

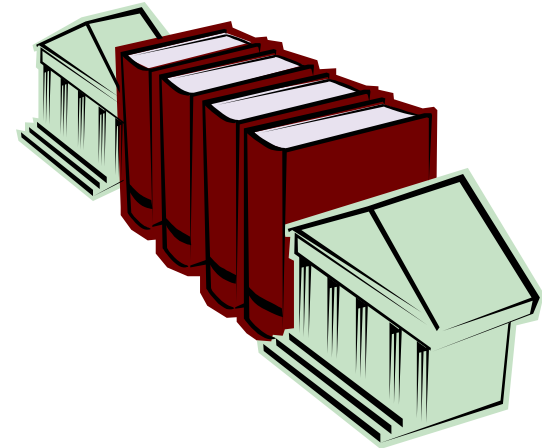
Therasense v. Becton

(Inequitable Conduct Law Update)

Thomas K. Scherer

Inequitable Conduct Law Update

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Therasense Case History

- Therasense, Inc. (now known as Abbott Diabetes Care, Inc.) and Abbott Laboratories, v. Becton, Dickinson and Company, and Nova Biomedical Corporation and Bayer Healthcare LLC
 - The United States District Court for the Northern District of California found U.S. Patent No. 5,820,551 (“the ’551 patent”) **unenforceable** due to **inequitable conduct**
- Appeal to the Court of Appeals for the Federal Circuit (CAFC)
 - Decision **upheld** unenforceability due to inequitable conduct
- Rehearing *en banc* by the CAFC
 - Full panel **vacated** previous decisions and **remanded** for further proceedings consistent with majority opinion

Therasense Case Facts

- The '551 patent involves disposable blood glucose test strips for diabetes management
- Claims recite test strip with an electro-chemical sensor for testing **whole blood** without a membrane over the electrode
- Claimed invention was distinguished from prior art by not requiring a **protective member** when analyzing **whole blood**
- Cited prior art (the '382 patent) contained a statement that a protective membrane was **optional, but preferred**

Therasense Case Facts

- Applicant submitted expert declaration explaining how the prior art statement in the '382 patent would have been understood by those skilled in the art
 - Whole blood contains **all** of its components, including red blood cells
 - Protective membrane was known as **optional**, but preferable **only** when analyzing blood **without red blood cells**, i.e., not **whole blood**
 - Those skilled in the art would understand that the protective membrane was **not** optional with whole blood
 - Instead, the statement that the membrane was optional would be understood as **merely patent phraseology** not technical teaching

Therasense Case Facts

- The '382 patent and '551 patent were **co-owned**
- Thus, the European counterpart application to the '382 patent was prosecuted by same Applicant
 - Prior art cited in EP case used diffusion-limiting membrane
 - Applicant distinguished the EP claims from the prior art based on the **kind** of membrane **optionally employed**
 - Applicant submitted statements explaining the understanding of those skilled in the art
 - Protective membrane **optionally** used was not for permeability control
 - Protective membrane is **optional**, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor
 - Thus, the statements, both from the **same Applicant**, are **directly contradictory** as to the membrane being optional

Therasense Case Facts

- Prior art cited against the '551 patent was **co-owned**
- European counterpart application to prior art was thus prosecuted by Applicant of the '551 patent
 - Prior art cited in EP case used diffusion-limiting membrane
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Rehearing *en banc* Overview

- Rehearing *en banc* granted by the Court of Appeals for the Federal Circuit (CAFC)
 - Decided [May 25, 2011](#)
 - Appeal heard by: Chief Judge Rader, and Circuit Judges: Newman, Lourie, Bryson, Gajarsa, Linn, Dyk, Prost, Moore, O'Malley, and Reyna (11 judges)
 - Majority Opinion by Chief Judge Rader
 - Joined in full by Circuit Judges Newman, Lourie, Linn, Moore, and Reyna (6 Judges / 7 Judges in-part)
 - Concurring-in-part and dissenting-in-part opinion filed by Circuit Judge O'Malley
 - Dissenting opinion filed by Circuit Judge Bryson
 - Joined by Circuit Judges Gajarsa, Dyk, and Prost (4 Judges)

