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Guidance For Determining Subject Matter Eligibility Of
Claims Reciting Or Involving Laws of Nature, Natural
Phenomena, & Natural Products

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Summary of Talking Points

- A *Wands* factor-based approach is inappropriate for 101 eligibility determinations
- Process claims and product claims should be evaluated under separate tests
- The Guidance is based on interpretations of *Mayo* and *Myriad* that are too broad

Wands Factor-Based Analysis & Reasoning

- On balance, if the totality of the relevant factors weigh toward eligibility, the claim qualifies as eligible subject matter. If the totality of the relevant factors weighs against eligibility, the claim should be rejected. ... The determination of eligibility ... is a conclusion reached by weighing the relevant factors, keeping in mind that the weight accorded each factor will vary based upon the facts of the application. This factor-based analysis, which requires consideration and subsequent weighing of multiple factors, is similar to the *Wands* factor-based analysis used to evaluate whether undue experimentation is required to make and use a particular claimed invention.
- PTO employs a *Wands* factor-based analysis because “Examiners are accustomed to weighing evidence (e.g., *Wands* factors for enablement)”. See Slide 33 of March 19th Slides.

Wands Factor-Based Analysis for §112

- *In re Wands* involved the question of undue experimentation under §112, not patent eligibility under §101.
- The court stated that the a determination of undue experimentation is a conclusion reached by weighing many factual considerations and that the factors to consider include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

101 Inquiry ≠ 112 Inquiry

- The question of 101 eligibility is completely different inquiry from enablement.
- The Court in *Mayo* stated:
 - Section 112 requires only a "written description of the invention ... in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same." It does not focus on the possibility that a law of nature (or its equivalent) that meets these conditions will nonetheless create the kind of risk that underlies the law of nature exception, namely the risk that a patent on the law would significantly impede future innovation.
 - These considerations lead us to decline the Government's invitation to substitute §§102, 103, and 112 inquiries for the better established inquiry under §101.

Result if *Wands* Approach Applied

- An ineligible factor can negate an eligible factor
 - Consider a process claim which involves a judicial exception, e.g., recites a law of nature. The process claim recites steps that integrates the judicial exception into a practical application thereby satisfies eligible factor e). However, the claim also recites steps that are well-understood, conventional, or routine and thereby satisfies ineligible factor j).
 - PTO's approach balances ineligible factor j) against eligible factor e).
 - What if one simply deletes the “conventional” steps?
 - What if the “conventional” steps are essential to performing the claimed process?

Absurdity if *Wands* Approach Applied

- If the *Wands* Approach is applied to the claims of *Diehr*, the steps of installing the rubber in the press and the subsequent closing of the press would negate the fact that the process integrated the algorithm into a practical application, i.e., curing and molding rubber.
- Supreme Court decisions which have found in favor of eligibility did not look for ineligible factors to negate (i.e., weigh against) their finding of eligibility.

If Not *Wands*, What Approach?

- Just because *Myriad* cites to *Mayo* does not mean process and product claims have the same eligibility considerations.
 - PTO mischaracterizes the “Rule against patents” statement in *Myriad*.
 - In *Myriad*, no method claims were considered.
 - In *Mayo*, only process claims were considered.
 - *Diehr* and *Bilski* cite *Chakrabarty*.
 - Should we ignore Supreme Court precedent distinguishing process claims from product (e.g., machine and articles of manufacture) claims?
- “Significantly different”, which = “significantly more” + “markedly different” is inappropriate.
 - Nowhere does the Court hold that a product must be both significantly more and markedly different.
- How are laws of nature different from abstract ideas?
 - If products of nature are considered equivalent to laws of nature, how are products of nature different from abstract ideas?

Analyze Processes & Products Separately

- There should be two separate and distinct tests for process claims and composition claims.
- Process Claims = “Significantly More”
- Product Claims = “Markedly Different Characteristic”

Process Claims – Significantly More

- The Guidance states that claims reciting abstract ideas should be examined under a different analysis than claims reciting laws of nature.
 - Abstract ideas → Bilski Guidance
 - Laws of nature → Mayo/Myriad Guidance
 - Abstract ideas + Laws of nature → Bilski Guidance
- Analyzing such process claims differently = crafting finely tailored rules for given technologies which the Court in *Mayo* stated is the role of Congress (not the PTO).
 - Thus, the analysis for process claims reciting laws of nature and process claims reciting abstract ideas should be the same.

