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Hot Topics in Patents and IP for Life Sciences Companies

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BILSKI AND THE SUPREMES – Will billions of dollars of assets really evaporate?

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Short Answer

Beats me.

The US Supreme Court is going on recess shortly and it was expected by many practitioners that we would have a result by now.

The time between the argument in Bilski and the opinion exceeds the longest previous case by some 60 days.

The Court releases opinions on Mondays (2 left before the end of term) but there is a rumor that the Court will issue at least one opinion this Thursday.

Where are we?

The Bilski case is about the patentability of business methods.

Class 705 is the class into which the PTO puts “business method patents”.

From 2006 to 2008: 27,152 applications were filed in this class.

From 2002-2008: 6,152 patents were granted in this class.

Assuming only $10,000 to file and prosecute these applications, the total investment in prosecuting these cases alone exceeded $330 million.

Where are we? (continued)

Keep in mind that if the patent application included other non-business method claims as well as business method claims, it would potentially be placed into another class.

And this does not take into account the numbers of software and other method patents which have been affected by the Bilski holding.

If one considers the number of businesses which have been built around these patents the assets that are potentially affected by a Bilski opinion easily extends into the billions.

How did we get here?

1998

State Street Bank & Trust Co. v Signature Financial Group, Inc

This case is generally credited with opening the business method patent application flood.

The patent relates to a “Hub and Spoke” structure of mutual funds whereby assets of the Spokes and costs of the fund are pooled in the Hub and the value of the asset pool attributable to each Spoke is a function of the amount of Spoke assets in the asset pool.

How did we get here? (continued)

State Street Bank & Trust (continued)

Simply put, the CAFC reversed the District Court's holding that the claims were not directed to statutory subject matter.

2008
In Re Bernard L. Bilski and Rand A. Warsaw

The claims in Bilski were directed toward a method of hedging risk in commodities trading.

How did we get here? (continued)

In Re Bilski (continued)

In upholding a decision by the Board of Patent Appeals and Interferences, the CAFC invoked the U.S. Supreme Court test in Gottschalk v Benson 409 U.S. 63 (1972) that to be patentable under 35 U.S.C. §101 the claimed process must be tied to a particular machine or apparatus or must transform a particular article into a different state or thing.

How did we get here? (continued)

The claims in Bilski were not directed toward any specific machine or apparatus and were not transformative.

One dissent asserted that this was a new restriction on the kinds of inventions that are patentable and that the CAFC achieved this result by redefining the word “process”.

Bilski appealed and the U.S. Supreme Court accepted cert.

How did we get here? (continued)

2009

Prometheus Laboratories, Inc. v Mayo Collaborative Services and Mayo Clinic Rochester

The patent related to a method of optimizing therapeutic efficacy while minimizing toxic side-effects by administering a drug, determining the level of the drug's metabolites and warning if the metabolite levels exceeded certain values.

How did we get here? (continued)

The District Court found that the patent was invalid because the first steps were just data collecting steps and the third step was a mental process and granted Summary Judgment.

The CAFC invoked the Bilski transformation test and concluded that the transformation of the drugs into metabolites that could be measured was sufficient and reversed the District Court.

The Supreme Court hearing

The Supreme Court hearing took place in November 2009.

The transcript makes interesting reading.

From the transcript there appears to be some confusion among the Justices as to the distinctions among §§ 101 (statutory subject matter), 102 (novelty) and 103 (obviousness).

i.e. The questions asked by the Justices appeared to blur the distinction between whether something is patentable and whether it should be patented.

§101 v § § 102 and 103

§101 is just a definition as to what inventions are *eligible* for patenting. Typically this is discussed in terms of the negative. i.e. not patentable

§102 (novelty) and §103 (obviousness) are tests for whether eligible inventions deserve a patent in view of what has gone before.

Many inventions are eligible for a patent but are not patentable because of what has come before (the prior art).

Issues

Policy (pro):

A good deal of money has been spent in obtaining and using business method patents.

