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PATENT PROTECTION FOR HIGH TECHNOLOGY



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

Inequitable Conduct: Therasense and Sensibilities

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Inequitable Conduct is an Equitable Defense

- Inequitable conduct is an equitable defense that if proved, bars enforcement of a patent.
 - *See* 35 U.S.C. § 282 (1)
- Inequitable conduct defense evolved from Supreme Court cases that involved really “bad actors.”
 - Bribery of “prior user” who filed false affidavit favoring patentee (Keystone Driller Co. v. General Excavator Co., 290 U.S. 240 (1933)).
 - Paying expert to write an article praising invention and submitting it to PTO (Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944)).
 - Patentee discovered and suppressed evidence of perjury by inventor to obtain favorable settlement (Precision Instruments Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 606 (1945)).

The Rise of “Rule 56”

- **Rule 56 (1949):** “any application fraudulently filed or in connection with which any fraud is practiced or attempted on the Patent Office may be stricken from the files.”
 - 37 C.F.R. § 1.56 (1949).
- Focus on “fraud.”
 - But fraud was not defined.
- **Courts:** began holding patents unenforceable for failure to submit material information to the PTO, not just for affirmative, deceptive acts.

“Materiality” remained undefined by statute

- **PTO Rule 56 (1977):** material information is when “there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”
 - 37 C.F.R. § 1.56
- The “reasonable examiner standard” was widely adopted by the courts.
- But what wouldn’t a reasonable examiner want to know about?

The Definition of “Materiality” Evolves

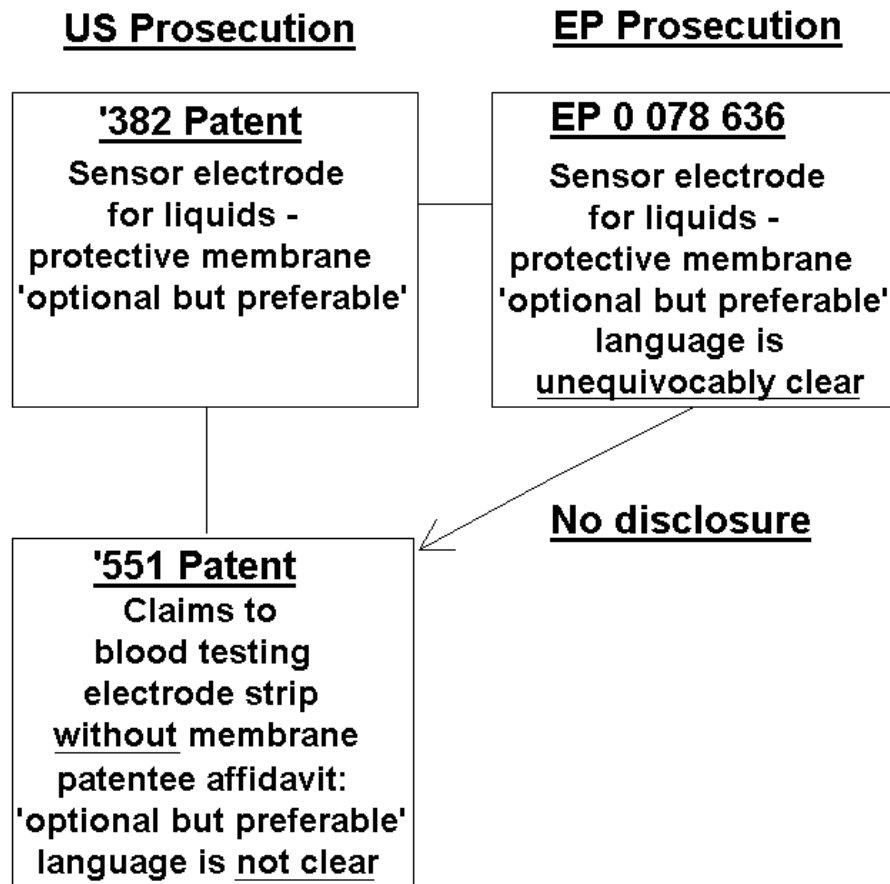
- **PTO Rule 56 (1992):** Information is material when it is not cumulative of information of record and:
 - (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
 - (2) It refutes or is inconsistent with, a position an applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

USPTO – Material Information

- **Rule 56 (1949):** fraud → application stricken.
- **Rule 56 (1977):** substantial likelihood a reasonable examiner would consider it important.
- **Rule 56 (1992):** not cumulative and
 - establishes a *prima facie* case of unpatentability or
 - is inconsistent with Applicant's position.

