



AFTER AMP v. MYRIAD

USING TRADE SECRET PROTECTION FOR
GENETIC TESTING INNOVATIONS



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Myriad's *BRCA1/2* Test

- DNA-based prognostic tests for breast and ovarian cancer
- ***BRACAnalysis***[®] - presence or absence of certain *BRCA1* and *BRCA2* gene mutations
- If no harmful mutation – relief
- If harmful mutation – take further steps (e.g., **cancer screening** or **double mastectomy**)
- Test accuracy is critical

The VUS Problem

- Myriad's test yields a definitive answer in most cases
- In a significant number of cases, the test identifies one or more **variants of unknown significance ("VUS")**
- These are a focus of intense and ongoing research
- Understanding the role of a VUS removes its "VUS" status
- A variant in the hands of a company that understands its role is not a VUS, even though it is a VUS in the hands of a company that does not



Patents and Trade Secrets

Myriad's *BRCAAnalysis*[®] test has raised vital questions regarding

- Patenting isolated DNA
 - Protecting VUS data and algorithms as trade secrets
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What is a Patent?

- A “negative right” – to stop another from making, using, selling, offering to sell, or importing an invention for a limited time
- A “stop sign”, and not a “green light” to practice one’s own invention
- A “hybrid” document
 - Technical content
 - Demarcates enforceable boundaries

What is a Patent Claim?

- Single-sentence description of an invention
- At least one claim in a patent, typically many
- Defines what's "covered" - the **business end** of a patent
- Example – "A **synthetic nucleic acid comprising a polynucleotide chain of 100 residues, wherein the chain comprises the sequence [CAGTTGA]₅**"
- Claims result from negotiation with a patent office

What is Required for Patentability?

- Patent-eligible subject matter
- Utility
- Novelty
- Non-obviousness
- Enablement, written description and definiteness

What is Patent-Eligible Subject Matter?

- Compositions
 - Processes
 - Machines
 - Articles of manufacture
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- A mere discovery, abstract principle or law of nature is not patent-eligible

AMP v. Myriad - History

- Myriad had many patents, and some claimed **isolated BRCA1/2 genes and fragments**
- In 2009, the ACLU coordinated a suit against Myriad for declaratory judgment of gene patent invalidity on the basis of **patent-ineligibility**
- Over 20 plaintiffs in the suit
- **Gene patents quickly became a major public policy issue**



AMP v. Myriad - History

- The District Court invalidated Myriad's gene patent claims
 - The Court of Appeals for the Federal Circuit reversed in favor of Myriad
 - **The ACLU defeated Myriad before the Supreme Court in 2013**
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AMP v. Myriad - Substance

- Sole question before the Supreme Court – **Are isolated DNA molecules patent-eligible?**
- The Court ruled – those corresponding to **genomic DNA are not**, but **cDNA molecules are** since cDNA does not occur in nature
- The Court used a **“markedly different”** standard
- Is this standard the correct one to apply in determining patent-eligibility? (The answer is complex and beyond the scope of this lecture)

AMP v. Myriad - Substance

- If it is, did the Court properly apply it to Myriad's patent claims?
- According to the Court
 - Isolating genomic DNA **fails** to confer markedly different characteristics on the DNA **despite ability to serve as a probe, etc**
 - cDNA **is** markedly different since it doesn't occur in nature, **despite a common sequence, routine production methods and the same function as isolated genomic DNA**

Myriad's Aftermath

- **Effect on Myriad Genetics**
 - Thrived for a while despite patent invalidity and expiration, stock and litigation setbacks
 - Myriad still had method patents in force
 - Those patents were due to expire anyway
- **Effect on other “gene patents”**
 - These are of waning importance since the human genome is public

Myriad's Aftermath

- **Effect on patents to *other* isolated compounds**
 - According to supporters, *Myriad* is limited to DNA patents
 - According to critics, *Myriad* would apply more broadly to small molecule drugs, polypeptides, antibodies and carbohydrates
 - **The answer is unclear**



What now?

- Non-patent protection
 - Service marks
 - Trade secret protection



Trade Secret Protection

- Used for
 - Patentable inventions while still a secret
 - Unpatentable inventions
 - Peripheral and undisclosed know-how surrounding patented inventions
 - Inventions for which patent protection is difficult, of dubious value or undesirable
- A company is free to maintain trade secrets **indefinitely** for competitive purposes (unless otherwise prohibited by law)



Trade Secret Defined

Information that

- Derives **economic value** from **not being known** to, or **not readily ascertainable** by proper means by, others who could obtain value from its disclosure and use, and
 - Is the subject of **reasonable** efforts to maintain its secrecy
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Maintaining Secrecy

- **Reasonable efforts** include, for example
 - Signing confidentiality provisions
 - Codifying secret reagents and procedures
 - Marking confidential documents
 - Physically controlling access
- Once a secret is disclosed or independently conceived by another, **its value is lost**

Patent v. Trade Secret Protection?

The answer is **always** fact-specific, and depends on factors such as

- Patentability
- Likelihood of obtaining meaningful claim scope
- Technology's expected commercial life
- Reverse engineerability of the technology
- Ease of preserving secrecy

A company can rely on trade secret and patent protection **simultaneously**

Example

- Technology – a new therapeutic compound
 - Defined structure
 - Expected 30-year product life
 - Reverse engineerable
 - Requires disclosure of structure for FDA approval
- Appropriate protection – **patent**

Example

- Technology – new cell-based assay to screen for drug candidates
 - Expected three-year commercial life
 - Intended solely for internal use
 - Requires no disclosure under the law
- Appropriate protection – **trade secret**

Myriad's Trade Secret Protection

- Myriad relies on trade secret protection for its VUS database and related information
- Unlike those at most other organizations, scientists at Myriad generally **do not share** their *BRCA1/2*-related findings and methods with public databases

The Resulting Imbalance

- A dichotomy exists
 - Myriad can rely on public information **and** its own proprietary information
 - Others can rely **only** on public information and their own (presumably smaller) databases
- Myriad can provide more accurate prognostic tests than any competitor – due in part to its reliance on trade secret protection for its database



Ethical Issue

Is Myriad ethically obligated to make its *BRCA1/2* data and enabling information public?



Public Disclosure – Pros

Strong argument in favor of disclosure

- Data sharing would avoid having to pursue a double mastectomy or oophorectomy **without a second opinion**

Public Disclosure – Cons

Strong arguments against disclosure

- Myriad saves lives **because** of its proprietary database
- Weakening the company would **jeopardize lives** otherwise saved via *BRACAnalysis*[®] and Myriad's other prognostic tests



Thank You!

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