Rehearing *en banc* Ruling

- Recognizing the problems created by the **expansion** and **overuse** of the inequitable conduct doctrine, *en banc* panel **vacates** judgment of inequitable conduct
 - Inequitable conduct is an **equitable defense** to patent infringement that, if proved, **bars enforcement** of a patent
 - The **equitable defense** evolved from a trio of Supreme Court cases that applied the **doctrine of unclean hands** to dismiss patent cases involving **egregious misconduct**:
 - *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933),
 - *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), overruled on other grounds by *Standard Oil Co. v. United States*, 429 U.S. 17 (1976), and
 - *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945)

Supreme Court Precedent

- *Keystone Driller Co. v. General Excavator Co.*
 - Case involved **manufacture** and **suppression** of evidence
 - Patentee **knew** of “a possible prior use” by a third party prior to filing a patent application but did not inform the PTO
 - After the issuance of the patent, the patentee **paid** the prior user to sign a **false affidavit** stating that his use was an abandoned experiment and bought his agreement to **keep secret** the details of the prior use and to **suppress** evidence
 - The **corrupt transaction** between the patentee and the prior user was discovered in during litigation of the patent
 - Supreme Court held that the corrupt transaction warranted **dismissal of the cause of action** because the party bringing the action did not come to the Court with clean hands

Supreme Court Precedent

- *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*
 - Case involved **manufacture** and **suppression** of evidence
 - During prosecution, the patentee's attorneys:
 - wrote an article describing the claimed invention **as a remarkable advance** in the art, and
 - had a well-known expert **publish** it in a trade journal **as his own**
 - After the patentee **submitted the article** to the USPTO in support of its application, the USPTO **granted** the patent
 - In litigation, the facts of the article's **origin** and attempts to **conceal the false authorship** of the article were discovered
 - Supreme Court explained that, if the district court had learned of the patentee's **deception** before the USPTO, it would have been warranted in dismissing the patentee's case under the doctrine of unclean hands

Supreme Court Precedent

- *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*
 - Patentee **suppressed evidence of perjury** before the USPTO and attempted to enforce the perjury-tainted patent
 - During interference proceedings, inventor's preliminary statement and testimony included **false dates** of conception, disclosure, drawing, description, and reduction to practice
 - Automotive learned of this, but instead of revealing the information, entered into an **agreement to conceal** and **brought lawsuits** on the patents, which was later discovered
 - Supreme Court held that dismissal was warranted because the patentee **failed to disclose** its knowledge of perjury to the USPTO, it had **actively suppressed evidence** of the perjury, and magnified its effects

Supreme Court Precedent

- Majority Opinion stresses that Supreme Court precedent involved particularly **egregious misconduct**, including perjury, the manufacture of false evidence, and the suppression of evidence
- All involved “**deliberately planned** and **carefully executed** scheme[s] to defraud” not only the USPTO but also the courts
- Dismissal of causes of actions for **unclean hands** based on **egregious misconduct** as in the Supreme Court precedent is still available, but such cases are **different** from the **inequitable conduct** doctrine that has developed from the Supreme Court precedent

Inequitable Conduct Doctrine

- Found for mere **non-disclosure** of information
- Resulted in **unenforceability** of the entire patent
 - Rather than mere **dismissal** of action
 - Finding **cannot be cured** by reissue or reexamination
- Required finding of **intent to deceive** and **materiality**
 - Standard was **clear and convincing evidence** for both
 - But standard **varied** and could be found on a **sliding scale**
 - Found at times for **gross negligence** or even **negligence**
 - On any information a “**reasonable examiner**” would want
- May raise **anti-trust** and **unfair competition** claims
- May result in **attorney’s fees** for “exceptional case” or **fraud exception** to the attorney-client privilege

Rehearing *en banc* Decision

- Majority Opinion held that the threat of inequitable conduct has resulted in **unwanted consequences**:
 - Effects of inequitable conduct to the Courts
 - Brought in every lawsuit which burdens courts
 - Increased adjudication cost and complexity
 - Reduced likelihood of settlement
 - Effects of inequitable conduct to the USPTO
 - Over-citation of information
 - Strained PTO resources
 - Increased PTO backlog
 - Impaired patent quality
- Thus, the **standards** for finding inequitable conduct are **being tightened** in order to redirect a doctrine that has been overused to the detriment of the public

Rehearing *en banc* Decision

- In order to find specific intent to deceive
 - 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
 - misrepresentation or omission amounting to gross negligence or negligence under a “should have known” standard **does not satisfy** this intent requirement
- Intent and materiality are **separate** requirements
 - Courts 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
 - Court may not infer intent **solely** from materiality
 - Unsubmitted information later found to be material **cannot, by itself, satisfy** the deceptive intent element of inequitable conduct

