

Therasense Inc. (Abbott) v. Becton Dickinson, et. al.

The Impact on Inequitable Conduct

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A VERY Quick Introduction

The defense of inequitable conduct

- A judicially-created defense with roots in
 - common law fraud; and
 - the doctrine of unclean hands
- Elements
 - A material misstatement or omission
 - Made with intent to deceive the PTO
 - Wherein the balance between materiality and intent warranted the “extreme sanction” of unenforceability

APLI - 2012

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A VERY Quick Introduction

1945- 2010

- Doctrine grew and contracted in response to Court decisions interpreting the three elements
- The PTO's definition of materiality also changed, first in response to Court decisions, and then in an attempt to lead the Courts
- Litigants and patent practitioners lived uneasily on an uncertain and fluctuating landscape

A VERY Quick Introduction

By 2010, the state of the law:

- Materiality:
 - **Any** of the historical standards may apply (*Digital Control Inc.*)
- Intent:
 - Gross negligence is not enough (*Kingsdown*) **but**
 - Absence of a “credible excuse” can be fatal (*Bruno Indep. Living; Cargill*)
- Balancing:
 - Separate third step: Is the conduct bad enough to warrant the “extreme sanction”? (*Dayco*)

Therasense District Court Fact Findings

- '551 Patent: Allowance of Claims
 - '551 application rejected 11 times over Abbott's own '382 patent disclosure
 - Pope and Sanghera get involved and brainstorm ideas for patentability
 - PTO interview record:
 - Pope says he will submit new claims to a membrane less glucose sensor
 - Examiner notes that '382 patent says membranes are "optionally but preferably" used
 - Examiner agreed to permit an affidavit demonstrating a membrane was considered essential to overcome this teaching

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Therasense District Court Fact Findings (cont'd)

- '551 Patent: Allowance of Claims, cont'd
 - Sanghera affidavit and Pope's parallel remarks:
 - POSA would not read '382 to teach membranes are optional or merely preferred, but that a membrane was "required"
 - In reliance on affidavit, Examiner allowed '551 patent

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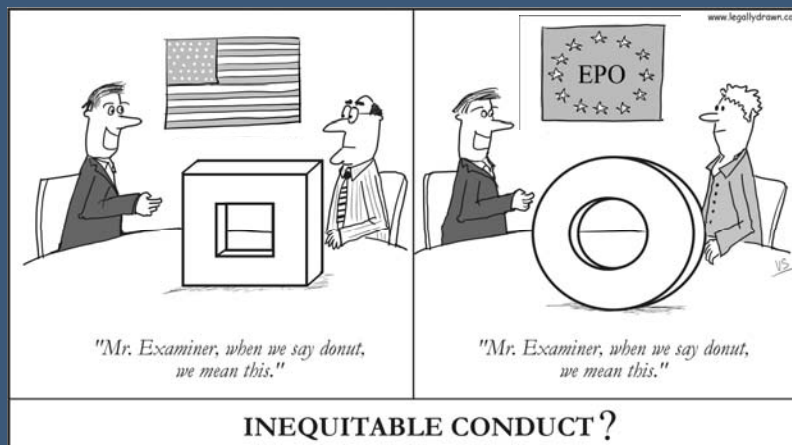
Therasense District Court Fact Findings

- What the PTO Did Not Know
 - Sanghera previously helped craft papers to the EPO arguing that same “optionally but preferably” disclosure “does not require a membrane”
 - Sanghera told Pope about the EPO papers before they submitted his affidavit to the PTO
 - Sanghera and Pope made a conscious and deliberate decision to withhold the prior statements from the PTO
 - Abbott marked the ‘382 patent on its membraneless Exactech sensor

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Inequitable Conduct



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Rule 56 Prior To *Therasense*

- Rule 56
 - [I]nformation 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:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability

Therasense District Court Decision

- Inequitable Conduct Conclusion
 - High materiality under Rule 56
 - Sanghera's declaration materially false and misleading
 - EPO papers material
 - Deceptive intent was single most reasonable inference
 - Consciously withheld information that went to the central question before the PTO
 - Sanghera and Pope's trial demeanor was not credible; Sanghera impeached numerous times
 - Sanghera affidavit was deliberately misleading
 - Excuses were implausible: their interpretation of EPO papers was contrary to plain English

Therasense District Court Decision (cont'd)

- Inequitable Conduct Conclusion, cont'd
 - On balance, materiality and intent on strong end of scale
 - If this conduct is allowed, PTO Rule 56 “would be dead letter”

Therasense Federal Circuit Decision

- Federal Circuit
 - Affirmed District Court’s inequitable conduct holding 2-1
 - High materiality under Rule 56
 - Single most reasonable inference is that both Sanghera and Pope intended to deceive the PTO
 - Any other result would completely “eviscerate the duty of disclosure”
 - Unanimously affirmed invalidity based on same prior art

The *En Banc* Opinion

Majority:

Rader, Moore, Newman, Lourie, Linn, Reyna

Concurring/Dissenting in part:

O'Malley

Dissent:

Bryson, Dyk, Gajarsa, Prost

Majority: Reason For *En Banc* Review

- Doctrine is overused in litigation
 - Significant litigation strategy
 - “Atomic bomb” against entire patent
 - Discourages settlement
 - Detracts from merits of validity/infringement
 - Spawns antitrust/unfair competition/exceptional case claims
 - May invoke crime-fraud exception to privilege
- Causes dumping of art on PTO in prosecution
- Doctrine has fluctuated over time
 - Different materiality and intent standards have been used
 - Sliding scale diluted materiality and intent elements

En Banc Intent Standard

- No disagreement as to specific intent requirement
- 3 part test for specific intent to deceive the PTO
 - Knew of reference
 - Knew it was material
 - Deliberately decided to withhold
- May be inferred from circumstantial evidence
- Must be single most reasonable inference
 - Cannot overlook equally reasonable inference of no deceit

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En Banc Limitation on Intent

- “Should have known” standard is insufficient
- Separate from materiality
 - No sliding scale
 - May not infer solely from materiality
- Absence of good faith explanation by itself insufficient
 - First need a threshold showing of intent by clear and convincing evidence

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The 6 to 5 Split On Materiality

Majority	Concurrence/ Dissent	Dissent
General Rule: But-for materiality Exception: Affirmative egregious misconduct	More Flexibility, no rigid rule but guidance: (1)but-for materiality (2>false/misleading misrepresentation (3)Integrity of PTO process wholly undermined	PTO Rule 56

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Majority: Materiality Standard

- General Rule: Failure to disclose art is “but-for” material if PTO would not have allowed claim had it been aware of the art
 - Legal Reliance
 - No Materiality standard in Supreme Court Trilogy
 - *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928) (refusing to extinguish presumption of validity based on misrepresentation that was immaterial to issuance)
 - Analogous to copyright law
 - Test derives from common law fraud, and based on whether patentee obtained an unfair benefit

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Majority: Materiality Standard (cont'd)

- Application
 - Patentability determination: preponderance of evidence under broadest possible construction (MPEP)
 - If claim invalidated based on withheld reference, then reference is necessarily material

Majority: Materiality Standard

- Exception: Affirmative egregious conduct
 - Based on type of conduct at issue in Supreme Court Trilogy
 - Specifically applies to false affidavits
 - Applicant unlikely to deceive unless it believes falsehood will affect issuance
 - Effectively establishes per se rule if falsity demonstrated
 - Intended to provide flexibility to capture extraordinary circumstances
 - But does not apply to omissions/failure to disclose subject to “but for” test

Majority: Why Not PTO Rule 56

- Court not bound by PTO Rules
- Overuse of inequitable conduct affects more than PTO
 - ABA and AIPLA support but-for test
- PTO Rule changed over time
- Current Rule is overbroad
 - Does not consider mitigating circumstances
 - Captures marginally relevant art

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J. O'Malley: Concurrence and Dissent

