Where Does *Myriad II* Fit With Supreme Court Patent Eligibility Jurisprudence?

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Myriad II

In Re BRCA1- And BRCA2-Based Hereditary Cancer Test Patent Litigation

University of Utah Research Foundation … and Myriad Genetics, Inc. v. Ambry Genetics Corp.

No. 2014-1361, -1366

Decided December 17, 2014

Prost, Clevenger, Dyk

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Representative Primer Claim

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.

~ U.S. Patent 5,747,282, claim 16

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Federal Circuit Analysis

- "not distinguishable from the isolated DNA found patent-ineligible in *Myriad*"
- "They are structurally identical to the ends of DNA strands found in nature."
- Rejected Myriad's arguments that the primers satisfied § 101
  - because they were made synthetically
  - because single-stranded DNA is not found in the body
  - because they have a "fundamentally different function ....as a starting material for a DNA polymerization process"

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Federal Circuit Analysis

"One of the primary functions of DNA's structure in nature is that complementary nucleotide sequences bind to each other. It is this same function that is exploited here—the primer binds to its complementary nucleotide sequence. Thus, just as in nature, primers utilize the innate ability of DNA to bind to itself."

"A DNA structure with a function similar to that found in nature can only be patent eligible as a composition of matter if it has a unique structure, different from anything found in nature."

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Critical Analysis

- The court confused “function” with “property”
- It is a <u>**property**</u> of DNA that it binds to its complementary sequence.
- That property can be exploited for different <u>**functions**</u>
  - Expressing genes, amplifying DNA (e.g., PCR), interfering with biological processes (RNAi, decoy binding sites), detecting complementary sequences, targeting delivery of conjugated moieties, etc.
- DNA with different function should be eligible

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Critical Analysis

- Supreme Court in Myriad I:

The rule against patents on naturally occurring things is not without limits, however, for "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," and "too broad an interpretation of this exclusionary principle could eviscerate patent law."

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Critical Analysis

- Supreme Court in Myriad I:

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.

Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA.

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Critical Analysis

- PCR is not a naturally-occurring process
- In PCR, primer pairs work together to amplify specific target sequences (*Cf. Funk Bros.*)
- The functioning of PCR primers does "rely in any way on the chemical changes that result from the isolation of a particular section of DNA,"

- A pair of primers useful for amplifying a specific target sequence should satisfy 101

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Critical Analysis

- DNA claims that can be distinguished from Myriad II
  - Specific sequences (SEQ ID NOs), particularly if they have a different function
  - Labeled DNA sequences
  - Chemically modified/conjugated DNA sequences
  - DNA sequences with non-naturally occurring sequence mutations
  - Recombinant constructs

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Representative Method Claim

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[,]

wherein a germline nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to genomic DNA isolated from said sample and detecting the presence of a hybridization product wherein a presence of said product indicates the presence of said allele in the subject.

U.S. Patent 5,753,441, claim 7 (which depends from claim 1)

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Federal Circuit Analysis

- Federal Circuit already held claim 1 invalid as directed to "abstract mental processes" (first in its vacated July 2011 decision, then reaffirmed in its August 2012 decision)
- Claim 7 analyzed under *Alice* (not *Mayo*):
  - Part I of claim is directed to abstract idea;
  - Does Part II "add enough" to make the claim eligible?

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Federal Circuit Analysis

"The second paragraphs of claims 7 and 8 do nothing more than spell out what practitioners already knew—how to compare gene sequences using routine, ordinary techniques."

"Nothing is added by identifying the techniques to be used in making the comparison because those comparison techniques were the well-understood, routine, and conventional techniques that a scientist would have thought of when instructed to compare two gene sequences."

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Critical Analysis

Supreme Court in Myriad I:

It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court. ....

[T]his case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that, "[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications."

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Critical Analysis

- How can a claim that recites a specific, physical laboratory step (hybridizing a probe to a DNA sample) be ineligible as an “abstract idea”?
- Did the Federal Circuit go astray by parsing the claim into parts?
- Could they have reached the same conclusion on a simpler claim?

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Critical Analysis

- Alternative claims:

A method for detecting the presence of a BRCA1 DNA sequence having Mutation Z in genomic DNA, comprising contacting a nucleotide probe that specifically binds to BRCA1 DNA sequences having Mutation Z with genomic DNA obtained from a subject under hybridizing conditions, and detecting the presence of a hybridization product comprising the probe and genomic DNA.

A method for detecting the presence of a BRCA1 DNA sequence comprising SEQ ID NO: 1 [a short sequence comprising a newly discovered mutation], comprising hybridizing a nucleotide probe that specifically binds to DNA sequences comprising SEQ ID NO: 1 with genomic DNA obtained from a subject, and detecting the presence of a hybridization product comprising the probe and genomic DNA.

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Critical Analysis

- Would the court have invalidated a claim like this under 101?

A method for detecting Ebola Virus X [a newly discovered particularly virulent strain] in a biological sample from a subject, comprising contacting the sample with an antibody that specifically binds to Ebola Virus X and does not specifically bind to other strains of ebola virus, and detecting the presence of a binding product comprising the virus and antibody.

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Critical Analysis

- Would the court have invalidated a claim like this under 101?

A method for detecting Compound X in a water sample, comprising contacting the water sample with a chelating agent that binds to Compound X, and detecting the presence of a binding product comprising the chelating agent and Compound X.

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