

# SCOTUS Shakes Subject Matter Eligibility: Implications for Natural Products

Presented by:

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# Outline

- What is eligible for patent protection?
- Chemical and biotechnology eligibility issues
- Myriad (Ass'n for Molecular Pathology vs. Myriad Genetics)
- USPTO Guidance with example claims
- Strategies

## Three Take Away Points

1. Genes are a species of isolated DNA  
- Glossary Handout
2. Myriad's holding - narrowly tailored to genes
3. The USPTO's current Guidance will significantly and negatively impact the pharmaceutical and consumer products industry

# What is Eligible for Patent Protection?

- U.S. Constitution – Article 1, section 8, clause 8  
“To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and **discoveries**”
- 35 U.S.C. § 101 (NOT novelty(§ 102); NOT nonobviousness(§ 103))  
“Whoever invents or **discovers** any new and useful [1]process, [2]machine, [3]manufacture, or [4]composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

# What is Eligible for Patent Protection?

- Not in the list and thus, not eligible for patent protection – “implicit exceptions”
  - Natural phenomena/naturally occurring phenomena
    - e.g., “products of nature”
  - Abstract ideas, and
  - Laws of nature

# Eligibility Issues for Compositions prior to Myriad & USPTO Guidance

- Compositions of matter – prior to Myriad
  - “Products of Nature” vs. “Hand of Man”
  - “Isolated” or “Substantially Pure” natural products can be eligible
    - Claims should exclude products of nature
    - Compound X from amazon plant
  - Genetically engineered organisms are eligible
    - BUT NOT
      - GENETICALLY ENGINEERED HUMANS (13<sup>th</sup> Amendment to U.S. Constitution and AIA)

# Myriad

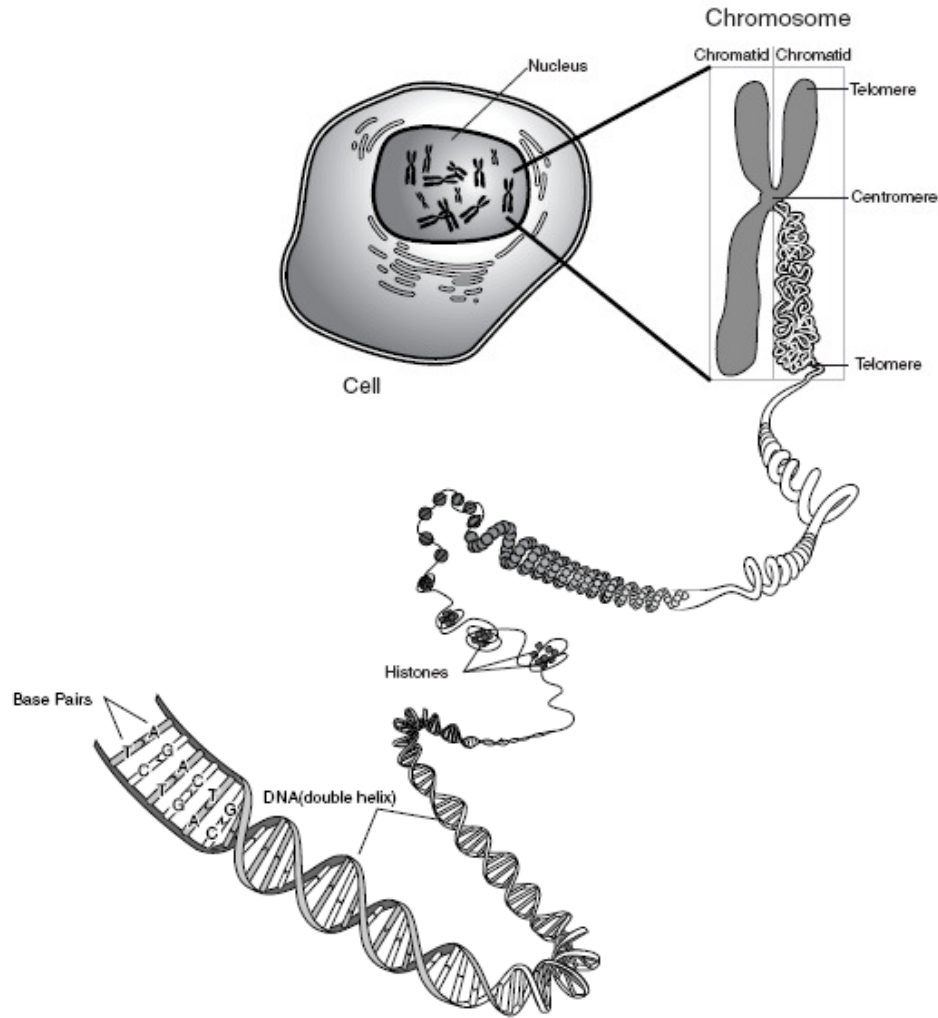
*Ass'n for Molecular Pathology, et al. vs. Myriad Genetics, Inc., et al., 569 U.S. \_\_\_\_\_ (2013)*

