MATTO Seminar

Diagnostic Inventions:
What is Patentable after Prometheus?

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Patentable Subject Matter

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvements thereof, may obtain a patent therefore, subject to the conditions and requirements of this title (35 U.S.C. §101)
Why does patent eligibility matter?

- Patent prosecution
- Investment due diligence
- Licensing
- Litigation
PerkinElmer, Inc. v. Intema Ltd.

Issue:

Whether claims directed to methods of determining the risk of fetal Down’s syndrome are patent-eligible under 35 U.S.C. § 101
PerkinElmer claims involved:

- **Measuring** the levels of screening markers from ultrasound scans in the first and second trimesters, and

- **Determining** the risk of Down’s syndrome by **comparing** the measured levels of the screening markers with observed relative frequency distributions of marker levels in Down’s syndrome pregnancies and in unaffected pregnancies.
PerkinElmer Findings

- The claims are not patent eligible under 35 U.S.C. § 101

- The claims recite:
  - a mental process, namely “comparing data to determine a risk level,”
  - and a law of nature, namely “the relationship between screening marker levels and the risk of fetal Down’s syndrome.”
PerkinElmer Findings, Cont.

- The “measuring” and “comparing” steps not sufficient to be a patent-eligible application
- Steps use known, conventional information
- Assaying can be performed without transforming the sample, “should science develop a totally different system ... that did not involve such a transformation.”
- Ultrasound scan recital does not necessarily involve the transformation of data.
Patentable Subject Matter

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(35 U.S.C. §101)
Patentability if the claimed invention:

- (1) directed to one of the four statutory categories: process, machine, manufacture, composition of matter;

and

- (2) not wholly directed to a judicially recognized exception.
Exceptions and Patentability

1. Law of Nature
2. Physical Phenomena
3. Abstract Ideas
4. Exception to the exceptions – partial use of 1-3
“The concept covered by these exceptions are part of the storehouse of knowledge of ‘all men, free to all men and reserved exclusively to none’”

-U.S. Supreme Court, *Bilski* (2010), quoting *Funk Brothers Seed Co.*, (1948)
- **Benson** (1972) – algorithms to connect binary code
- **Flook** (1978) – catalytic reaction by mathematics for all steps
- **Diehr** (1981) – chemical reaction using mathematics for some steps
Exceptions

- Laws of nature, natural phenomena, and abstract ideas
  - “[P]atents cannot issue for the discovery of the phenomena of nature . . . , free to all men and reserved exclusively to none.” *Funk Bros. v. Kalo Inoculant Co.*

  - “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are . . . the basic tools of scientific and technological work” *Gottschalk v. Benson*
Application of the law can be Patentable

“an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection, BUT:

- “the prohibition against patenting abstract ideas ‘cannot be circumvented by attempting to limit the use of the formula to a particular technological environment’ or adding ‘insignificant postsolution activity’”

- One must do more than simply state the law of nature while adding the words “apply it”
Relevant Precedent

- “... The “novelty” of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the §101 categories of possibly patentable subject matter.” (Diehr)

- “[Diehr] nowhere suggested that all these steps...were in context obvious, already in use, or purely conventional. ...--they transformed the process into an inventive application of the formula.” (Prometheus)
USPTO Factors for Considering Patentability

Factors To Be Considered in an Abstract Idea Determination of a Method Claim

- (a) Whether the method involves or is executed by a particular machine or apparatus
- (b) Whether performance of the claimed method results in or otherwise involves a transformation of a particular article
- (c) Whether performance of the claimed method involves an application of a law of nature, even in the absence of a particular machine, apparatus, or transformation
- (d) Whether a general concept (which could also be recognized in such terms as a principle, theory, plan or scheme) is involved in executing the steps of the method
Is it too General? (USPTO Factors)

- Whether a general concept (which could also be recognized in such terms as a principle, theory, plan or scheme) is involved in executing the steps of the method
  
  (a) The extent to which use of the concept, as expressed in the method, would preempt its use in other fields;
  
  (b) The extent to which the claim is so abstract and sweeping as to cover both known and unknown uses of the concept, and be performed through any existing or future-devised machinery, or even without any apparatus;
Is it too General? (USPTO Factors, Cont.)

- (c) The extent to which the claim would effectively cover all possible solutions to a particular problem;
- (d) Whether the concept is disembodied or implemented, in some tangible way;
- (e) Whether the performance of the process is observable and verifiable rather than subjective or imperceptible.
USPTO Examples of general concepts

- Basic economic practices or theories (e.g., hedging, insurance, financial transactions, marketing);
- Basic legal theories (e.g., contracts, dispute resolution, rules of law);
- Mathematical concepts (e.g., algorithms, spatial relationships, geometry);
- Mental activity (e.g., forming a judgment, observation, evaluation, or opinion);
USPTO Examples of general concepts, Cont.

