitable Conduct)

**Facts:**

- Aventis holds two patents that cover its branded chemotherapy drug Taxotere. Aventis sued to prevent Hospira from bringing a generic form to market.

- Inventor had known about references which the district court ultimately used to hold some of the patent claims invalid as obvious → they were material.

- Inventor admits reference shaped his thinking, but explains he didn’t believe he needed to disclose it because he believed the reference described failed experiments.

- Inventor’s explanation not found credible and the district court ruled the patents unenforceable due to inequitable conduct for failing to disclose material prior art during prosecution.
Post-Therasense: Uncited art issues

*Sony Computer v. 1st Media LLC*, Docket No 12-1086 (on petition for writ of certiorari 2013)

- Supreme Court has asked the Solicitor General to file a brief
- District Court: Finding Inequitable Conduct
  - Three references used to reject the equivalent foreign cases were never submitted to USPTO for consideration.
- Federal Circuit: Reversed district court
  - Defendant failed to prove by clear and convincing evidence that individuals with a Rule 56 duty "made a deliberate decision to withhold" the references
- Petitioner Argument: Fed. Cir. rule is overly rigid (recalling *KSR* and *Bilski*)
**Post-Therasense: Uncited art issues**

**American Calcar, 651 F.3d 1318 (Fed. Cir. 2012) (Remanded)**

**Facts:**

- ACI asserted various patents relating to aspects of vehicle computer systems against Honda
- ACI failed to disclose a number of key features from a prior art computer system from Honda ("96RL")
  - 96RL anticipated one of the asserted patents
  - Inventor had access to the 96RL prior to patent filing
  - Patents contain figures that look similar to the 96RL
- District court found that the patentees committed inequitable conduct with respect to certain asserted patents
Post-Therasense: Uncited art issues

**American Calcar**, 651 F.3d 1318 (Fed. Cir. 2012) (Remanded)

**Federal Circuit:**

- **Materiality:**
  - The 95RL is likely to be material because it anticipated one of the asserted patents
  - Remanded because district court failed apply the “but for” standard for another asserted patent

- **Intent:**
  - Improperly applied “sliding scale” analysis, using a purported finding of materiality to support intent.
  - Remanded to district court to evaluate if inventors knew that the information was material and made a deliberate decision to withhold the information
Post-Therasense: Uncited art issues


Facts:

- Declaratory judgment against the validity and enforceability of a Cephalon patent for modafinil (sleep disorder drug)
- Cephalon failed to disclose to the PTO about past working relationship with Lafon
- Lafon had produced and supplied modafinil to Cephalon prior to the filing of the patent-in-suit
Post-Therasense: Uncited art issues


**District Court: Inequitable Conduct**

- **Material:** Lafon information rendered the patent-in-suit invalid, thus the information was material

- **Intent:** “*T*he complete concealment of another company's extensive involvement in the product which is the subject of the claimed invention definitively establishes Cephalon's deception by clear and convincing evidence.”

- **In-house attorney unconvincing in arguing desire to keep Lafon’s confidential information out of the file history**
### Post-Therasense Summary

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| **Credibility of Inventor**   | • Evasive and self-serving inventor testimony probative on intent (*HTC*, *Aventis*)  
• Still needs to meet the clear and convincing standard of an intent deceive                                                                                             |
| **Invalidity is Materiality** | • Information that would have rendered patent anticipated or obvious is “but for” material (*Apotex*)  
• Failure to update PTO on Petition to Make Special not material (*Powell*)                                                                                                                                 |
| **Difficulty of Proving Intent** | • Lack of independent evidence on intent fatal to inequitable conduct claim (*Outside the Box*)  
• Need independent evidence regarding patentee’s acknowledgment and decision to disregard the information (*Calcar, Apotex*)  
• Evidence of selective disclosure is probative on intent (*Aventis*)                                                                                                      |
## Post-Therasense Summary

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| **Materiality**             | **Variable Standard** - A “reasonable examiner” would have considered the information or prior art important. | **Single Standard**  
But-For Materiality: The USPTO would not have allowed the patent if it had been aware of the withheld information |
|                             | A misrepresentation that  
• was so material that the patent would not have issued  
• caused the examiner to approve the patent application  
• influenced the patent examiner in the course of prosecution |                                                                                        |
| **Intent**                  | General intent to deceive based on totality of circumstances                                         | **Specific intent to deceive with evidence of knowing and deliberation**                             |
| **Sliding Scale**           | A strong showing of intent can offset a weak showing of materiality, and vice versa                 | **No Sliding Scale**                                                                                |
Practical Practice Tips

• Systems for disclosing references still important, but not worthy of angst

• Increased pressure on inventor credibility
  – Have you received everything the inventor knows about?
  – Have you brought all the inventor-known information (including non-publications) before the office?
  – Is the inventor withholding something for their own (irrelevant) reason?

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<td>§ 1.56 Duty to disclose</td>
<td>Information is material to patentability if:</td>
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<td>(1) The Office would not find a claim patentable if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or</td>
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<tr>
<td>§ 1.555 Information material to patentability</td>
<td>(2) The patent owner engages in affirmative egregious misconduct before the Office as to the information.</td>
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## Conclusions: AIA and Inequitable Conduct

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| **Section 12: Supplemental examination**   | • Can be used to cure inequitable conduct, but not where the inequitable conduct allegations were already pending  
  • Cannot cure fraud which must be reported to the attorney general for consideration of criminal sanctions. |
| **Section 20: Technical Amendments**       | "error without deceptive intent" is no longer a requirement for the following:  
  • correcting inventorship and addressing inventorship issues (Sections 116 and 256)  
  • obtaining a foreign filing license (Sections 184 and 185)  
  • obtaining a reissue patent (Section 251)  
  • disclaimer (Section 253)  
  • suing for patent infringement (Section 288) |