- Concurs on Intent Standard
- Dissents on Materiality Standard
 - Inequitable conduct doctrine is not independent of unclean hands principles
 - Supreme Court requires that applicants must act “fairly and without fraud or deceit”
 - District Courts should not be bound by formula or rigid rules
 - Majority and dissent tests lack flexibility
 - Policy concerns do not justify adopting a legal standard that diverges from Supreme Court doctrine
 - Assertions of inequitable conduct can be curbed by Exergen, sanctions and flexibility in the remedy

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Dissent: Materiality Standard

- Pre-*Therasense* Rule 56
 - Federal Circuit precedent follows PTO rule
 - PTO best knows what information it needs
- Pre-*Therasense* Rule 56 reflects Supreme Court principles
 - Basic purpose of inequitable conduct doctrine and Rule 56 are same
 - Public interest in patents “free from fraud or other inequitable conduct”

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Dissent: Criticism of Majority’s Materiality Standard

- Significant and unwise departure from precedent
 - “Radical Approach” -- comes close to abolishing the doctrine
 - Federal Circuit has always followed Rule 56, and repeatedly rejected “but-for” test
 - Supreme Court did not require “but-for” test
- Difficult to draw line between nondisclosure and affirmative misrepresentation
- Adverse to PTO’s interests and public at large
 - “[T]here will be little incentive for applicants to be candid with the PTO...”
 - PTO cannot police misconduct

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Application To The Facts of *Therasense*

- Majority:
 - Remand for findings under “but-for” materiality and “knowing and deliberate” intent
 - Draws no conclusions on the facts
- O’Malley:
 - Affirms materiality under “but-for” standard; District Court’s materiality conclusions were thorough and correct
 - District Court should have opportunity to assess intent under current standard

Application To The Facts of *Therasense* (cont’d)

- Dissent:
 - District Court’s materiality and intent findings are not erroneous
 - “[T]his case is a compelling one for applying the principles of inequitable conduct”.

Therasense Remand Decision

- District Court finds inequitable conduct
 - EPO briefs are “but-for” material
 - Sanghera and Pope had knowledge of “but-for” materiality and specific intent to deceive
- District Court did not address issue of affirmative egregious misconduct due to false declaration

Open Questions

- What is meant by the majority’s statement that unclean hands “remains available for egregious misconduct like that in the Supreme Court cases”?
- Can the “but-for” test be satisfied without first proving invalidity?
- What constitutes “affirmative misconduct”?
- Will it now be easier to prove inequitable conduct if there is a false statement in a declaration?

Open Questions (cont'd)

- What is the difference between an affirmative false statement and an intentional omission?
- Will the new standard really result in a lesser burden on patent prosecutors and the PTO?
- Will more invalid patents issue given the new materiality standard?
- Will the “but-for” test survive Supreme Court scrutiny?

Am. Calcar, Inc. v. Am. Honda Motor. Co. (Fed. Cir. June 27, 2011)

- Alleged conduct: Withheld prior art
- Result: Vacate and remand
- Court’s reasoning:
 - Patent 1: agreed withheld § 102 reference was necessarily material
 - Patent 2: remand on “but-for” materiality of withheld art (District court used old Rule 56)
 - Remand on specific intent (District court used sliding scale and lack of credibility)
 - On remand: inequitable conduct
 - Patent 2: withheld art “but for” material and not cumulative
 - Inventor knew prior art was material and selectively withheld it from his attorney; this was deliberate withholding, not negligence
 - Partial disclosure during later reexam still omitted relevant details

Apotex Inc. v. Cephalon, Inc. (E.D. Pa. Oct. 31, 2011)

- Alleged conduct: Failed to disclose third party's role
 - third party prior art batches and license agreement showed derivation and sale
- Result: inequitable conduct
- Court's reasoning:
 - Materiality:
 - Information not disclosed related to obviousness, an issue repeatedly raised by patent examiner during prosecution
 - PTO would not have allowed patent if it had known about third party's substantial role in claimed invention
 - Intent:
 - Concealed third party's involvement in invention
 - Affirmative misrepresentations regarding modifications to product
 - Declaration missing data

