

Biotechnology/Chemical/Pharmaceutical Customer Partnership

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Evaluating Subject Matter Eligibility Under 35 USC § 101



June Cohan, Office of Patent Legal Administration
Ali Salimi, Office of Patent Legal Administration
Daniel Sullivan, SPE Art Unit 1611

United States Patent and Trademark Office



Today's Discussion

- Purpose of today's discussion is two-fold:
 - Provide insight into how the Guidance was developed, and its basis in Supreme Court precedent.
 - Discuss how applicants can claim natural products in a manner that demonstrates a significant difference from the natural products themselves.



Public Comments and Feedback

- Office invites public comments and feedback on any aspect of the Guidance, including the Guidance document itself and the training slides.
- Ways to provide comments and feedback:
 - Written comments; and/or
 - Public forum on May 9, 2014.
- The Office will monitor the comments, feedback, and developing law regarding subject matter eligibility, and will provide additional guidance and modifications and updates as appropriate.



Next Steps

- Ongoing dialog with public and review of public comments and feedback.
- First round of training: currently in progress.
- Second round of training: currently in development. Plans include provision of additional claim examples and workshop training.
- Update MPEP.



Overview of Presentation

- Meaning of “Laws of Nature” & “Natural Products”
- Discoveries vs. Practical Applications
- Meaning of “Significantly Different”
- Broadest Reasonable Interpretation: Gunpowder Example
- Additional Information/Questions



