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PATENT PROTECTION FOR HIGH TECHNOLOGY

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Intent to Deceive and Practical Tips

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Outline

- Inequitable Conduct – a short case history leading to Therasense
- Practical Applications
- OED Implications

Supreme Court and Inequitable Conduct

- **Equity and Unclean Hands**
- **Hazel-Atlas Glass Co. v Hartford-Empire Co., 322 U.S. 238 (1944)**
 - Fraud – wrote fake article
- **Precision Instrument Mfg. Co. v. Automotive Co., 324 U.S. 806 (1945)**
 - Perjury and fraud - copied invention

Inequitable Conduct

- **Renders Patent Unenforceable**
 - Materiality of the evidence to patentability
 - Intent to deceive
 - Proving intent is a moving target
 - Then balance materiality and intent
 - Egregious enough to take down the whole patent?

Hope in 1988

– Kingsdown 1988

- Failure to disclose material information, or submission of false information, with intent to deceive as proven by clear and convincing evidence.
- Version of one claim amended to cover a competitor product did not correspond with previously allowed claims.
- New counsel copied wrong claim. Oops.
- Gross negligence is not sufficient

New Versions of Intent Emerge

Aventis v Amphastar (5-14-2008)

- Inventor should have known
- Failure to add dosage information evidence of intent
- Lack of action was evidence of intent
- Rader – mixing intent and materiality lowers the standard

Materiality = Intent?

- Issue in every case is usually failing to submit a reference.
- Aventis uses this universal fact to infer intent.
- Same as inferring intent from the materiality of the evidence.
- Only if a reference is material, and only if you don't cite it, is there a chance that rule 56 has been violated.
- This reasoning leads to intent being inferred in every case without need for other evidence of intent to deceive.

Intent

- **Praxair v ATMI (9-29-2008)**
 - High materiality
 - Should have known
 - No explanation of why it was not cited
 - District Court properly inferred intent

Relief?

- **Abbott v Sandoz 2008 (Oct. 21, 2008)**
 - Do not infer intent based on materiality of the reference
 - DC found not material and no intent regarding one patent in suit
 - Reasonable examiner would not consider it important

Note: is it harder to reverse a finding of no inequitable conduct?

Intent

- **Larson Manufacturing v Aluminart (9-28-09)**
 - 3 references cumulative – clearly erroneous
 - 2 Office actions material
 - Intent inferred by DC from five references not cited.
 - No excuses for not submitting provided
 - Re-determine the intent issue
 - Single most reasonable inference able to be drawn
 - Materiality does not presume intent
 - Balance - Is conduct egregious enough to invalidate the whole patent?

Intent

- **In re Bose (8-31-2009)**
 - Statement of use for tape players when only repaired and shipped. – Inequitable Conduct found by Board.
 - “By equating “should have known” of the falsity with a subjective intent, the Board erroneously lowered the fraud standard to a simple negligence standard.”
 - At least TM cases have it right (Michel)

Therasense v. Becton Dickinson

- Federal Circuit – rehearing *en banc* re inequitable conduct
- Six Questions of Law:
 - Should the materiality-intent-balancing framework be modified or replaced?
 - How?
 - *Tie directly to fraud or unclean hands*
 - *if so, what should the standard for them be?*

Six Questions of Law

- What is the proper standard for materiality?
 - Should PTO rules define materiality?
 - But for alleged misconduct claim would not have issued?
- When should intent be inferred from materiality?
- Should balancing materiality and intent be abandoned?
- Do materiality and intent standards in other contexts shed light on the appropriate standard for patents?

January 25, 2010 Decision

- NDC Cal. Found unenforceable and invalid
- Affirmed
- Statements made to EPO during proceeding of related patent not disclosed to PTO. Related patent filed by predecessor.

Review Standard

- First find threshold levels of materiality and intent by clear and convincing evidence
 - Std of review: clear error
- Balance levels to find inequitable conduct
 - Std of review: abuse of discretion

US Facts

- '551 patent prosecution in US – filed in 1984 – thirteen years of prosecution – half dozen continuation applications.
- Glucose meter strips – blood glucose changes electrical current in the strip
- New claims submitted without membrane
- Result of brainstorming session with atty Pope and Dr. Sanghera – Dir. R&D
- Declaration that membrane needed for whole blood

More USPTO Facts

- Pope argued that the “optionally, but preferably” language in the ‘382 patent taught that a membrane was required for testing blood.
- Sanghere provided affidavit that one skilled in the art would not read the language as saying that use of a membrane with whole blood was optional or merely preferred. The art continued to believe that. Even the working examples support this conclusion. The “optionally, but preferably” language was mere patent phraseology.

