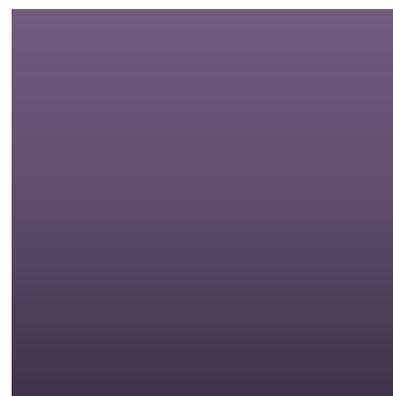
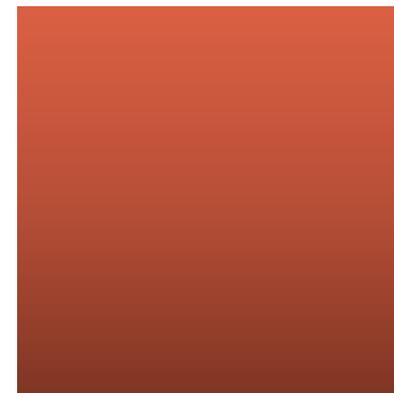


USPTO Forum on Guidance For Determining Subject Matter Eligibility

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Why Are We Here?



- The Supreme Court's *Myriad* decision invalidated the USPTO's 30-year practice of granting patents on "isolated" DNA molecules.

“We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.”

Expected Guidance:



- Explain how the *Myriad* decision applies to other products that can be “isolated” from nature.
 - Proteins?
 - Antibodies?
 - Stem cells?
 - Bacteria?
 - Small molecule chemicals?

Issued Guidance:



- Extends *Myriad* to subject matter that was not before the Court and/or that the Court expressly stated that it was not addressing:
 - Compositions of matter
 - Methods of treatment
 - Methods of manufacture

Issued Guidance:



- In both *Myriad* and *Mayo*, the Supreme Court warned against overly-broad applications of the subject matter eligibility exceptions:

The Court has recognized, however, that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.

- The USPTO Guidance threatens to do just that—eviscerate patent law and stifle investment and innovation

Issued Guidance:



- Of 1,355 drugs approved between 1981 and 2010 over 2/3 (968, 71%) are outside the scope of the Guidelines
- 50% of all small molecule drugs are natural products (2000-2010)
- 75% of antibacterial drugs are natural products or derived from natural products

Source: Sherry Knowles; Kevin Noonan; NIH Natural Product Branch Report (Newman and Craig, J. Nat. Prod. 75(3): 311-55 (2012))

Where the USPTO Went Wrong:



- Overly narrow interpretation // overly broad application of *Funk Bros.*
- Parsing of claim elements rather than considering claims as a whole
 - Only claim elements that are not a “judicial exception” can support patent eligibility (“claim recites elements/steps in addition to the judicial exception(s) that”)

Funk Brothers:



Representative claim 4:

An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant.

Funk Brothers:



The aggregation of select strains ... into one product is hardly more than an advance in the packaging of the inoculants. 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.

USPTO Guidance based on *Funk Bros.*:

- A product is a non-eligible natural product unless it is “markedly different in structure” from the natural product.
- A composition (combination of products) is non-eligible unless at least one of the components is not a natural product (juice) or unless the components have a specific physical interrelationship (firework).

USPTO Guidance based on *Funk Bros.*:

- The USPTO focuses on this sentence in *Myriad* about *Funk Bros.*:

The Court held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way.

- But *Myriad* also discusses *Chakrabarty*:

The Court held that the modified bacterium was patentable. The *Chakrabarty* bacterium was new “with markedly different characteristics from any found in nature,” 447 U. S., at 310, due to the additional plasmids and resultant “capacity for degrading oil.”

Chakrabarty:

Cites this entire passage from *Funk Bros.*:

The aggregation of select strains ... into one product is hardly more than an advance in the packaging of the inoculants. 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.

Chakrabarty:



Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.

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.” (quoting *Hartranft v. Wiegmann*, 121 U. S. 609, 615 (1887)).

Alternative Test For Compositions:



- The Supreme Court has not questioned the eligibility of pharmaceutical compositions

Unlike, say, a typical patent on a new drug ... the [Prometheus] patent claims do not confine their reach to particular applications of those laws. (*Mayo*)

[T]his case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes. (*Myriad*)

Alternative Test For Compositions:

Alternative test based on *Funk Bros.*

- Is any component of the claimed composition markedly structurally different from a product of nature?
- Does the composition as claimed have a “different use” from its naturally-occurring components?
- Does the composition as claimed offer an “enlargement of the range of ... utility” as compared to its naturally-occurring components?
- Does the composition as claimed have a different effect from the effect that the naturally-occurring components “always had” in their natural environment?
- Does the composition as claimed “improve in any way” the natural functioning of the naturally-occurring components?
- Does the composition as claimed serve any ends other than “the ends nature originally provided”?
- Do the components of the composition as claimed act in concert (e.g., is their function dependent on the effort of the patentee)?

Alternative Test For Compositions:



Alternative test based on USPTO Guidance

- (b) Does the composition as claimed impose meaningful limits on the claim scope vis-à-vis the individual, naturally-occurring components?
- (c) Do the components relate to each other in a significant way?
- (d) Does the composition as claimed confine the natural products to a particular application?
- (e) Does the composition as claimed embody a particular machine or particular transformation?
- (f) Does the composition as claimed possess a feature that is more than well-understood, purely conventional or routine?

Alternative Test For Compositions:



Composition comprising Juice + Preservative

- **(b)** The composition as claimed meaningfully limits claim scope to a particular application of the natural products.
- **(c)** The components relate to each other in a significant way because the preservative prevents the juice from spoiling.
- **(d)** The composition as claimed confines the preservative to a particular application (in the juice).

Alternative Test For Compositions:



(e) The composition embodies a transformation due to the physical interrelationship among components (emulsion, liposomes, etc.).

(f) The composition exhibits properties that are more than well-understood, purely conventional or routine.

Why Are Method of Manufacture Claims Subject To Eligibility Scrutiny?



- *Funk Bros.* does not address method claims:

We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable.

- *Myriad* does not address method claims:

It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court.

Why Are Method of Treatment Claims Subject To Eligibility Scrutiny?



- **Mayo** did not undermine eligibility of method of treatment claims:
Unlike, say, a typical patent on ... a new way of using an existing drug, the [Prometheus] patent claims do not confine their reach to particular applications of those laws.
- **Myriad** indicated method claims would be eligible:
[T]his case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes. Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.

What Can Applicants Do?



- Many Examiners feel “top down” pressure to reject claims under the Guidance
- Will Examiners/Supervisors withdraw rejections that don’t exactly fall under a “patent eligible” example?
- Do we need to meet with Group Directors?
- Do we need to take every case to the PTAB?
- Will the PTO offer an expedited route to a PTAB decision?

Thank You



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