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Via email: myriad-mayo_2014@uspto.gov

The Honorable Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property and
Deputy Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

RE: Comments on Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, and Natural Products

Dear Deputy Under Secretary Lee:

Thank you for this opportunity to provide comments on the "Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, and Natural Products" (Guidance). Also attached is the speech I presented at the May 9th Forum.

1. MAYO AND MYRIAD SHOULD BE NARROWLY APPLIED

The Guidance inappropriately exceeds the narrow rulings of *Mayo*, *Myriad*, and other Supreme Court precedent.

1A. The Mayo process claims did nothing more than refer to a law of nature without any process steps requiring that the law of nature be applied to achieve a particular result

In *Mayo*, the question before the Court was "whether the claims do significantly more than simply describe [the] natural relations" or put another way "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?" Slip op. p. 8 (emphasis in original). Throughout the decision, the Court distinguished patent eligible processes as those which do more than simply referring one to the law or principle. Although Prometheus' claims recited routine or conventional steps, there were no steps (either conventional or unconventional) which required the referenced law of nature to be applied to achieve a practical result.

The preambles of the Prometheus claims state that the claimed methods are for "optimizing therapeutic efficacy for treatment". However, the claims do not recite any step that requires one to actually apply the law of nature in order to achieve the practical result. Instead, the "wherein"

clauses, as analyzed by the Court, simply refer to the relevant law of nature without requiring a doctor to actually apply the law in order to achieve a result. Slip op. page 8-9. Thus, the Court reasoned that the Prometheus claims do nothing more than refer to the law of nature.

The Court's analysis should not be interpreted to mean that a claim must recite at least one step that is not "well-understood, routine, conventional activity" in order to make the process claim patent eligible. Nor should the Court's analysis be interpreted to mean that a well-understood, routine, or conventional process step can never make a claim involving a law of nature patent eligible.

Prometheus' claims can be distinguished from those of *Diehr* in that, in *Diehr*, the law of nature was integrated with the process step of opening the press automatically when the comparison based on the law of nature indicated the curing was completed. Conversely, in *Flook*, the Court reasoned that the algorithm added nothing more to the process steps which were conventional and routine. The Court explained that the claims in *Flook* did nothing more than refer to a law of nature (algorithm) without any practical application because the claims did not require how the variables used in the algorithm are selected and therefore the claims do not set forth how the algorithm is practically applied. Slip op. p. 12-13. Thus, Prometheus' claims are more akin to those in *Flook*. In fact, in *Mayo*, the Court reasoned that the recited administering and determining steps were conventional and routine and the recitation of the law of nature did not do anything more than simply refer doctors to the law of nature. Slip op. p. 9-11.

It should be noted that 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 apply the given law of nature. Prometheus' claims, however, do not recite <u>any</u> 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 there is at least one process step that involves applying the law of nature to achieve a practical result. In addition, nowhere in *Mayo* does the Court require that for diagnostic claims to be patent eligible, the claims must involve the use of a patentable reagent.

Thus, the Guidance should be amended to make clear that claim limitations, whether or not routine or conventional, which apply or use the law of nature may make the claim patent eligible so long as the limitations do not simply recite the law of nature and instead integrate the law of nature and the process steps into a practical application.

1B. Myriad's DNA claims are unique in that the invention was to the informational content of the DNA itself and the informational content of the isolated DNA was no different than when it is present in nature as part of an organism's genome

The Court's conclusion that Myriad's claims were directed to mere products of nature depended on two findings:

(1) the patentee had not created or altered the genetic information in the BRCA1 and BRCA2 mutations, nor did the patentee create or alter the structure of the claimed DNA; and

(2) the claims were written in such a way that they <u>relied solely on the genetic information</u> in isolated polynucleotide. Slip op. at 11-12 (emphasis added).