## Myriad (p. 5-6) - Sample Claims for Discussion in U.S. Pat. No. 8,747,282

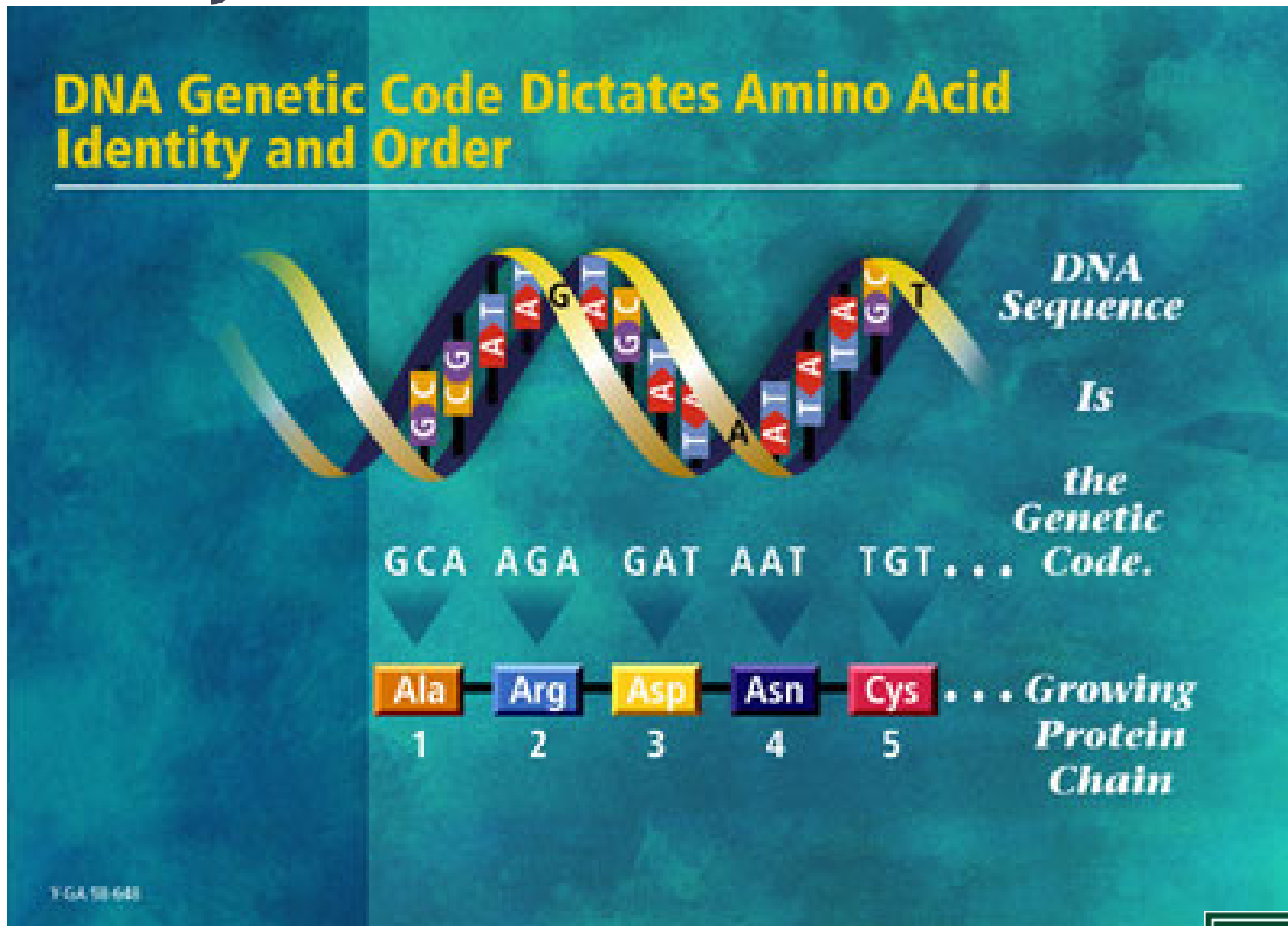
- 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID No: 2. [DNA sequence encompasses the gene in the chromosome]
- 2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID No: 1. [a single cDNA – not identical to the DNA sequence in the chromosome]
- 5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1. [Encompasses full gene of claim 1]



