The *Therasense* Standards in Action: What Have We Learned?

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Agenda

- New inequitable conduct standards:
  - But-for materiality
  - Affirmative egregious misconduct
  - Deceptive intent
- Examples: the new standards in operation
- Summary of lessons from the cases
New Judicial Standards - Therasense

Proving Inequitable Conduct

- Challenger must “prove that the applicant misrepresented or omitted material information with the specific intent to deceive the [USPTO]”

- Revised materiality and intent standards

New Judicial Standards - *Therasense*

- **Materiality** - either:
  - But-for material ("the [USPTO] would not have allowed a claim had it been aware of the undisclosed" or correct information), OR
  - Affirmative egregious misconduct

- **Deceptive intent:**
  - Specific intent to deceive is required
  - Gross negligence and "should have known" do not suffice
  - Deliberate decision to withhold required

- No "sliding scale": a district court may not infer intent solely from 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.”

“I n making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.”
New Standards in Operation: 

*But-for Materiality*

- **Prior art** that anticipates or renders a claim obvious is but-for material

  *American Calcar, Inc. v. American Honda Motor Co.*, 651 F.3d 1318 (Fed. Cir. 2011);
  *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1321 (Fed. Cir. 2012)

- **Undisclosed product** is not material, even if qualifies as on-sale prior art, where it “would not render the asserted claims obvious in view of the other cited prior art”

  *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278 (Fed. Cir. 2011)
New Standards in Operation: But-for Materiality

- Undisclosed information other than prior art?
  - *Therasense*:
    - Did not expressly address, but the court approved the potential materiality of such information via the remand
    - However: “[T]his [inequitable conduct] doctrine should only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim. . . . After all, the patentee obtains no advantage from misconduct if the patent would have issued anyway.”
New Standards in Operation: But-for Materiality

- Undisclosed information other than prior art?
- See also:
  - Undisclosed information bearing on inventorship is not material unless the challenger can show that it “would have altered the patent examiner’s finding of inventorship”

New Standards in Operation: 

**But-for Materiality**

- What about undisclosed information that could not itself ground a rejection?
- Compare:
  - Patentee’s allegedly inconsistent prior IND statements “cannot be but-for material for inequitable conduct purposes, since the [USPTO] could not have rejected the claimed inventions as obvious in view of these legally irrelevant statements.”

New Standards in Operation:  
**But-for Materiality**

**With:**

- “The prosecution history ... demonstrates that the examiner found the claims to be patentable based on [the patentee’s reliance on “incorrect” and “scientifically impossible” data], and if aware of the [correct] data, it is more likely than not that the examiner would have rejected the claims. Accordingly, the Court finds the Defendants have satisfied the materiality standard.”

New Standards in Operation: But-for Materiality

- And see *Therasense* (on remand):
  - “It is manifest that the withheld EPO briefs would have contradicted Abbott's declaration and submission. . . . Had the EPO briefs been presented to him, the examiner would have seen through Abbott's representations to him. In that event, the examiner would have persisted in the 13–year history of rejections. This is an inference but it has been shown by clear and convincing evidence.”

New Standards in Operation: 
**But-for Materiality**

- Also, several post-*Therasense* Federal Circuit panels clearly contemplate the potential for information that could not (itself) support a rejection to be but-for material. See:
  - Existence of litigation regarding a parent patent was not material to the prosecution of a continuation where the litigation did not involve allegations of invalidity or unenforceability.

  *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285 (Fed. Cir. 2012)
New Standards in Operation:  
*But-for Materiality*

See also:

- “This is not a case where a declarant hid adverse test results from the PTO in favor of more promising data selected post hoc.”
- “Nor is this a case where the declarant's omission expressly undermined his stated opinion.”

*Novo Nordisk A/S v. Caraco Pharm. Laboratories, Ltd.*, 719 F.3d 1346, 1358 (Fed. Cir. 2013)
New Standards in Operation: *But-for Materiality*

- However, applicant’s failure to update a Petition to Make Special (to alert the USPTO that he was no longer under an obligation to manufacture, as previously alleged) “obviously fails the but-for materiality standard”

“Although but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct, *this court recognizes an exception in cases of affirmative egregious misconduct.*”

“This exception . . . incorporates elements of the early unclean hands cases before the Supreme Court, which dealt with ‘*deliberately planned and carefully executed scheme[s]*’ to defraud the PTO and the courts.”
New Judicial Standards – Therasense

Affirmative Egregious Misconduct

“When the patentee has engaged in affirmative acts of egregious misconduct, *such as the filing of an unmistakably false affidavit*, the misconduct is material.”

“After all, a 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*. ”
"Because neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct, claims of inequitable conduct that are based on such omissions require proof of but-for materiality."

"[T]he materiality standard set forth in this opinion includes an exception for affirmative acts of egregious misconduct, not just the filing of false affidavits."