The Court explained that, despite the fact that the act of isolating DNA severs chemical bonds and creates a non-natural molecule, it is not what the patentee claimed. "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." Slip op. at 14-15 (emphasis added). The Court stated that Myriad's claims are "concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition…" Slip op. at 15 (emphasis added). The Court discussed *Chakrabarty* and *Funk Brothers* and noted that the bacterium of Chakrabarty was eligible because it exhibited markedly different characteristics from any found in nature, but the mixture at issue in *Funk Brothers* was not eligible as the bacteria did not have any markedly different characteristics as isolates or as mixtures compared to how they are found in nature.

Thus, the exception to patentability expressed by the Court is 2-pronged: (1) although the claims were expressed in terms of isolated DNA, the invention was directed to the information contained in the sequence (genetic code of the molecule), and (2) the 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 isolated or purified from nature are patent ineligible.

In addition, primer pairs, i.e., two short sequences of nucleic acid molecules where one anneals to the 5' end of a DNA molecule and the other anneals to the 3' end of the DNA molecule, do not exist in nature. Unlike the isolated DNA at issue in *Myriad*, primer pairs do not embody information as they do not encode genetic information. Thus, *Myriad* should not be interpreted as holding that other DNA claims, e.g., claims to primer pairs are ineligible.

Other isolated nucleic acid molecules have markedly different characteristics in that, when isolated, they can have a characteristic that they do not have in their native (non-isolated form). Consider, for example, the markedly different therapeutic characteristics of small interfering RNA and DNA vaccines. One should also consider purified compositions and that unpurified compositions (as they are in nature) often do not exhibit therapeutic efficacy and/or result in adverse results due to impurities.

Thus, the USPTO should not interpret *Myriad* as meaning that all compounds and compositions isolated or purified from nature are patent ineligible unless markedly different in structure.

2. THERE SHOULD BE TWO SEPARATE AND DISTINCT TESTS FOR PROCESS CLAIMS AND COMPOSITION CLAIMS

The Guidance combines the eligibility analyses for process claims and composition claims into one overall process by requiring that the claim recites something "significantly different" than the judicial exception. The Guidance incorrectly requires that process claims be "significantly more" than the judicial exception, and product claims be both "significantly more" and "markedly different" in structure as compared to the natural product. Nowhere do *Chakrabarty*,

Mayo, or *Myriad* require that product claims be both "significantly more" and "markedly different" as required by the USPTO. Instead, Supreme Court precedent requires that, to be patent eligible, products must be markedly different and processes must be significantly more than the law of nature.

Thus, the USPTO should establish two separate sets of guidance materials – one for process claims involving abstract ideas and/or laws of nature and one for compositions (including products of nature).

2A. Process claims – Abstract Ideas, Laws of Nature, and Abstract Ideas + Laws of Nature

The Guidance states that claims reciting abstract ideas should be examined under a different analysis than claims reciting laws of nature. In particular claims reciting abstract ideas should be examined under MPEP 2106(II) (Bilski Guidance) while claims reciting laws of nature should be examined under the Guidance, but if a claim recites both a law of nature and an abstract idea, then the claim should be examined under the Bilski Guidance.

The Court in *Mayo* specifically cautions against such a result and notes that crafting finely tailored rules for a given technology is the role of Congress. Slip op. p. 23-24. However, by analyzing claims reciting abstract ideas (Bilski Guidance), laws of nature (Mayo/Myriad Guidance), and abstract ideas + laws of nature (Bilski Guidance) under different standards, the likely result will be a general set of patent rules that apply to one technological field, but not another.

Should the USPTO continue to distinguish laws of nature from abstract ideas, it is recommended that the USPTO set forth definitions for each and how one can be distinguished from another – after all, are not all algorithms based on laws of nature? Often diagnostic assays involve the application of a particular logistic regression algorithm and many methods of treatment involve the use of a computer or device. Additionally, a process for analyzing eligibility for claims reciting both algorithms and laws of nature should be established and followed consistently across all Art Units within the USPTO.

