Making *Therasense* out of Inequitable Conduct

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Inequitable Conduct and the Supreme Court (History)

- *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933) –

  Patents unenforceable due to patentee's unclean hands, in that patentee knew of possible prior use of invention, did not disclose it to patent office, and paid alleged prior user to keep details of possible prior use secret

- *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944)

  Patent unenforceable due to patentee's fraud on the patent office and the courts in concealing the authorship of an article relied upon to obtain patent issuance

- *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945)

  Patent unenforceable due to patentee's failure to disclose known perjury and fraud to patent office during prosecution

Potential Consequences

- Entire patent unenforceable
- Related patents unenforceable
- Antitrust claims
- Crime fraud exception to AC privilege
- Fees
- Attorney Discipline at PTO
- Malpractice Claims

Burden of Proof / Standard of Review

- Burden of Proof – Clear and convincing evidence
- Standard of Review – Underlying factual findings are reviewed for clear error, and ultimate decision as to inequitable conduct is reviewed for abuse of discretion

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.,
537 F.3d 1357 (Fed. Cir. 2008)

Before *Therasense*: Elements

- First, a threshold showing must be made that:
  - Applicant made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and
  - Intended to deceive the Patent Office

- Then, the court balances the equities to determine whether conduct is egregious enough to warrant holding entire patent unenforceable

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.,
537 F.3d 1357 (Fed. Cir. 2008)

Before *Therasense*: Materiality

Reasonable examiner standard: "Information is material when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent."

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357 (Fed. Cir. 2008)

Not cumulative, and

- Establishes prima facie unpatentability (alone or in combination) OR
- Refutes or inconsistent with applicant's position in (1) opposing PTO argument, or (2) asserting an argument for patentability

37 C.F.R. §1.56(b)

Before *Therasense*: Intent

Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867 (Fed. Cir. 1988) (en banc in relevant part) –

- "To be guilty of inequitable conduct, one must have intended to act inequitably."
- A finding of "'gross negligence' does not justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive."

Before *Therasense*: Intent

Scanner Techs. Corp. v. ICOS Vision Sys. Corp., 528 F.3d 1365 (Fed. Cir. 2008) –

- "Whenever evidence proffered to show either 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."

Before *Therasense*: Intent

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357 (Fed. Cir. 2008) –

- Holding that while "intent can be inferred from indirect and circumstantial evidence," . . . "such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement."

- "[T]he inference must not only be based on sufficient evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.

Before *Therasense*: Intent

Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc., 525 F.3d 1334 (Fed. Cir. 2008) –

- Despite multiple explanations proffered by patent owner, Federal Circuit affirmed finding of deceptive intent, stating: "[t]he district court heard [the declarant's] testimony and considered it along with all other evidence relevant to deceptive intent, yet determined that it did not outweigh the cumulative evidence evincing an intent to deceive."

Before *Therasense*: Intent

Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306 (Fed. Cir. 2008) –

- "Tolomei's testimony does not suggest that, at the time of the prosecution . . . he believed that disclosure of the [] art would have been cumulative; he also does not actually state that the alleged cumulativeness was the reason he failed to disclose prior art []devices to the PTO; and he was unable to identify any specific reference that rendered the [prior art] cumulative."

- "Hindsight construction of reasons why a reference might have been withheld cannot suffice as a credible explanation of why, at the time, the reference was not submitted to the PTO."

Before *Therasense*: Intent

Advanced Magnetic Closures, Inc. v. Rome Fastener Corp., 607 F.3d 817 (Fed. Cir. 2010) –

- "A party can prove intent to deceive the PTO based on direct evidence or on circumstantial evidence 'with the collection of inferences permitting a confident judgment that deceit has occurred.'"
- "[F]abricated drawings and contradictory testimony, provided a sufficient basis on which to infer that Mr. Bauer intended to deceive the PTO."

