Natural Products: Function Matters

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Natural Product – The 2014 USPTO Memorandum

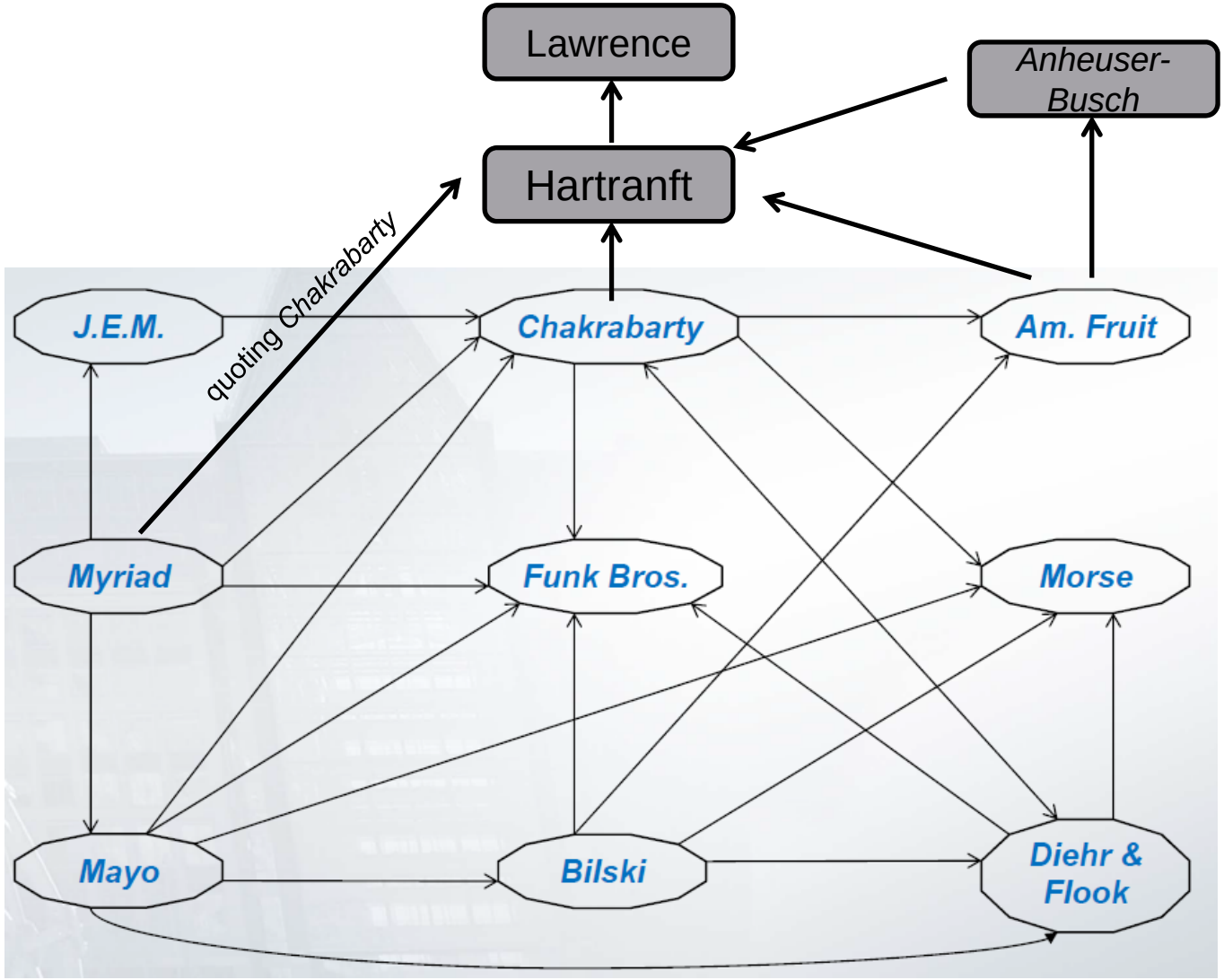
The Problem and Solution

- According to the Memorandum, subject matter comprising only natural products must have a marked structural difference from the corresponding natural product in order to be patent eligible.
- Absent structural modification, no consideration is given to the function of the claimed subject matter.
- This does not analyze the claimed subject matter as a whole, misapplies relevant legal precedent, and misinterprets *Myriad*.
- The test for patent eligibility should be whether the claimed subject matter, as a whole, has:

  1) a physical difference (e.g., structure, form, purity, etc.) relative to the natural product(s); and

  2) a different function or use relative to the natural product(s).