Carl Zeiss Vision Int'l GMBH v. Signet Armorlite, Inc. (S.D. Cal. Dec. 19, 2011)

- Alleged conduct:
 - Withheld prior art
 - Failed to disclose problems with invention that were revealed in prosecution of separate patent
 - Used same drawings to represent different things across patents
- Result: no inequitable conduct (summary judgment)
- Court's reasoning focused on intent:
 - Mere failure to disclose insufficient
 - Equally reasonable to infer certain references were cumulative
 - No cited authority for consideration of prosecution of one patent as evidence of inequitable conduct for another patent

Mformation Techs., Inc. v. Research In Motion Ltd. (N.D. Cal. Dec. 19, 2011)

- Alleged conduct:
 - Withheld prior art
 - Failure to name an inventor
- Result: no inequitable conduct (summary judgment)
- Court's reasoning focused on intent:
 - One reference was disclosed in provisional application
 - Reasonable to infer attorney did not consider other references disclosed in different application on different technology material
 - Unnamed inventor never told anyone he should be added when asked to review draft application

Kimberly-Clark Worldwide v. First Quality Baby Prods. (M.D. Pa. Feb. 17, 2012)

- Alleged conduct:
 - Withheld prior art was argued in prosecution of another patent
- Result: no inequitable conduct (summary judgment)
- Court's reasoning focused on intent:
 - Reasonable inference that attorney did not appreciate materiality
 - Portion of reference discussed in other prosecution was not at issue here
 - Other prosecution focused on different product features than asserted patent
 - No proof attorney deliberately withheld art

Aventis Pharma. S.A. v. Hospira, Inc. (Fed. Cir. Apr. 9, 2012)

- Alleged conduct: Withheld prior art
- Result: Affirmed inequitable conduct
- Court's reasoning:
 - Materiality:
 - Affirmed invalidity based on withheld art
 - Intent:
 - Inventor disclosed art showing problem, but concealed art that showed the solution he pursued
 - Inventor reviewed another reference prior to signing declaration, but purposefully decided not to disclose it
 - Inventor lacked credibility
 - Direct testimony focused on experiments that supported excuses
 - Cross testimony conflicted with documents

Santarus, Inc. v. Par Pharm., Inc. (Fed. Cir. Sep. 4, 2012)

- Alleged conduct:
 - Delay in informing the PTO that inventor had administered the formulation to hospital patients as recorded in hospital records, before filing priority application
 - Misleading declaration submitted to PTO about *in vitro* test data
- Result: no inequitable conduct (district court affirmed)
- Court's reasoning:
 - No clear and convincing evidence to establish deceptive intent
 - District court found some information material and that inventor's explanation for delayed disclosure "strained credibility," but not enough evidence to prove intent

1st Media, LLC v. Elec. Arts, Inc. (Fed. Cir. Sep. 13, 2012)

- Alleged conduct: Withheld prior art
- Result: no inequitable conduct (district court reversed)
- Court's reasoning:
 - Applicants knew of references and may have known they were material, but there was no evidence of deliberate withholding
 - District court's analysis did not cite evidence of deliberate withholding or "anything that support such an inference"
 - District court erred in relying on applicants' "inability to offer a good faith explanation" to infer a deliberate decision to withhold

Outside the Box Innovations, LLC v. Travel Caddy, Inc. (Fed. Cir. Sep. 21, 2012)

- Alleged conduct:
 - Failure to disclose current litigation on parent patent-in-suit during prosecution of continuation patent-in-suit
 - Claim of small entity status despite license to large entity
- Result: no inequitable conduct (district court reversed)
- Court's reasoning:
 - Litigation only involved infringement as of the relevant time
 - Not material where no prior art or validity issues were yet raised
 - No suggestion of how withholding litigation could have deceived PTO
 - Need not decide whether declaration of small entity status qualifies as unmistakably false affidavit
 - No evidence that anyone with duty to disclose knew of license to large entity

