



# Playing Fair (or not) in the PTO: Inequitable Conduct in the 21<sup>st</sup> Century

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## OVERVIEW OF PRESENTATION

- **History of doctrine**
- **Elements of proof**
- **Circumstances where inequitable conduct was found**
- **Where is the doctrine going?**
- **Bright line rule possible?**

## WHAT GOES AROUND...

- “Fraud” on the Patent Office...
- ...became “Inequitable Conduct”
- And the floodgates opened to allegations of “inequitable conduct” to render claims unenforceable
- But now, Rule 9(b) pleading (as, for example, fraud) now applies

## INEQUITABLE CONDUCT CONSEQUENCE

- **Unenforceability for otherwise valid claim**
- **Potential exposure to “exceptional case” liability for attorney’s fees**
- **Professional discipline in light of necessary finding of “intent to deceive”**

**Material  
Misrepresentation/  
Omission...  
and....  
Intent to Deceive  
PTO**



## Balance Equities

Materiality

Intent

Overall Circumstances



**EASY TO DESCRIBE; HARD TO DO**

- **Like many tests...**
- **Methodology harder than description of test**
- **Potter Stewart test?**
- **Materiality a legal determination**
- **Intent to deceive, factual**

## Intent to Deceive?



**Difficult  
to  
Predict**

## IS THE PAST PROLOGUE? OR...?

- Change from “fraud” to inequitable conduct increased pleading
- *Exergen* appeared to signal change to tighten pleading
- *Therasense* signaled seriousness of charge, when proven

JUST WHEN YOU THOUGHT IT WAS SAFE



BARCROFT MEDIA

INEQUITABLE CONDUCT CHANGING---  
or is it?

- *Therasense* granted *en banc* review
- *Leviton Manufacturing v. Universal Security Instruments* remands for hearing on inequitable conduct finding
- What direction may be gleaned from this?
- What does the *Festo*, *KSR*, *Bilski* trilogy tell us for *this* issue?

- 1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
- 2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? [omitting citations] If so, what is the appropriate standard for fraud or unclean hands?

- 3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
- 4. Under what circumstances is it proper to infer intent from materiality? See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc).

- **5. Should the balancing inquiry (balancing materiality and intent) be abandoned?**
- **6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context?**

**DOOMED?**

**Materiality**

**Intent**

**Overall Circumstances**



**ORAL ARGUMENT SCHEDULED**

- **Court will hear argument November 9**
- **Decision in the Spring?**
- **Likely outcomes?**

## The Nine Deadly Sins Courts Identify

1. Art Not Disclosed
2. Data Related Issues
3. Tense/Prophetic Examples
4. Use/Sale
5. All Declarations
6. Co-pending Prosecutions
7. Best Mode
8. Translations/Burying
9. Declarant Interest



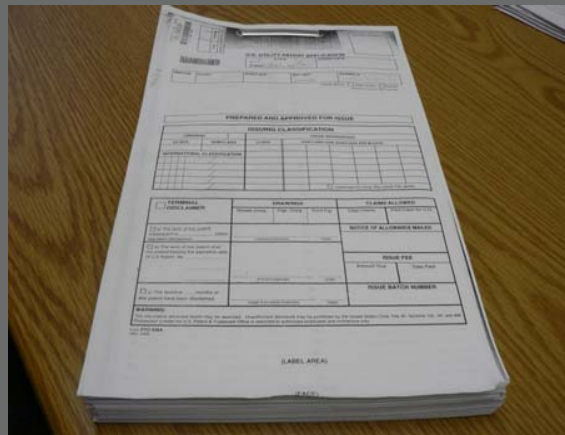


# PATTERNS OF INEQUITABLE CONDUCT FROM PAST DECISIONS

A Catalog of Misdeeds and Misfires

- *Agfa v. Creo* — Failure to disclose competitor's machines despite internal memos re: design showed intent
- *Cordis v. Boston Scientific* — Failure to site "X" reference - but sent back on intent
- *Digital Control v. Merlin* — No duty to disclose cumulative

