


## In preparation for the talk:

Before the talk, take 10 minutes to watch the following two video clips.

- ACLU-produced video segment:
  - <http://www.youtube.com/watch?v=6h6X46-qz14>
- Excerpt from documentary:
  - <http://www.youtube.com/watch?v=wffdT0T3wggw>
- Disclaimer: The following guest presentation is not intended to present an official position of BIO, any of its members, or the USPTO. While BIO has appeared as an *amicus curiae* in this case opposing plaintiffs' contentions, any views expressed in this presentation, and any errors or omissions, are the presenter's alone. No party to this case is a member or affiliate of BIO.



Perspectives on “Gene Patents:”  
*Association for Molecular Pathology et  
al. v. USPTO et al.:*

Guest Presentation at the June 1, 2010  
Biotechnology/Chemical/  
Pharmaceutical Customer Partnership  
Meeting,

United States Patent and  
Trademark Office

Hans Sauer,  
Biotechnology Industry Organization

# *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.*

- May 12, 2009; declaratory judgment action in Federal District Court (SDNY); challenges patent claims directed towards the BRCA1 and BRCA2 genes.
- Plaintiffs:
  - Association for Molecular Pathology;
  - American College of Medical Genetics;
  - American Society for Clinical Pathology;
  - College of American Pathologists
  - Laboratory clinicians and genetic counselors
  - Women's health activist groups
  - Individual women plaintiffs
- Represented by ACLU and PubPat Foundation
- Defendants:
  - USPTO;
  - Directors of University of Utah Res. Found.
  - Myriad Genetics Inc.



# *AMP, et al. v. USPTO, et al.*

## The challenged claims:

- **Patent claims alleged to cover natural human genes: e.g. U.S. 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.*
- **Patent claims alleged to cover natural human genes with natural mutations: e.g. U.S. 5,693,473**
- *An isolated DNA comprising an altered BRCA1 DNA having at least one of the alterations set forth in Tables 12A, 14, 18 or 19 with the proviso that the alteration is not a deletion of four nucleotides corresponding to base numbers 4184-4187 in SEQ. ID. NO:1.*



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## The challenged claims (2)

- Patent claims alleged to cover any method “of looking for mutations of natural human genes:” e.g. U.S. 5,709,999;
- *1. 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.*
- Patent claims alleged to cover “the thought that two genes are different, including the thought that [differences correlate with cancer susceptibility];” e.g. U.S. 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.*

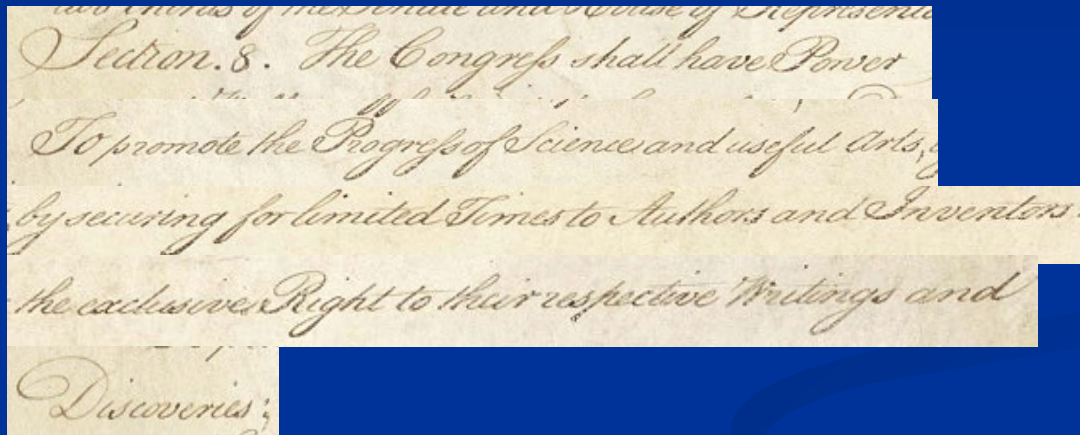
*AMP, et al. v. USPTO, et al.*  
Legal theory

- Legal arguments: The challenged claims are supposedly:
- invalid under 35 U.S.C. 101;
- unconstitutional under the First Amendment;
- invalid under Article 1, Section 8, Clause 8 of the Constitution

# *AMP, et al. v. USPTO, et al.*

## Invalidity under the IP Clause

- **Argument:** the claims are invalid under Article 1, Section 8, Clause 8 of the Constitution



- The patent claims are said to impede rather than promote the progress of science:
  - Patents are not necessary to incentivize the identification and sequencing of genes;
  - Patents are not necessary to incentivize physicians to conduct genetic testing and counseling;
  - Patents impede research, clinical development, and quality of genetic testing



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### Unconstitutionality under the First Amendment

- **Argument: the claims are unconstitutional under the First Amendment of the Constitution**
- *Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.*
- Analogy to copyright law: an idea is not copyrightable; but its expression is. Believed to have First Amendment roots.
- First Amendment prohibits Government from limiting human thought and available knowledge. The patents are said to do both, and are therefore unconstitutional.