2B. Process Claims – "Referring to" versus "Applying"

The Guidance takes the "significantly more" language from *Mayo* and vastly expands it to the point where it is unclear what is to be considered "significantly more" and what is not. Based on the Guidance and input from practitioners, the USPTO seems to interpret "significantly more" to require unduly narrow limitations directed to the step of applying the law of nature, e.g., Example F of the Guidance reasons that using flow cytometry to detect the protein ABC bound by antibody XYZ sufficiently narrows the scope of the claim and weigh toward eligibility because another can use other methods such as radioimmunoassay to detect the binding.

It is important to point out that the excerpts of Supreme Court precedent relating to mere instructions to "apply it" do not mean that the process steps which practically apply the law of nature must be narrowly set forth. Instead, in *Mayo*, the Court distinguishes between simply

telling one to refer to a given law of nature and actually requiring that the law of nature be applied in a practical way. Slip op. p. 9.

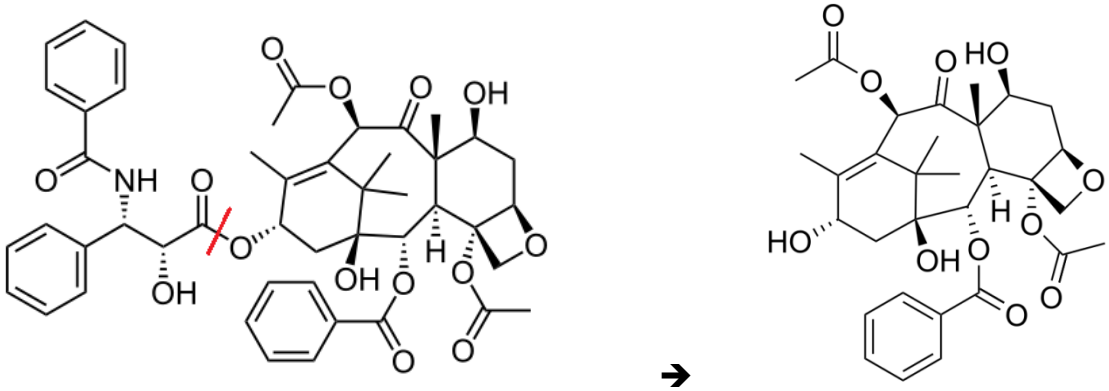
Additionally, more examples and guidance is necessary on what constitutes insignificant pre- and post-solution activity as it is unclear what specific narrow limitations the USPTO deems to be ones that add "significantly more" and what ones are deemed to be insignificant pre- and post-solution activity.

The inquiry into what is "significantly more" and insignificant pre- and post-solution activity should be whether the process steps do significantly more than simply reference a law of nature such that at least one process step requires the law of nature to be applied in order to achieve the "goal" of the process claim. The analysis for such an inquiry could be quite simple and akin to analyzing a process claim for the "omission of essential steps". If the claim, as a whole, lacks one or more steps essential to carrying out the process, the claim merely recites the law of nature without applying the law of nature to achieve a practical result, i.e., the goal of the process. If a step which purports to require the law of nature to be applied can be omitted and yet the goal of the process can still be achieved, the step is likely insignificant pre- or post-solution activity.

2C. Composition Claims – Markedly Different "Characteristic" versus "Structure"

The Guidance requires that, to be patent eligible, products of nature exhibit a markedly different "structure". However, the actual language in *Chakrabarty* is markedly different "characteristics". *Myriad* did not overrule *Chakrabarty* nor is it inconsistent. As explained above, *Myriad* should be interpreted as being narrowly applied to the unique situation presented by nucleic acid molecules and the claim invention being directed to the information contained in the sequence (genetic code of the molecule).