- Interpersonal interactions or relationships (e.g., conversing, dating);
- Teaching concepts (e.g., memorization, repetition);
- Human behavior (e.g., exercising, wearing clothing, following rules or instructions);
- Instructing “how business should be conducted.”
Mayo Collaborative Services v. Prometheus Laboratories

Issue:

Whether claims directed to methods of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder were patent-eligible under 35 U.S.C. § 101
**Mayo: What the inventors contributed**

- **What was already known:**
  - use of 6-MP and azathioprine to treat IBD
  - 6-MP is converted to metabolites such as 6-methyl-mercaptopurine and 6-TG in the patient
  - measurement of 6-MP metabolite levels can be used to predict clinical efficacy and tolerance to azathioprine or 6-MP

- **Discovery:** the *level* at which concentration of the metabolites correlated with optimized therapeutic efficacy and toxicity
1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) **administering** a drug providing 6-thioguanine (6-TG) to a subject having said immune-mediated gastrointestinal disorder; and

(b) **determining** the level of 6-TG in said subject having said immune-mediated gastrointestinal disorder,

– wherein the level of 6-TG less than about 230 pmol per 8 x 10^8 red blood cells (rbcs) indicates a need to increase the amount of said drug subsequently administered to said subject and

– wherein the level of 6-TG greater than about 400 pmol per 8 x 10^8 rbcs indicates a need to decrease the amount of said drug subsequently administered to said subject.
Mayo History

- District Court Decision:
  - The patent claims are not patent-eligible

- Federal Circuit I: Reversed the District Court decision
  - The patent claims are eligible

- Supreme Court: Vacated and remanded back to FC

- Federal Circuit II: Reiterated its previous decision

- Supreme Court Decision: The patent claims are not patent-eligible
Mayo Supreme Court Findings

- Administering step
  - Limits claim scope to a particular environment or audience

- Determining step
  - Not specific; tells doctors to determine the patient’s metabolite levels using any process they wish
  - Well-understood, routine and conventional activity

- Wherein clause
  - Recitation of the relevant natural law / natural phenomenon
  - At most, a suggestion they should consider the test results when making their treatment decisions
Mayo Supreme Court Holding

- The claims are not patent eligible under 35 U.S.C. § 101
- The administering and detecting steps are not sufficient to confer patent eligibility
- “Transformation” alone is not sufficient
- Limiting claims to a particular technological field is not sufficient either
  - Not the same as reciting a specific application
AMP v. Myriad Genetics

Issue:

Whether claims directed to isolated BRCA1 and BRCA2 genes and related diagnostic methods, and methods to identify drug candidates, are patent-eligible under 35 U.S.C. § 101
Myriad Representative Claims

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

- **Method Claims**
  - A method for detecting a germline alteration in a BRCA1 gene . . . which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample ...
Myriad Representative Claims

- Method Claims

- A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises...
  - comparing a first sequence... made from mRNA from said tumor sample with a second sequence...

- A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene..., growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth..., wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.
Myriad History

- District Court Decision
  - The patent claims are not patent-eligible

- Federal Circuit I:
  - Reversed district court's decision that an isolated DNA sequence is patent-ineligible, and district court's decision that methods for screening cancer therapeutics is patent-ineligible
  - Affirmed district court's decision that claims for comparing DNA sequences are patent-ineligible

- Supreme Court: Vacated and remanded back to FC

- Federal Circuit II: Reiterated its previous holding

- Supreme Court Decision: To be decided
“[T]he [isolated DNA] claims are drawn to patentable subject matter because the claims cover molecules that are markedly different—have a distinctive chemical identity and nature—from those found in nature.”

The method claims that recite only “‘comparing’ or ‘analyzing’ two gene sequences fall outside the scope of §101 because they claim only abstract mental processes.”

The method claims for screening potential cancer therapeutics are patent eligible because the “growing” step is transformative and does more than simply apply a law of nature.
Claim drafting suggestions

- Consider restructuring your diagnostic claim as a therapeutic claim.
- Consider adding:
  - Novel steps/novel combinations of steps
  - Steps incorporating a machine or transformation which is demonstrably integral to the claimed invention.
    - E.g., Novel algorithm, performed on a computer
Claim drafting suggestions

- Consider adding steps incorporating a machine or transformation or “active” step
  - Must be integral to the claimed invention.
    - Potential Examples:
      - Use of a novel algorithm, performed on a computer
      - Isolating cells and extracting nucleic acids...
      - Growing cells
      - “assaying”, “amplifying”, “sequencing”, hybridizing”, possibly
  
- Consider adding dependent claims with additional features
Claim drafting suggestions

- Consider claiming certain features more narrowly
  - Specific panels of markers
  - Specific samples (e.g., blood, urine or saliva)
  - Specific assays to determine/detect/measure

- Present claims of differing scope in the patent application
Claim drafting suggestions

Consider other (non-diagnostic method) types of claims to capture the invention, e.g.:

- Isolated genes and cDNAs (possibly, see *Myriad*)
- Compounds, e.g., therapeutics
- Novel uses (e.g., disease treatment) of a known compound
- Cell lines, plasmids, gene constructs
- Novel antibodies/antibodies to novel antigen
- Novel Assays and assay steps
- Transformative methods of drug screening
Questions?

Thank you

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