Myriad and *Prometheus* and Molecular Diagnostics – Oh My!

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Patentable Subject Matter
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Matthew Pavao, Ph.D.

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Overview

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Inconsistent

Contradictory

Dangerous

Irresponsible

Evolving

In Flux

Vague

Overview *(cont'd.)*

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- Prometheus and Myriad + Alice in Wonderland
  - U.S. Supreme Court Decisions – Clarity or Confusion?
- USPTO Interim Guidance on Patent Subject Matter Eligibility
  - Three Part Test – Improved Framework or No?
- More Recent U.S. Court Decisions
  - Federal Circuit to the Rescue?
- USPTO Prosecution Trends
  - Strategies for Obtaining Patentable Subject matter

35 U.S.C§101

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- 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.

Except

- Laws of Nature, Natural Phenomena and Abstract Ideas

Prometheus (2012)

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

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

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

wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

- Federal Circuit – Transformative Steps (*Bilski v. Kappos* - 2010)
- Supreme Court - Drafting efforts designed to monopolize the correlation between the naturally-produced metabolites and therapeutic efficacy
- A newly discovered law of nature is itself unpatentable and the application of that newly discovered law is **normally unpatentable if the application merely relies upon elements already known in the art**.

Myriad (2013)

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

A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human 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 with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.ell in the presence of said compound is indicative of a cancer therapeutic.

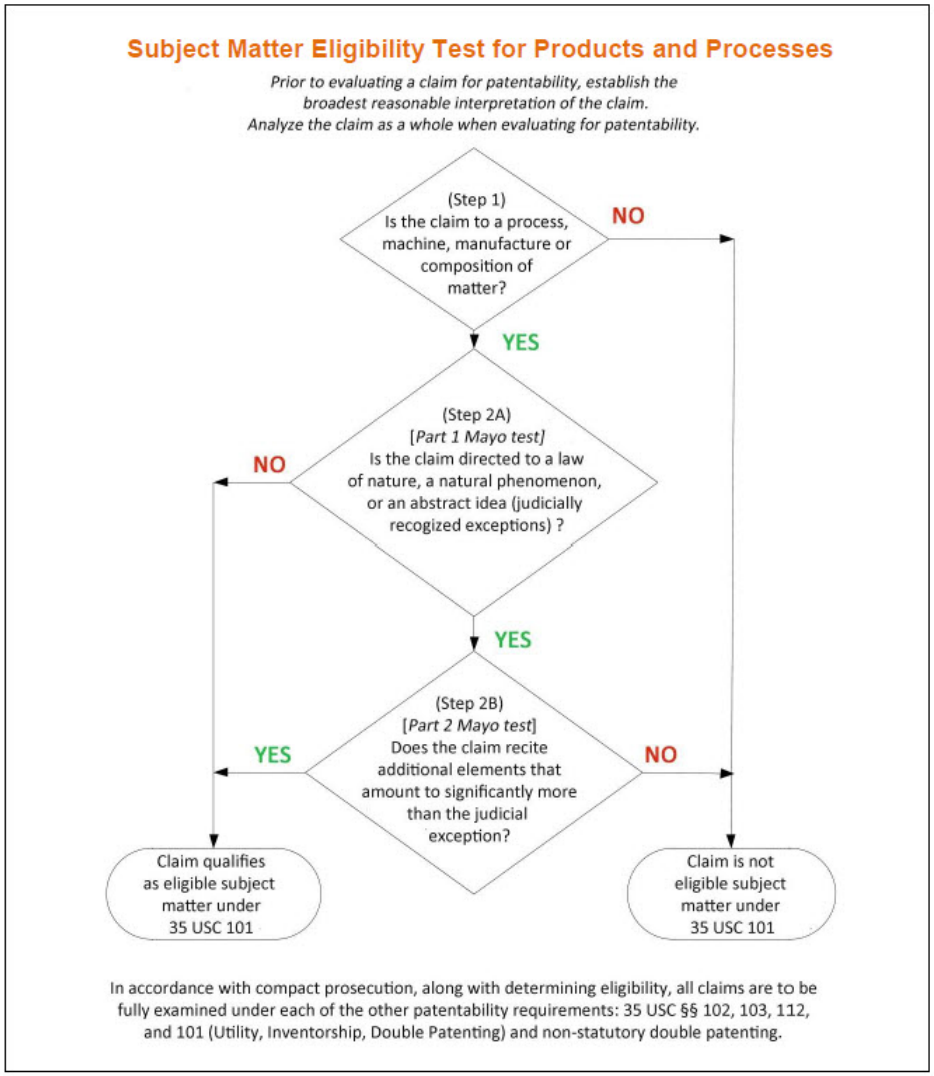
- Federal Circuit – Isolated DNA is Chemically Distinct; Comparison Methods Only Contain Abstract Method Steps (*Mayo*)
- Supreme Court (Products) – Isolating is Insufficient; cDNA is Non-Naturally Occurring
- Supreme Court (Methods) – "This case does not involve patents on ***new applications*** of knowledge about the BRCA1 and BRCA2 genes"