# Myriad - Cells to DNA



# Myriad -Genes to Proteins



# Myriad - Claims to Genes

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID No: 2.  
[DNA sequence encompasses the gene in the chromosome]
- All claimed DNA sequences that encode for a BRCA1 polypeptide

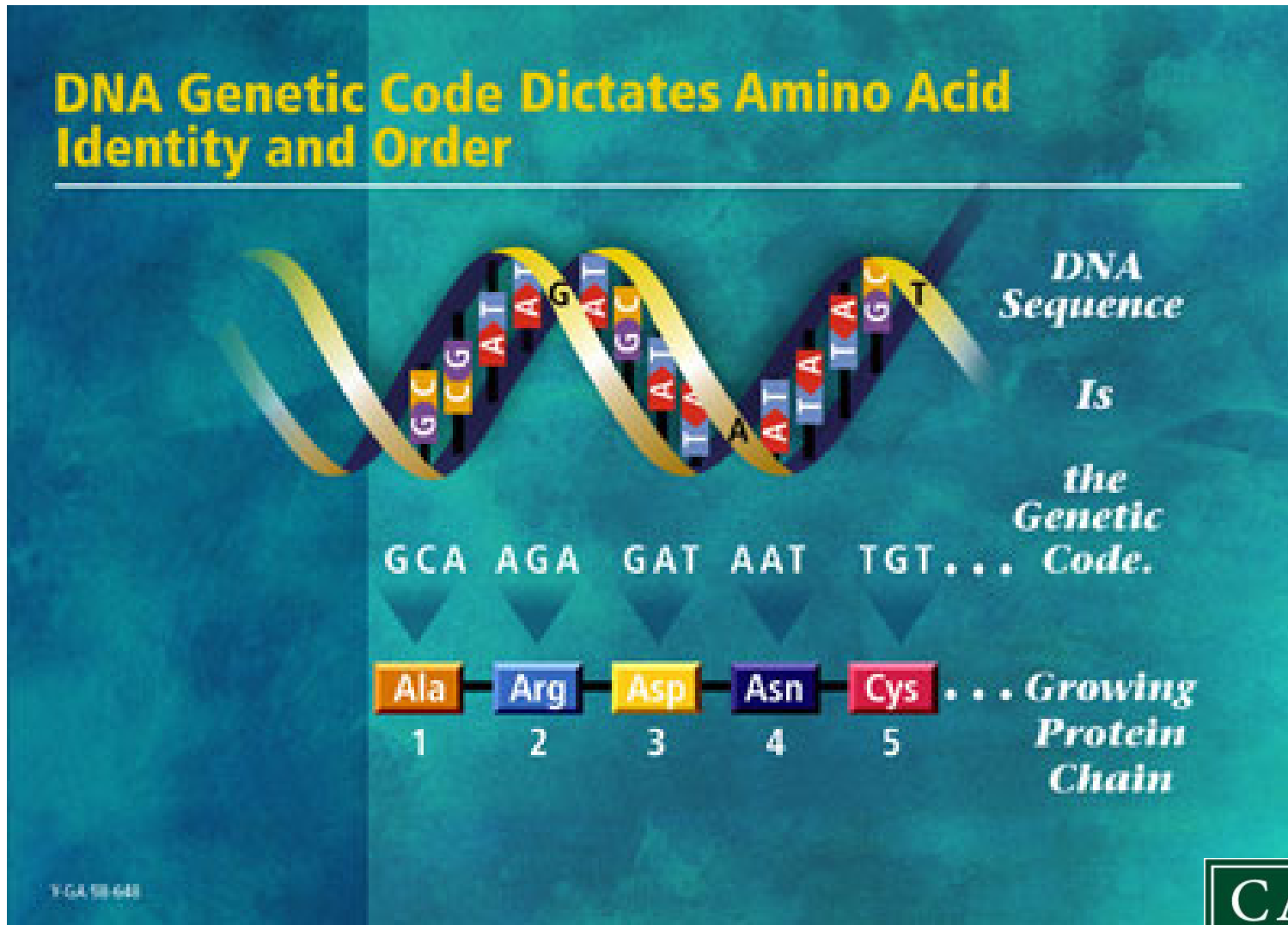
# Multiple DNA codons give rise to the same amino acid