The *Therasense* Facts

- **District Court (ND Cal.)**: U.S. Patent 5,820,551 is unenforceable due to inequitable conduct.



• *Therasense, Inc. v. Becton, Dickinson & Co.*, 565 F.Supp. 2d 1088 (N.D. Cal. 2008).

The *Therasense* Facts

- **Prior Art '382 + '636 specifications:** *“Optionally, but preferably when used on live blood, a protective membrane surrounds [the sensor]...”*
- **'551 US Declaration:** *one skilled in the art at time of '382 would*
 - *feel protective membrane was needed for whole blood tests*
 - *not read the '382 patent to teach that the use of a protective membrane was optional or merely preferred with whole blood.*
- **'636 EP associate:** *“optionally, but preferably” language is “unequivocally clear” -- membranes are optional but preferred for live blood testing.*

Fed. Cir. 2010: *Therasense* Decision

- **Fed. Cir.:** Therasense made contradictory arguments to the EPO and the USPTO re the “optionally but preferably” language:
 - **Therasense to the EPO:** the language is “unequivocally clear” - a membrane is optional for ‘live blood’.
 - **Therasense to the USPTO:** the language is mere "patent phraseology" that did not convey a clear meaning.
- **Fed. Cir.:** The representations to the USPTO were not merely lawyer argument; they were factual assertions as to the views of those skilled in the art, provided in affidavit form.
 - Therefore the statements to the EPO were highly material.
 - 593 F.3d 1289 (Fed. Cir. 2010).
- **Fed. Cir. (2010) affirmed ND Cal decision** using USPTO standards of materiality under *37 CFR §1.56(b)(2)*.

Fed. Cir. - Intent to Deceive

- **Fed. Cir. (2010):**

- Declaration submitted to the USPTO was critical to allowance of '551 patent.
- Declarant and attorney both knew of EP statements but consciously withheld them.
- Declarant and attorney explanations at trial were not believable, suggesting intent to deceive.
- Citing: *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) ("the involved conduct, viewed in light of all the evidence ... must indicate sufficient culpability to require a finding of intent to deceive.")

Analogous to McKesson?

- McKesson Inform. Sol'ns, Inc. v. Bridge Med., Inc., 487 F.3d 897 (Fed. Cir. 2007).
- Patent held unenforceable: attorney failed to cite art cited by different Examiner in application containing similar claims, even though attorney had disclosed the existence of the application.
- Court balanced the “levels or materiality and intent, with a greater showing of one factor allowing a lesser showing of the other.”
 - Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309 (Fed. Cir. 2006).
- No credible explanation about why withheld ≈ deceptive intent.
- Court used “reasonable examiner standard” of materiality.
- Factor: Firm did not have procedures in place for citing office actions in co-pending applications.
 - McKesson at 911-912.

Therasense (2010) Strong Dissent by Judge Linn

- **Judge Linn:** Whenever evidence of materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.
- **Judge Linn re Materiality:**
 - EP associate statements are immaterial because they were cumulative of the '382 + '636 specification and are not inconsistent with statements made in the US during the prosecution of the '551 patent.
 - Therasense never told the EPO that the '382/'636 electrode "*needed no* membrane at all for use with blood."
- *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289 (Fed. Cir. 2010)

Prima Facie Materiality covers a lot

- **Material?** Abstract containing statements or results later contradicted by the full paper.
- **Material?** Concealed information even though it would not invalidate the patent.
 - See, Li Second Family LP v. Toshiba Corp., 231 F.3d 1373 (Fed. Cir. 2000).
- **Material?** Information relating to a claim that was later cancelled.
 - Duty exists until claim is cancelled. 37 C.F.R. § 1.56(a)
- **Material?** Information relating to a claim not in suit.