# U.S. Lawsuit Discovery



**Patent File**



**U.S. Court Case:  
Entire Project**

- *Cargill v. Canbra* — Duty to err on side of disclosure
  - Broad discovery vs. limited file wrapper
- Lack of data or conflicting data has resulted in inequitable conduct (e.g. *Housey*)
- But courts usually see trumped up data arguments (e.g. *Zyprexa*; *Rilutek*)

- Xalatan (Glaucoma) 17-phenyl-PGF
- Prior art 20-ethyl-PGF
- Inventor Declaration
  - “Even at high dosages of 45  $\mu$ m 20-ethyl-PGF does not cause significant decrease in IOP”
- Inventor Article
  - “Topical application of 45  $\mu$ m 20-ethyl-PGF causes a significant IOP reduction w/o side effects”
- Article not submitted to PTO
- Unenforceable for Inequitable Conduct

## Australia (12/06) and Canada (1/07)

### Courts: “Selective Use of Data”

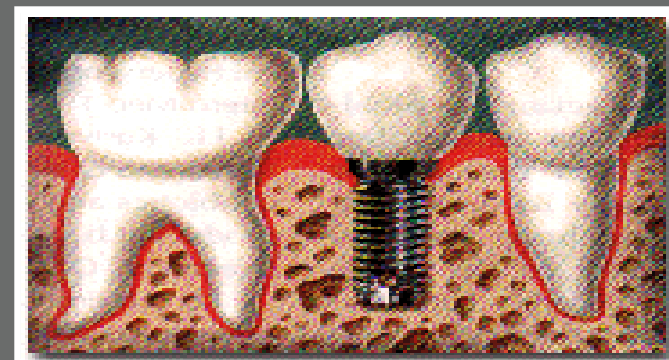
- Only Data from 5/13 Runs Used
- Improper comparison of  $\text{Ca}^+$  to  $\text{Na}^+$
- Solubility Issues in only Head to Head
- Unsupervised biologist used wrong solvent
- In Vitro memos admitted 2X



- *McKesson v. Bridge* — Must inform about related prosecution results and art even where same examiner



- Highly Material:
  - Unlike 112...Intent required for Inequitable Conduct
- Intentional Suppression → Unenforceable
- *Noblepharma v. Implant Innovations*, 141 F.3d 1059 (CAFC 1998)





## *Purdue Pharma v. Endo*

- Controlled release oxycodone
- Spec. said “has been discovered that 4 fold dose range controlled pain in contrast to 8 fold for other drugs” **USED PAST TENSE**
- But at time of patent filing **NO DATA** only insight

## Purdue Won but at Great Cost

- Trial court : Invalid for material misrepresentation



Layoffs: **1800/3300 (57%)**



- Appeals Court: Reverses
- Settled - Generics Respect Patent



- *Ferring v. Barr*
  - Failure to disclose declarant experts had former relationships with company applicant after examiner asked for “non-inventor” declarations



## Formerly Thought to be Less Risky Issues



- Inventorship
- Attorney Argument

## WHAT'S ARGUMENT AND WHAT'S NOT

- Facts vs. opinion
- Characterizations
- Conclusions
- Legal argument
- Rule 11 Standard? Is it a guide?
- What's cumulative? How do you decide?

## WHAT'S THE PROPHYLACTIC?

- Simple rule: What would you want to know if *you* were the Examiner?
- Harder rule: What will a court think *it* would have wanted at the time of the application, based on hindsight?
- The Golden Rule alloyed for patent law: Do unto others as you would have others do unto you.

- **Basic rule: It's always the right thing to do the right thing.**
- **When there's a question what to do, does that *always* suggest the answer?**
- **Remember, hindsight is always 20/20.**
- **What will conduct look like after full discovery?**

- **“Conscience is the inner voice that warns us somebody may be looking.”**

**H. L. Mencken**





# Questions?

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