<b>Codon</b>	<b>Amino acid</b>
GCA; GCC; GCG; GCT	Alanine (Ala)
AGA; AGG; CGA; CGC; CGG; CGT	Arginine (Arg)
AAC; AAT	Asparagine (Asn)
GAC; GAT	Aspartic acid (Asp)
TGC; TGT	Cysteine (Cys)
CAA; CAG	Glutamine (Gln)
GAA; GAG	Glutamic acid (Glu)
GGA; GGC; GGG; GGT	Glycine (Gly)
CAC; CAT	Histidine (His)
ATA; ATC; ATT	Isoleucine (Ile)
CTA; CTC; CTG; CTT; TTA; TTG	Leucine (Leu)

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# Myriad - GCA can be GCC and not change the amino acid

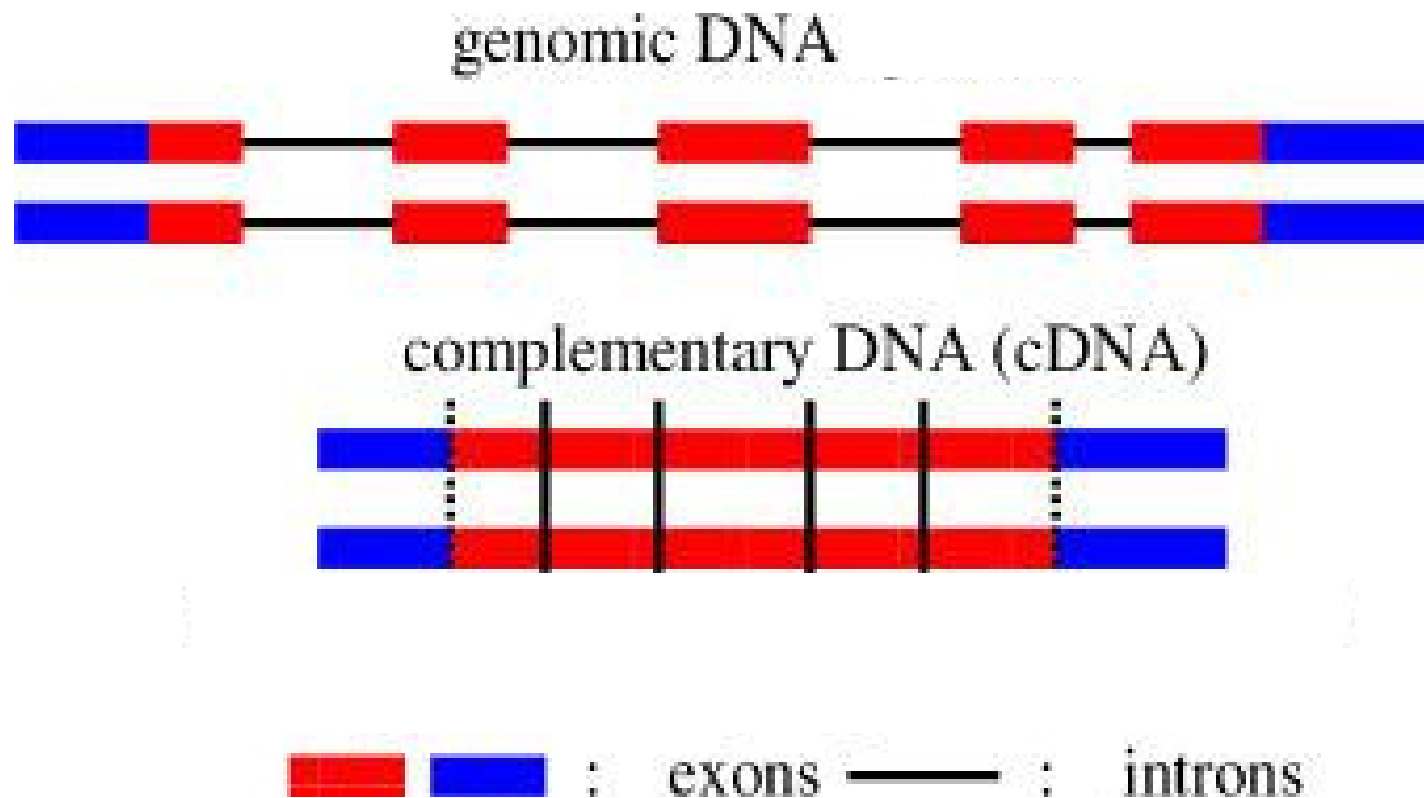


# Implications for the number of sequences that can code for BRCA1/2

- BRCA1 protein
  - Full gene ~ 80,000 nucleotides (A,T,C,G)
  - Coding portion ~ 5,500 nucleotides or 1,800 codons
  - Potential number of DNA sequence variations –  
>  $2^{1800}$
- BRCA2 protein
  - Full gene ~ 80,000 nucleotides (A,T,C,G)
  - Coding portion ~ 10,200 nucleotides or 3,400 codons
  - Potential number of DNA sequence variations –  
>  $2^{3400}$

