

**Panelists:**

- Alex Kozinski**, Chief Judge of US Court of Appeals for the Ninth Circuit
- Nathan Kelley**, Deputy Solicitor at US Patent and Trademark Office
- Ben Jackson**, Senior Director of Legal Affairs at Myriad Genetics
- Vern Norviel**, Wilson Sonsini Goodrich & Rosati
- Robert Barr**, BCLT & Berkeley Law
- Michael Shuster**, Fenwick & West

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1

## **Introduction to *Myriad***

Vern Norviel



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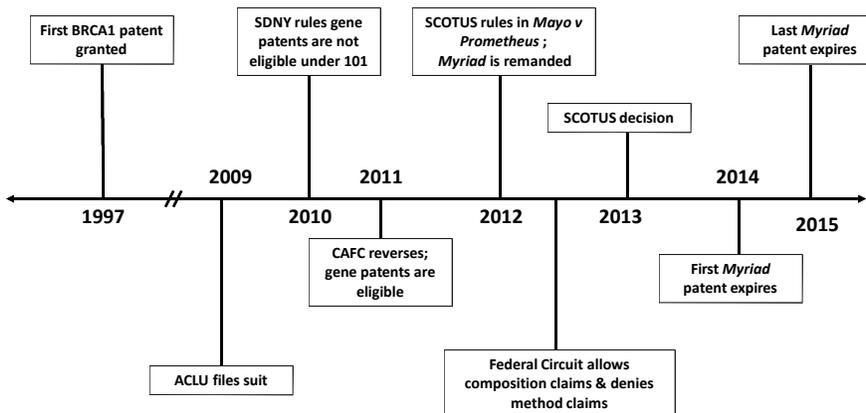
2

# Are human genes patentable?

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3

## Timeline



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4

***Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office,***  
**702 F. Supp. 2d 181 (S.D.N.Y. 2010)**  
March 29, 2010

- 15 claims contested; 7 patents (179 total claims)
  - Composition
  - Method
- “Are isolated human genes and the comparison of their sequences patentable?”
- Summary judgment granted
  - All 15 claims not eligible (35 U.S.C. § 101)

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5

**Exemplary uncontested composition claim**

US 5,747,282

16. 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.

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6

### **Exemplary uncontested method claim**

US 5,710,001

19. A method for detecting an alteration in a BRCA1 gene from a tumor sample from a human subject, said alteration selected from the group consisting of the alterations set forth in Tables 11 and 12, which comprises analyzing a BRCA1 gene or BRCA1 RNA isolated from said tumor sample or analyzing a BRCA1 cDNA made from mRNA isolated from said tumor sample for the presence of said alteration.

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7

### **Exemplary contested composition claims**

US 5,747,282

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the 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.

\* SEQ ID NO: 1 is a 5,914 nucleotides BRCA1 cDNA sequence.

\* SEQ ID NO: 2 is a 1,863 amino acid BRCA1 polypeptide.

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8

## Exemplary contested method claim

US 5,753,441

1. 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.

5650226

9

*Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office,*  
**653 F.3d 1329**  
 July 29, 2011

- Reverse composition claims
  - The “molecules as claimed do not exist in nature” because they are isolated DNA
  - Isolated DNA molecules are “markedly different--have a distinctive chemical identity and nature--from molecules that exist in nature.”
- Affirm method claims
  - “analyzing” or “comparing” DNA does not include transformative steps.

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10

### Did the CAFC get the science right?

- Isolated DNA fragments occur in nature
  - e.g. cell-free DNA

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11

***Mayo Collaborative Services v. Prometheus, Inc.,***  
**132 S. Ct. 1289 (2012)**  
March 20, 2012

- Thiopurine drugs to treat autoimmune diseases
  - Claims: administer + determine + wherein
- A “determining” step is not sufficient to transform unpatentable natural correlations

***Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office***  
**132 S. Ct. 1974 (2012)**  
March 26, 2012

- SCOTUS remands to CAFC in light of *Mayo*.

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12

***Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office***  
**689 F.3d 1303 (Fed. Cir. 2012)**  
August 16, 2012

- Allowed composition claims
- Denied method claims (except one)
  - “analyzing” or “comparing” are not transformative steps

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13

### **Eligible method claim**

20. A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.

5650226

14

***Ass'n for Molecular Pathology v. Myriad Genetics, Inc.***  
**569 U.S. \_\_\_\_ (2013)**  
June 13, 2013

- Justice Thomas:
- “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.”
- No claim-by-claim analysis

5650226

15

**Exemplary patentable claim?**  
US 5,747,282

2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO: 1.

\* SEQ ID NO: 1 is a 5,914 nucleotides BRCA1 cDNA sequence.

5650226

16

### **Exemplary unpatentable claims?**

US 5,747,282

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.

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17

### **Patentability unclear**

US 5,747,282

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

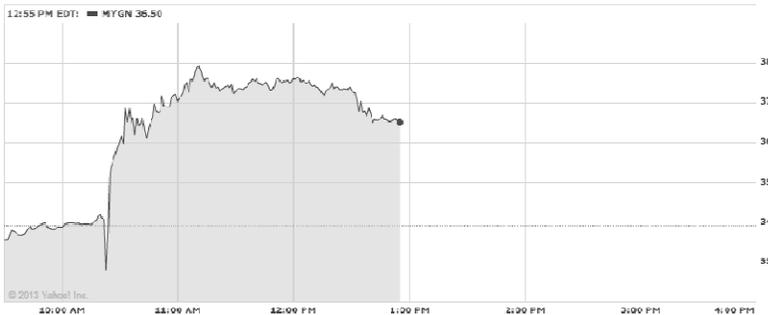
- Does natural DNA “code”?

\* SEQ ID NO: 2 is a 1,863 amino acid BRCA1 polypeptide.

5650226

18

### Myriad Stock



MYGN on Thursday June 14, at 12:55 pm

5650226

19

### Appendix

5650226

20