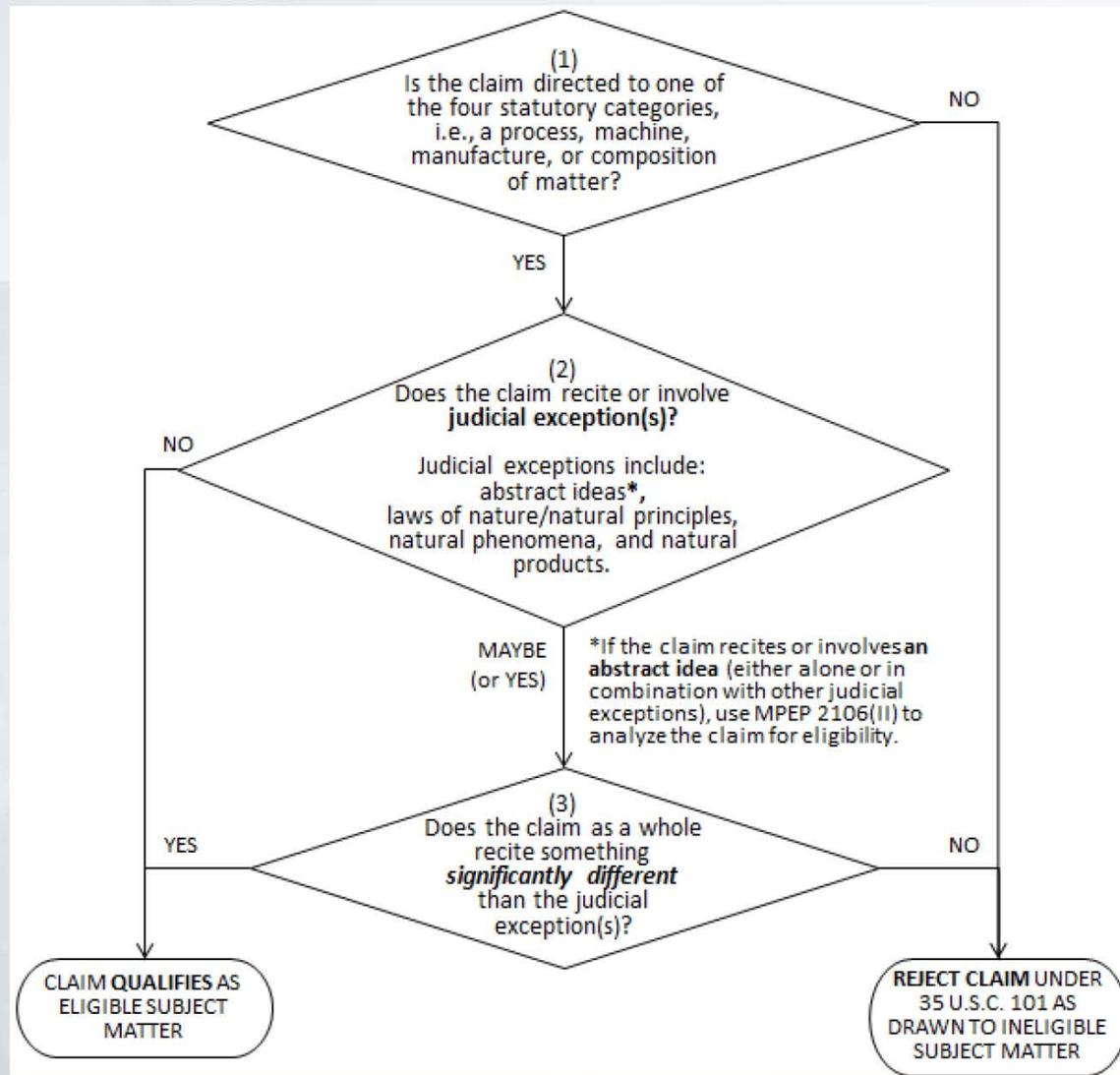
35 U.S.C. § 101

§ 101 - Inventions Patentable:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.



Overall Process: Flowchart





Overall Process: Summary

- Summary of eligibility analysis:
 - The claim as a whole is given its **broadest reasonable interpretation** (BRI)
 - Using the BRI, the claim is evaluated to determine whether it falls within at least one of the **statutory categories** of invention (Flowchart Question 1)
 - If it falls within an eligible category, the claim is evaluated to determine whether it **recites or involves a judicial exception** (Flowchart Question 2)
 - If the claim does recite/involve one or more judicial exceptions, the claim as a whole is evaluated to determine whether it **recites something significantly different than the judicial exception** (Flowchart Question 3)



Meaning of “Laws of Nature” and “Natural Products”



Laws of Nature/Natural Principles and Natural Phenomena

- “Laws of Nature” and “Natural Phenomena” include natural principles, naturally occurring relations or correlations, etc.
- Examples:
 - The law of gravity
 - The disinfectant qualities of ultraviolet light
 - The relationship between blood glucose levels and diabetes



Human Actions Can Trigger Manifestations of Laws of Nature

Prometheus' patents set forth laws of nature-namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. ... While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body -entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

– *Mayo*, 132 S. Ct. at 1296-97.



When Does A Claim Recite or Involve A Law of Nature?

Claim Language That Does Recite or Involve Laws of Nature

- Diagnosing a condition based on a naturally occurring correlation of levels of a substance produced in the body when a condition is present.
- Identifying a disease using a naturally occurring relationship between the presence of a substance in the body and incidence of disease.

Claim Language That Does Not Recite or Involve Laws of Nature

- Treating a patient by performing a medical procedure.
- A new way of using an existing drug.

Note that claims reciting such language are not necessarily eligible, because they may contain other language that does recite or involve a law of nature, or that recites or involves a *different* judicial exception (e.g., a natural product).



Claim Involving A Law of Nature

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Judicial Exception (Law of Nature)

Relationship between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.

This claim needs analysis under Question 3.



Things That May Be Natural Products

- Products requiring further analysis to determine whether they are “natural products” include, but are not limited to:
 - chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.);
 - foods (e.g., fruits, grains, meats and vegetables);
 - metals and metallic compounds that exist in nature;
 - minerals and natural materials (e.g., rocks, sands, soils);
 - nucleic acids;
 - organisms (e.g., bacteria, plants and multicellular animals);
 - proteins and peptides; and
 - other substances found in or derived from nature.
- These products may or may not be eligible, depending on the results of the analysis under Question 3.



But Wasn't *Myriad* About DNA?

- Why are we talking about natural products that are not nucleic acids?
- In other words, why does the Guidance extend the decision in *Myriad* beyond nucleic acids?



Guidance Addresses Multiple Decisions Of The Supreme Court

- Guidance is not limited to *Myriad*, but instead addresses *Myriad* in context of other Supreme Court decisions, including:
 - *American Fruit Growers*
 - *Benson*
 - *Bilski*
 - *Chakrabarty*
 - *Diehr*
 - *Flook*
 - *Funk Brothers*
 - *J.E.M. Ag Supply*
 - *Mayo*
 - *Morse*
- Why address these decisions together?