Process Claims – Practical Application

- Process Claims: Does the claim recite steps that are significantly more than the judicial exception itself?
- What is “significantly more”?
 - Actually applying the judicial exception to achieve a practical application rather than simply referring to the judicial exception.
 - In other words, steps that integrate the judicial exception into a practical application.
- Thus, the first question should be: Is the claim directed to achieving a practical application?
 - Practical Application = Utility, i.e., usefulness

Process Claims – Integration

- The second question should be: Does the claim recite steps that integrate the judicial exception into the practical application?
- Implicit to this question of integration is whether the step(s) is essential to achieving the practical application or whether the step(s) is merely pre- or post-solution activity.
- Proposal: Determine whether the practical application can still be achieved by omitting the given step(s).
 - If can be omitted = pre- or post-solution activity. As a result, the claim merely “refers to” the judicial exception.
 - If can’t be omitted = essential. As a result the claim integrates, i.e., actually applies, the judicial exception.

Product Claims – Marked Difference

- The Guidance requires that patent eligible product claims must exhibit a markedly different “structure”.
 - *Chakrabarty* = markedly different “characteristics”.
 - *Myriad* and *Mayo* do not overrule *Chakrabarty* nor are they inconsistent.
- The “characteristic” can be structure or function.
 - This is consistent with *Funk* and *Myriad* in that when the product at issue was isolated or in a mixture, there was no new, different, or change in “characteristic”.
 - In *Funk*, the unchanged characteristic was the biological activity of the organisms.
 - In *Myriad*, the unchanged characteristic was the information.

Product Claims – Characteristic

- Product Claims: Does the claimed product or composition exhibit a markedly different characteristic?
- First, consider the entire product/composition as claimed, i.e., the invention “as a whole” (inventive product).
 - If the claim is directed to a composition comprising mixture of a product of nature + other ingredients, the inventive product is the mixture and so the characteristics of the mixture “as a whole” must be considered rather than the characteristic of the product of nature by itself.
 - If the claim is directed to an isolated, recombinant, or synthesized compound, e.g., protein, antibody, etc., the inventive product is the compound itself and so the characteristic of the compound by itself is to be considered.
- Then ask: Does the “inventive product” have a characteristic that is different from the naturally occurring product of nature?
 - Answer = Yes if either the structure or function is different.

Product Claims – Markedly Different

- Then ask: Is the characteristic markedly different?
- The question is: What is a “markedly different” characteristic?
- Proposal: A markedly different characteristic is one that confers an improved or different use from its naturally occurring form?
 - Why “use”? Supreme Court precedent.
 - Why “different”? Different evidences new.
 - Why “improved”?
 - Section 101: 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.

Mayo – Improperly Broad Interpretation

- The Guidance is based on an interpretation of *Mayo* that is too broad.
- Based on the Guidance, the PTO seems to interpret the “apply it” discussion in *Mayo* as requiring unduly specific process steps.
- In *Mayo* – There was no active step that actually integrated the law of nature into a practical result.
 - Instead, the “wherein” clauses simply refer to the relevant law of nature without requiring a doctor to actually apply the law in order to achieve a result. Thus, the claims do nothing more than refer to the law of nature.

Mayo – Proper Interpretation

- Some of the process claims which have been found to be patent eligible by the Court recite seemingly simple steps. Nevertheless, the seemingly simple steps are ones which practically applied the given judicial exception to achieve a practical result.
- The claims at issue in *Mayo* do not recite any step which practically applies the law of nature.
- Thus, Mayo should not be interpreted as requiring highly detailed claim limitations.
- Instead, all that should be required is that the claim recite a step(s) that integrates the judicial exception into a practical application.

Myriad – Improperly Broad Interpretation

- The Guidance is based on an interpretation of *Myriad* that is too broad.
- In *Myriad* – The issue and analysis was whether the isolated DNA at issue had any markedly different characteristic from DNA as it exists in nature.
- Based on the Guidance, the PTO appears to interpret *Myriad* as applying to all things, isolated or synthesized, that can be derived from a product of nature. Slide 27 of March 19th Slides.
 - PTO: [T]here is a “rule against patents on naturally occurring things”.
 - PTO mischaracterizes the statement in *Myriad*:
 - *Myriad* citing *Mayo*: The rule against patents on naturally occurring things is not without limits, however, for “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” and “too broad an interpretation of this exclusionary principle could eviscerate patent law.” (emphasis added).

Myriad – DNA is a Unique Situation

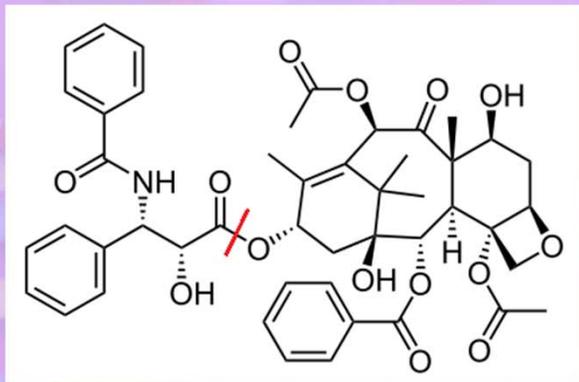
- Court: “Myriad’s claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA.”
- The Court stated that Myriad’s claims are “concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition...” (emphasis added).
- The Court reasoned that information in the isolated DNA molecule is the same as it is in nature, and hence, the chemical changes resulting from its isolation did not result in a markedly different characteristic, e.g., change to the information.
- Therefore, *Myriad* does not stand for the rigid proposition that all compositions and molecules that originate from products of nature are patent ineligible.