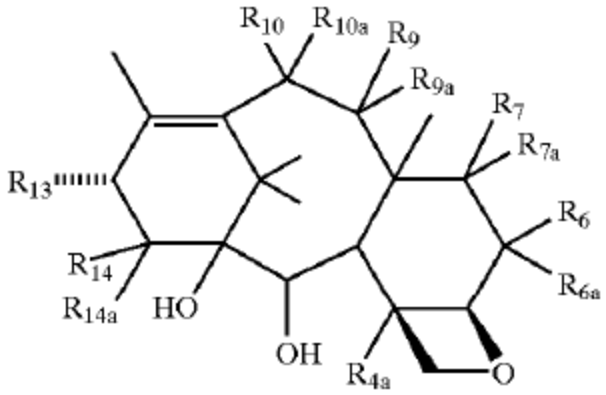
By requiring all isolated or purified products of nature have a markedly different "structure", the Guidance categorically excludes all products of nature from being patent eligible. Additionally, the Guidance indicates that synthetically made products of nature are not patent eligible if they do not have a markedly different structure. This means that any compounds and small molecules that can be made by breaking chemical bonds in the parent compound (which is found in nature) are not patent eligible. Consequently, a significant number of therapeutic compounds are not patent eligible. For example, consider paclitaxel which is isolated from the Pacific yew tree. Breaking the bond, where indicated in the structure below, results in Baccatin III, which is also an isolate of the Pacific yew tree.



Paclitaxel → Baccatin III

The USPTO's position appears to be that claims directed to one of these compounds by itself should not be patent eligible because the compounds are as they are in nature. However, claims directed to formulations comprising these compounds in therapeutically effective amounts for treating cancer should be patent eligible as these compounds, when found in nature, are within the Pacific yew tree and such a tree is not a "formulation" or "composition" which comprises the compounds in therapeutically effective amounts.

Now consider claim 19 of US 6,727,369 which is directed to a compound of formula



where R13 is hydroxyl and the remaining R groups can by hydrogen. Such a compound could be considered to be an "isolate" of Baccatin III, since breaking certain bonds of Baccatin III results in the compound of claim 19.

Certainly, *Myriad* and *Chakrabarty* cannot be interpreted to require that <u>all</u> products of nature, whether isolated, purified, or synthetically produced, must have a markedly different <u>structure</u> from that found in nature in order to be patent eligible as all small molecules which have part of the structural backbone of a larger compound that can be isolated from nature would not be patent eligible even if the small molecules are nowhere to be found in nature. Clearly, the "bond breaking" analysis in *Myriad* was meant to only apply to the unique situation presented by claims directed to the informational content of DNA.

Consider a slight change to claim 1 of Example B in the Guidance such that it recites a composition comprising purified amazonic acid. To require the amazoic acid to have a markedly different structure fails to consider the claim as a whole – the markedly different characteristic of the composition as compared to the Pacific yew tree. Additionally, the Guidance fails to consider a purified amazoic derivative where the derivative is essentially amazoic acid minus a methyl group (perhaps by a broken chemical bond).

Further, Example B seems to be taken from *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701, 705 (7th Cir. 1911) *cert. denied*, 220 U.S. 622, in which the USPTO has renamed acetylsalicylic acid as "amazonic acid." In *Kuehmsted* the 7th Circuit held that purified aspirin is patentable over unpurified aspirin, because unpurified aspirin (present in leaves) contains impurities that cause severe damages to digestive organs. It was cited in the vitamin B-12 case, *Merck & Co. v. Olin Mathieson Chemical Corporation*, 253 F. 2d 156 (4th Cir. 1958) holding purified B-12 compositions patent eligible (claims were limited by maximum and minimum concentrations).

Thus, by requiring that purified products must be markedly different in structure to the product as it is in nature in order to be patent eligible is in conflict with case law. Additionally, interpreting *Myriad* to apply to other products of nature will most likely eviscerate our patent laws and incentive based innovation to, for example, discover and develop cures to cancer.