Myriad Relied On Earlier Precedent

- One reason for this approach is that *Myriad* explicitly relies on earlier Supreme Court precedent:
 - *Myriad* relies on *Chakrabarty* and serves as a reminder that *Chakrabarty*'s markedly different criterion is the eligibility test across all technologies for product claims reciting natural products; and
 - *Myriad* cites *Mayo* in support of its statement that there is a “rule against patents on naturally occurring things”.



Many Claims Concern Multiple Types Of Judicial Exception

- Another reason for this approach is that many claims presented by applicants concern two or more different types of judicial exceptions, for example both natural products and laws of nature, and so our examiners needed guidance on how to examine these types of claims.



“Naturally Occurring Things”

- Yet another reason is that the Supreme Court has made it clear that “naturally occurring things” is a broad term:
 - *Funk Brothers*: “patents cannot issue for the discovery of phenomena of nature” such as bacterial properties, the heat of the sun, electricity, or the properties of metals
 - *Chakrabarty*: “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.”
 - *Myriad*: “DNA's informational sequences and the processes that create mRNA, amino acids, and proteins occur naturally within cells.”



Discoveries vs. Practical Applications



Why Go To Question 3 When Applicant Made A Discovery?

- Before *Mayo* and *Myriad*, valuable discoveries relating to natural products and biological correlations were eligible. Why aren't these discoveries eligible anymore?
- In other words:
 - If applicant was the first to discover a naturally occurring thing, why do we have to proceed to Question 3?
 - Why is more than the “hand of man” required now?
 - Why is the Office not giving weight to the term “discovery” in 35 U.S.C. 101?



Office Must Follow Supreme Court Decisions

- Over the last 65 years, the Supreme Court has repeatedly explained, in *Chakrabarty* and other decisions, that a **mere discovery of nature's handiwork is not eligible**.
 - In other words, eligibility requires more than the “hand of man”.
- We are bound by the Supreme Court's interpretation of the statute.



1948: Mere Discovery Of Natural Phenomena Is Not Enough For Eligibility

[Patentee] does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. See *Le Roy v. Tatham*, 14 How. 156, 175. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.

- *Funk Brothers*, 333 U.S. at 130.



1978: Natural Phenomena and Laws of Nature Are Not Eligible Discoveries

The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of “discoveries” that the statute was enacted to protect.

- *Flook*, 437 U.S. at 593.



1980: Section 101 Does Not Embrace Every Discovery

This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.... Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.” *Funk, supra, at 130.*

- *Chakrabarty*, 447 U.S. at 309 (citations omitted).



2013: Even Brilliant or Groundbreaking Discoveries Are Not Eligible By Themselves

Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry. In [*Funk Brothers*], this Court ... held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way. (“There is no way in which we could call [the bacteria mixture a product of invention] unless we borrowed invention from the discovery of the natural principle itself”). His patent claim thus fell squarely within the law of nature exception. So do Myriad’s. Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes “new . . . composition[s] of matter,” §101, that are patent eligible.

- *Myriad*, 133 S. Ct. at 2117.



However, A Discovery May Be Eligible When It Is Practically Applied

- As explained in *Funk Brothers* at 130:
He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.
- *See also Myriad*, 133 S. Ct. at 2120:
Similarly, this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that, “[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge.”



How To Claim An Eligible Practical Application Of A Discovery

- To be eligible, a discovery of a naturally occurring thing must be claimed in a manner that demonstrates a practical application of the discovery:
 - A claim reciting nothing more than a law of nature or a natural product or phenomenon is not eligible.
 - However, a claim that demonstrates a practical application of the naturally occurring thing may be eligible, if the claim as a whole recites something significantly different than the law of nature or natural product or phenomenon by itself.
- We'll explore this concept in more detail with respect in the next section.