To come to a decision now that these inventions are not patentable affects not only those who relied on the patentability of business methods but also substantially anyone obtaining a patent on anything.

A collateral effect may be the thought that if patentability under §101 can change so significantly what is the value of a patent?

Issues (continued)

Policy (con):

Business methods are more abstract than most patentable inventions.

At what point should such abstract concepts be held by a single patentee.

After all, we do not allow patents on mathematical formulae or laws of nature.

Likely outcome?

As the saying goes: “Prediction is very difficult, especially about the future.”

Variously attributed to:

Robert Storm Petersen
Niels Bohr
Samuel Goldwyn and

Yogi Berra

Likely outcome (continued)

Bilski is not the greatest case to resolve all the issues.

It isn't about software and it isn't about diagnostics.

The Court tends to decide these issues narrowly.

My opinion is that *all* business method patents will not go away.

However, it is likely that any such claims will have to be written in terms of transformation or hardware and strict methods without a technology nexus will be unpatentable.

Likely outcome (continued)

As a result there will be future cases to define what needs to be involved for the hardware connection to be significant and what types transformation are required.

I believe this case will raise more issues than it settles.

Questions

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Post *eBay* – The State of Permanent Injunctions

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Pre-*eBay:*

"General Rule": A permanent injunction should follow upon proof of infringement of a valid patent. Injunctions denied only in the "unusual" case, under "exceptional circumstances" and " 'in rare instances … to protect the public interest.' "

The theory behind the practice: A patent gives the holder the right to *exclude* others.

Post-*eBay:*

"The decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards."

eBay v. MercExchange LLC, 547 U.S. 388, 394 (2006).

The traditional four-factor test applies:

1. Irreparable injury;
2. Inadequate remedies available at law;
3. Balance of hardships; and
4. Public interest.

eBay v. MercExchange LLC, 547 U.S. 388, 391 (2006).

Post-*eBay* Injunction Rulings

126 district court cases since May 15, 2006.*

Grant of permanent injunction: **72%** (91 cases)

Denial of permanent injunction: **28%** (35 cases)

*University of Houston Law Center's Patstats (updated 5/1/2010)

Justice Kennedy's Concurring Opinion

In cases now arising trial courts should bear in mind that in many instances the nature of the patent being enforced and the economic function of the patent holder present considerations quite unlike earlier cases. An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees.

eBay v. MercExchange LLC, 547 U.S. 388, 397 (2006) (Kennedy, J., concurring).

Justice Kennedy's Concurring Opinion

For these firms, an injunction, and the potentially serious sanctions arising from its violation, can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent. When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, **legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest.**

Id.

Factors

- Patentee Practices Invention
- Direct Competition
- Willful Infringement
- Lost Market Share/Sales Linked to Infringement
- Licensing Others
- Harm to Reputation
- Impact on Infringer’s Business
- Public Interest

Questions

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USER-GENERATED CONTENT

Testimonials, Patient Communities, and On-Line Commentary

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The Proliferation of User-Generated Content (UGC)

Commercial Sites – Amazon, eBay
Review Sites – TripAdvisor, CNET
YouTube (Viacom v. Google)
LimeWire (Grokster)
Bloggers – commenters
On-line communities: organic, created; Issue-oriented; Product-oriented

UGC can create liability

Relevant Law

Copyright Act 17 U.S.C. §§101-810
Trademark Act 15 U.S.C. §§1051-1141; state; common
Defamation and other tort law; state
Advertising Law; state; FTC

Digital Millennium Copyright Act, 17 U.S.C. §512
Communications Decency Act, 47 U.S.C. §230

How to manage liability?

Importance of Terms of Use

Enforceability?