Correct Interpretation of *Myriad*

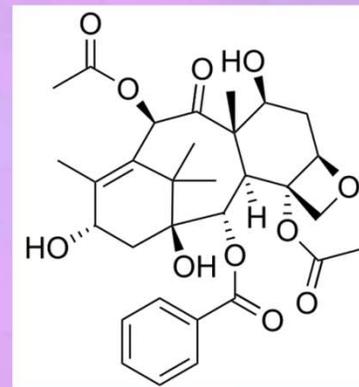
- Whether the inventive product exhibits a markedly different characteristic.
 - Primer pairs = different use = use in PCR, which DNA as it is in nature cannot be used.
 - siRNA and other isolated nucleic acid molecules = different use = use as therapeutic compositions and genetic vaccines, which DNA as it is in nature cannot be used.
 - Purified compositions = different or improved use = where unpurified products of nature often do not exhibit therapeutic efficacy and/or result in adverse results due to impurities.
- PTO should not interpret *Myriad* as requiring markedly different structure.
- Instead, *Myriad* should be interpreted to apply to the unique situation presented by nucleic acid molecules, i.e., where the invention is directed to the genetic information itself.

Absurdity of Broad Interpretation of *Myriad*

- Purified or Isolated Compounds:



Paclitaxel

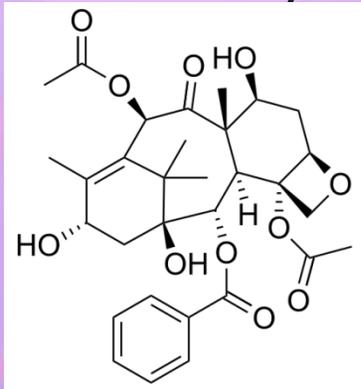


Baccatin III

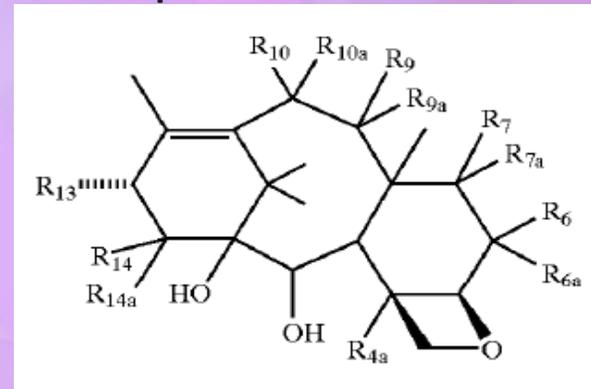
- Claims directed to formulations comprising these compounds in therapeutically effective amounts for treating cancer should be patent eligible as when in nature, the Pacific yew tree is not a “formulation” or “composition” which comprises the compounds in therapeutically effective amounts.
- But, the PTO’s interpretation indicates such therapeutic compositions would not be eligible.

Absurdity of Broad Interpretation of *Myriad*

- Small molecules and synthesized compounds:



Baccatin III



Patented Compound

- When R13 is hydroxyl and the remaining R groups can be hydrogen, the patented compound can be considered an isolate of Baccatin III, as “breaking” certain bonds of Baccatin III results in the patented compound.
- The backbone structure is the same as that of Baccatin III.
- Certainly the “bond breaking” isolating analysis of *Myriad* was meant to only apply to the unique situation of DNA.
- What about proteins and protein fragments?

Absurdity of Broad Interpretation of *Myriad* and *Funk*

- Compositions and mixtures containing products of nature:
- Gunpowder: A particular combination of natural elements, sulfur, charcoal, and potassium nitrate.
 - A mixture having 99.9% charcoal and the remainder being sulfur and potassium nitrate will not likely be explosive. Mixtures containing the particular amounts of the natural elements that make it explosive do not exist in nature.
- Catalyst compositions in the automobile industry are often mixtures of elements, e.g., alumina doped with a particular amounts of Pd and Pt.
 - Not eligible per Slides 44-45 of the Training slides.
- What about nutraceuticals?

Further Steps

- Continue the dialog
- Allow applicants of current applications in prosecution to switch inventions elected after a restriction requirement
- More training for both Examiners and Practitioners
 - Make underlying policies and procedures transparent
- Provide real examples and the 101 analyses readily accessible to the public so we can all learn
- Establish a procedure for review of 101 eligibility determinations to ensure consistency and compact prosecution
 - Recommend a 101 Panel Review, like pre-appeal brief review