Meaning of “Significantly Different”



“Significantly Different”

- Guidance brings together the outcomes of both *Myriad* and *Mayo* in its expression of the “significantly different” standard for eligibility.
- “Significantly different” standard addresses the Supreme Court’s two articulated pathways to eligibility for claims reciting judicial exceptions such as natural products:
 1. **Marked difference** from what exists in nature; or
 2. Addition of **significantly more** to the judicial exception.



No Bright Line Rules

- The Guidance does not set forth bright line rules or *per se* categories of ineligible subject matter.
- Key to eligibility is whether the claim as a whole recites something significantly different than the judicial exception(s) that are recited or involved in the claim.



Do Not Jump To Conclusions

- Do not make conclusory judgments based on the mere recitation of particular words in the claim.
 - E.g., words such as “cDNA”, “composition”, “isolated”, “primer”, “purified”, “recombinant”, “synthetic”, and “vector”.
 - These words may reflect “hand of man” but are not necessarily determinative of eligibility.
 - For example, in *Myriad* some claims to “isolated DNA” were ineligible, and other claims to “isolated DNA” were eligible.



Evaluate “Significantly Different” By Weighing Factors

- New guidance follows the common theme from previous guidance of evaluating factors that weigh for, or against, eligibility.
- The examiner’s analysis should carefully consider every relevant factor, related evidence, and the claim as a whole before making a conclusion.



Summary of Factors

Factors that weigh toward eligibility (significantly different)

- a) Product claim recites something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products.

Claim recites elements/steps in addition to the judicial exception(s) that:

- b) Impose meaningful limits on the claim scope.
- c) Relate to the judicial exception(s) in a significant way, e.g., they are more than insignificant extra-solution activity.
- d) Do more than describe the judicial exception(s) with general instructions to apply/use it.
- e) Include a particular machine or particular transformation, which implements or integrates the judicial exception(s).
- f) Add a feature that is more than well-understood, purely conventional or routine.

Factors that weigh against eligibility (not significantly different)

- g) Product claim recites something that appears to be a natural product that is not markedly different in structure from naturally occurring products.

Claim recites elements/steps in addition to the judicial exception(s) that:

- h) Are recited at a high level of generality.
- i) Must be used/taken by others to apply the judicial exception(s).
- j) Are well-understood, purely conventional or routine.
- k) Are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s).
- l) Amount to nothing more than a mere field of use.



Factors Fall Into Two Groups

- Group One: Two factors applicable only to product claims
 - Factors a) and g)
 - Concern the structure of natural products and things that appear to be natural products
 - Represent *Chakrabarty's* “markedly different” pathway to eligibility
- Group Two: Ten factors applicable to all claims
 - Factors b)-f) and h)-l)
 - Concern whether the claim recites elements or steps in addition to the judicial exception(s), and whether those elements/steps add significantly more to the judicial exception(s)
 - Represent *Mayo's* “significantly more” pathway to eligibility



First Pathway: Marked Difference

- Group One factors represent *Chakrabarty*'s “**marked difference**” pathway to eligibility, which was applied in *Myriad*.
 - Product claim involving or reciting a natural product includes features demonstrating a **marked difference** from what exists in nature.
 - Requires a structural difference from what exists in nature, and that the structural difference is marked or significant, i.e., more than an incidental or trivial difference.
 - If the structural difference results in change to properties or characteristics of the product, it is more likely to be a marked difference.



Myriad Explains Marked Difference

In *Chakrabarty*, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. *447 U. S., at 305, 100 S. Ct. 2204, 65 L. Ed. 2d 144, and n. 1.* The Court held that the modified bacterium was patentable. It 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, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (quoting Hartranft v. Wiegmann, 121 U. S. 609, 615, 7 S. Ct. 1240, 30 L. Ed. 1012 (1887); alteration in original).* The *Chakrabarty* bacterium was new “with markedly different characteristics from any found in nature,” *447 U. S., at 310, 100 S. Ct. 2204, 65 L. Ed. 2d 144*, due to the additional plasmids and resultant “capacity for degrading oil.”



