

CLASS 18

DEFENSES TO INFRINGEMENT

PATENT LAW & POLICY
PROFESSOR WAGNER



Today's Agenda

Inequitable Conduct

Experimental Use

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Inequitable Conduct

Inequitable Conduct

Considers Behavior Before the PTO

Can include misrepresentations, failure to disclose, or submission of false information.

Is this important from a policy perspective?

In Therasense, The Federal Circuit refers to Inequitable Conduct as “the atomic bomb” of patent law. Why?

What are the policy implications?

Note the Difference:

Inequitable Conduct (JP Stevens)

Fraud in Procuring Patents (Walker-Process Fraud)

Inequitable Conduct

Two Components:

Materiality and Intent

Inequitable Conduct

A two-step decision-making process:

- [1] Establish that baseline levels of materiality and intent exist.
(Factual analysis.)
- [2] Balance materiality and intent to determine equities involved. (Discretion by Court.)

Intent

Therasense: a “specific intent to deceive the PTO”

How does one prove deceptive intent?
(What is the standard?)

Note Kingsdown: gross negligence is not sufficient.

Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. . . . However, to meet the clear and convincing evidence standard, the specific intent to deceive must be “the single most reasonable inference able to be drawn from the evidence.” . . . Indeed, the evidence “must be sufficient to require a finding of deceitful intent in the light of all the circumstances.” . . . Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found. . . .

- Therasense, 649 F.3d at 1290-91

Because the party alleging inequitable conduct bears the burden of proof, the "patentee need not offer any good faith explanation unless the accused infringer first ... prove[s] a threshold level of intent to deceive by clear and convincing evidence." The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.

- Therasense, 649 F.3d at 1291

Materiality: Critikon v Becton-Dickenson (Fed. Cir. 1997)

- The materiality standard is the PTO's rules for materiality
 - Pre-1992: 'important to a reasonable examiner'
 - Post-1992: 'establishes prima facie case of invalidity / refutes argument put forth by applicant'

Materiality: Therasense (Fed. Cir. 2011)

- The materiality standard is “but for” materiality
 - “in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.”

[Does this kill inequitable conduct?]

Materiality: Therasense (Fed. Cir. 2011)

- The materiality standard is relaxed for “egregious conduct”
 - filing false affidavits
 - other “affirmative egregious acts”

[Does this resurrect inequitable conduct?]

Therasense (Fed. Cir. 2011)

- O'Malley's concurrence: why does she think (some) ambiguity is important here? Is she right?
- Bryson dissent (joined by Gajarsa, Dyk, Prost)
 - "but for" is a HUGE change in the law
 - the best policy approach is to enforce the PTO's standards of materiality (Rule 56)
 - why does Bryson think small adjustments will work to reduce claims of IC?

Inequitable Conduct: Case 1

Halfway through the prosecution process, you find relevant prior art. In order to avoid slowing the process, you simply amend the claim to avoid the art (everyone agrees you were successful in doing so) rather than notifying the examiner. Inequitable conduct?

Inequitable Conduct: Case 2

After finding relevant prior art, you file a notice with the PTO, listing the problematic reference together with 350 other less relevant (but not irrelevant) documents. Inequitable conduct?

You claim to have submitted the quantity of art to impress the examiner with the scope of your search. Any change?

Inequitable Conduct: Case 3

The inventor of the patent application you are prosecuting tells you that she does not know of any relevant prior art; accordingly, you do not notify the PTO of any. After the patent has issued, it becomes clear that the inventor did know of relevant prior art. Inequitable conduct?

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Experimental Use

Experimental Use

[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.

– Whittemore v. Cutter (C.C.D.Mass., 1813)

Experimental Use

Statutory Experimental Use
[35 USC 271(e)]

Common-Law Experimental Use

Statutory Experimental Use

271 (e) (1)

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.



Merck v. Integra Lifesciences (USSC 2005)

The defendant used the patented RGD peptides as 'positive controls' when screening for efficacy of new drug candidates.

Does this avoid infringement under 271(e)(1)?

What is Integra's argument?

Under Merck, what is the scope of 271(e)(1)?

Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drug-maker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is "reasonably related" to the "development and submission of information under . . . Federal law."

U.S. Patent Feb. 3, 1987 Sheet 1 of 4 4,641,103



Madey v. Duke (Fed Cir 2002)

The court holds that experimental use is both an exception and a defense, not only an affirmative defense.

Why does this matter?
Who bears the burden?

Under Madey, what is the scope of experimental use?

In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.

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Experimental Use

Statutory
Experimental Use
[35 USC 271 (e)]

broadly applies

Common Law
Experimental Use
[Madey v. Duke]

very narrow

NEXT CLASS

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