Patent Nation Seminar

The Supreme Court Decision(s) in *Myriad*: What Did the Justices Say? What Does It Mean for Industry?

FOLEY

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Presenters

Host:

- **Harold C. Wegner,** Partner, Foley & Lardner

Moderator:

- **Courtenay C. Brinckerhoff,** Partner, Foley & Lardner

Panelists:

- **The Honorable Paul R. Michel (ret.)**, United States Court of Appeals for the Federal Circuit
- **Kevin Noonan, Ph.D.**, Partner, McDonnell Boehnen Hulbert & Berghoff LLP
- **Hans Sauer, Ph.D.**, Deputy General Counsel for Intellectual Property, Biotechnology Industry Organization (BIO)

Presentation Format

- Background on § 101 and the Myriad case
- Summary of the Supreme Court decision
- Panel discussion
- Audience Q & A
- Concluding Remarks

Background

- 35 USC § 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.
- Not to be confused with:
  - §102 (novelty)
  - §103 (non-obviousness)
  - §112 (sufficiency of disclosure)

Background

Three Exceptions

- Laws of nature (*Prometheus*)
- Products of nature (*Myriad*)
- Abstract ideas (*Bilski*)

Background

Representative Myriad Claims (U.S. Pat. 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.
6. An isolated DNA having at least 15 nucleotides of the DNA of claim 2.

Background

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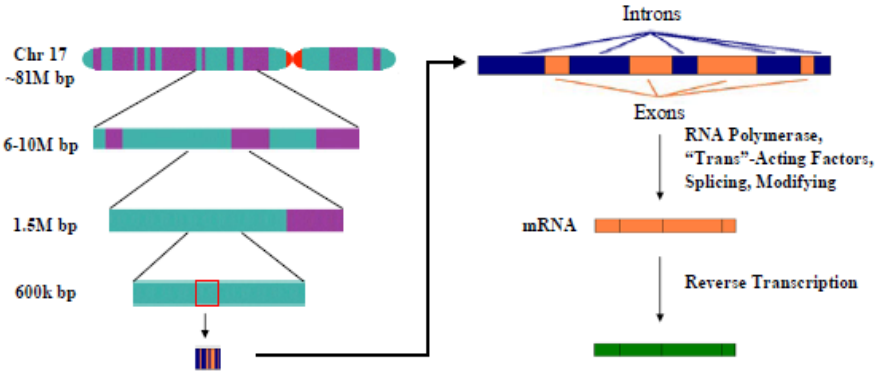
Natural Product Genomic Screening

1990 – 1993
Investigate Familial Data and conduct linkage analysis to narrow sequence embracing natural BRCA1 gene

Myriad Chemical Manipulation:
24 splicing sites

1994
Patent application covering BRCA1 cDNA construct



Isolated BRCA1 gene - 100,000 bp
(includes introns and exons)
20 coding exon segments = about 10% of gene

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Myriad-made BRCA1 cDNA construct - 5,914 bp
(no introns)
U.S. Patent #5,747,282, Claim 2, SEQ ID NO:1

Background

District Court Decision (SDNY 2010) (Sweet, J.)

- In light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences [between native and isolated DNA] render the DNA "markedly different." . . .
- The preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature.

Background

2011 Federal Circuit Decision

Split 2-1 decision upholding all DNA claims

- J. Lourie (most senior, only chemist)
  - Uphold all DNA claims because "isolated DNA" is "markedly different" based on "breaking covalent bonds"
- J. Moore – concurring opinion
  - also considered policy reasons

Background

2011 Federal Circuit Decision

- J. Bryson – dissenting opinion
  - "The isolated BRCA genes are identical to the BRCA genes found on chromosomes 13 and 17. They have the same sequence, they code for the same proteins, and they represent the same units of heredity."
  - "The naturally occurring genetic material has not been altered in a way that would matter under the standard set forth in *Chakrabarty*"
  - Upholds only cDNA claims

Background

2011-2012 Supreme Court Proceedings

- granted cert in *Myriad*
- decided *Mayo v. Prometheus*
- issued GVR in *Myriad*

2012 Federal Circuit Decision

- essentially the same as the 2011 decision

Supreme Court Decision

- Unanimous decision authored by Justice Thomas

  For the reasons that follow, we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.

- Justice Scalia's concurring opinion concurs in the judgment but steers clear of the discussion of the "fine details of molecular biology."

Panel Discussion

- After the oral hearing, some commentators criticized the Justices for discussing baseball bats and cookie recipes. Does this decision hold up from a scientific perspective?

Panel Discussion

- Do you think the Court would have had an easier time with the technology if this case had evolved as a patent infringement case, with a specific accused infringing product?
- Do you think the Court would have reached a different conclusion?

Panel Discussion

- The opinion says that the *Myriad* claims would give Myriad

  "the exclusive right to isolate an individual's BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes) by breaking the covalent bonds that connect the DNA to the rest of the individual's genome."

  How does this compare to methods that companies typically use to detect specific genetic mutations?

Panel Discussion

- Some commentators are saying that this decision will not undermine the biotech industry because most companies are not patenting isolated, naturally-occurring DNA anymore. Do you agree?
- Does the ability to patent cDNA adequately protect biotech companies primarily interested in making recombinant proteins?

Panel Discussion

- Does this decision reach other products that can be isolated from nature? (proteins, antibodies, small molecule chemicals?)
- Does this decision reach synthetic copies of products that can be isolated from nature?
- How can a chemical compound made in a lab be disqualified from patenting as a "product of nature"?

Panel Discussion

- During the oral hearing, several Justices suggested that Myriad might be able to obtain "use" claims related to its diagnostic methods, and the decision is careful to say that it is not ruling on the patent-eligibility of "new *applications* of knowledge about the BRCA1 and BRCA2 genes."

  Can these suggestions be reconciled with the Court's decision in *Mayo v. Prometheus*?

Panel Discussion

- §101 reads:

  Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter … may obtain a patent therefor …

  but the decision seems to criticize Myriad's contribution as mere "discovery."

  Did the Court read "discovery" out of the statute?

Panel Discussion

- In view of this decision, what incentives will companies have to undertake the “extensive efforts” required to discover, validate and develop genetic diagnostic tests?

Panel Discussion

- The opinion characterizes the patent system as striking "a delicate balance between creating "incentives that lead to creation, invention, and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention."

  Is the idea that patent-eligibility should be decided through this "balancing" lens new?

Panel Discussion

- Justice Thomas discusses the 1948 *Funk Brothers* case, where a combination of four naturally-occurring microbes was held not patentable.

  Does this decision end the debate over whether *Funk Brothers* was a "patent eligibility" case or an "obviousness" case?

Panel Discussion

- If *Funk Brothers* was a "patent eligibility" case, could it be cited against claims to a pharmaceutical composition comprising a protein isolated from a natural source?
  - What if the pharmaceutical composition is used to achieve the natural function of the protein (such a insulin)?

Panel Discussion

- Do you think “the sky is falling” for biotech patents?
- What strategies can be used to protect biotech inventions in view of *Mayo* and *Myriad*?
- Is there likely to be a legislative reaction to this case?

Audience Q&A

- We welcome questions from our audience.
- Please click “Q&A” on the menu bar and type in your question.

Concluding Remarks

- What do you want our audience to understand about the *Myriad* Supreme Court decision?

Thank You!

- We will circulate an e-mail to all registered audience members when the presentation materials and recording are available online.
- A PDF of the presentation materials can also be downloaded by clicking on the files tab on the right hand side of the AdobeConnect Web Conference screen.
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Survey

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