Rehearing *en banc* Decision

- Court may infer deceptive intent from indirect or circumstantial evidence, as direct evidence is rare
 - However, the specific intent to deceive must be “the **single most reasonable inference** able to be drawn from the evidence”
 - When there are **multiple reasonable inferences** that may be drawn, intent to deceive **cannot** be found
 - Because the party alleging inequitable conduct **bears the burden of proof**, patentee need **not** offer any good faith explanation unless a threshold level of intent to deceive is first proved by **clear and convincing** evidence
 - Absence of a good faith explanation for withholding a material reference **does not, by itself, prove intent** to deceive

Rehearing *en banc* Decision

- The standard for materiality **required** to establish inequitable conduct is **but-for materiality**
- Court cites prior Supreme Court case addressing materiality
 - Patentee had submitted two affidavits, **falsely** claiming that the invention had been used in the production of rubber goods when in fact only test slabs of rubber had been produced
 - Because the misrepresentation was not the **but-for cause** of the patent's issuance, the Supreme Court held that it was **immaterial** and **refused to extinguish** the patent's presumption of validity:
 - “Production of rubber goods for use or sale was not indispensable to the granting of the patent. Hence the affidavits, though perhaps reckless, were not **the basis** for it or **essentially material** to its issue. The **reasonable presumption of validity** furnished by the grant of the patent, therefore, would **not** seem to **be destroyed**.” *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928).

Rehearing *en banc* Decision

- The standard for materiality **required** to establish inequitable conduct is **but-for materiality**
- When an applicant fails to disclose prior art, that prior art is **but-for material** if the USPTO **would not have allowed** a claim **had it been aware** of the undisclosed prior art
- In making this patentability determination, the Court should apply the **preponderance of the evidence** standard and give claims their **broadest reasonable construction**
- Thus, even if a district court does not **invalidate** a claim based on a deliberately withheld reference, the reference may be **material** if it would have blocked patent issuance under the USPTO's different evidentiary standards
 - Courts require **clear and convincing** evidence to find invalidity

Rehearing *en banc* Decision

- The application of inequitable conduct should be fair
 - Just as it is inequitable to permit a patentee who obtained his patent through **deliberate misrepresentations** or **omissions of material information** to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee committed only **minor missteps** or acted with **minimal culpability**
 - The patentee obtains **no advantage** from misconduct if the patent would have **issued anyway**
 - Enforcement of an otherwise valid patent **does not injure** the public merely because of misconduct, lurking somewhere in patent prosecution, that was **immaterial** to the patent's issuance
 - Because neither **mere nondisclosure of prior art references** to the USPTO 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**

Rehearing *en banc* Decision

- Majority opinion concludes that these new standards strike a necessary balance between **encouraging honesty** before the USPTO and **preventing unfounded accusations** of inequitable conduct
- Majority notes that the Supreme Court has made clear that such standards serve an important purpose in **limiting the discretion** of Courts of equity
- Majority notes that **but-for proof** is already required to invalidate both copyrights and trademarks based on applicant misconduct
- Majority does **not follow** the Rule 56 definition of materiality as doing so would result in **less certainty**

Dissenting Opinion

- Agrees inequitable conduct is in unsatisfactory state
- Disagrees with the Majority **not simply following** the Rule 56 definition of materiality
 - USPTO is in **best position** to know what it needs
 - Fraud is not only performed in situations **affecting issuance**
- Previous cases addressed the **unwanted developments** with inequitable conduct **without** instituting a new higher standard
 - Gross negligence and negligence are **not** specific intent
 - Federal pleading rules require **specific** pleading of causes of action and, thus, **general assertions** may be dismissed
 - Courts can use **discretion** in finding inequitable conduct

Dissenting Opinion

- Duty of candor is based on the following principles:
 - Inequitable conduct requires proof, by **clear and convincing** evidence, that the applicant or attorney **intended to mislead** the USPTO with respect to a **material** matter
 - Materiality is measured by what the **USPTO demands** of those who apply for and prosecute patent applications. The disclosure standard that the USPTO expects those parties to comply with is set forth in the current version of the USPTO's **Rule 56**
 - Intent to mislead and materiality must be **separately** proved. There is no “**sliding scale**” under which the degree of intent that must be proved depends on the strength of the showing as to the materiality of the information at issue