- click-wraps
- browse-wraps

Restrictions in Terms of Use

- protection from liability
- create rules and remedies
- name and likeness issues
- implementation for safe harbors/secondary liability

Digital Millennium Copyright Act

Copyright Law:

- original expression
- life plus 70 years
- not mere facts or data
- text, graphics, photos, video, music

DMCA:

- Safe Harbor structure: conduit, cache, host, search (§§512(a-d))
- Must: register agent, terminate repeat offenders, implement notice and takedown, allow standard technical measures
- Can fall out: actual knowledge, red flag context, direct financial benefit

FAIR USE

Trademark Law

No Safe Harbor
Fair Use
Policies, such as ….

Tiffany v. eBay

- must have sufficient knowledge of specific acts
- eBay acted appropriately to police trademark issues - structure

Communications Decency Act

"No provider of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information provider."

Broad definitions

Pre-empts state tort law – defamation

Does NOT cover intellectual property rights

Advertising Law

State regulations

FTC – online advertising guidelines
– Behavioral advertising
– Transparency and consumer control
– Blogger disclosures

Questions

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A myriad of section 101 uncertainties and possibilities:

The case against Myriad Genetics, Inc.

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The Case

Association for Molecular Pathology, et al.,

vs.

United States Patent and Trademark Office, Myriad Genetics, Inc., Directors of the University of Utah Research Foundation

U.S. District Court Southern District of New York
Amended Opinion filed April 5, 2010
Judgment entered April 19, 2010

Deadline for Filing Notice of Appeal: June 18, 2010

The Controversy

As framed by the amended opinion:

Are isolated human genes
and
the comparison of their sequences
patentable?

Brief Profile of Plaintiffs

-Association for Molecular Pathology, nonprofit research entity

-American College of Medical Genetics, nonprofit organization of clinical and lab geneticists

-American Society for Clinical Pathology

-College of American Pathologists

-Drs. Haig Kazazian and Ganguly, Prof of Molecular Med U Penn School of Medicine (began BRAC1 and 2 testing as early as 1996 and Assoc Prof at Hospital of U Penn (screening testing) ceased in response to Myriad cease and desist letters

-Dr. Chung, Columbia University can not provide testing services

-Several health care cooperatives

-Several patients e.g. #1: oncologist and genetic counselor recommended testing but Myriad would not accept her insurance coverage and patient unable to pay full cost out of pocket; e.g. patient#2: sought second opinion and confirmatory testing but no other US testing service available.

[ACLU not a plaintiff but represented certain plaintiffs]

Brief Profile of Defendants

Myriad Genetics, Inc.

University of Utah Research Foundation

U.S. Patent & Trademark Office

Who is Myriad Genetics, Inc.?

What is their platform?

Cancer screening
Most notably BRCA1 and BRCA2 genetic testing
Provide genetic testing; 2002 Comprehensive BRACA and 2006 Supplemental BRCA and certain special "high risk patient" tests
$3000 per test
2008: $222 million in revenues; $32 million in costs

What is their business model?

Exclusive testing service for BRCA1 and BRCA2
Currently 90% of tests performed are covered by insurance at over 90% cost of test
Plaintiff data asserting Myriad only accepts full or close to full insurance coverage per patient but
Supposedly Myriad offers scholarships to qualified low income patients
No confirmation for negative tests; appears to be some limited confirmation for positive tests under license from Myriad at U Chicago and Yale

Why Myriad?

Historically, about 9 labs offering a breast cancer test before Myriad's patents issued
Yale, U of Pennsylvania Genetics Diagnostic laboratory, OncorMed, NCI, Georgetown
Since issuance of patents, only company in US with testing service for past 12 years
Myriad sued U Penn; cease/desist letter to Yale; sued and eventually acquired OncorMed

Myriad not unaccustomed to controversy

U.S.: Inventorship controversy(s) regarding certain BRCA patents and discoveries. Sent cease/desist letters to various academic and not-for-profit institutions. Acquired OncorMed following infringement suit filed by OncorMed. Perceived to be unwilling to permit basic research on genes and mutations.

Canada: Perceived to alienate regulators and health care policymakers. Presented threatening letters to various entities and regional governments.