Non-Markedly Different DNA

Claimed
Isolated DNA



Isolated
BRCA1 gene

Naturally occurring
genomic DNA



BRCA1
gene

Claimed DNA
is not
markedly
different

Claim is not
eligible

- 1. Non-naturally occurring** because the isolated DNA is a “stand alone” molecule, whereas in nature the gene is part of a very long strand of DNA (a chromosome).
- 2. No marked difference in structure.** Isolated DNA is structurally different from chromosomal DNA, (e.g., chemical bonds on either end of gene have been “broken”) but this difference does not rise to the level of a marked difference for this claim, because there is no change to the genetic information.



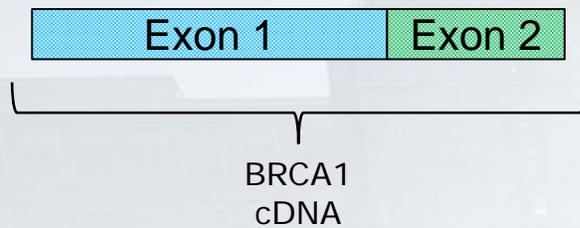
Myriad Changed Our Understanding Of The Law

- For 30+ years, Office practice was that “isolation” or “purification” of **an otherwise unchanged** naturally occurring product was sufficient for eligibility.
- Supreme Court gave no deference to past Office practice.
- Supreme Court made it clear in *Myriad* that isolating a natural product such as a gene, even though it “creates a nonnaturally occurring molecule”, is **not enough for eligibility**. Instead, eligibility requires the creation of something not naturally occurring, which is markedly different from what exists in nature.

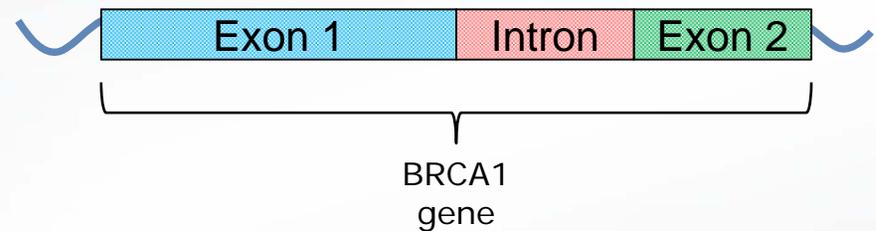


Markedly Different DNA

Claimed
cDNA



Naturally occurring
BRCA1 gene



**Claimed DNA
is markedly
different**

**Claim is
eligible**

- 1. Non-naturally occurring** because the exons-only cDNA molecule does not exist in nature. In nature, the gene includes both exons and introns.
- 2. Markedly different in structure.** The cDNA has an altered structure (the nucleotide sequence) that is distinct from the naturally occurring chromosomal DNA due to the removal of the intron. This altered structure rises to the level of a marked difference.



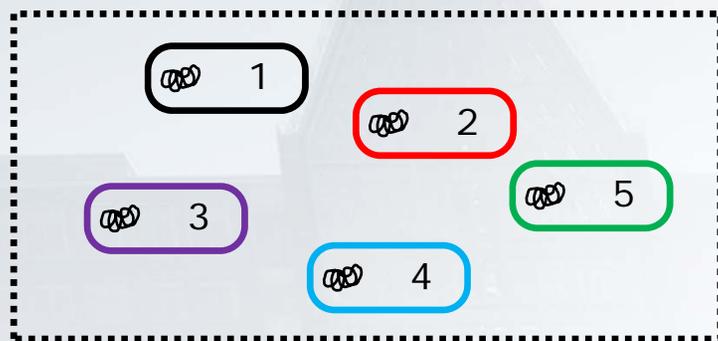
Not All cDNA Is Eligible

- A claim to a cDNA sequence may or may not be eligible, depending on the nucleotide sequence.
- No assumptions should be made based on usage of the term “cDNA”. Instead, must examine cDNA for eligibility on a case-by-case basis.
- Two points to keep in mind:
 - Don’t make assumptions about whether a gene has introns. E.g., although most bacterial genes lack introns, some do have them. Similarly, although most mammalian genes have introns, some do not.
 - Even if a gene has introns, a cDNA of that gene may not be eligible, e.g., because it does not span an exon-exon junction.