Pleading Requirements

Exergen Corp. v. Wal-Mart Stores,
575 F.3d 1312 (Fed. Cir. 2009)

1. Rule 9(b) requires who, what, where, when, and how of the material misrepresentation or omission
2. Pleading must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual

   (a) knew of the withheld material information or of the falsity of the material misrepresentation, and

   (b) withheld or misrepresented this information with a specific intent to deceive the PTO

Exergen Corp. v. Wal-Mart Stores, 575 F.3d 1312 (Fed. Cir. 2009)

- "Who"= naming a specific individual
- "What" and "where" = which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found
- "Why" and "how" = why information is material and not cumulative and how examiner would have used it in assessing patentability of claims
- Must also give rise to a reasonable inference of intent to deceive = facts from which it can reasonably be inferred that the specific individual named knew of the specific material information in the identified references

Therasense Panel

Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289 (Fed. Cir. 2008) –

- Panel majority affirmed district court's judgment that patent is unenforceable
- Withholding of contradictory attorney arguments about prior art made to EPO constituted failure to disclose material information
- Applied higher standard to declarants, and held that district court's inference of deceptive intent not clearly erroneous

En Banc Argument

- Argued November 9, 2010
- Three viewpoints argued:
  - Plaintiffs
    - Materiality: Fraud standard – "but for"
  - Patent Office
    - Materiality: Rule 56(b)
  - Defendants
    - Materiality: Rule 56(b)
- All agreed intent standard should be specific intent, and that if intent is inferred, the inference of deceptive intent must be the single most reasonable inference.

Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011) (en banc)

- Intent requires knowledge and deliberate action
- Intent and materiality are separate requirements. No sliding scale. Intent may not be inferred solely from materiality.
- 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 to deceive.

Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011) (en banc)

- As a general matter, "but for" materiality is the standard
- Art is "but for" material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art
- In making patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.
- Exception from "but for" standard -- affirmative egregious misconduct

Post *Therasense* at the Federal Circuit

Am. Calcar, Inc. v. Am. Honda Motor Co., 651 F.3d 1318 (Fed. Cir. 2011) –

- Vacated and remanded district court inequitable conduct finding

Post *Therasense*

Insufficiently pled inequitable conduct:

- *Pfizer Inc. v. Teva Pharms. United States*, 2011 U.S. Dist. LEXIS 119611 (E.D. Va. Oct. 17, 2011)
- *Schwendimann v. Arkwright Advanced Coating, Inc.*, 2011 U.S. Dist. LEXIS 101453 (D. Minn. Sept. 8, 2011)
- *Abaxis, Inc. v. Cepheid*, 2011 U.S. Dist. LEXIS 95589 (N.D. Cal. Aug. 25, 2011)
- *Recticel Auto. Gmbh v. Auto. Components Holdings, LLC*, 2011 U.S. Dist. LEXIS 127261 (E.D. Mich. Nov. 3, 2011)

Summary judgment of no inequitable conduct:

- *MeadWestvaco Corp. v. Rexam PLC*, 2011 U.S. Dist. LEXIS 92947 (E.D. Va. Aug. 18, 2011)

Post *Therasense*

No inequitable conduct:

- *Metris U.S.A., Inc. v. Faro Techs., Inc.*, 2011 U.S. Dist. LEXIS 105865 (D. Mass. Sept. 19, 2011)
- *Linear Tech. Corp. v. Monolithic Power Sys.*, 2011 U.S. Dist. LEXIS 101876 (D. Del. Sept. 9, 2011)
- *Pozen Inc. v. Par Pharm., Inc.*, 2011 U.S. Dist. LEXIS 86619 (E.D. Tex. Aug. 5, 2011)
- *Ameranth, Inc. v. Menusoft Sys. Corp.*, 2011 U.S. Dist. LEXIS 56470 (E.D. Tex. May 26, 2011)
- *Osram Sylvania, Inc. v. Am. Induction Techs., Inc.*, 2011 U.S. Dist. LEXIS 125652 (C.D. Cal. Oct. 28, 2011)
- *Duhn Oil Tool, Inc. v. Cooper Cameron Corp.*, 2011 U.S. Dist. LEXIS 112887 (E.D. Cal. Sept. 30, 2011)

Post *Therasense*

- Only a single district court case finding inequitable conduct

- *Apotex Inc. v. Cephalon, Inc.*, 2011 U.S. Dist. LEXIS 125859 (E.D. Pa. Oct. 31, 2011)
  - Materiality found because references invalidated claims
  - Specific intent found, but . . . stay tuned

Practical Considerations

In asserting inequitable conduct:

- Consider pleading standards
  - *Walmart v. Exergen*
- Develop strong evidence on intent
- Try to develop materiality evidence satisfying "but for" causation standard if possible
- Understand and advise clients on difficulty of prevailing on such claims in present judicial environment

In defending against inequitable conduct charge:

- Consider motion to dismiss for failure to plead with particularity
- Develop evidence of other reasonable inferences that can be drawn from facts relevant to intent
  - Focus on actual reason reference not submitted, preferably where prosecuting attorney kept contemporaneous notes
- Try to show cumulativeness