Intent – Standards Have Varied

- **Gross negligence or even negligence** (*Driscoll v. Cebalo*, 731 F.2d 878 (Fed. Cir. 1984) (“knew or should have known” of materiality plus failure to disclose = Inequitable Conduct).
- **Gross negligence sufficient** (*Orthopedic Equip. Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376 (Fed. Cir. 1983)).
- **High materiality could offset weak evidence of intent** (*Amer. Hoist and Derrick*, 725 F.2d at 1362).
- **Intent cannot be inferred from gross negligence** (*Kingsdown Medical Consultants v. Hollister Inc.*, 863 F.3d 867 (Fed. Cir. 1988)).

Who is subject to Inequitable Conduct?

- **PTO Rule 56 (1992):** who has a duty of disclosure
 - “Each individual associated with the filing and prosecution of a patent application to disclose to the office all information known to that individual to be material to patentability as defined in this section.” 37 C.F.R. § 1.56(a)
- This can encompass a lot of people, inside and outside of the patentee organization.

The “atomic bomb” of patent law.

- If properly pled and proven with respect to even one claim, defense of inequitable conduct renders all of the claims of the patent unenforceable, not just the “tainted claims.”
- Unenforceability may extend to claims of progeny patents (“the fruit of the poisonous tree”).
- Defendant has little to lose – multiple “applicants” may be tarred by “fraud” charges.

Judge Rader defuses the “atomic bomb” of Patent Law

- On April 16, 2010, the Fed. Cir. vacated the split panel decision and ordered rehearing *en banc*. The Fed. Cir. requested briefing on the viability of the materiality-intent-balancing framework.
- On May 15, 2011, the Fed. Cir. issued an opinion authored by Chief Judge Rader that vacated and remanded the district court’s decision.
- 99 U.S.P.Q.2d (BNA) 1065, WL 2028255 (Fed. Cir. 2011).

The standards for finding both materiality and intent were “tightened”

- “To prevail on a claim of [IC], the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO” [citing Star Scientific and Kingsdown].
- “In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known, material reference.”
- “[T]he accused infringer must prove...that the applicant knew of the reference, knew that it was material and made a deliberate decision to withhold it.”

The “sliding scale” was rejected.

- A [D.C.] should not use a “sliding scale where a weak showing of intent may be found sufficient based on a strong showing of materiality and vice-versa. Moreover, a [D.C.] may not infer intent solely from materiality.”
- Proving an 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.

Courts may still infer intent, but...

“to meet the [c/c] evidence standard, the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the evidence.’ Star, 537 F.3d at 1366...the evidence ‘must be sufficient to *require* a finding of deceitful intent...’ Kingsdown, 863 F.2d at 873 (emphasis added)...when 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...”

“The court adjusts as well the standard for materiality”

- Current Rule 56 is not to be followed when determining materiality.
- “*Prima facie* case” is too broad because information is considered material even if it would be rendered irrelevant when applicant’s rebuttal evidence is considered.
- “Refutes or is inconsistent with” standard is too broad because it “encompasses anything that could be considered marginally relevant to patentability.”

Standard for materiality of undisclosed references is “hard” but-for.

- Reference must be able to block issuance of patent even after all evidence is of record.
- For example, if judge or jury, using reference, invalidates a claim under clear and convincing standard, reference is material.
- However, if claim is found valid, fact-finder would still be required to test reference under preponderance of evidence (PTO) standards, giving the claims broadest reasonable construction, e.g., not actual Philips construction.

Withheld Art not material to cancelled claims.

- IC “should only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of *receiving* an unwarranted claim.” [emphasis added]
- “After all, the patentee obtains no advantage from misconduct if the patent would have issued anyway.”
- Query: Is this also an implicit endorsement of “no obligation to submit cumulative art”?

IC can be based on non-prior art misconduct

- Characterized as an exception to the but-for rule of materiality.
- Most often will involve submission of false declarations, whether or not they are but-for cause of issuance.
- “There is no room to argue that submission of false affidavits is not material.” Rohm & Haas Co. v. Crystal Chem. Co., 722 F.2d 1556 (Fed. Cir. 1983).

PTO Response

- 76 Fed. Reg. (July 21, 2011)
- Section 1.56 is amended by revising paragraph (b) to read as follows:
- “Information is material to patentability if it is material under the standard set forth in [Therasense]. Information is material to patentability under Therasense if:
 - (1) the Office would not allow a claim if it were aware of the information, applying a 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.”

Comments?