Consequently, the eligibility test for products and compositions should be the test set forth in *Chakrabarty*, which was relied upon Court in *Myriad*. Specifically, the test should be whether the claimed product or composition has a "markedly different characteristic" from any found in nature.

In addition, the USPTO's interpretation and reliance on *Funk* (e.g., Training slides, slide 74) appears to be misplaced. The Court in *Funk* found that the patent claims were not patent eligible because no species, alone or as a mixture with other specific species of bacteria, resulted in a markedly different characteristic. Even though *Funk* is a pre-1952 case and thus relates to obviousness, considering *Funk* as a 101 eligibility case, the *Funk* decision should be interpreted in view of the fact that the Court found that the bacterial species in the mixture did not take on any markedly different characteristic and the mixture itself did not have any markedly different characteristic as the bacteria continued to exhibit the same characteristics as they do in nature.

Further, "the bacteria themselves were not structurally altered by being mixed together" as recited on slide 74 of the Training slides. Often combinations, i.e., mixtures of various ingredients, result in a product that is more than the sum of its parts. The example in the Training slides relating to a composition containing juice obtained from a pomelo and vitamin E could be shown to have a markedly different characteristic than pomelo juice alone.

This is clearly the situation of gunpowder. Gunpowder is a particular combination of natural elements, sulfur, charcoal, and potassium nitrate. The explosive nature of gunpowder is due to the specific amount of each element in the mixture. A mixture having 99.9% charcoal and the remainder being sulfur and potassium nitrate will not likely be explosive. The particular amounts of the natural elements that make gunpowder be explosive does not exist in nature.

Thus, gunpowder, which is a particular mixture of sulfur, charcoal, and potassium nitrate, has a markedly different characteristic than that found in nature.

Another example of a mixture of naturally occurring elements resulting in a composition having markedly different characteristics includes catalyst compositions for treating exhaust gases in the automobile industry. Many of these catalyst compositions are slurries, i.e., mixtures of elements, e.g., alumina doped with a particular amount of palladium. Such compositions are not alloys, but are instead mixtures of naturally occurring elements. However, according to slides 44-45 of the Training slides, such catalyst compositions are not patent eligible under the Guidance.

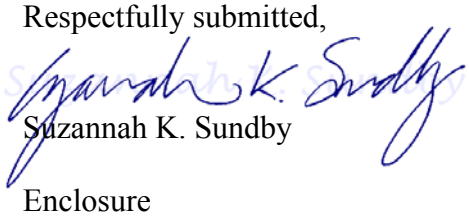
3. THE GUIDANCE SHOULD NOT WEIGH INELIGIBLE FACTORS AGAINST ELIGIBLE FACTORS

The Guidance indicates that an *In re Wands* factor-based analysis is used. However, nowhere has the Supreme Court of Federal Circuit set forth a Wands factor-based analysis as being proper. In fact, no court decision holds that one pro-eligibility factor can be negated by an ineligibility factor. Instead, in the Supreme Court decisions where the Court has found the claims being directed to patent eligible subject matter, all that was required was one factor that indicated the claim was directed to more than the judicial exception itself. Allowing an ineligibility factor to negate a pro-eligibility factor could often result in a zero balance or an ineligible determination because, for example, a practical application of law of nature would be negated by the recitation of the law of nature.

Thus, the Guidance should be modified to itemize examples of factors that indicate patent eligible subject matter and at least one pro-eligibility factor may be sufficient to make the claimed invention patent eligible.

Again, thank you for the opportunity to comment on the Guidance.

Respectfully submitted,



Suzannah K. Sundby

Enclosure

The opinions expressed herein are mine and should not be attributed to any other person or client of Canady + Lortz LLP.

USPTO Forum
Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products

9 May 2014

Suzannah K. Sundby

Slide 1

Thank you for the opportunity to speak at this Forum.