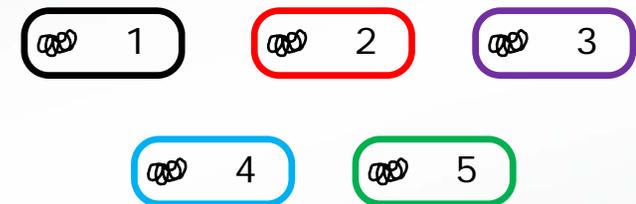


Non-Markedly Different Mixture of Natural Products

Claimed Inoculant



Naturally occurring
Rhizobium bacteria



Claimed inoculant is not markedly different

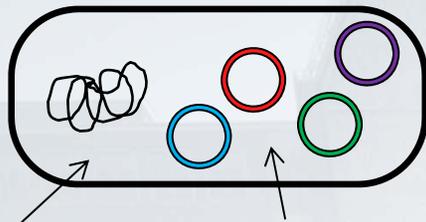
Claim is not eligible

1. Fails to satisfy non-naturally occurring requirement, because bacteria all exist in nature.
2. **No structural difference** because the mere aggregation of naturally occurring bacteria together as an “inoculant” does not change the structure of the bacteria.



Markedly Different Combination of Natural Products

Genetically modified claimed
Pseudomonas bacterium

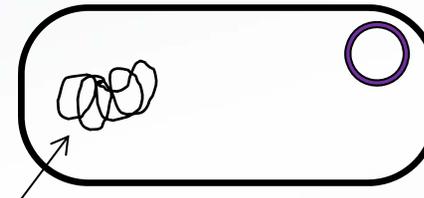


Can degrade four
hydrocarbons

Bacterial
chromosome

Added plasmids

Naturally occurring
Pseudomonas bacterium



Can only degrade
one hydrocarbon

Bacterial
chromosome

**Claimed
bacterium is
markedly
different**

**Claim is
eligible**

1. Non-naturally occurring because bacterium with multiple plasmids does not occur in nature, but instead was created by human manipulation.

2. Markedly different in structure

- structural difference (includes multiple plasmids that are not found in naturally occurring *Pseudomonas* bacteria);
- structural difference results in change to properties of bacterium (able to degrade multiple hydrocarbons as compared to naturally occurring *Pseudomonas* bacteria that can only degrade a single hydrocarbon).



Focus Remains On Product, Not How It Was Made

- “Markedly Different” inquiry focuses on the structural characteristics of the product, not how it was made:
 - Don’t have to use new techniques.
 - Don’t have to use laboratory or engineering techniques.
 - Extent of effort required to make product is not relevant.
- Examples:
 - A cDNA with an altered sequence can be eligible, even though creating cDNA is routine in the biotechnology art.
 - A hybrid plant can be eligible, even if it was created via manipulation of natural pollination and fertilization processes.



Why Do The Marked Difference Factors Only Apply To Product Claims?

- Rationale One: As applied in *Chakrabarty* and *Myriad*, the marked difference inquiry focused on the structural characteristics of the product, not how it was made or how it was used.
- Rationale Two: For many process claims, there are multiple types of judicial exceptions recited. Even if something that appears to be a natural product turns out to be markedly different, the claim may still recite/involve an abstract idea, law of nature, or natural phenomenon that precludes eligibility. So the marked difference factors are rarely determinative of eligibility for process claims.



Why Is “Marked Difference” Limited To Structure?

- Supreme Court has never held a claim reciting a natural product eligible unless it was structurally different than what exists in nature (and even then, the structural difference has to be marked):
 - *American Fruit Growers* (citrus fruit impregnated with borax ineligible because “no change in the name, appearance, or general character of the fruit”);
 - *Funk Brothers* (mixture of bacteria ineligible because patentee “did not alter the bacteria in any way”);
 - *Chakrabarty* (bacterium transformed with multiple plasmids eligible because it had “markedly different characteristics” due to the additional plasmids and resultant capacity to degrade oil); and
 - *Myriad* (isolated DNA is a “nonnaturally occurring molecule” but is not eligible; cDNA can be eligible if nucleotide sequence differs from natural sequence).



There Are Other Options For Claiming A Natural Product

- Even if the natural product is not changed structurally, there are other options for claiming it.
 - The natural product can be combined with something else in a way that makes the combination markedly different, e.g., it can be practically applied.
 - E.g., the *Chakrabarty* bacterium.
 - The natural product can be combined with something else that adds significantly more to the natural product.
 - E.g., a method of using the natural product, or a manufacture comprising the natural product and additional components.



