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2012: A Landmark Year for Patenting Biotechnology Related Inventions

**by Lisa C. Pavento
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Intellectual Property Lawyers



Biotechnology/Pharmacogenetic Claim Types

- ❖ A newly synthesized chemical/drug
 - A method of using a newly synthesized chemical/drug to treat a disease

- ❖ A newly discovered gene/nucleotide sequence/protein
 - Method of determining genetic predisposition to/diagnosing a disease
 - Method of using the gene to treat a disease (gene therapy)
 - Method of using protein to treat a disease

- ❖ Method of using a known drug or gene for the treatment or diagnosis of a new disease



A newly synthesized chemical/drug

- Still generally patentable subject matter, no change in the law based on cases decided by U.S. Supreme Court and Federal Circuit this year (not considering if new or non-obvious)
- Patenting issues that still remain: broadening the composition to a group of closely related drugs/chemical compositions
- Broaden by expansion of R group definitions



A method of using a newly synthesized chemical/drug to treat a disease

- Still generally patentable subject matter, no change in the law based on cases decided by U.S. Supreme Court and Federal Circuit this year
- Utility/Enablement and “treating” instead of “curing”
- In vitro or animal data can be sufficient to support claims directed toward therapeutic use in humans
 - “Reasonable” correlation between in vitro and in vivo required
 - Except for a disease for which there are no previously successful treatments



Biotechnology/Pharmacogenetic Claim Types

- ❖ A newly synthesized chemical/drug – Patentable subject matter
 - A method of using a newly synthesized chemical/drug to treat a disease – Patentable subject matter

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A newly discovered gene/nucleotide sequence/protein

- Up until March of 2010, newly discovered genes were held to be patentable compositions
- Held not patentable in *The Association for Molecular Pathology, et al v. Myriad Genetics* (District Court judge in New York)
- Case relates to BRCA1 and BRCA2 genes – mutations therein indicative of predisposition to breast and ovarian cancers



Isolated Gene – Patentable?

- Patentable subject matter requirement of 35 USC §101
- 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.
- However, “laws of nature, natural phenomena, and abstract ideas” are not patentable.



Isolated Gene – Patentable?

- “Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”
- Prevents Einstein from patenting $E=mc^2$ and Newton from patenting the law of gravity.
- Such discoveries are “manifestations of...nature, free to all men and reserved exclusively to none.”



Isolated Gene – Patentable?

- Product of Nature and therefore unpatentable?
- “Isolated” polynucleotide sequence “markedly different” than the same polynucleotide sequence found in nature?
- Answer was yes prior to March 2010
- DC judge in NY held not markedly different



Isolated Gene – Patentable?

- Federal Circuit decision July 2011 – isolated genes patentable
- Supreme Court decision March 2012 – directs back to Federal Circuit in view of Mayo v. Prometheus
- Federal Circuit decision August 2012 – isolated genes patentable
- Isolated DNA is eligible because it is man-made and is markedly different from that found in nature due to its “distinctive chemical structure and identity.”



Isolated Gene – Patentable?

Petition for Supreme Court to hear again – June 2013

Uncertainty until then?



Isolated Gene – Patentable?

In my opinion, isolated genes will be held as patentable

- Prior Supreme Court decision made clear that compositions of matter are not analyzed as laws of nature under *Prometheus v. Mayo*
- Supreme Court has not criticized Federal Circuit holding regarding isolated genes being man made and markedly different
- Public policy - thousands of patents would be invalidated otherwise



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Method of determining genetic predisposition to/diagnosing a disease – Patentable?

Myriad also had claims to:

- 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



Method of determining genetic predisposition to/diagnosing a disease – Patentable?

- Federal Circuit held the method not patentable
- Does this mean all genetic testing methods are not patentable?

Not likely – clever claim drafting should make patentable



Method of determining genetic predisposition to/diagnosing a disease – Patentable?

- Why was the claim held unpatentable?
- Considered twice by the Federal Circuit to be a patenting of “an abstract mental process”



Method of determining genetic predisposition to/diagnosing a disease – Patentable?

Federal Circuit

A **method** for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of...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

Abstract mental process



Method of determining genetic predisposition to/diagnosing a disease – Patentable?