I commend the PTO for reaching out to stakeholders and practitioners for input in order to provide better examination guidelines that do not adversely impact our patent system to the point of eviscerating our patent laws.

Slide 2

I'm Suzannah Sundby and the views expressed today are my own.

However, these views are based on my experience:

AS a patent attorney working with clients who include universities, research institutions, start-up companies, and pharmaceutical companies, on inventions in the biotech, chemical, pharmaceutical, and medical device sectors;

AS a former adjunct professor of Advanced Biotech Patent Preparation and Prosecution at Franklin Piece Law Center, now UNH School of Law;

AND AS a former cytogeneticist on the Berkeley Drosophila Genome Project.

Slide 3

There are 3 points I'd like to make today.

FIRST, the Wands-factor based approach is inappropriate for 101 eligibility determinations.

SECOND, separate tests should be used for process claims and product claims.

THIRD, the Guidance is based on interpretations of *Mayo* and *Myriad* that are so broad that it threatens to do exactly what the Supreme Court warns against – eviscerate our patent laws.

Slide 4

The Guidance employs a Wands factor-based analysis. The PTO indicates that this approach is used because Examiners are familiar with weighing evidence. In this Wands approach, ineligible factors weigh against pro-eligible factors.

Slide 5

However, *In re Wands* involved the question of undue experimentation under Section 112, <u>not</u> 101 patent eligibility.

Slide 6

The Supreme Court clearly states that the patent eligibility inquiry under Section 101 is a completely different determination from 112 enablement and written description inquiries.

Slide 7

Why is the Wands approach inappropriate for 101 determinations? Because an ineligible factor can negate an eligible factor.

Therefore, a process claim reciting steps that integrate the judicial exception into a practical application can become ineligible for also reciting well-understood, conventional, or routine steps.

Thus, under the Guidance, a positive factor e) can be negated by factor j).

Slide 8

The absurd result is that the process of *Diehr* could become ineligible as the conventional steps of installing the rubber in the press and closing the press will negate the fact that the process actually integrated the algorithm into the practical application of curing and molding rubber.

Supreme Court decisions have not weighed negative factors against positive factors.

Instead, in its analyses the Court has searched and evaluated factor after factor for one that confers eligibility and if none is found, the claim is directed to the judicial exception itself.

Slide 9

If not Wands, what approach should be used?

One that does not confuse and combine "significantly more" and "markedly different" to give the "significantly different" analysis set forth in the Guidance.

Slide 10

There should be two separate and distinct tests for process claims and product claims.

"Significantly more" should be applied to process claims.

"Markedly different characteristics" should be applied to product claims.

Slide 11

Further, there should not be separate tests for different types of process claims.

How is a law of nature different from an abstract idea?

Under what analysis should a claim reciting an algorithm based on gravity be examined? The *Bilski* Guidance? The *Mayo/Myriad* Guidance? Or Both?

Distinguishing different process claims based on a given technology sector, for example life sciences versus software, results in crafting finely tailored rules for a particular technology which is the role of Congress, not the Patent Office.

Slide 12

For process claims, the Supreme Court requires that the claim is directed to significantly more than the judicial exception itself.

The Supreme Court has held that "significantly more" means actually applying the judicial exception rather than simply referring one to it.

Thus, the first question should be whether the claim is directed to achieving a practical application.

What is a practical application? Something that has utility or usefulness.

Slide 13

The next question should be whether the claim recites a step that integrates the judicial exception into the practical application.

Implicit to this question is whether the step is essential to achieving the practical application or if the step is insignificant pre- or post-solution activity.

Thus, a way to determine if steps are insignificant pre- or post-solution activity is whether the steps could be considered omitted essential steps.

Slide 14

For a product claim, the Guidance requires that the product exhibits a markedly different "structure". This is improper.

Supreme Court decisions indicate all that is needed is a markedly different "characteristic".

A characteristic can be structure or function.