EPO Statements

- '382 patent – prior art also owned by Abbott.
- EP counterpart of '382, the applicant at the time (neither Pope, nor Sanghere) argued that the membrane in a reference (D1) was used to control the permeability to achieve a linear relationship between the current and substrate concentration.
- They argued that the membrane in '382 was permeable to water and glucose molecules, quoting language from the '382 application: “**Optionally, but preferably** when being used on live blood, a protective membrane...”

EPO Facts

- Then argued, use in '382 is a safety measure to prevent coarse particles from interfering, not as a permeability control”
- Then further argued in a brief: “It is submitted that **this disclosure is unequivocally clear**. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood...from interfering with the electrode sensor”

Panel in Affirming

- DC found that these statements contradicted PTO representations:
- Described the “optionally, but preferably” as unequivocally clear in the EPO, but as mere “patent phraseology” during testimony.
- EPO documents said the membranes were merely preferred for live blood
- CAFC – these findings are not clearly erroneous and indeed are manifestly correct.

Panel Opinions

- Big argument between majority and dissent regarding the “unequivocally clear” statement. Was it directed toward how the membrane functioned, or whether it was optional?
- Majority – only one way to read it – optional.
- Dissent – can also read it as directed toward how the membrane functioned – to block fouling particles.
- **Why is this discussion taking place under the materiality prong?**

Panel Opinion cont.

- Majority – in a close case, material should be submitted to the examiner. “Close cases should be resolved by disclosure, not unilaterally by the applicant.”
- The majority indicates that contrary statements made in another forum need to be submitted.
- What is a forum?
 - EPO or other patent office, yes,
 - IRS? It is a federal agency.
 - Customs?
 - Customers?

Intent can be inferred from indirect and circumstantial evidence

- DC made five findings:
 - Statements made to PTO in overcoming the '382 patent were critical
 - EPO statements would have been very important
 - Pope and Sanghera both new about the EPO statements and withheld them
 - No credible explanation for failing to submit them
 - So incredible they suggested intent to deceive (Majority – Judge's credibility determinations are virtually unreviewable") (Pope not a convincing witness. Sanghera – unconvincing demeanor)

Credibility of Patent Attorney in the Eyes of the Court

- Pope agreed that “normal English construction” “it is submitted” refers to what comes immediately before it, but went on to say “as a patent attorney” you need to look at the context of what was being conveyed. In that context, they were not trying to convey anything about the optional but preferred language.

Dr. Sanghera

- Sanghera provided the EPO documents to Pope. This should have saved him from inequitable conduct, right? “Cases involving affidavits or declarations are held to a higher standard. *Innogenteics*, 512 F. 3d at 1379.” Therefore, Sanghera should not have stated what he did in the declaration. Merely providing the EPO documents did not absolve him.

Linn Dissent

- Detailed reasons were provided for why they subjectively believed that the information was immaterial.
- Such an explanation will defeat a charge of inequitable conduct if it is “plausible”.
- This belongs under the subjective intent prong.

Linn Dissent

- Cites: Scanner Technologies Corp v ICOS Vision Systems Corp., 528 F. 3d 1365 (Fed. Cir. 2008)
 - “rigid comparison” of potentially infringing product to expedite handling – actually only black box was on open display.
- Equally reasonable interpretation was that it did not require physical inspection.
- Must be single most reasonable inference to meet the clear and convincing standard.

Dissent - Materiality

- Abbott never argued “merely preferred and not required” They only directly cited language from the ‘382 patent that was already before the USPTO.
- Reasonable to interpret “optionally” as referring to interstitial fluid. (consistent with Pope’s testimony)
- DC erred in extending “optionally” to refer to both blood and interstitial fluid.

Dissent

- “unequivocally clear” language in EPO submission may just as reasonably be interpreted to refer to the dual role of the membrane, not whether one was optional.
- Abbott never told the EPO that no membrane was needed for blood. Rather, it went into a detailed argument about how the membrane in D1 controlled the diffusion rate of glucose so the sensor was not overloaded. This was the entire point Abbott was trying to make and was bought by the EPO Board.

Dissent

- Once again, one interpretation was adopted over an equally reasonable interpretation to render the patent unenforceable. This is clear error under Scanner.
- The interpretations adopted by the DC and majority appeared to rely on phrases taken in isolation, not in the context, and completely ignorant of the purpose for which they were submitted. The alternative interpretations are supported by the record.

Tabloid Proof

- Sound bite jurisprudence!
- But, “persons of ordinary skill must look to the full context in which a term is used. *Phillips v. AWH Corp.*, 415 F. 3d 1303, 1314 (Fed. Cir. 2005) (en banc).
- “The court anchored its assessment of Attorney Pope’s subjective beliefs to the court’s previous finding of materiality.”