Dissenting Opinion

- The **but for** standard is too restricted and departs from Supreme Court precedent
- The Supreme Court has set forth the following principles regarding inequitable conduct:
 - the public has a special interest in seeing that patent monopolies “spring from backgrounds **free from fraud** or other **inequitable conduct**”
 - patent applicants “have an **uncompromising duty** to report to [the Patent Office] all facts concerning **possible fraud** or **inequity** underlying the applications”
 - all facts relevant to such matters **must be submitted** to the Patent Office, “which can then pass upon the **sufficiency of the evidence**”

Dissenting Opinion

- The Supreme Court has set forth the following principles regarding inequitable conduct:
 - the **intentional failure** to disclose to the Patent Office that a patent application is **tainted by fraud** is sufficient cause to justify **not enforcing** the patent
 - the misconduct in question need **not** constitute **actionable fraud**; it is sufficient if the conduct constitutes a **willful act** that violates **standards of equitable conduct** in dealing with the Patent Office
- Materiality must include factors **other than the patentability** of the claims to have real meaning
- On the facts at hand, the finding of inequitable conduct should have been **affirmed**, not remanded

Concurring Opinion

- Disagrees with the creation of the **but-for standard**
- Disagrees with dissent's use of the **Rule 56 definition**
- States that only guidance should have been given:
 - Courts should exercise **sound discretion**, keeping in mind equitable remedies are intended to be **flexible**
 - While previously, a finding of inequitable conduct rendered unenforceable **all claims** of the wrongly procured patent and, in certain circumstances, related patents, this singular remedy is neither compelled by statute, nor consistent with the **equitable nature** of the doctrine
 - Courts may choose to render **fewer than all claims** unenforceable, may simply **dismiss** the action before it, or may **fashion some other reasonable remedy**

Concurring Opinion

- Thus, **materiality** should be found in situations when:
 - **but for** the conduct (whether it be in the form of an affirmative act or intentional non-disclosure), the patent **would not have issued** (as stated by the Majority opinion)
 - the conduct constitutes a **false** or **misleading representation of fact** (rendered so, either because the statement made is false on its face or information is omitted which, if known, would render the representation false or misleading)
 - the behavior is found to be **so offensive** that the Court is left with a firm conviction that the **integrity** of the PTO **process** as to the application at issue was **wholly undermined**
- Using this guidance, Courts should exercise discretion in determining inequitable conduct

Concurring Opinion

- Based on either the **test** of the Majority or of the dissent, or using the **suggested guidance**, the facts of the present case amount to **inequitable conduct**
 - The Examiner called for extrinsic evidence and only evidence in **favor** of patentability was **submitted** by the Applicant, while contrary evidence on the **exact same point** made by the same Applicant was **omitted**
 - Such conduct must be found as an **intent to deceive** the Examiner
 - Accordingly, the finding of inequitable conduct should have been **affirmed**, not remanded
- Many tools are available to Courts that can be used to curb litigation abuses (dismissals, sanctions, etc.)

Summary of Inequitable Conduct

- In order to assert inequitable conduct, one must:
 - prove, by **clear and convincing** evidence, a specific **intent to deceive** the USPTO with respect to a **material** matter
 - where Intent and Materiality are **separately** proven
- Intent requires that the applicant:
 - actually **knew** of the reference
 - actually **knew** that it was **material**, and
 - made a **deliberate decision to withhold** it
- Materiality requires:
 - showing that the USPTO would **not have issued** a patent **but for** the lack of consideration of the omitted information
 - applying the **preponderance of the evidence standard** and giving claims their **broadest reasonable construction**

Summary of Inequitable Conduct

- Inequitable conduct now has a **heightened standard**
- What does it mean to USPTO practice?
 - No need to cross cite Office Actions from other U.S. cases
 - Only **known, relevant** information *needs* to be considered
 - Foreign Office Action may cite relevant information (X or Y prior art)
 - Do **not** submit inventor/expert declarations that are **false**
- Appeal to the Supreme Court could **change** the law
 - Supreme Court has **not yet** accepted the case, but **could**
 - Supreme Court may agree with dissent and apply a **broader, less certain** inequitable conduct standard
 - See *Bilski* decision, which deemed the CAFC's clear machine-or-transformation test as only **one useful test** for 101 patentability
 - A predictable test was lost and the law was **returned** to a **gray area**



THANK YOU

Thomas K. Scherer

scherer@oshaliang.com