Europe: Perceived to alienate regulators and health care policymakers. European patents opposed by multiple parties and appreciably narrowed.

Australia: Granted exclusive license for testing as settlement in infringement suit. Recent case filed in Australia challenging legitimacy of patent monopoly in Australia.

Some Breast Cancer Statistics

1 in 9 woman will develop breast cancer

1 in 27 women will die of breast cancer

5 to 10 percent of breast cancers associated with a mutated allele; BRCA1 and BRCA2 mutations represent about three to ten percent

Women with these mutations have 40-85% risk of breast cancer and 16-40% risk of ovarian cancer; risk in general population is less than 13% and 2%, respectively

Inherited BRCA1 risk is 40-52% and inherited BRAC2 risk is 15-25%

Men with mutations have an increased risk of breast and prostate cancers

Back to the Issues Before the District Court

Challenge was carefully crafted. Only 15 claims in 7 patents out of possible 23 patents

Challenge did not include claims directed to vectors, host cells, BRCA sequences operatively linked to regulatory sequence, kits, methods of amplification

Are the composition claims-in-suit patentable?

An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

An isolated DNA coding for a BRCA2 polypeptide set forth in SEQ ID NO: 2, wherein said mutated form of the BRCA2 polypeptide is associated with susceptibility to cancer.

The Court held NOT patentable

Question: "Whether or not claims directed to isolated DNA containing naturally-occurring sequences fall within the products of nature exception?"

Answer: Yes

And thus is not patentable subject matter

The Court held NOT patentable

- "In sum, the clear line of Supreme Court precedent and accompanying lower court authorities, stretching from American Wood-Paper through to Chakrabarty, establishes that purification of a product of nature, without more, can not transform it into patentable subject matter. Rather, the purified product must possess "markedly different characteristics in order to satisfy the requirements of" patentable subject matter.
- "In light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native DNA and the isolated DNA claimed in the patents-in-suit render the claimed DNA "markedly different." This conclusion is driven by the overriding importance of DNA's nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form. The preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature."

Doctrinal shift ?

DNA=information

as opposed to

DNA=chemical

Are the method claims-in-suit patentable?

A method for detecting a germline alteration in BRCA1 gene . . . which comprises analyzing a sequence of BRCA1 gene . . . .

A method for diagnosing a predisposition for breast cancer in a human subject which comprises comparing the germline sequence of the BRCA2 gene . . . with the germline sequence of the wild-type BRCA2 gene, . . . wherein an alteration indicates a predisposition to said cancer.

The Court held NOT patentable

“The language of the method claims-in-suit and the plain and ordinary meanings of the terms "analyzing" or "comparing" establish that the claims-in-suit are directed only to the abstract mental processes of comparing or analyzing gene sequences."

The Court held NOT patentable

- "The essence of what is claimed is the identification or a predisposition to breast cancer based on "analyzing" or "comparing" gene sequences.
- Court relied on claim differentiation to broadly interpret independent method claims since dependent claims were unchallenged for lack of physical transformation steps or unchallenged as being solely dependent upon mental processes.
- Myriad argued that isolating and sequencing were inherently transformative properties within the meaning of analyzing and comparing--Court rejected this argument asserting that preparatory transformations relating to DNA can not be relied on. Even if accepted, this would only result in "transformations which constituted no more than data-gathering steps" which are not "central to the purpose of the claimed process."

How to reconcile this case with other DNA or gene cases?

Arguably the first case in which DNA was a diagnostic indicator rather than a means for producing a therapeutic product or as a vector or as a cell/cellular component.

Statement of the Court's Rationale

"Resolution . . . is based upon long recognized principles of molecular biology and genetics: DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA's existence in an "isolated" form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to "isolated DNA" containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter . . . . Similarly, because the claimed comparisons of DNA sequences are abstract mental processes, they also constitute unpatentable subject matter . . . .

