

Patent Procurement and Strategy 3.0

What Has Changed and Why Does it Matter?

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Intellectual Property Law



בית הספר הגבוה לטכנולוגיה בירושלים
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Agenda

- **What's The Future For:**
 - **The Patentable Subject Matter Requirement For Process Claims?**
 - Why Does It Matter?
 - Business Methods
 - Life Sciences
 - **Inequitable Conduct?**

Bilski Rulings

- Bilski claimed methods of hedging risk in commodity trading
- Federal Circuit (en banc) held the claims invalid as failing to meet the “machine or transformation” test (MOT), which it held to be the exclusive test for patentable subject matter
- Supreme Court affirmed invalidity, but determined that the MOT test is not the exclusive test
- The Supreme Court alluded that it is not sure that this test is adequate for the information-age, to wit:
 - “But there are reasons to doubt whether this test should be the sole criterion for determining the patentability of inventions in the information-age

Bilski Rulings

- The Supreme Court held that:

“Section 101 . . . precludes the broad contention that the term ‘process’ categorically excludes business methods.”

Why *Bilski* Matters

- “Technical” innovation is no problem
- But as you get closer to abstract ideas or natural processes, watch out
- Business effect of a patent is strongly related to the scope of the granted claims.
- But keep in mind that one broad patent is not enough. Seek a collection of narrower claims that adequately cover the entire field.

Patentable Subject Matter

- United States Patent And Trademark Office Issued Guidelines After *Bilski* (July 27, 2010)
 - The Supreme Court has called out three exceptions to patentable subject matter: abstract ideas, laws of nature, and physical phenomena.
 - These judicially recognized exceptions have been described using various other terms, e.g., mental processes, natural phenomena, products of nature, scientific principles, disembodied concepts, mathematical algorithms and formulas.

USPTO Quick Eligibility Reference

Factors Weighing Toward Eligibility:

- ❖ Recitation of a machine or transformation (either express or inherent).
 - Machine or transformation is particularly meaningful, limits the execution of the steps.
 - Machine implements the claimed steps.
 - Article being transformed is particular.
 - Article undergoes a change in state or thing (e.g., objectively different function or use).
 - Article being transformed is an object or substance.

USPTO Quick Eligibility Reference

Factors Weighing Toward Eligibility:

- ❖ The claim is directed toward applying a law of nature.
 - Law of nature is practically applied.
 - Application of law of nature meaningfully limits execution of steps.

USPTO Quick Eligibility Reference

Factors Weighing Toward Eligibility:

- ❖ The claim is more than a mere statement of a concept.
 - The claim describes a particular solution to a problem to be solved.
 - The claim implements a concept in some tangible way.
 - The performance of the steps is observable and verifiable

AMP et al. v. USPTO et al. ("Myriad")

❖ Claims:

- Methods of screening for new cancer therapeutic drugs using host cells transformed with mutant BRCA nucleic acids, and comparing growth in presence/absence of drug candidate.
- ❖ Diagnostic method claims rejected under the "machine or transformation" test (District Court Decision)
 - Claims directed only to abstract mental processes of "comparing" or "analyzing" gene sequences, not molecules
 - Do not require "isolating" or "sequencing;" and, isolating and sequencing would be mere data-gathering steps that would not save the claims in any case
- ❖ Screening claims rejected as claiming a basic scientific principal; transformative steps are nothing more than "preparatory, data-gathering steps"

AMP et al. v. USPTO et al. ("Myriad")

- ❖ U.S. Dept. of Justice Amicus Brief
 - §101 requires more than “identifying and isolating” what exists in nature
 - Isolated genomic DNA is unpatentable; cDNA, vectors etc. are patentable

- ❖ Federal Circuit has not heard argument yet.

- ❖ However, the Federal Circuit has spoken in *Prometheus v. Mayo*

Medical Treatments: Prometheus v. Mayo

- ❖ Claim to administering a drug, detecting metabolite levels, and comparing against predetermined levels
- ❖ Mayo argued that the claim covered a natural phenomenon: the observed correlation between drug levels and efficacy and toxicity.
- ❖ Based on Bilski, the issue before the Federal Circuit was:
 - “Natural phenomenon” (not patentable)
 - or
 - “an application of a law of nature or mathematical formula to a known structure or process” (patentable)
 - “We conclude they are drawn to the latter.”

Medical Treatments: Prometheus v. Mayo

❖ Notable Quotes From The Federal Circuit:

“Prometheus’s claims are drawn not to a law of nature, but **to a particular application of naturally occurring correlations**, and accordingly do not preempt all uses of the recited correlations between metabolite levels and drug efficacy or toxicity.”

“the steps involve a particular application of the natural correlations: **the treatment of a specific disease by administering specific drugs and measuring specific metabolites.**”

Medical Treatments: Prometheus v. Mayo

❖ Notable Quotes From The Federal Circuit:

“The asserted claims are in effect claims to methods of treatment, **which are always transformative** when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.”

Medical Treatments: Prometheus v. Mayo

- ❖ Compare to mere “data gathering” processes
 - “immunizing mammals . . . according to said immunization schedule, and comparing the incidence [of] disorder . . . in the treatment group, with that in the control group.”

- ❖ Patentable?
 - Not limited to a specific drug or specific application
 - No analysis of particular interaction of vaccine with human body
 - Classen Panel already found not patentable

Making Sense Out of *Therasense*

- *Therasense Inc. v. Becton Dickinson* (Fed. Cir. 2010)
- Prior Law: Inequitable Conduct requires that omission or misrepresentation be;
 - Material to patentability
 - Made with Intent to deceive PTO
 - Kingsdown Medical (CAFC 1988)
- Problem – Conflicting CAFC Decisions that merge materiality and intent
- Clarification needed to enable compliance by Attorneys and Patentees

Therasense Facts

- Patentee made statements to USPTO that were inconsistent with statements made to EPO about foreign counterpart of prior art reference cited during US prosecution
- District Court found Inequitable Conduct because Patentee knew statements to PTO were inconsistent with statements to EPO
- Affirmed by CAFC (2010)
- Petition for rehearing en banc granted
- Argued to full CAFC November, 2010
- Decision (probably March 2011)

What to do?

- Failure to make reasonable inquiry can be a problem
 - Buried reference anticipates a claim
 - Application filed with claim anticipated by inventor's prior publication
- Today, continue to disclose EVERYTHING
 - Prior art
 - Foreign office actions
 - Foreign search reports
 - Inventorship challenges
 - Query whether letters from opposing parties describing prior art should be turned in?
- Maybe we will have a better rule in the future, but there is a risk from non-disclosure today

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