

*Myriad:*  
**Let the Discussion Begin**

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## *Myriad*

- Claims that encompass naturally occurring DNA are not patent eligible under §101
- Myriad holding broader than human DNA
  - Not limited to human DNA
  - Where did the Supreme Court draw the line on nucleic acid molecules?
- What about other isolated from nature materials?
  - Proteins?
  - Compounds?
  - Other?

## Key Guidance

- *Myriad* opinion finds isolated genomic DNA falls within the “product of nature” exception
- Also finds that fragments of genomic DNA, even if chemically synthesized, are also unpatentable
- “As a result, cDNA is not a ‘product of nature’ and is patent eligible under §101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.”

## ***Bilski to Mayo to Myriad***

- *Bilski*: Method of hedging energy trades claimed only an abstract idea; not a patent-eligible invention
- *Mayo*: Diagnostic method consisting of “law of nature” plus “well-known, routine, conventional” steps was not an “invention”; “something more” was required
- *Myriad*: Removal of introns represents “something more” and is “invention”

## Product of Nature: History (According to *Myriad*)

- Patentable
  - *Diamond v. Chakrabarty*
    - Call the patented invention a “modified bacterium”
    - New “with markedly different characteristics from any found in nature”
      - “A product of human ingenuity ‘having a distinctive name, character [and] use.’”
- Not Patentable
  - *Myriad*
    - Claimed DNA focused on genetic info. Encoded
      - “Myriad’s principal contribution was uncovering the precise location and genetic sequence”
      - Not enough (“genes and the information they encode are not patent eligible... simply because they have been isolated...”)
  - *Funk Brothers*
    - Claims focused on... Selected strains of multiple Rhizobia species were found compatible and could be used as a single mixed culture to apply to groups of leguminous plants without inhibiting each other’s efficiency.
- *In re Kratz* not mentioned

## What About Other Isolated Materials?

- What does it do in nature?
- Does it have markedly different characteristics when isolated?
  - Perhaps proteins, chemicals, other naturally occurring materials have, upon isolation, new uses that are markedly different
    - Therapeutic
      - Isolated adrenalin as a therapeutic (*Parke-Davis*) (though not mentioned in *Myriad*)
    - Industrial
      - Genetically modified bacterium for treating oil (*Diamond v. Chakrabarty*)

## Spectrum

- Isolated v. modified
- Natural v. non-natural

## What Options to Challenge

*Yes (if jurisdiction)*

- District court declaratory judgment action

*Maybe (Down the road)*

- Post-Grant Review: limited to patent claims with effective filing date on/after March 16, 2013

*No*

- *Ex Parte* Reexam, *Inter Partes* Review: limited to §§102 and 103 using patents and printed publications



## Pending Cases

- Look for non-naturally occurring claim elements
  - DNA: tags
  - Expression vector...
  - Therapeutic proteins (though may nonetheless be patentable even where naturally occurring):  
PEGylated, Fc fusion
  - Covalent v. mixtures

## Pending Cases (con't)

- Claim Types
  - Plants
  - Seeds
  - Oil
- Event
  - Vectors
- Ex-US

## Patentee Options for Issued Patents

- Patents
  - Reissue
  - Claim interpretation

## License Issues

- Licensee/Licensors Discussions
  - Including patent abandonment
  - US vs. ex-US activities (DNA still patentable elsewhere)
  - Related contract provisions
    - How are the licensed patents defined?
      - Is there a valid claim provision (note definition of a pending or issued claim that is not found to be invalid)?
    - Termination provisions (including notice)
    - Know-how provision
- District court declaratory judgment action (*MedImmune*)