## *AMP, et al. v. USPTO, et al.*

### Unconstitutionality under the First Amendment (2)

- For First Amendment purposes, claims divided into:
  - “Claims for reaching conclusions about the genes” (process claims)
  - “Claims to the genes themselves” (composition of matter claims)
- The **process claims** are said to preempt the mental act of comparing e.g. mutated with wild-type sequences and concluding e.g. that the carrier is cancer-susceptible. These claims are said to:
  - preempt human thought;
  - violate a right to scientific inquiry believed to reside in the First Amendment
- The **claims to the polynucleotides** themselves are said to cover genetic information. It is argued that the essence of a gene is the information it contains, and the composition of matter claims preempt all use of that information; amounting to a monopoly on pure genetic information (Granting patents = censoring newspapers or banning books).

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## Invalidity under 35 U.S.C. 101

- Method claims alleged to violate prohibition against abstract ideas or laws of nature;
- Nucleotide claims said to violate prohibition against patenting products of nature
- Examples of challenged method claims: U.S. 6,033,857
- 1. *A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises comparing the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence, wherein a difference between the suspected mutant and the wild-type sequences identifies a mutant BRCA2 nucleotide sequence.*
- 2. *A method for diagnosing a predisposition for breast cancer in a human subject which comprises comparing the germline sequence of the BRCA2 gene or the sequence of its mRNA in a tissue sample from said subject with the germline sequence of the wild-type BRCA2 gene or the sequence of its mRNA, wherein an alteration in the germline sequence of the BRCA2 gene or the sequence of its mRNA of the subject indicates a predisposition to said cancer.*



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## Invalidity under 35 U.S.C. 101

- Examples of challenged nucleotide claims: **U.S. 5,747,282**
- 2. *[An isolated DNA coding for a BRCA1 polypeptide,] wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.*
- The claim is said to be to a product of nature:
  - Claimed sequence is identical to natural sequence;
  - Encodes the same protein;
  - Mirrors the naturally-occurring mRNA
  - Serves no new function and has no different quality from the natural sequence
  - Isolating and/or purifying is not sufficient to confer patent-eligibility on a natural product;

## *Isolation and purification from nature*

- “Products of nature” would today typically be rejected under 35 U.S.C. 101.
- Caselaw dealing with “products of nature” is quite old and the legal foundation of the prohibition is unclear and unexplained. The issue sometimes seems to be novelty, sometimes obviousness, rarely patent-eligibility.
- *American Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. 566 (1874) (pure cellulose pulp preparation prepared by novel chemical process held not novel over prior art cellulose pulp preparations made by old process);
- *Cochrane v. BASF*, 111 U.S. 293 (1884)(claimed “artificial alizarine” prepared by new chemical process not novel over prior art impure alizarine extracts from madder root);
- *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931)(Borax-treated citrus fruit is insufficiently changed from natural fruit, and not a manufacture within the meaning of the Patent Act);
- *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)(claimed inoculate of mutually non-inhibitive root-nodule bacteria held not inventive over preexisting state of the art).

## *Isolation and purification from nature*

- Much of the caselaw on isolation and purification deals with distinguishing the invention over the prior art – not with determining whether the purified product is patent-eligible when the natural precursor is not in the prior art.
- When the question was unambiguously one of patent-eligibility, the Supreme Court has identified human intervention as the touchstone. *Diamond v. Chakrabarty*; (“the invention is not nature’s handiwork, but his own”), accord *J.E.M. Ag-Supply*
- *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.N.Y. 1911). (Purified adrenaline so superior to previous adrenal gland extracts so as to be different not just in degree, but in kind);
- *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156 (4<sup>th</sup> Cir. 1958).
- Concept supported by caselaw: the invention must have been transformed through human intervention from the natural thing into something that is qualitatively different, new, and man-made.
- **Never been addressed for “isolated and purified DNA.”**



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## Policy arguments

- Gene patents:
  - Are not necessary to incentivize gene discovery
  - Are not necessary to incentivize commercialization of gene tests
  - Lead to fewer genetic test providers
  - Cause inflated prices for genetic tests
  - Restrict patient access to genetic tests
  - Lead to lower quality of genetic tests and other genetic technology
  - Stifle basic or applied research into new or improved genetic technologies
  - Create infringement liability for women who donate cancer samples for research
  - Prevent patients from getting a second opinion

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## Public support

- Public support through many amicus briefs, press releases or supporting statements:
  - American Medical Association, American College of Obstetricians and Gynecologists, other medical associations;
  - March of Dimes, NORD, other patient groups; Greenpeace, Indigenous Peoples Council on Biocolonialism, others;
  - United Methodist Church, Southern Baptist Convention;
  - Gender / minority-focused civil rights groups.
- Amicus briefs opposing plaintiffs' position:
  - BIO ; Boston Patent Law Association; Rosetta Genomics; George Mason University; BayBio; Celera Corp., Genetic Alliance; Coalition for 21st Century Medicine; Genomic Health, Inc.; Qiagen, N.V.; Target Discovery, Inc.; XDx, Inc.; Kenneth Chahine; Kevin E. Noonan.

# *AMP, et al. v. USPTO, et al.*

## Status and context

- Status of the case:
  - Motions to dismiss denied Nov. 2, 2009; summary judgment motion heard Feb. 2.; Opinion issued Mar. 29.; Judgment entered Apr. 19.
- Discussion of the opinion
- Context of the case





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