Putting the Holding in an Industry Context

How many gene patents in U.S.?

Statistics vary widely among numerous sources

- 25,000 genes in human genome
- 25,000 issued patents contain 1 or more claims directed to DNA
- other sources indicates that as of April 2009, UPSTO issued its 50,000 patent with at least one claim to a nucleic acid sequence
- 5,000 of these directed to human DNA
- 20% human genome subject of patents--about 1000 genes; 4382 of 23,688 genes listed in the National Center for Biotechnology Information—nearly 20% of human genes—are patented
- Over 3,000 issued gene patents
- Nearly 10,000 genes have been patented

Hand-Wringing *vs.* Ho-Hum

What's been the impact of and reaction to this case?

What happened in the markets?

- Two indices which track overall performance of biotech stocks indicated that stocks declined less than 1% when decision released
- Myriad's stock declined about 6-12% when decision released ($24.90; now at $18.04)

BIO press release

E.g., NYT, WJ, NPR, BioWorld Today

Single gene versus multi-gene testing

What Now?

What to do while we wait for outcome of an Appeal to CAFC or Supreme Court (or another similar suit against a different company)?

If you are a patent attorney:

All the things you should already be doing now for your clients

-multiple categories of claims (DNA, manufactured DNA, gene pairs, multigene combinations, vectors, cells, kits, methods, combinations of the foregoing)

-careful use of claim terms (isolated, comparing, analyzing)

-diagnostic methods should include transformative step rather than merely informational or data gathering

-reissue considerations

What Now?

What to do while we wait for outcome of an Appeal to CAFC or Supreme Court (or another similar suit against a different company)?

For corporate and in-house attorneys:

Re-strategize or re-configure partnering terms and conditions

For CEOs and business development executives:

Manage the corporate message

Don’t underestimate the power and role of good will

Stay Tuned

Appeal deadline is June 18

Myriad has stated that it will appeal even though certain of its patents begin expiring in 2014 and numerous of its patents/claims unaffected by this decision

Stay Tuned

HHS Secretary's Advisory Committee on Genetics, Health and Society recently released a report April 2010:

"Report on Gene Patents and Licensing Practices an Their Impact on Patient Access to Genetic Tests"

stating that as a matter of public policy and health care, there will soon be a crisis given the intersection of multiplex genetic testing, whole genome sequencing and gene patents. SACGHS has called for Congress to sort out the biotech patent debate.

About $2 million of federal funds invested in BRCA research at U Utah—are federal "march-in rights" on the horizon for Myriad and other companies with similar business models?

Biotech commerce *versus* access to genetic testing *versus* development of genetic tests—wherein lies a policy resolution?

Resource Materials & Recommended Reading

Gold and Carbone, “Myriad Genetics: In the eye of the policy storm,” *Genetics in Medicine*, Volume 12, Number 4, April 2010 Supplement.

Gold and Carbone, “Detailed legal analysis of gene patents, competition law and privacy law,” 2008; available at: www.theinnovationpartership.org

Pressman et al., “The licensing of DNA patents by US academic institutions: an empirical survey,” *Nature Biotechnology*, Volume 24, pp. 31-39 (2006).

“Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests,” *Report of the Secretary’s Advisory Committee on Genetics, Health and Society*, April 2010; available at:

http://oba.od.nih.gov/SACGHS/sacghs_documents.html#GHSDOC_011

http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_patents_report_2010.pdf

Thanks for your time.

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Inequitable Conduct – Dead or Alive?

