



Topics

- **Overview of Eligibility Guidance**
- **Discoveries v Practical Applications**
- **Meaning of “Significantly Different”**
- ***Chakrabarty* Pathway**
- ***Mayo* Pathway**
- **Broadest Reasonable Interpretation:
Gunpowder Example**



Overview of Eligibility Guidance



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.
- Imposes three requirements (MPEP 2104):
 - Double patenting
 - Eligibility
 - Utility



USPTO Eligibility Guidance

- Two sets of eligibility guidance are in effect at the USPTO:
 - Claims reciting **abstract ideas** are examined in accordance with MPEP 2106 and 2010 *Bilski* Guidance.
 - Claims reciting or involving **naturally occurring things (laws of nature, natural products, and natural phenomena)** are examined in accordance with the Guidance For Determining Subject Matter Eligibility Of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products (issued March 4, 2014; not yet in MPEP) aka “New Guidance.”



Summary of Examination Process Under The New Guidance

The claim as a whole is given its **broadest reasonable interpretation** (BRI), and then:

1. The claim is evaluated to determine whether it falls within at least one of the **statutory categories** of invention (Flowchart Question 1);
2. If it falls within an eligible category, the claim is evaluated to determine whether it **recites or involves a judicial exception** (Flowchart Question 2); and
3. 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).



Claims Reciting Naturally Occurring Things May or May Not Be Eligible

- “**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
- Examples of things that *may* be “**natural products**” include:
 - chemicals derived from natural sources
 - minerals and natural materials
 - organisms

Claims reciting these products may or may not be eligible, depending on the results of the analysis under Question 3.



New Guidance Addresses Multiple Decisions Of The Supreme Court

- Why are we talking about natural products that are not nucleic acids? Wasn't *Myriad* about DNA?
- New 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*