Rejecting the concurrence’s assertion that AEM is limited to the filing of an unmistakably false affidavit, and describing the “court’s approach” as “sensitive to varied facts and equitable considerations.”
New Standards in Operation:

Affirmative Egregious Misconduct

- “[I]n order to be considered ‘material,’ inequitable conduct [even affirmative egregious misconduct] must result in ‘the unfair benefit of receiving an unwarranted claim.’”
- Accordingly, allegations that the inventor misrepresented her ownership and assignment of the patents at issue to the USPTO fail to plead materiality.

New Standards in Operation:

**Affirmative Egregious Misconduct**

- Inventor’s “purposefully evasive” litigation testimony regarding his relationship with a collaborator “does not constitute affirmative egregious misconduct” because the relevant conduct before the USPTO was nondisclosure (regarding the collaboration) and “it is the **affirmative** conduct before the patent examiner that serves as the basis for the exception to the ‘but-for’ materiality requirement.”

New Standards in Operation: 
Affirmative Egregious Misconduct

- Nondisclosure of foreign litigation material (an invalidity claim), which was not itself but-for material, did not constitute affirmative egregious misconduct, and “[t]o attempt to characterize [this] lack of action as a ‘carefully executed scheme[] to defraud the PTO,’ would strain Therasense’s distinction between affirmative acts and nondisclosures to the point of breaking.”

“Affirmative egregious misconduct, as described in *Therasense*, is a relatively narrow category; the examples given . . . include truly extreme misdeeds, such as filing unmistakably false affidavits, suborning perjury, bribing witnesses, and actively suppressing evidence.”


New Standards in Operation: **Affirmative Egregious Misconduct**

- Applicant’s **failure to update a Petition to Make Special** (to alert the USPTO that he was no longer under an obligation to manufacture, as previously alleged) . . . is not the type of unequivocal act, ‘such as the filing of an unmistakably false affidavit,’ that would rise to the level of ‘affirmative egregious misconduct’”

New Standards in Operation: 
**Affirmative Egregious Misconduct**

- But see:
  - Is filing a false declaration of small entity status “affirmative egregious misconduct”?
  - Split panel declined to decide, where there was inadequate evidence of deceptive intent (although “on its face, it appears that a false small entity declaration would fall within the definition of an ‘unmistakably false affidavit,’ particularly since [it is a] sworn written declaration”)

*Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285 (Fed. Cir. 2012)
New Judicial Standards – Therasense

Deceptive Intent

“To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO.”

“A finding that the misrepresentation or omission amounts to gross negligence or negligence under a ‘should have known’ standard does not satisfy this intent requirement.”

“In a case involving nondisclosure’ . . . 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.”
New Judicial Standards – *Therasense*

**Deceptive Intent**

- “Moreover, a district court may not infer intent solely from materiality.”
- “Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.”
New Judicial Standards – Therasense

Deceptive Intent

“Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence.”

However, to 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.’”
New Standards in Operation: Deceptive Intent

- No deceptive intent where “the inferences argued by [the patentee] are supported by evidence of record and are as reasonable as those inferences argued by [the challengers].”
  
  *Cordis Corp. v. Boston Scientific Corp.*, 658 F.3d 1347 (Fed. Cir. 2011)

- Although the undisclosed references at issue were material, unenforceability was not established because “deceptive intent was not the single most reasonable inference”
  
  *In re Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511 (Fed. Cir. 2012)
New Standards in Operation: Deceptive Intent

“[E]ven a strong inference” of deceptive intent “is not sufficient” where there is “an equally reasonable inference” of negligence or carelessness

New Standards in Operation:  

**Deceptive Intent**

- Deceptive intent found (and affirmed) based on the district court’s specific findings that the witness’s explanations for withholding the references at issue lacked credibility and evidence relating to the witness’s knowledge of the relevant prior art, his selective citation of information to the USPTO, and inconsistencies between the witness’s testimony and corporate documents regarding relevant experiments.

*Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324 (Fed. Cir. 2012)
Summary:

What the Cases Teach

- Withheld information that invalidates is but-for material
- But-for materiality is not limited to prior art (or other rejection-supporting) information
- USPTO-required information may nonetheless not be material
Summary: What the Cases Teach

- Open question: Does/how does the court’s “unwarranted claim”/“would have issued anyway” language limit the scope of the “affirmative egregious misconduct” exception?
- The intent element is increasingly determinative (law regarding materiality will now develop more slowly)
- The courts are carefully scrutinizing proffered intent evidence
  - Findings based significantly on the materiality of the withheld or misrepresented information will be vulnerable on appeal
May 13, 2013: Supreme Court CVSG in *Sony Computer v. 1st Media LLC*

Question Presented:

*Did the Court of Appeals for the Federal Circuit err in restricting district courts' equitable discretion in evaluating patent unenforceability, contrary to this Court's precedent in Keystone Driller, Hazel-Atlas, and Precision Instrument, by applying a rigid test that (a) forecloses district courts from considering the entire circumstantial record; and (b) precludes district courts from granting equitable remedies where a patent applicant has violated the PTO's duty of candor?*
Questions? Comments?