Inequitable Conduct – Litigation

- When are inequitable conduct claims appropriate?
 - Reason for allowance is clear on the record and/or withheld art sufficient to invalidate patent
 - Affirmative misconduct shown as to material information
 - Misconduct goes to heart of invention and infects asserted claims
 - A practical, not legally required consideration

Inequitable Conduct – Litigation

- What facts support a finding of inequitable conduct?
 - High materiality of withheld information
 - Information not cumulative
 - Actual knowledge of withheld information
 - Actual knowledge of materiality
 - Implausible excuses for withholding
 - Witnesses not credible

Inequitable Conduct – Litigation

- Courts looking for real cases
 - Did the withheld information really matter?
- Do not ask courts for extreme remedy for relatively innocuous behavior
- Your position must be reasonable

Inequitable Conduct Litigation – Defeating It

- Challenge materiality
 - Information was cumulative to record
 - Little or no significance of information or affirmative conduct to issuance/validity
 - Closer prior art disclosed during prosecution
- If there is a good faith explanation, press it
 - Innocent mistakes cannot establish specific intent
 - Disclosure of closer prior art shows good faith
- Challenge pleading under *Exergen* standard
- Seek summary Judgment under *Therasense* standard

Best Practices: Some Considerations

- Should current practice be changed relating to:
 - Disclosure of Prior Art
 - Application Drafting
 - Submission of Declarations
 - Other Aspects of Prosecution
- Answer: Not significantly

Materiality - Proposed New Rule 56

(b) Information is material to patentability if it is material under the standard set forth in *Therasense, Inc. v. Becton, Dickinson & Co.*, ----- F.3d ----- (Fed. Cir. 2011).
Information is material to patentability under *Therasense* if:

- (1) The Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or
- (2) The applicant engages in affirmative egregious misconduct before the Office as to the information.

Best Practices Considerations: Disclosure of Prior Art

- The Federal Circuit's goal is to encourage applicants to provide "the most relevant information and reduce the incentive for applicants to submit information disclosure statements containing only marginally relevant information out of an abundance of caution"

Best Practices Considerations: Disclosure of Prior Art (cont'd)

- Does *Therasense* change current practice?
 - Still need to disclose any reference or position on art that may impact patent issuance
 - If you believe a foreign language document is material, fully translate and disclose
 - Disclose related litigation on validity issues and references cited

Best Practices Considerations: Disclosure of Prior Art

- Potential Changes Post *Therasense*
 - Less risk for failure to cite marginally relevant art
 - No need to pull cases from issuance to submit marginally relevant art cited in related cases
 - Consider limiting cross-citation practice to families that could be fairly rejected for obviousness-type double patenting
 - For existing families, what should you disclose in new continuing applications?
 - Copy IDS of parent application or risk questions on how list was selected
 - Post Dayco/McKesson practice of cross-citation of office actions etc. may be simplified

Best Practices Considerations: Application Drafting

- Does *Therasense* change current practice?
 - Write experimental sections in past tense when experiments have actually been performed
 - Disclose post filing negative test results not present in specification
 - If data is presented, provide sufficient experimental details

Best Practices Considerations: Submission of Declarations

- Does *Therasense* change current practice?
 - Do not file declarations unless absolutely necessary
 - Each statement should be parsed for accuracy
 - When opining on the same item in more than one application, it is crucial to take a consistent position
 - If position changes, bring to the Examiner's attention
 - Consider a memo to file explaining why the change is justified (new understanding of a reference, difference in law, etc.)
 - Fully disclose relationship of Declarant to applicant

Best Practices Considerations: Additional Considerations

- Priority claims – misclaiming priority can be material
- Entity Status – misclaiming small entity status can be material
- Litigation/interferences – disclose with respect to any related application

Possible Claims of Affirmative Misconduct

- Outright fraud
- Misleading translations of foreign-language prior art
- False test data
- False statement in declaration or application
- Misrepresentation of relationship between declarant and applicant
- Misrepresentation of inventorship
- False claim of priority date

Best Practices Considerations: Key Takeaways

- Still follow prudent, practical disclosure practice
- Be consistent
- Greatest risk comes with affirmative statements