(Brief) Patent Primer

- A patent is a property right in an invention.
- A limited right:
  - Limited in time – 20 years from earliest filing date
  - Limited in scope – no affirmative right to practice, just a right to exclude others
  - Limited in exercise – a right to sue in Federal court for damages and injunction (hard to get)
- Property right defined by the claims
(Brief) Patent Primer

- Claims define the scope of the patent right, just like boundary lines define real property.
- The *quid pro quo*: the right to the patent grant is conditioned on adequate disclosure.
- The invention becomes public property, freely practiced by all, once a patent expires.
Gene Patenting Myths

- **The Ownership Myth**
  - Michael Crichton, ACLU
  - and “Who Owns You”

- **The Information Myth**
  - “Physical Embodiment of Genetic Information”
  - Information not what’s patented
    - “DNA is a chemical compound, albeit a complex one”
Gene Patenting Myths

- The “Inhibits Research” Myth
  - No evidence of research inhibition
    - >9,000 science articles on BRCA genes
  - Progress promoted by disclosure

- The “Natural Product” Myth
  - Natural products not patent-ineligible \textit{per se}
  - Isolated DNA not found in nature
  - cDNA not found in nature
Is DNA a “product of nature”? 

- Genomic DNA may be 
  - But chemically modified from native state 
- cDNA certainly is not 
  - Claims limited to specific sequence that does not exist prior to human intervention
Isolated DNA claims

- “Isolated DNA” comes in two forms: genomic DNA and cDNA
- Significant differences in structure and how isolated/prepared
“Isolation” vs. “Purification”

- Federal Circuit: “isolated” DNA as claimed patent-eligible because it has been chemically transformed

- cDNA patent-eligible because not found in nature – man-made product

- Thus, “isolated” DNA has not “merely” been “purified”

- Important implications for other biological molecule-based inventions
Diagnostic method claim structure

- Typically in the form of a “determine and infer” claim:
  - Characterized by one or more “determining” steps that involve assays, etc.
  - Produce *information* in the form of a conclusion or an inference based on outcome of determining steps
  - Claim preamble directs method to activity (e.g., diagnosing) based on inference
Should DMC be patent-eligible?

- Protects “correlation” discoveries – basis for molecular diagnostics
- Promotes disclosure from academic/medical scientists, and translation of information into commercial technologies = innovation
- Alternatives – such as trade secret – greater negative effects
  - Risk of upsetting balanced approach to innovation (academics do basic research, industry develops commercial embodiments)
Thank you!

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