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A Statistical View

Between 1/1/2006 and 5/20/2009, out of all CAFC patent-related opinions:

- Inequitable conduct was raised in 48% (64 cases)
- Among these 64 cases:
  - 66% - no inequitable conduct
  - 20% - inequitable conduct
  - 14% - remanded

Source: BNA's Patent, Trademark & Copyright Journal, 79 PTCJ 299, 1/15/2010

Out of all patent cases decided (by district courts and CAFC) in 2008-2009:

- inequitable conduct alleged re 131 patents
- 29 (22%) found unenforceable

Source: www.patstats.org (University of Houston Law Center)

Elements for Inequitable Conduct

Infringer needs to prove by *clear and convincing evidence* that

- *a person substantively involved in the preparation or prosecution of the patent*
- *affirmatively misrepresented a **material** fact, failed to disclose **material** information, or submitted false **material** information*
- *with an **intent** to deceive the PTO*

Inequitable Conduct Analysis

Step 1. Infringer must show:

threshold level of **materiality** and

threshold level of **intent**

although a greater showing of one allows a lesser showing of the other.

Step 2. Patent holder can rebut with *good faith* explanation to counter evidence of intent to deceive (e.g., plausible, legitimate reasons for withholding prior art)

Step 3. Court's balancing of equities

Materiality

Rule 56:

- Pre-1992 Amendment
  Materiality is determined by **reasonable examiner** standard

- 1992 Amendment
  Information is material if it is not cumulative to what is already of record and either establishes "**a *prima facie* case of unpatentability of a claim**" or "**refutes**, or is **inconsistent with**" a position taken during prosecution

However, courts (including the Federal Circuit) continue to apply the pre-1992 **reasonable examiner** standard.

Intent

Disparities between different panels in the Federal Circuit on the legal standard for intent:

"Single most reasonable inference"

versus

"Should have known" standard

"Single most reasonable inference"

- Inferences "must not only be based on sufficient evidence and be reasonable in light of that 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 – *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008)

Finding no intent to deceive – intent to deceive not the single most reasonable inference:

- Ariad Pharmaceuticals Inc. v. Eli Lilly & Co. Inc., 560 F.3d 1366 (Fed. Cir. 2009)

"Should have known"/ "Gross negligence"

- Intent may be inferred where a patent applicant knew, or ***should have known***, that withheld information could be material to the PTO's consideration of the patent application - *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997)

Finding of inequitable conduct affirmed based on:

- Failure by patent attorney to investigate sale of the invention – *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 137 (Fed. Cir. 2001)
- Failure to disclose to the PTO that several declarations submitted to support patentability were from paid consultants – Ferring B.V. v. Barr Laboratories, Inc., 437 F.3d 1181 (Fed. Cir. 2006)
- Misrepresentation in declaration regarding dosage information - *Aventis Pharma S.A. v. Amphastar Pharmaceuticals Inc.*, 525 F.3d 1334 (Fed. Cir. 2008)
- Failure to disclose highly material prior art - *PraxAir Inc. v. ATMI Inc.*, 543 F.3d 1306 (Fed. Cir. 2008)

Good Faith Evidence

- Larson Manufacturing Co. v. Aluminart Products Ltd., 559 F.3d. 1317 (Fed. Cir. 2009) – Federal Circuit regarded Larson's notification to the Reexamination Panel of the simultaneous prosecution of related application, and disclosure of court documents in a related litigation, including Aluminart's allegations of inequitable conduct, as evidence of good faith

Recent Fed. Cir. cases

Do not need "wholly distinct facts" to show intent versus materiality; intent properly inferred from disclosing and distinguishing double top stitch while withholding closer stitch - *Taltech Ltd. v. Esquel Enters. Ltd.*, No. 2009-1344 (Fed. Cir. May 12, 2010).

Late disclosure (during reexamination) may be evidence of good faith; vacated and remanded for evidentiary hearing – *Leviton v. Universal Security*, No. 09-1421 (Fed. Cir. May 28, 2010)

Inference of intent not drawn despite "high" materiality and lack of explanation for failure to disclose, affirming SJ of no inequitable conduct – *Optium v. Emcore*, No. 09-1265 (Fed. Cir. May 5, 2010)

Therasense En Banc Questions

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? If so, what is the appropriate standard for fraud or unclean hands?
3. What is the proper standard for materiality? What role should USPTO'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?
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.

Questions

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