




The New U.S. Patent Law and Other Recent Developments in Patents and Investor Perspective in Global IP Management

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**§101 Patent Eligibility:
*Myriad, Prometheus and Classen***

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35 U.S.C. §101


- **§101 Inventions patentable.**
 - Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.



Three Exceptions

- Laws of nature
- Physical phenomenon
- Abstract ideas







Patent Eligible Subject Matter


What types of compositions of matter can be patented?

- Isolated DNA , proteins, other compounds found in nature?

What types of methods can be patented?



- Diagnostic and analytical methods?
- Therapeutic methods?


 



Patentable Subject Matter: *Myriad*



- *Ass'n for Molecular Pathology v. USPTO* (Fed. Cir. July 29, 2011)
 - Also known as ACLU/Myriad gene patenting case
 - Background: Plaintiffs challenge validity of Myriad's patents with claims directed to isolated DNA and methods of using the genes in diagnosis


 



Patentable Subject Matter: *Myriad*



- Plaintiffs argue that isolated genes are products of nature and therefore are non-statutory subject matter
- Plaintiffs argue that diagnostic method claims only recite mental steps and are non-statutory subject matter



Patentable Subject Matter: *Myriad*

- District court summary judgment decision held all claims of Myriad's patents invalid
- Myriad appealed to U.S. Court of Appeals for Federal Circuit
- Federal Circuit held as patent eligible:
 - isolated DNA claims patent eligible and method of screening claims patent eligible
- Federal Circuit held as patent ineligible:
 - method of analyzing and comparing DNA sequences patent ineligible



Patentable Subject Matter: *Myriad*

Representative composition claims:

U.S. Patent No. 5,747,282


1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having an amino acid sequence set forth in SEQ ID NO:2.
2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.
5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.



Patentable Subject Matter: *Myriad*

- Rationale of decision (composition claims):
 - Patentability of compositions turns on what is “markedly different” from what is found in nature.
 - Majority opinion states that isolated DNA is not a purified form of a natural material, but a distinct chemical entity
 - Structural distinctions should be sufficient
 - But other portions of opinion indicate that functional differences between what is found in nature may be sufficient to satisfy “markedly different.”






 **Patentable Subject Matter: *Myriad***

Representative method claims:
U.S. Patent No. 6,033,857


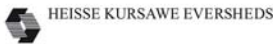
1. A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises **comparing** the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence wherein a difference between the suspected mutant and the wild-type sequences identifies a mutant BRCA2 nucleotide sequence.


* Other claims recite “**analyzing**” a sequence, although one claim recites “**growing**” a cell.

 **Patentable Subject Matter: *Myriad***

- Rationale of decision (method claims):
 - Court’s decision regarding comparing/analyzing claims unanimous
 - Court found the claimed methods contained only mental processes and therefore patent ineligible. Comparison of two sequences can happen by inspection alone.
 - Screening claim patent eligible because recited transformation step and measuring step.

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- Current Status:
 - Myriad filed a petition for panel rehearing
 - Myriad challenges standing of ACLU plaintiffs
 - Federal Circuit found only one plaintiff had standing and status may have changed since decision
 - Petition denied on September 16, 2011
 - ACLU also filed a petition for panel rehearing
 - Cited factual and legal errors regarding an issue of standing and patent eligibility
 - Petition denied on September 13, 2011
 - Supreme Court?



Patentable Subject Matter: *Prometheus*

- *Prometheus Labs v. Mayo* (2010):
 - Prometheus's claims relate to personalized methods of optimizing the dose of specific drugs used to treat gastrointestinal autoimmune diseases.
 - Prometheus patent claims are directed to (i) “administering” a drug to a subject, (ii) “determining” metabolite levels of the drug, and (iii) comparing metabolite levels in the subject to a reference metabolite level, “wherein” the measured levels “indicate a need” to increase or decrease drug dosage





Patentable Subject Matter: *Prometheus*

- District court held claims not patentable subject matter
- Fed Cir (2009) reversed and held method claims patentable subject matter.
- Supreme Court vacated the Federal Circuit's *Prometheus* decision and remanded for a new opinion.
- Fed Cir (2010) arrived at same conclusion for same reasoning as before – claims patentable.



Patentable Subject Matter: *Prometheus*

- Representative claims
 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
 - (a) **administering** a drug . . . ; and
 - (b) **determining** the level of [drug metabolite] in said subject having said immune-mediated gastrointestinal disorder, wherein the level [drug metabolite] less than [a reference level] indicates a need to increase the amount of said drug subsequently administered to said subject; and wherein the level of [drug metabolite] greater than [a reference level] indicates a need to decrease the amount of said drug subsequently administered to said subject.





Patentable Subject Matter: *Prometheus*

46. A method of optimizing therapeutic efficacy and reducing toxicity associated with treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) **determining** the level of [drug metabolite] in a subject administered a drug. . . ,

wherein the level of [drug metabolite] less than [a reference level] indicates a need to increase the amount of said drug subsequently administered to said subject,

and

wherein the level of [drug metabolite] greater than [a reference level] indicates a need to decrease the amount of said drug subsequently administered to said subject.