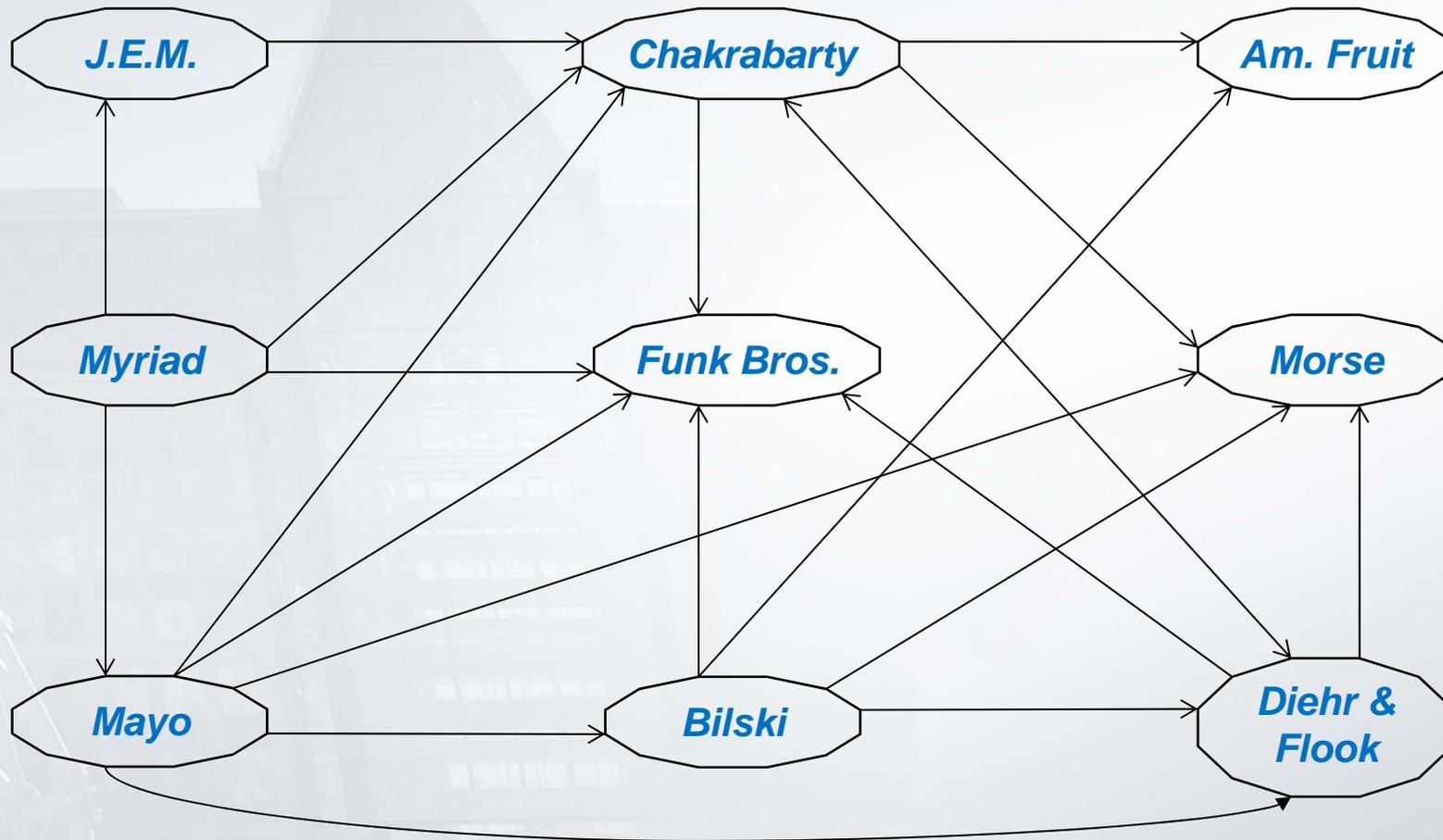


Why Is The New Guidance So Comprehensive?

- *Myriad* **explicitly relies** on earlier Supreme Court precedent including *Chakrabarty* and *Mayo*;
- Examiners needed guidance on **claims concerning multiple types of judicial exceptions**, e.g., both natural products and laws of nature; and
- Supreme Court has made it clear that **“naturally occurring things” is a broad term**, e.g., *Chakrabarty*’s statement that “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.”



Supreme Court Eligibility Decisions Are Interrelated



Diehr and *Flook* have been combined to simplify the drawing. Note that *Diehr* is later in time than *Chakrabarty* and *Flook*, and cites both. *Chakrabarty* cites only *Flook*.



Discoveries vs. Practical Applications



Why Aren't Discoveries Of Natural Things Eligible Anymore?

- We've received feedback stating that the New Guidance does not give weight to the term "discovery" in 35 U.S.C. § 101.
- Over the last 65 years, the Supreme Court has repeatedly explained that a **mere discovery of nature's handiwork is not eligible**.
- We are bound by the Supreme Court's interpretation of the statute.



Supreme Court Has Explained That “Discovery” Is Not Enough For Eligibility

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 (1948).

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.... 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 (2013).

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 (1978).

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 (1980).



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

- Supreme Court has also provided guidance about how to claim a **practical application** of a naturally occurring thing. See *Funk Brothers*, 333 U.S. at 130; *Mayo*, 132 S. Ct. at 1289; *Myriad*, 133 S. Ct. at 2120.
- To be eligible, a discovery of a naturally occurring thing (law of nature or natural product/phenomenon) must be claimed in a manner that demonstrates a practical application of the discovery.
 - Not eligible: a claim that simply states the naturally occurring thing while adding the words “apply it”.
 - Eligible: a claim that as a whole recites something **significantly different** than the naturally occurring thing by itself.



Meaning of “Significantly Different”



“Significantly Different” Addresses Supreme Court’s Two Pathways to Eligibility

- New 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.