The Web of Relevant Cases



Manufactures

Tariff Cases and *American Fruit Growers*

- *Hartranft v. Wiegmann,* 121 U.S. 609 (1877) - (tariff case) Sea shells with the 1st layer cleaned off by acid and the 2nd layer ground away = not manufacture.
  - "They had not been manufactured into a new and different article, having a distinctive name, character, or use from that of a shell."
- *Lawrence v. Allen*, 48 U.S. 785 (1849) - (tariff case) India-rubber shoes = manufactured article (c.f. to India-rubber sheets made by the same process and material)
  - "they were 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."
- *American Fruit Growers, Inc. v. Brogdex Co.,* 283 U.S. 1 (1931) - (patent case) Orange with rind impregnated with borax = not manufacture.
  - It "does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property...There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange, fit only for the same beneficial uses as theretofore."
- Conclusion: A "manufacture" requires a new or distinctive form, character, name, or use.

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Other Natural Product Cases

Collections, Compositions, Living Organisms

- *Funk Brothers Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127 (1948) – bacterial collection
  - "Each of the species of root nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided, and act quite independently of any effort of the patentee."
- *Merck v. Olin Mathieson*, 253 F.3d 156 (4th Circ. 1958) – Vitamin B(12), purified from fungus
  - "had such advantageous characteristics as to replace the [naturally occurring] liver products. What was produced was, in no sense, an old product."
- *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) - genetically-modified bacteria that can degrade oil.
  - "His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity 'having a distinctive name, character [and] use.' ***Hartranft v. Wiegmann,*** 121 U. S. 609, 121 U. S. 615 (1887). ... [B]y **contrast** [to the invention in *Funk*], the patentee has produced a new bacterium with markedly different characteristic**s** from any found in nature, and one having the potential for **significant utility**."
- Conclusion*:* The consideration of functional changes as relevant to patent eligibility is in accordance with historical tarriff and patent cases, which consider whether products derived from nature have different functions and uses.

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How *Myriad* Uses *Funk* and *Chakrabarty*

Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013)

- "The [*Chakrabarty*] Court ... explained that the patent claim was "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity '**having a distinctive name, character [and] use**.' " Id., at 309–310 (quoting ***Hartranft v. Wiegmann,*** 121 U. S. 609, 615 (1887); alteration in original). The *Chakrabarty* bacterium was new "with markedly different characteristic**s** from any found in nature," 447 U. S., at 310, due to the additional *plasmids* **and** resultant "*capacity* for degrading oil."

- "The [*Funk*] Court held that the composition was not patent eligible because the patent holder did not **alter the bacteria in any way**. ... His patent claim thus fell squarely within the law of nature exception. So do Myriad's."

- Conclusion: *Myriad's* use of *Chakrabarty* and *Funk* is perfectly compatible with considering whether a functional change can convert an otherwise "natural product" into patent eligible subject matter.

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Myriad's Application c

Myriad uses the term "information" when referring to DNA function (e.g., "[s]equences of DNA nucleotides contain the information necessary to create strings of amino acids ..."). To the Court, DNA "information" is dictated by DNA "sequence" (e.g., "DNA's informational sequences...").

The Court entwines DNA's functional aspect (information), with DNA's molecular structure (sequence).

- Holdings:
  - cDNA is not a "product of nature" ar ver.
  - naturally occurring gDNA segment (rely because it has been isolated;
- Myriad is NOT about an isolated molecule with modified structure c tion.
  - "It is undisputed that Myriad did not create or alter any of the genetic **information** encoded in the BRCA1 and BRCA2 genes. The location and **order of the nucleotides** existed in nature before Myriad found them. Nor did Myriad create or alter the genetic **structure** of DNA."
- Myriad's claims are NOT directed to discreet chemical compositions (e.g., like purified (B)12), but rather to information:
  - "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. Instead, the claims understandably focus on the genetic **information** encoded in the BRCA1 and BRCA2 genes. ... [Myriad's] claim is concerned primarily with the **information** contained in the genetic sequence, not with the specific chemical composition of a particular molecule."
- *Myriad* addresses a product, that, according to the Court, does not have a different function or structure from that which is found in nature.

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Myriad's Application of Natural Products Doctrine to DNA

Conflation of Molecular Structure with Function

- For genor… *Myriad* conflates sequence (molecular structure) with function (information):
  - "DNA's inf… and the processes that create mRNA, amino acids, and proteins occur naturally within cells."
  - "Seque… information necessary to create strings of amino acids, which in turn are used in the bo…
  - "Know… allowed Myriad to determine their typical nucleotide sequence. That …ts …"
  - "Myriad obviously wo…ned primarily with the information contained in the genetic *sequence*
- The Court views DNA as a mea…he structure is the function.
  - "genes and the information they encode are not … been isolated from the surrounding genetic material."
- And, after all, this is how Myriad wrote the claims anal…
  - "[Myriad's] claim is concerned primarily with the **information** contained in … ecific chemical composition of a particular molecule."
- Thus, the traditional natural product inquiry, which considers both structure a… collapsed into a single question for DNA:

"Has the DNA sequence changed from that which is found in nature?"