Alice (2014)

A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange institution, the credit records and debit records for exchange of predetermined obligations, the method comprising the steps of: (a) creating a shadow credit record and a shadow debit record for each stakeholder party to be held independently by a supervisory institution from the exchange institutions; (b) obtaining from each exchange institution a start-of-day balance for each shadow credit record and shadow debit record; (c) for every transaction resulting in an exchange obligation, the supervisory institution adjusting each respective party's shadow credit record or shadow debit record, allowing only these transactions that do not result in the value of the shadow debit record being less than the value of the shadow credit record at any time, each said adjustment taking place in chronological order; and (d) at the end-of-day, the supervisory institution instructing ones of the exchange institutions to exchange credits or debits to the credit record and debit record of the respective parties in accordance with the adjustments of the said permitted transactions, the credits and debits being irrevocable, time invariant obligations placed on the exchange institutions.

- Federal Circuit (*en banc*) – 10 member panel decided patent-ineligible
- Supreme Court – Cited Mayo "abstract idea" and "substantially more" test; Claims are "drawn to an abstract idea and merely requiring generic computer implementation fails to transform that idea into a patent-eligible invention"

Interim Guidance – December 15, 2014



Three-Step Test

- Step 2A
  - Directed To
  - Markedly Different
- Step 2B
  - Significantly More
- Streamlined Analysis
  - "Tie Up" or Monopolize a Law of Nature
- 21 Working Examples

Interim Guidance *(cont'd.)*

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- Directed To
  - The judicial exclusion is or forms part of the technical features of the invention as defined (and not merely that the exclusion is involved)

- Markedly Different
  - Difference in Structure, Function and/or Properties – Compared to Natural Equivalent
  - Purified or Isolated Natural Product – Patent eligible when there is a resultant change in characteristics that shows it is different from the naturally occurring form (Antibiotic)
  - Combinations of Natural Products (Ex. Juice/Preservative, Gun Powder)
  - Modified Natural Products (Ex. Fluorescently Labeled Nucleic Acid)
  - Antibodies (Ex. Humanized, Specific CDR Sequences)
  - Methods of Treatment (Doesn't Require Markedly Different Analysis) – Focused on practically applying the product to treat a particular disease and does not foreclose all uses of the product

- Streamlined Analysis
  - A claim that involves a nature-based product, or abstract idea "when viewed as a whole, clearly does not seek to tie up any judicial exception such that others cannot practice it"