- Could go back to Supreme Court – June 2013
- Will the Supreme Court find this claim patentable under the machine or transformation test?

Likely not.



Method of determining genetic predisposition to/diagnosing a disease – Patentable?

Supreme Court - Potentially

A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of...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

- | | |
|-------------------------------|--------------|
| 1. Method? | Yes |
| 2. Law of Nature? | Yes |
| 3. Machine or transformation? | No - nominal |



Method of determining genetic predisposition to/diagnosing a disease – Patentable?

Does that mean all genetic testing methods are henceforth unpatentable?

Some have said yes

I believe clever claim drafting can make patentable



Method of determining genetic predisposition to/diagnosing a disease – Patentable?

Federal Circuit Test

- Include more than mental processes and abstract ideas in the claim – specifically describe the transformation steps (hybridization, sequencing)
- Include a novel composition: Federal Circuit found a method claim in Myriad patentable subject matter because it recited the use of a transformed eukaryotic host cell containing an altered BRCA1 gene



Method of determining genetic predisposition to/diagnosing a disease – Patentable?

Supreme Court Test

- USPTO Guidelines indicate: “a claim that recites a novel drug or a new use of an existing drug, in combination with a natural principal, would be sufficiently specific to be eligible [under §101] because the claim would amount to significantly more than the natural principal itself.”



Method of determining genetic predisposition to/diagnosing a disease – Patentable?

Drafted as a Use of a Isolated and Novel Gene

A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of...which comprises ~~analyzing a sequence of~~ **sequencing a** BRCA1 gene or BRCA1 RNA from a human sample or ~~analyzing a sequence of~~ **sequencing a** BRCA1 cDNA made from mRNA from said human sample **by using an isolated BRCA1 polynucleotide sequence (defined to include all possible primer sequences)**



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Method of using a known drug or gene for the treatment or diagnosis of a new disease

- Subject of 2012 Supreme Court case Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.
- Claim was held unpatentable subject matter – law of nature (not a use of a new drug or gene)
- Are all methods of using a known drug or gene for treatment or diagnosis unpatentable subject matter?

NO



Method of using a known drug or gene for the treatment or diagnosis of a new disease

1. 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 GI disorder
 - b) determining a level of 6-thioguanine in said subject having said immune mediated GI disorder
 - c) wherein a level of 6 thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
 - d) greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.



Law of Nature Broadly Defined

- c) wherein a level of 6 thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
- d) greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

“While it takes human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body – entirely natural processes.”



Supreme Court Ineligible Subject Matter: Law of Nature

1. 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 GI disorder (**nominal transformation step**)
 - b) **determining** a level of 6-thioguanine in said subject having said immune mediated GI disorder (**nominal transformation step**)
 - c) **wherein a level of 6 thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and**
 - d) **greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.**



Why Transformations Were Nominal

- Administering step is nominal because it defines an audience that was pre-existing -- doctors already used thiopurine drugs (including 6-thiopurine) to treat these same patients
- Determining step is nominal because doctors were already measuring metabolite levels as part of their investigation into the efficacy and toxicity of thiopurine compounds



Add Transformation to Correct Prometheus Problem

1. 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 GI disorder (nominal transformation step)
 - b) **determining** a level of 6-thioguanine in said subject having said immune mediated GI disorder (nominal transformation step); and
 - c) **increasing** the amount of said drug subsequently administered to said subject to approximately XX **when a level of 6 thioguanine less than about 230 pmol per 8×10^8 red blood cells**; and
 - d) **decreasing** the amount of said drug subsequently administered to said subject to approximately XX **when the level is greater than about 400 pmol per 8×10^8 red blood cells**.



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Questions?

Please let us answer any questions that you may have.





Thank you!

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AIA Rules Taking Effect September 16, 2012

- Filing and prosecution by assignee allowed
 - Assignee to sign the power of attorney
- Inventor Oath/Declaration
 - Can delay filing up until application is in condition for allowance
 - May not want to delay in U.S. National stage application because patent term adjustment statute gives the USPTO 14 months from fulfillment of §371 that requires an oath/declaration.
 - Can be combined with the assignment