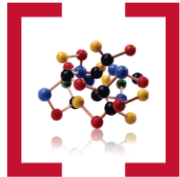




(Brief) Patent Primer

- A patent is a property right in an invention



- A limited right:

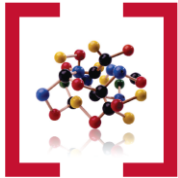
- Limited in time – 20 years from earliest filing date
- Limited in scope – no affirmative right to practice, just a right to exclude others
- Limited in exercise – a right to sue in Federal court for damages and injunction (hard to get)



- Property right defined by the claims



(Brief) Patent Primer



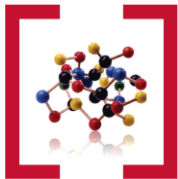
- Claims define the scope of the patent right, just like boundary lines define real property
- The *quid pro quo*: the right to the patent grant is conditioned on adequate disclosure
- The invention becomes public property, freely practiced by all, once a patent expires

Gene Patenting Myths



- The Ownership Myth

- Michael Crichton, ACLU and “Who Owns You”



- The Information Myth

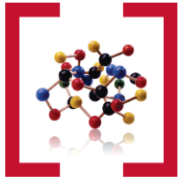
- “Physical Embodiment of Genetic Information”
- Information not what’s patented
 - “DNA is a chemical compound, albeit a complex one”



Gene Patenting Myths



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

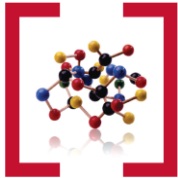


- The “Natural Product” Myth
 - Natural products not patent-ineligible *per se*
 - Isolated DNA not found in nature
 - cDNA not found in nature

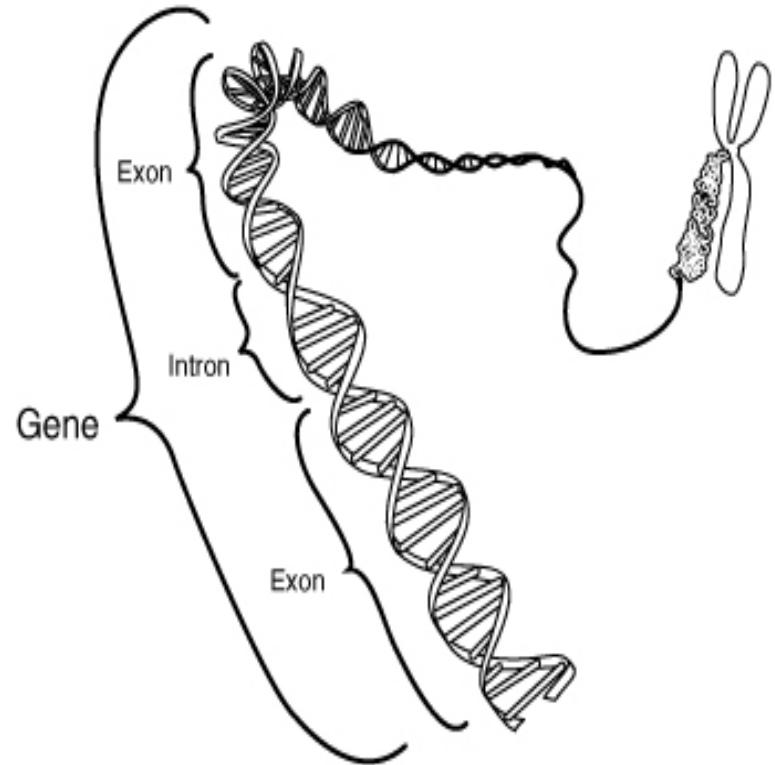




Is DNA a “product of nature”?



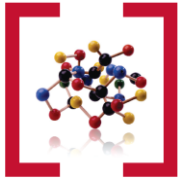
- Genomic DNA may be
 - But chemically modified from native state
- cDNA certainly is not
 - Claims limited to specific sequence that does not exist prior to human intervention



Isolated DNA claims



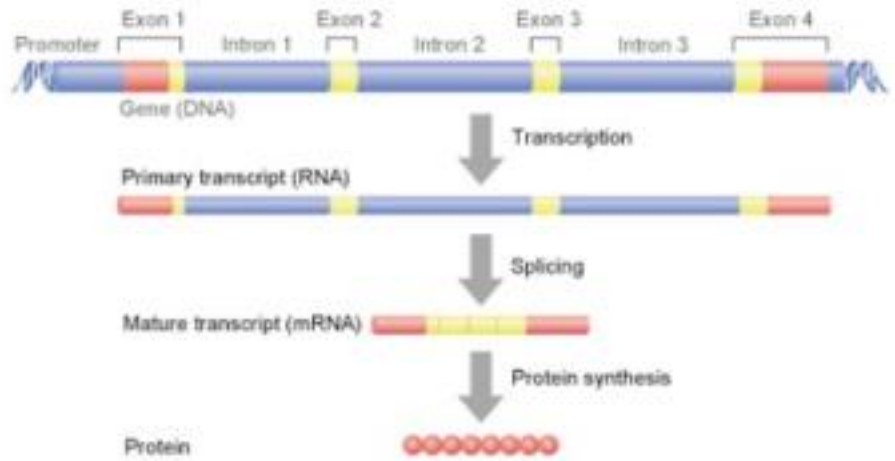
- “Isolated DNA” comes in two forms: genomic DNA and cDNA



- Significant differences in structure and how isolated/prepared



Structure of a Gene

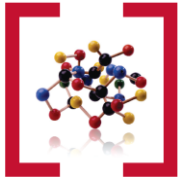


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“Isolation” vs. “Purification”



- 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



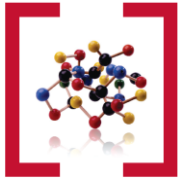
- Thus, “isolated” DNA has not “merely” been “purified”



- Important implications for other biological molecule-based inventions



Diagnostic method claim structure



- Typically in the form of a “determine and infer” claim:

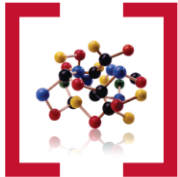


- Characterized by one or more “determining” steps that involve assays, etc.
- Produce *information* in the form of a conclusion or an inference based on outcome of determining steps
- Claim preamble directs method to activity (e.g., diagnosing) based on inference





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



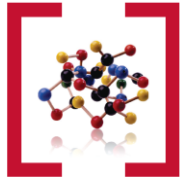
- Alternatives – such as trade secret – greater negative effects



- Risk of upsetting balanced approach to innovation (academics do basic research, industry develops commercial embodiments)



Thank you!



Kevin E. Noonan, Ph.D.



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