Second Pathway: Adding Significantly More

- Group Two factors represent *Mayo*'s “**significantly more**” pathway to eligibility.
- Guidance recites 10 factors directed to the “significantly more” pathway, which factors require a claim to recite elements or steps that:
 - are in addition to the judicial exception(s); and
 - that add significantly more to the judicial exception(s).
- Adding “significantly more” can occur in multiple ways (that’s why there are 10 different factors).



Mayo On Significantly More

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent eligible processes that *apply* natural laws? We believe that the answer to this question is no.

- *Mayo*, 132 S. Ct. at 1297.



Mayo On Elements/Steps In Addition To A Judicial Exception

[Earlier Supreme Court cases] insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an “inventive concept,” sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.

- *Mayo*, 132 S. Ct. at 1294.

If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.

- *Mayo*, 132 S. Ct. at 1297.



Broadest Reasonable Interpretation: Gunpowder Example



Guidance Example C

A fountain-style firework comprising: (a) a sparking composition, (b) calcium chloride, (c) gunpowder, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder...

- This claim is eligible. Although the calcium chloride and gunpowder are not markedly different from what occurs in nature, the claim recites meaningful limitations (the cardboard body) that narrow the scope of the claim, relate to the natural products in a significant way, and do more than describe the natural products with general instructions to use or apply them. See Example C in the Guidance.



Gunpowder: An Explosive Example?

- The intent behind Example C's statement that "gunpowder" was not markedly different was to emphasize that there are no "magic" words that automatically confer eligibility on a claim. Instead, examiners must give the claim its **broadest reasonable interpretation**, and then examine the claim for eligibility.
- In order to improve understanding of the issues raised by this example, the next few slides break down the Office's analysis.



Broadest Reasonable Interpretation

- Eligibility analysis is based on the **broadest reasonable interpretation** (BRI) of the claim. See MPEP 2111.
 - Because applicant has the opportunity to amend the claims during prosecution, giving a claim its BRI will reduce the possibility that the claim, once issued, will be interpreted more broadly than is justified.
 - Remember, BRI is a different claim interpretation standard than used in the federal courts with respect to issued patents.



So What Does “Gunpowder” Mean? There Are At Least Four Different Types

1. **Simple Mixture**: A mixture of three naturally occurring materials: potassium nitrate, sulfur and charcoal. Vibration causes separation back into its component parts. Such a mixture is not markedly different because none of the components have been changed.
2. **Corned Gunpowder**: A wet-ground intimate mixture of fine-grained powder comprising potassium nitrate, sulfur and charcoal, formed into corn-sized clumps and then dried. Corned gunpowder is markedly different from what exists in nature:
 - Corned gunpowder is structurally different from what exists in nature, because the materials have been combined in a particular way (e.g., particular grain size, intimate mixture, wet-ground, clump size) to yield a manufacture that is entirely different from a mere mixture of the raw materials from which it was formed.
 - In addition, the structural difference results in a change to the properties of the powder (has reduced moisture absorption as compared to the simple mixture).



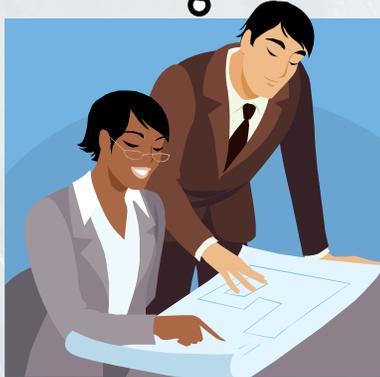
So What Does “Gunpowder” Mean? There Are At Least Four Different Types

3. **Glazed Powder**: A glazed powder formed from four naturally occurring materials: sodium nitrate, sulfur and charcoal are intimately mixed and then granulated, and then the granulated particles are coated with a thin layer of graphite. This powder is markedly different from what exists in nature:
 - This glazed powder is structurally different from what exists in nature, because the materials have been combined in a particular way (intimate mixing, granulation, coating) to yield a manufacture that is entirely different from a mere mixture of the raw materials from which it was formed. In addition, the structural difference results in a change to the properties of the powder (it can no longer deliquesce due to the coating).
4. **White Powder**: A mixture of insoluble nitrocellulose, soluble nitrocellulose, and paraffin, formed into sheets and flaked. White powder is markedly different from what exists in nature (cellulose is a natural component of wood), because of the structural differences caused by chemically changing the cellulose into nitrocellulose and combining it with paraffin in a particular way (intimate mixing, sheeting and flaking).