Slide 15

Thus, the inquiry for product claims should be: Does the claimed product or composition exhibit a markedly different characteristic?

Under this inquiry, one should first consider the invention as a whole – the entire thing claimed – the inventive product, whether it is a single molecule or a composition or a mixture.

Then ask whether the inventive product has a characteristic that is different from the naturally occurring product of nature.

The answer is clearly yes if either the structure or function is different.

Slide 16

Then the question is whether the different characteristic is markedly different.

A markedly different characteristic is one that confers an improved or different use from its naturally occurring form.

Slide 17

The Guidance is based on an interpretation of *Mayo* that is too broad.

The PTO appears to interpret the "apply it" analysis in *Mayo* as requiring claims to recite unduly detailed steps. This is an incorrect interpretation of *Mayo*.

The claims at issue in *Mayo* did not recite any active step that actually integrated the law of nature into a practical result.

Instead, the "wherein" clauses simply tell doctors to refer to the relevant law without any instruction what to do with it.

Slide 18

One should note that some process claims found eligible by the Supreme Court recite seemingly simple steps.

However, such simple steps were ones that practically applied the judicial exception to achieve a practical result.

Thus, *Mayo* should not be interpreted as requiring highly detailed claim limitations.

All that should be required is that the claim recites a step that integrates the judicial exception into a practical application.

Slide 19

The Guidance is based on an interpretation of *Myriad* that is too broad.

The PTO points to *Myriad* as stating that there is a rule against patents on naturally occurring things and then reasons that *Myriad* applies to any product claim reciting a substance that is "derived" from nature. This is an incorrect interpretation of *Myriad*.

Myriad cited *Mayo* for indicating that the rule is not without limits because at some level all inventions originate from laws of nature, natural phenomena, or abstract ideas and too broad of a rule can eviscerate our patent laws.

Slide 20

Myriad applies to the unique situation of genetic material and the information it contains.

The claims at issue in *Myriad* embodied "genetic information" because the claims were not expressed in terms of a chemical composition. And because this genetic information was the same as that of DNA in nature, the claims were not eligible.

This interpretation of *Myriad* is consistent the Federal Circuit's decision in *In re Roslin*.

Slide 21

So under the correct interpretation of *Myriad*, one looks to whether the inventive product exhibits a markedly different characteristic.

Under this interpretation, nucleic acid molecules, purified products of nature, and compositions containing a product of nature which exhibit an improved or different characteristic, such as therapeutic efficacy, should be patent eligible.

If *Myriad* is not interpreted as applying to the unique situation presented by nucleic acid molecules in which the invention is directed to the genetic information itself…

Slide 22

Absurdity results.

Consider taxol and baccatin.

Claims directed to formulations comprising these compounds in therapeutically effective amounts for treating cancer should be patent eligible as they are not therapeutically effective in the form in which they are found in nature.

Slide 23

Now what happens if we apply the "bond breaking" isolation analysis of *Myriad* to these compounds? This compound which is a patented compound would be ineligible.

Certainly, *Myriad* should only apply to the unique situation of claims directed to genetic information.

Slide 24

What about mixtures?

As set forth in the Guidance and PTO training slides, particular mixtures of ingredients that result in improved or different characteristics are not eligible even where the mixtures or specific percentages of the ingredients are not found in nature.

Slide 25

Clearly, the Guidance must be revised such that the 101 eligibility inquiry is the coarse filter it was meant to be, because if it isn't, nothing is eligible as all things originate from laws of nature, natural phenomena, and abstract ideas.

I am a strong supporter of the Patent Office. What you are asked to do is challenging and I hope the Office rises to the occasion and:

revises the Guidance to be consistent with court precedent,

continues the dialog with stakeholders and practitioners,

allows applicants to re-elect inventions,

provides more training for examiners and practitioners,

provides real examples and analyses, and

establishes a procedure for reviewing 101 eligibility determinations before the appeal process.

Thank you.