Intent

- Not intent to withhold, but intent to deceive
- Can't be implied where reasons given for withholding are plausible Dayco 329 Fd at 1367.
- Is it plausible that the applicant believed the reference was immaterial?

Inequitable Conduct what to do

- Be careful
- Worry
- Lose sleep
- Cite everything
- Lobby

Practical Problems

- First Filing Requirements
 - Multiple inventors from different countries
 - Conflicting requirements
 - Catch 22
- Export Regulations
 - Civil and Criminal Penalties
 - Conflict with License/Permission?
- McKesson References
- Office Action Cites Art Owned by Another Client
 - Published Applications
 - How can you tell?

First Filing

- Failure to seek permission to file outside a country first
 - Inventors in US and in China
 - Material to patentability?
 - Not really
 - “no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted”

First Filing

- What about intent?
 - Not very material
 - Can't infer from materiality
- Is failure to seek a license in another country evidence that might be relevant in establishing intent?
 - Pattern of negligence and bad practices
 - Willful ignorance of requirements

First Filing

- All inventors not listed
- Can be material
- What is the reason?
 - Avoiding potential inventor remuneration?
- List all inventors regardless of economic considerations

McKesson Uncertainty

- Failure to cite response that is inconsistent with arguments in present application.
- Search report art
- Related case art
 - What is a related case
 - How do you track it
 - Can you cite after allowance to get in file history

McKesson Uncertainty

- Related case art
 - Can a case be later unrelated
 - Notice of allowance in related case
 - Same examiner?
 - Cites further art?
 - Time responses to avoid RCEs?
- Review art to determine materiality
 - Too much art – no budget for review
 - Just file it all? – obfuscation – read every paper?

McKesson Uncertainty

- Find un-cited art after allowance
 - Reexam?
 - Need to assert substantial new question of patentability
 - If art not cited because thought to be cumulative, can you assert SNQ?
 - Do additional search until you find closer art, then cite all?
 - Reissue – not permitted for art already known

Responses

- Characterizing references
 - Safest to quote sections and not characterize
- Reference owned by another client
 - Withdraw from representation
 - Close art - withdraw
 - Easy and clear to distinguish – maybe
- Reference without assignee
 - Published applications
 - Duty to investigate?

OED

- Skirmish story number I (1986)
- Application filed with 16 inventors
- Added one more inventor after filing
- OED opens investigation
- Letter sent showing spreadsheet of claims asking inventors for contribution indication
- Never heard back

Violating a Law

- Red Flag
- What if not a US Law?
- It's only a patent Law
- What if there is no or little penalty?

OED

- Skirmish Story Number II (2008)
 - Attorney moved to new state
 - Warned to inform bar of all encounters with the law
 - Speeding ticket with failure to obey hand gesture
 - State bars – why are you telling us this?
 - OED – opened investigation

The Rules/Laws

- Rule 56
- Cannons – 27 CFR 10
- ABA Model Rules
- State Ethics Rules
- OED

Rules and Canons

- § 10.23(b) states that “A practitioner shall not:
 - (3) Engage in illegal conduct involving moral turpitude.
 - (4) Engage in conduct involving dishonesty, fraud, deceit, or misrepresentation.

Rules and Canons

- ABA Rule 8.4 Misconduct It is professional misconduct for a lawyer to:
 - (a) violate or attempt to violate the Rules of Professional Conduct, knowingly assist or induce another to do so, or do so through the acts of another;
 - (b) commit a criminal act that reflects adversely on the lawyer's honesty, trustworthiness or fitness as a lawyer in other respects;
 - (c) engage in conduct involving dishonesty, fraud, deceit or misrepresentation

Cannon 2

- 37 CFR § 10.31 (iii) indicates that you should withdraw from representation if your client "Insists that the practitioner pursue a course of conduct that is illegal.
- No express limit to illegal conduct in the US
- ABA Rule 1.16 is similar

Canon 5

- § 10.61 A practitioner should exercise independent professional judgment on behalf of a client

Canon 6

- § 10.77 Failing to act competently. A practitioner shall not: (a) Handle a legal matter which the practitioner knows or should know that the practitioner is not competent to handle, without associating with the practitioner another practitioner who is competent to handle it.

More Cannons

- § 10.85 (a) In representation of a client, a practitioner shall not:
 - (7) Counsel or assist a client in conduct that the practitioner knows to be illegal or fraudulent.
 - (8) Knowingly engage in other illegal conduct or conduct contrary to a Disciplinary Rule.
- § 10.110 Canon 9. A practitioner should avoid even the appearance of professional impropriety.

Ethical Conclusion

- First filing violations should only affect patent in country where violation occurred
- Inventor issues could affect patent in US
- Keep your license
 - Know the rules
 - Consult the right resources



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