Evaluate “Significantly Different” By Weighing Factors

- Guidance introduces **no bright line rules** or *per se* categories of ineligible subject matter. There are no “magic words” that automatically confer eligibility on a claim.
- New Guidance follows the common theme from previous guidance of **evaluating factors** that weigh for, or against, eligibility. No one factor is controlling.
- **Flexible test** accommodates all technologies, and allows examiners to consider relevant factors, 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.



Chakrabarty Pathway



First Pathway To Eligibility: Marked Difference

- Factors **a** and **g** represent *Chakrabarty*'s “**marked difference**” pathway to eligibility, which was applied in *Myriad*.
 - Factors **a** and **g** concern whether a product claim reciting something that appears to be a natural product includes features demonstrating a **marked difference in structure** from what exists in nature.
 - Inquiry focuses on the structural characteristics of the product, not how it was made:
 - Don't have to use new or non-routine techniques.
 - Don't have to use laboratory or engineering techniques.
 - Extent of effort required to make product is not relevant.



Examiner Must Provide Supporting Rationale or Evidence

- Initial burden is on the examiner to establish a *prima facie* case of ineligibility.
- When rejecting claim, examiner must provide rationale or evidence to reasonably support a determination that a product is not markedly different from what exists in nature.
 - Evidence is not limited by filing date of application.
 - Mere speculation about hypothetical products does not amount to reasonable support.
- Example (from *Myriad's* footnote 8):
 - A theoretical possibility that nature *might* have randomly created a product similar to the claimed product is not enough to negate eligibility.



Several Supreme Court Decisions Provide Guidance

- *Myriad* gave examples of eligible & ineligible DNA claims:
 - Isolated DNA is a non-natural and structurally different molecule than natural DNA, but it is not markedly different → ineligible.
 - cDNA with a sequence altered to be non-natural is markedly different → **eligible**.
- *Funk Brothers vs. Chakrabarty*
 - Mere aggregation or co-location of naturally occurring bacteria together as an “inoculant” did not alter the bacteria → ineligible.
 - Combining natural products together to form a new structure (bacterium containing multiple plasmids) that has new functional characteristics created a marked difference → **eligible**.



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 made it clear in *Myriad* that isolating 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.



CAFC - *In re Roslin Institute* (*Edinburgh*)

- Yesterday's decision by Judge Dyk:
 - Added a new data point (cloned mammals) in support of the position that *Chakrabarty's* marked difference test is the eligibility test for all natural products (*Chakrabarty* – bacterium; *Myriad* – DNA).
 - Affirmed that subject matter eligibility analysis is a case-by-case inquiry that focuses on what is claimed.



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 had 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).



Can A Functional Difference On Its Own Amount To A Marked Difference?

- Our interpretation of *Myriad* led us to conclude that the answer is no.
 - Briefs submitted to the Supreme Court argued that the isolated DNA of *Myriad's* claims performed new functions and new utilities that native DNA cannot perform.
 - Arguments did not alter the Court's decision that eligibility hinged on a markedly different structural change.
- We are open to hearing alternative interpretations and considering examples.



There Are Other Options For Claiming A Natural Product

- There are several ways to make a claim reciting or involving a natural product eligible, even if the natural product is not markedly different from what exists in nature.
 - Combine the natural product with something else, and draft a claim to the embodiments of the combination that possess **markedly different characteristics** from any found in nature, while excluding any embodiment that does not reflect a marked difference, e.g., mere aggregation of components.
 - E.g., the *Chakrabarty* bacterium.
 - Combine the natural product 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.



Mayo Pathway



Second Pathway To Eligibility: Adding Significantly More

- Group Two factors represent *Mayo*'s “**significantly more**” pathway to eligibility.
- 10 factors (**b-f & h-l**) concern whether a claim recites 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.

For more explanation of the “significantly more” factors, see *Benson*, *Flook*, and *Diehr*, and *Mayo*’s discussion of these decisions.



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.**