- PTO could have given this revision some more content.
- No reason to abandon cumulativeness exception to materiality.
- Should clarify para. (a) to indicate that art is not material unless it would have blocked an issued claim. Accused infringer should not be able to argue IC based on failure to submit a reference arguably material to a claim that did not issue.

Therasense goes out for a test drive

- American Calcar, Inc. v. Amer. Honda Motor Co., Inc., App. No. 2009-1503, -1567 (Fed. Cir. June 27, 2011).
- Patents directed to vehicle diagnostic systems.
- Jury invalidated '497 patent as anticipated by Acura owner's manual that ACI inventors were aware of, but did not submit to PTO = "material" under Therasense - "clear and convincing" evidence exceeds "but-for" preponderance stnd.
- Jury found two related patents (the "search patents") "not invalid" over art including the manual.
- Jury rendered advisory opinion finding no inequitable conduct.

District Ct. Judge Disagreed on IC

- Judge ruled on a motion by Honda, finding that ACI had committed inequitable conduct with respect to all three patents due to failure to disclose the manual to the PTO.
- Federal Circuit reversed – reaffirming that IC is “equitable in nature, with no right to a jury, and the trial court has the obligation to resolve the underlying facts of materiality and intent.” Slip op. at 23.

The '497 patent

- Manual was “material” due to jury’s anticipation finding, but...
- Lack of credibility of one inventor does not *per se* provide sufficient evidence of intent to deceive PTO.
- “A district court should not use a ‘sliding scale’ where a weak showing of intent may be found sufficient based on a strong showing of materiality.”
- Fed. Cir. rev’d, finding insufficient evidence of record that “applicant made a deliberate decision to withhold a known material reference.”

The two “search patents”

- Intent – Fed. Cir. found that only the fact of “withheld” had be adequately established, and that judge had not found that inventors knew that the manual was material to the claims, and then made a deliberate decision to withhold it.
- Materiality – Manual was not cumulative but judge evaluated materiality “based on the PTO’s Rule 56 standard and the ‘reasonable examiner standard,’ both standards we rejected in Therasense.” On remand, judge should resolve “but-for” question.

What's the Judge to do?

- The jury found clear and convincing evidence that the two search patents were “not invalid,” but did not evaluate patentability under the preponderance of the evidence standard, giving claims broadest reasonable interpretation.
- Judge could find specific intent to deceive regarding the parent ‘497 patent, and then rule that the progeny search patents are unenforceable as “the fruit of the poisonous tree.” [my term I think]
- “Atomic bomb” of patent law could end this suit.

Cordis Corp. v. Boston Scientific Corp.

- App. 2010-1311, 1316 (Fed. Cir. Sept. 28, 2011).
- Inventor's attorney "just scanned" a "Y" reference and inventor testified he just compared the figures to the figures in his application. They did not cite it in the parent stent application but cited it in a continuation.
- D.C. found reference material and that parties "purposefully" neglected their duty of candor by "putting their heads in the sand" regarding prior art showing a key feature. Both patents were held unenforceable.
- Fed. Cir. reversed, and required additional findings on intent.

Plaintiffs got a “Get out of Jail Free” card.

- D.C. reconsidered and ruled that inferences of culpable intent and good faith were both present = no IC.
- Fed. Cir. affirmed, stating that, while there was substantial evidence calling inventor’s veracity into question, district court should receive “great deference” regarding witness credibility.
- Query: What happened to that deference to the earlier ruling of purposeful blindness?
- Take-away: Unless evidence of specific intent is “unequivocal”, don’t find IC.

America Invents Act

- Passed by Senate, Sept. 9, 2011: H.R. 1249.
- Sec. 12 – Supplemental examinations to consider, reconsider, or correct information.
- Initiated by patent owner – leads to reexamination.
- Can be used to “purge fraud” due to failure to disclose information or submission of “incorrect information.”
- But “material fraud” shall be referred to the A.G. for possible criminal or anti-trust charges.

Take-Away's

- Therasense probably will not change the district court's opinion re IC. Intent was not solely grounded on materiality and court could still find but-for materiality, if not egregious misconduct.
- Good practice: cite all art, actions and responses in related U.S. and foreign applications to U.S. Examiner – no one reversed McKesson, Therasense involved failure to disclose an EP response and IC has never been found for “burying” alone. Related applns. have “SS claims.”
- Declarations, more than ever, are time-bombs.

Thank you for your attention, and good luck!

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