Interim Guidance *(cont'd.)* – Significantly More

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- Qualifying Limitations
  - Adding a specific limitation other than what is well-understood, routine and conventional in the field, or adding unconventional steps that confine the claim to a particular useful application (*Mayo*)
  - Improvements to another technology or technical field (*Alice*)
  - Improvements to the functioning of the computer itself (*Alice*)
  - Applying the judicial exception with, or by use of, a particular machine (*Bilski*)
  - Effecting a transformation or reduction of a particular article to a different state or thing (*Diehr*)
  - Other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment (*Alice*)
- Non-Qualifying Limitations
  - Adding insignificant extra-solution activity to the judicial exception, e.g., mere data gathering in conjunction with a law of nature or abstract idea (*Mayo*)
  - Generally linking the judicial exception to a particular technological environment or field of use (*Mayo*)
  - Adding the words "apply it" (or an equivalent) with the judicial exception, or mere instructions to implement an abstract idea on a computer (*Alice*)
  - Simply appending well-understood, routine and conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, *e.g.*, a claim to an abstract idea requiring no more than a generic computer to perform generic computer functions that are well-understood, routine and conventional activities previously known to the industry (*Alice*)

U.S. Federal Circuit

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- Univ. of Utah Research v. Ambry Genetics – December 17, 2014

A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene.

A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject, wherein a germline nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to genomic DNA isolated from said sample and detecting the presence of a hybridization product wherein a presence of said product indicates the presence of said allele in the subject.

- Primers – Patent Ineligible
- Methods – Analyzed under Alice (Not Mayo) – Comparison is Abstract Idea
- Hints? – Noted that method claims not for any specific purpose (Ex. Method of determining breast or ovarian cancer risk employing the comparative step for detection of mutated BRCA1 that correlated to cancer risk).

U.S. Federal Circuit *(cont'd.)*

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- American Bar Association's Section of Intellectual Property Law Conference – March 26, 2015

- "It seems to me that the Federal Circuit is absolutely terrified. I think they're going to bend over backwards to not look like they're bucking the Supreme Court."
  - Paul Michel (former Chief Judge of the Federal Circuit – retired in 2010)

- "What is an abstract idea?" "There really is no test for that. It's very difficult to come up with a test on what is an abstract idea."
  - Robert Bahr (USPTO Senior Patent Counsel)

USPTO Prosecution Trends

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- A method of diagnosing disease X in a patient by detecting biomarker Y.
- A method of diagnosing disease X in a patient by detecting biomarker Y, wherein biomarker Y is detected using novel antibody Z.
- A method of diagnosing disease X in a patient by detecting biomarker Y, wherein biomarker Y is detected using novel assay Z.
- A method of diagnosing disease X in a patient by detecting a combination of biomarkers A, B and C, wherein the patient is diagnosed with disease X if biomarkers A, B and C are detected.

USPTO Prosecution Trends *(cont'd.)*

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- A method of diagnosing and treating disease X in a patient comprising detecting biomarker Y, wherein the patient is diagnosed with disease X if biomarker Y is detected; and administering drug Z to treat the disease.

- A method of diagnosing and treating disease X in a patient comprising requesting a test providing the results of an analysis to detect biomarker Y; and administering drug Z to treat the disease if biomarker Y is detected.

- A therapeutic composition for treating disease X in a patient comprising drug Z, wherein drug Z demonstrates efficacy against disease X in patients expressing biomarker Y.

USPTO Prosecution Trends *(cont'd.)*

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- A biomolecular tool (kit/antibody/probe) to detect biomarker Y in a patient, wherein the absence of biomarker Y indicates the presence of disease X.

- A method of diagnosing disease X in a patient, wherein disease X is characterized by the presence of biomarker Y comprising: (a) contacting a biological sample with a probe specific for biomarker Y, where the presence of biomarker Y forms a probe/biomarker Y complex; (b) contacting the probe/biomarker Y complex with an agent; and (c) diagnosing disease X in the patient when the agent from step (b) is detected.

Patentable Subject Matter

Cooley LLP

Matthew Pavao, Ph.D.

1-617-937-2340

mpavao@cooley.com