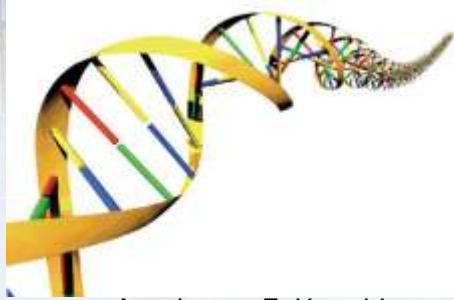


# The Gene Patenting Debate



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## Patent Law is Suddenly Public



- LA Law
- Law & Order
- Ally McBeal
- Raymond Burr
- Harry's Law

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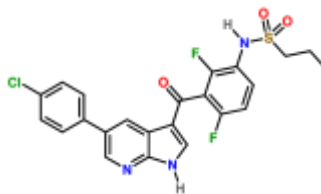
## At the Forefront

- *The right treatment for the right patient at the right time.*
- In late 2009, PWC Estimated:
  - U.S. market for Personalized Medicine at \$232 billion
  - Annual 11 % Growth Rate, doubling in size by 2015 to over \$450 billion
  - Core diagnostic and therapeutic segment around \$24 billion with an estimated 10 % annual growth

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## First Companion Diagnostic FDA Approval

- Plexxikon: Zelborabov improves survival in patients with BRAF<sup>V600E</sup> mutation-positive inoperative or metastatic melanoma
- Companion diagnostic test also approved



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***Association for Molecular Pathology, et al. v. U.S.  
Patent and Trademark Office, et al.,  
99 USPQ 1398 (Fed. Cir. 2011)***

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- Myriad provides services to detect BRCA1 and BRCA2- related mutation, which correlates with increased risk of breast and ovarian cancers.
- Coalition of plaintiffs (doctors, laboratories, patients), sued in SDNY, alleging that the patents were invalid for failing to satisfy § 101 (utility).

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***Association for Molecular Pathology, et al. v.  
U.S. Patent and Trademark Office, et al.***

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- Coalition of plaintiffs included women who did not have health insurance that covered the test or could afford it without insurance.
- Defendant is patent owner of the tools (gene fragments) and diagnostic test. Myriad did not extensively license the technology.

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## ***Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.***

- Exemplary Gene Claim:
  - An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
    - Isolated DNA fragments; isolated genomic DNA and cDNA
- Diagnostic Claim:
  - A method for detecting a germline alteration in a BRCA1 gene, said alteration.... analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample....
    - Also assay claims

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## ***Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.***

- Supreme Court Precedent
  - *Diamond V. Chakrabarty*, 447 U.S. 303 (1980), interpreted the constitution to allow patenting of “products of nature.”
  - *In re Bilski*, 545 F.3d. 943 (Fed. Cir. 2008), *affirmed on other grounds by Bilski v. Kappos*, 130 S.Ct. 3218 (2010), held that “abstract ideas” are not patentable; however, algorithms and methods are patentable if connected to the transformation of matter or requires the use of a machine. “*Machine or transformation test.*”

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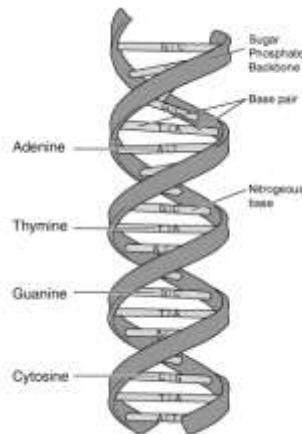
## *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*

- SDNY – held on summary judgment that claims were invalid for failing to satisfy § 101.
- U.S. PTO should not have granted patents because “genes” and “fragments” should not be patented.
- On Appeal, the Federal Circuit reversed – 3 separate opinions.

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## *Judge Lourie for the Panel*

- The key distinction turns on ***a change in the claimed composition’s identity compared with what exists in nature.***
- Isolated DNA and cDNA: are patentable because the claimed subject matter is **markedly different** in it has **a distinctive chemical identity.**



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## *Judge Moore's Concurrence-In-Part*

- Agreed for the most part with Judge Lourie's opinion,
  - Isolation is not enough. Patent-eligibility requires that the isolated DNA possess markedly different properties that are directly responsible for a new and significant utility.
  - Purified Products: “‘markedly different characteristics,’ as compared to the impure products, which resulted in ‘the potential for significant utility’.”
  - Strong policy reasons for concurrence

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## **Judge Bryson's Concurrence and Dissent**

- Isolated genomic DNA, in any form, should not be patentable, but cDNA is patent-eligible.
- Analogizing DNA and genes to naturally occurring minerals: the process of extraction and isolation may be difficult and could impart new qualities to the resulting product, is insufficient to impart patentability.

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## ***Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.***

- Diagnostic Claims
  - Those that disclose transformative steps such as analyzing a physical sample, are patent-eligible.
  - Those that would encompass only “mental steps” are not patent-eligible.



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## ***Looking Ahead***



- Petition just filed by ACLU for *en banc* review by the Federal Circuit

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## Congressional Action ?

- In February 2007, Representatives Becerra of California and Weldon of Florida introduced in Congress H.R. 977 or the "**Genomic Research and Accessibility Act**"
  - Prohibits patenting of “human genetic material.” The proposed language of the bill prohibits the patenting of "a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.”
- Not passed, and not yet reintroduced.

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## Patent Reform

- House of Representative’s Version of the Bill:
  - Requires the PTO to undertake a study on the anti-competitive effects of diagnostic test patents:
    1. The impact of the current lack of independent second opinion testing on the ability to provide the highest level of medical care and on inhibiting innovation to existing testing and on inhibiting innovation to existing testing and diagnosis;
    2. The effect that providing independent second opinion testing would have on the existing patent and license holders of the exclusive genetic test;
    3. The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, such as the interpretation of testing results and performance of testing procedures;
    4. The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

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## In the meantime



- Vary scope – add “man-made elements”
  - Tags, vectors, cell lines, etc. combined with DNA
  - Include “transformative steps”, such as screening a sample
  - Disclose distinctive uses and utilities of the isolated and/or purified products

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## Follow the Issue

- **Foley’s *Personalized Medicine Bulletin***
  - The source for legal, business, and regulatory developments shaping an evolving industry
  - <http://www.personalizedmedicinebulletin.com/>

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