# Claim 1 Scope: genomic DNA and cDNA

## Introns vs. Exons



# Myriad - Claim 1

1. An isolated DNA **coding for a BRCA1 polypeptide**, said polypeptide having the amino acid sequence set forth in SEQ ID No: 2. [DNA sequence encompasses the gene in the chromosome]
- **All** DNA sequences that encode for a BRCA1 polypeptide
  - Codon redundancy of DNA and variation of introns
  - Genomic DNA and cDNA encompassed by claim 1
    - Only make protein from DNA sequences in exons (introns are not used to make protein)



# Myriad - Claims and science take away points

1. All claims under consideration encompass DNA sequences that code for proteins.
2. Claim 1 represents a **gigantic** number of DNA sequences
  - only require that it code for BRCA1 protein
  - informational/functional.
3. Claim 2 is a **single** DNA sequence drawn to cDNA, which has only the required sequences (exons) needed to code for the protein.
4. Randomly chosen isolated DNA from the DNA sequence encompassed by claim 1 will not likely produce a protein.

# Myriad - Cited Case Analysis

*Ass'n for Molecular Pathology, et al. vs. Myriad Genetics, Inc., et al., 569 U.S. \_\_\_\_\_ (2013)*

# Myriad - Case Analysis

- Chakrabarty (1980 Supreme Court) - eligible
  - Claim - a bacteria created by humans that was able to break down many components of crude oil
  - New with “**markedly different** characteristics from any found in nature due to [1]the additional plasmids and [2]resultant capacity for degrading oil” (emphasis added)
    - [1] STRUCTURE
    - [2] FUNCTION
  - The claimed bacteria is “a product of human ingenuity having a distinctive name, character [and] use” - Citing Hartranft v. Weigmann (1887)
    - Is something a “manufacture” for import taxation?
    - Hartranft states “distinctive name, character **or** use”

## Myriad - Case Analysis

- Funk Bros. (1948 Supreme Court) – not eligible
  - Claim - a mixture of naturally occurring species of bacteria that don't inhibit each other and that fix nitrogen
  - STRUCTURE
    - “Did not alter the bacteria in any way”
  - FUNCTION
    - “borrowed invention from the ... natural principle”
    - “No enlargement of the range of utility” Funk Bros.

# Myriad Holding (II.B.)

## Genes not eligible

- “[D]iscovery, by itself, does not render the BRCA genes ...patent eligible.”
- STRUCTURE - Not saved by severed bonds used to “create[] a nonnaturally occurring molecule”
  - “not expressed in terms of chemical composition, nor do they result in any chemical changes that result from the isolation of [the] DNA.”
- FUNCTION is the same - Information is claimed
  - “claims understandably focus on the genetic information”
  - “claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule”

# Myriad Holding (II.C.)

## cDNA eligible

- cDNA is eligible under §101
  - cDNA - only coding portion of the gene (no introns)
- STRUCTURE is distinct compared to the gene
  - a “molecule that is not naturally occurring”
  - “not a product of nature”
  - Humans “unquestionably create something new when cDNA is made”
- Claim 2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID No: 1. [a single cDNA molecule – not identical to the gene]

## Myriad- Holding (II.C.) if cDNA=gene?

- If cDNA and gene have the same sequence, then not eligible
  - “except in so far as very short series of DNA may have no intervening introns to remove when creating cDNA”
  - fn 8 – “the possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable” (emphasis in original)

## Myriad - Holding

### Final Substantive Sentence

- “We merely hold that **genes** and the information they encode are not patent eligible under §101 simply because they have been isolated from their surrounding genetic material.”  
(emphasis added)
- Does Myriad hold that a non-gene, isolated DNA sequence is not eligible?