Examiners And Applicants May Be Thinking About “Gunpowder” In Different Ways

*BRI includes Types 1-4.
Type 1 (simple mixture)
is not markedly
different.*



**Examiners
applying BRI**

“Gunpowder”

*Gunpowder could be
Type 3 glazed powder,
or Type 4 white powder,
both of which are
markedly different.*



Applicant



BRI Of “Gunpowder” Includes All Four Types

- In Example C, there is no indication (in the claim or the background facts) that “gunpowder” is being used in a particular way to refer to only one or a few of the multiple types of gunpowder. Thus, “gunpowder” is given a broadest reasonable interpretation from the perspective of the POSITA.
 - BRI includes non-markedly different (Type 1 simple mixture) and markedly different (Types 2, 3 and 4) embodiments.
 - Because the BRI of “gunpowder” includes an embodiment (Type 1 simple mixture) that is not markedly different, the term “gunpowder” in this Example is not considered to be markedly different from what exists in nature.



Does This Mean “Gunpowder” Is Never Markedly Different?

- No. Remember, there are no bright line or *per se* rules.
- In another application, the BRI of “gunpowder” could be different, for example because:
 - The claim language is different, e.g., the claim recites features that demonstrate that the particular claimed gunpowder is markedly different; and/or
 - The specification is different, e.g., the specification expressly disclaims a broad interpretation of gunpowder.
- **Another important point: the claim in Example C is eligible, even though various claimed components are not markedly different.**



Additional Information



More Information



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USPTO Issues Guidance on Patent Subject Matter Eligibility

The USPTO has issued a memorandum to patent examiners to implement changes in the law relating to subject matter eligibility in view of recent court decisions including *Myriad* and *Mayo*. Feedback is welcome.



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Guidance Web Page

- Guidance, training materials, and related documents
- Forum information
 - Forum is May 9th
 - Details in Fed. Register Notice of April 17th
- Link to submit public comments

www.uspto.gov/patents/announce/myriad-mayo.jsp



Case Citations

- Note, text emphasized by the Office is underscored. All other emphases are in the original text.
- Case citations:
 - *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 133 S. Ct. 2107, 106 USPQ2d 1972 (2013)
 - *Mayo Collaborative Services, v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012)
 - *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010)
 - *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980)
 - *Parker v. Flook*, 437 U.S. 584, 198 USPQ 193 (1978)
 - *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948)



Courts Are Expected To Provide Additional Guidance Soon

- *Alice v. CLS Bank* is pending at the Supreme Court.
- Three appeals are pending at the Federal Circuit:
 - *In re Roslin Institute (Edinburgh)* – product claims reciting cloned mammals
 - *Ariosa Diagnostics v. Sequenom* – methods of detecting DNA in a sample
 - *University of Utah Research Foundation v. Ambry Genetics Corp.* – product claims reciting primers, and methods of comparing and analyzing DNA



Comments?

Comments are welcome on any aspect of the Guidance, including the Guidance document itself and the training slides. Suggested examples for future examiner training are also welcome. Comments will be publicly posted.

myriad-mayo_2014@uspto.gov

The Office will monitor the feedback and developing law regarding subject matter eligibility, and will provide additional guidance and updates as necessary.



THANK YOU!

June E. Cohan

Legal Advisor, Office of
Patent Legal Administration
571.272.7744
june.cohan@uspto.gov

Ali Salimi

Legal Advisor, Office of
Patent Legal Administration
571.272.0909
ali.salimi@uspto.gov

Daniel Sullivan

Supervisory Patent Examiner
Art Unit 1611
571.272.0779
daniel.sullivan@uspto.gov

QUESTIONS?