Myriad applied the analysis used for over a century in considering the patent eligibility of natural products – "is there a difference in structure (sequence) and function (information)?" The Court simply saw these "characteristics" as inseparable.

Myriad has very limited applicability – only to subject matter in which molecular structure and function completely collapse, e.g., DNA.

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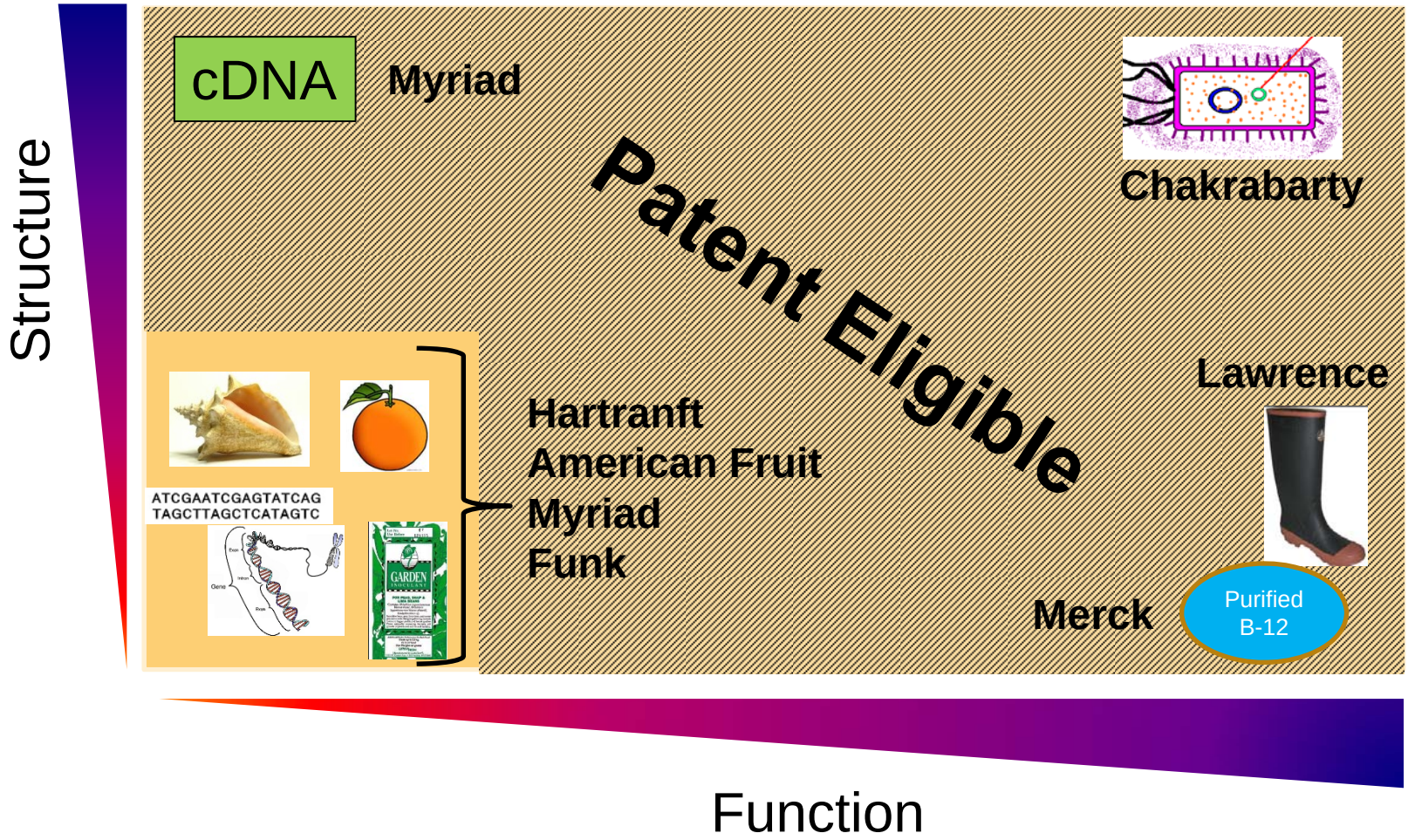
Conclusion: As it was, so should it be



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Backup

The technology

Product	Different structure, form, or purity	Different function or use
Sea shells	✓ (acid cleaned and ground)	x
Orange	✓ (borax in rind)	x
India-rubber	✓ (formed into boots) ✓ (formed into sheets)	✓ x
Vitamin B-12	✓ (purified)	✓
bacteria	✓ (all naturally-occurring components collected together)	x
bacteria	✓ (plasmid inserted into bacteria)	✓
cDNA	✓ (exons removed)	X (but irrelevant, as cDNA is completely synthetic and cannot be isolated from nature)
genomic DNA/small cDNA	X (no further inquiry due to collapse of structure/function)	

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