# USPTO Guidance (March 4, 2014):

- Drastic changes!
- How does Myriad justify?
  - Genes vs. all natural products

[http://www.uspto.gov/patents/law/exam/myriad-mayo\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf)

## USPTO Guidance:

### Myriad on isolated steroids

- Guidance – mixes analysis of products and processes
  - SCOTUS did not do this
  - Unnecessarily complicated
- Guidance asks: Is the claimed product “non-naturally occurring” and “markedly different” in **structure** compared to a naturally occurring product?
  - If **STRUCTURE** is the same -> not eligible
    - Compound X from amazon plant – no longer eligible

# USPTO Guidance: Myriad on isolated steroids

- Only **STRUCTURE** is analyzed
- No mention of **FUNCTION** in the “How to Analyze” section of the Guidance
- If **STRUCTURE** is non-natural (strawberry example)
  - How much structural change is needed to make “markedly different”?
  - Different function also needed from the different, but similar structure? (amazonic acid vs. strawberry examples)

# USPTO Guidance (base on amazonic acid/strawberry example)

## Harry's Example - Taxol treats cancer

- Claim 1. A composition comprising taxol at a concentration of [higher than in tree bark & effective to treat cancer].
  - Taxol - bark of a Pacific Yew tree
- USPTO analysis (predicted) – Taxol in bark has same structure as taxol in claim
  - DONE – Not eligible
- FUNCTION - Is there an “enlargement” of utility?! Does nature use taxol to treat cancer in mammals?
  - Supreme Court– This is relevant to analysis
  - USPTO – This isn't relevant to analysis

# USPTO Guidance - Pomelo Juice

## USPTO Example in Training Slides

- Claim 1. A beverage composition comprising: (a) pomelo juice and (b) a preservative.
  - Preservative can be Vitamin E (not in pomelo juice)
- USPTO analysis – (a) naturally occurring fruit/juice and (b) Vitamin E is naturally occurring
  - DONE – Not eligible
- FUNCTION – Is this an “enlargement” of utility!? Does nature use Vitamin E as a preservative?
  - Supreme Court– This is relevant to analysis
  - USPTO – This isn’t relevant to analysis
- Preservative X saves the day!

# The [patent practitioner] doth protest too much?

- Of the new approved drugs during 1981-2010 (1355), ~47% would be at risk of being unpatentable in light of the USPTO Guidance<sup>1</sup>
  - Antibiotics - ~75% at risk
  - Small molecule anti-cancers - ~80% at risk
- ~1-5 billion dollars per drug<sup>2</sup> - who will invest?
- Many Art Units at USPTO – 1600/1700...
- Consumer demand for natural-based products

1 - Sherry Knowles at Managing Intellectual Property Blog (April 24, 2014)

2 - Forbes April 11, 2013

# USPTO Guidance

## Harry's Example (sort of)

- Claim 1. Shoes consisting of hardened India-rubber.
  - India-rubber shoes made by simply allowing the sap of the India-rubber tree to dry and harden in a mold
- Import/export tax issue with central issue, is it a manufacture? – Lawrence v. Allen (1849) also summarized in Hartranft v. Weigmann (1887)
  - Standard (partial) – it is a manufacture if it has “a distinctive name, character, or use ”
  - Held – this is a manufactured article, because it had a use as a shoe
    - “it was capable of use in that shape as a shoe” and
    - “had been put into a new form capable of use and designed to be used in such new form”
- USPTO analysis (predicted) – India-rubber sap has composition as in claim, not eligible
  - STRUCTURE - markedly different from natural product-dried, hardened solid vs. liquid?
  - NO FUNCTION ANALYSIS- Won't look at enlargement of utility (i.e., use as a shoe)

# Strategies - Applications

- Arguments/prosecution
  - Argue FUNCTION (enlargement of utility – Funk Bros.)
  - Myriad only speaks to genes/information, not isolated DNA – quote last sentence
  - Initially elect method claims – buy time for revised Guidance
- Drafting Applications
  - Dependent claim to “further comprising a non-natural substance” (broadly defined in specification)
  - Include dependent claims to a composition in a useful form
    - Solid, tablet...
- Kit claims
  - e.g., with container - See fireworks example in Guidance
- Method claims to making or using
  - Expressly not addressed by Myriad



# Strategy - Issued Patents

- Patent - Reexamination
  - Substantial new question of patentability
  - Patents and publications only, but can amend claims
- Patent - Reissue
  - Admit error in patent
  - Complete examination
- Patent - Licensee
  - Negotiation to do one of the above
  - Seek to invalidate patent via declaratory judgment, if circumstances warrant
    - May terminate entire agreement
    - Check terms of agreement for other implications

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# Thank You!

## Questions or Comments?

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