- Although many claims recite both an "administering" step and a "determining" step, some claims recite only a "determining" step



Patentable Subject Matter: *Prometheus*

- Rationale of Federal Circuit 2010 decision:
 - Federal Circuit applied the “machine or transformation test” for method claims.
 - methods of treatment claims are always transformative because drug administered is transformed into a different state or thing (chemical and physical changes of drug), and this transformation is central to the claimed process





Patentable Subject Matter: *Prometheus*

- Rationale of decision (cont'd):
 - Determining step is also transformative because determining the levels of metabolites in a subject necessarily involves a transformation because that cannot be determined by mere inspection.
 - Specification and claims described specific detection methods that were transformative



Patentable Subject Matter: *Prometheus*

- Current status:
 - March 2011, Mayo filed petition for certiorari to the U.S. Supreme Court
 - Certiorari was granted, briefs due October 2011, oral argument scheduled for December 2011





Patentable Subject Matter: *Classen*


- *Classen Immunotherapies, Inc. v. Biogen IDEC* (2011)
 - Background: Classen asserted three patents against Biogen Idec and other defendants who participated in studies evaluating the risks associated with different vaccination schedules.
 - Patents are based on Dr. Classen's discovery that the particular schedule of infant immunization for infectious diseases can affect the later occurrence of chronic immune-mediated disorders such as diabetes, asthma, hay fever, cancer, multiple sclerosis, and schizophrenia.



Patentable Subject Matter: *Classen*



- Classen's claims to a method of determining whether an immunization schedule affects the incidence or severity of a condition which comprises (1) immunizing animals and (2) comparing the treatment group with the control group.






Patentable Subject Matter: *Classen*


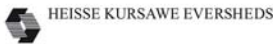
- District Court (2006) held claims invalid for patenting abstract idea
- Fed Cir (2008) affirmed district court decision
- June 2010 Supreme Court also issued GVR order --remanded case back to Fed Cir in view of *Bilski* 2010 decision
- Fed Cir (2011) held certain method claims not patent eligible, others okay







Patentable Subject Matter: *Classen*



- Representative claims:
US 6,638,739 and US 6,420,139
 1. A method of **immunizing** a mammalian subject which comprises:
 - (I) **screening** a plurality of immunization schedules . . . by
 - (a) **identifying** [first and second patient populations that were immunized with] . . . “infectious disease-causing organism-associated immunogens according to” . . . [first and second immunization schedules] and
 - (b) **comparing** the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder ...
 - (II) **immunizing** said subject according to a subject immunization schedule . . . [with] . . . lower risk





 **Patentable Subject Matter: *Classen***

– Rationale of decision:

- the Federal Circuit finds that the ‘139 and ‘739 patents are directed to “a method of lowering the risk of chronic immune-mediated disorder,” and so “are directed to a specific, tangible application.”



 

 **Patentable Subject Matter: *Classen***

– Representative claims:

US 5,723,283

1. A method of **determining** whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder . . . which comprises **immunizing** mammals . . . and **comparing** the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.



Patentable Subject Matter: *Classen*

- Rationale of decision:
 - Claims of 283 patent not patent eligible
 - Claims relate to "methods of 'determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder,' by reviewing information on whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder."
 - No subsequent "action" step, e.g., immunization step, tied to method
 - Knowledge gained from comparison step not put to practical use.



Patentable Subject Matter: *Classen*

- Current Status:
 - Petition for rehearing or cert?





Possible Practice Tips: Products

- Consider drafting claims to “isolated” products instead of “purified” products.
- Consider describing how an “isolated” version of the product differs from a form that is “purified” or “a physical separation”.
- Consider describing (or identifying) in the specification how the “isolated” product is structurally and chemically distinct from what is found in nature.
 - e.g., describe chemical manipulations
 - any covalent bonds broken during isolation?



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Possible Practice Tips: Products

- Consider describing (or identifying) in the specification any new uses or functions of the claimed product, as compared to a natural product in its natural environment.



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Possible Practice Tips: Products

- Include claims directed to commercial embodiments.
- Include claims reciting a modified version of the product
- Include claims reciting the product plus something else, e.g., a pharmaceutical excipient or buffer in the case of pharmaceuticals



Possible Practice Tips: Methods

- For process claims, consider explicitly reciting at least one active, physical transformative step associated with the process, e.g., an aspect of a laboratory technique (purifying, labeling, detecting, administering, etc.)





Possible Practice Tips: Methods

- Consider drafting method claims that involve the use of a machine, e.g., an apparatus used to sequence a nucleic acid or protein, or to measure a particular parameter.
- Although a “determining” step may not be a mental process step if it cannot be performed by mere inspection, consider adding language that also recites the manipulation step that permitted the determination step to occur.
 - e.g., obtaining a blood sample before level of metabolites determined.



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Possible Practice Tips: Methods

- For other method claims, consider including at least one “end result” step that follows an analysis or comparison, e.g., adjusting a dosage or treatment protocol, or other act ultimately tied to the purpose of the method being conducted.
- But be careful to avoid a joint infringement situation, i.e., try to provide claims that are likely to be infringed by a single infringer, or recite steps that will be directed by a single entity.



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Possible Practice Tips

- For issued patents of particular significance, consider filing a reissue application, as needed to add or amend claims to recite additional features to support patent-eligibility
- Continuations



Thank you for your attention!

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