

New Patent Office Guidance Takes Steps Toward Clarifying Subject Matter Eligibility

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The USPTO's latest Guidance on subject matter eligibility takes some positive steps toward stabilizing the examination rules in the context of complex and dynamic case law. The USPTO is accepting comments about the Guidance until March 16, 2015, and plans to release additional examples and refinements. Pierce Atwood will keep you informed of these developments. **Please contact us if you would like to discuss submitting comments to the USPTO.**

On December 16, the USPTO published its long-awaited [2014 Interim Guidance on Patent Subject Matter Eligibility](#) (79 Fed. Reg. 74618-74633). The Guidance's primary purpose is to provide a framework for examiners to examine patent applications for subject matter eligibility under 35 U.S.C. § 101 in view of recent decisions by the Supreme Court and the Court of Appeals for the Federal Circuit. The Guidance applies, to all categories of patentable subject matter, the general two-part test that the Supreme Court set forth in *Mayo v. Prometheus*: (1) Is the claim "directed to [a judicial exception]?" and (2) If so, does the claim recite "additional elements that amount to significantly more than the judicial exception?"

The Guidance supersedes the controversial March 4, 2014, Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products ([March 2014 Mayo/Myriad Guidance](#)) and supplements the June 25, 2014, Preliminary Examination Instructions in View of the Supreme Court Decision in *Alice Corp.* Like the March 2014 *Mayo/Myriad* Guidance, the Guidance presents a flowchart (see page 4 below) to assist the examination of subject matter eligibility, which has been updated to reflect changes.

The Guidance presents a shift from the analytical framework set forth in the March 2014 *Mayo/Myriad* Guidance, which is superseded by the Guidance. But the Guidance also leaves many issues unresolved. Some of those issues, detailed here, include consistency in examining a claim "as a whole," conditions for claims that qualify for a streamlined analysis, and defining an "inventive concept" in various areas of technology.

1. Focusing on whether the claim "as a whole" is "directed to" a judicial exception

As required by *Mayo* part one, the Guidance emphasizes that the claim should be examined "as a whole" to determine whether the claim is "directed to" a judicial exception. This formulation is an improvement over the March 2014 *Mayo/Myriad* Guidance, which first asked whether the claim "recites" or "includes" such an exception. The Guidance then regresses, however, by collapsing "directed to" and "recites": "A claim is *directed to* a judicial exception when [a judicial exception] is *recited* (i.e., set forth or described) in the claim."

The implication of considering whether a claim "recites" a judicial exception seems to curtail a consideration of the claim "as a whole" because the analysis focuses on identifying any part of the claim that includes an abstract idea, law of nature, or natural phenomenon.

Practice Tip: The Guidance focuses the examination of subject matter eligibility on preemption, i.e., the risk that a claim would "tie up" the excepted subject matter. The Guidance also says to

“tread carefully”, recognizing that “at some level all inventions” include a judicial exception. Therefore, applicants may be able to overcome subject matter eligibility rejections by showing that the claim, considered as a whole, does not tie up the excepted subject matter.

2. Streamlined analysis for claims whose “eligibility will be self-evident”

One might ask whether there is a way off the “directed to”-“recites” merry-go-round. The Guidance provides a “streamlined eligibility analysis,” which allows certain claims to bypass the extensive *Mayo* analysis. This pathway is available to claims that “clearly *do not seek to tie up the judicial exception.*”

The Guidance does not define the conditions for such claims but provides some examples:

- A claim directed to a complex industrial product or manufacturing process that “recites meaningful limitations”, such as a robotic arm assembly that operates according to certain mathematical relationships.
- A claim that recites a nature-based product but “clearly does not attempt to tie up the nature-based product”, such as an artificial hip prosthesis coated with a naturally occurring mineral.
- A claim that includes an ancillary nature-based component, such as a cellphone with an electrical contact made of gold or a plastic chair with wood trim.

Practice Tip: Whenever possible, applicants should draft claims for which they can argue that the eligibility of the claim, considered as a whole, is self-evident because it clearly would not tie up excepted subject matter. Some clues may be derived from the examples in the Guidance.

3. Broader definition of “markedly different” for nature-based products

The Guidance has also refocused the analysis of claims that recite a product of nature, which would not be subject to further scrutiny if the nature-based product exhibits “markedly different” characteristics from a naturally occurring counterpart. In this case, also, the claim should be considered as a whole, and “[c]are should be taken not to overly extend the . . . analysis to products that . . . are not nature based.”

Moreover, and in contrast to the March 2014 *Mayo/Myriad* Guidance, which focused only on structural differences, the Guidance recognizes that markedly different characteristics can additionally include a nature-based product’s function or other properties.

Together with the Guidance, the USPTO published updated Nature-Based Product Examples (www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf), which replace the previous controversial examples included in the March 2014 *Mayo/Myriad* Guidance. Of note, the Guidance does not include a *Wands*-like approach involving factors that favor eligibility against factors that disfavor eligibility, which was presented in the March 2014 *Mayo/Myriad* Guidance, and the Guidance has reversed course by stating that gunpowder (Example 1) is eligible subject matter.

Practice Tip: The Guidance proscribes that “even a small change can result in markedly different characteristics.” The expansion of those characteristics to include functional and other non-structural properties provides fodder to argue for patentability in a manner analogous to an unexpected results argument in the face of a *prima facie* case of obviousness.

4. Searching for an “inventive concept” in Mayo test, part two

Regarding part two of the *Mayo* test, the Guidance primarily relies on case law-derived categories of limitations that qualify as “significantly more” than a judicial exception. These categories include:

- Using a particular machine;
- Transforming an article into a different state or thing;
- Improving another technology or the functioning of a computer;
- Adding specific, unconventional, non-routine limitations or steps that confine the claim to a particular application; and
- A seemingly catch-all category of “[o]ther meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment.”

Practice Tip: Defining what qualifies as “significantly more” than a judicial exception is a difficult task for both the applicant and the examiner. The Guidance requires the examiner to (1) identify the exception in the claim, (2) explain why it is an exception, (3) identify additional elements of the claim, and (4) explain why the additional elements do not add significantly more to the exception. An applicant may be able to overcome subject matter eligibility rejections by showing that the examiner has not met those requirements.

5. Eligibility of computer-based technologies or business methods

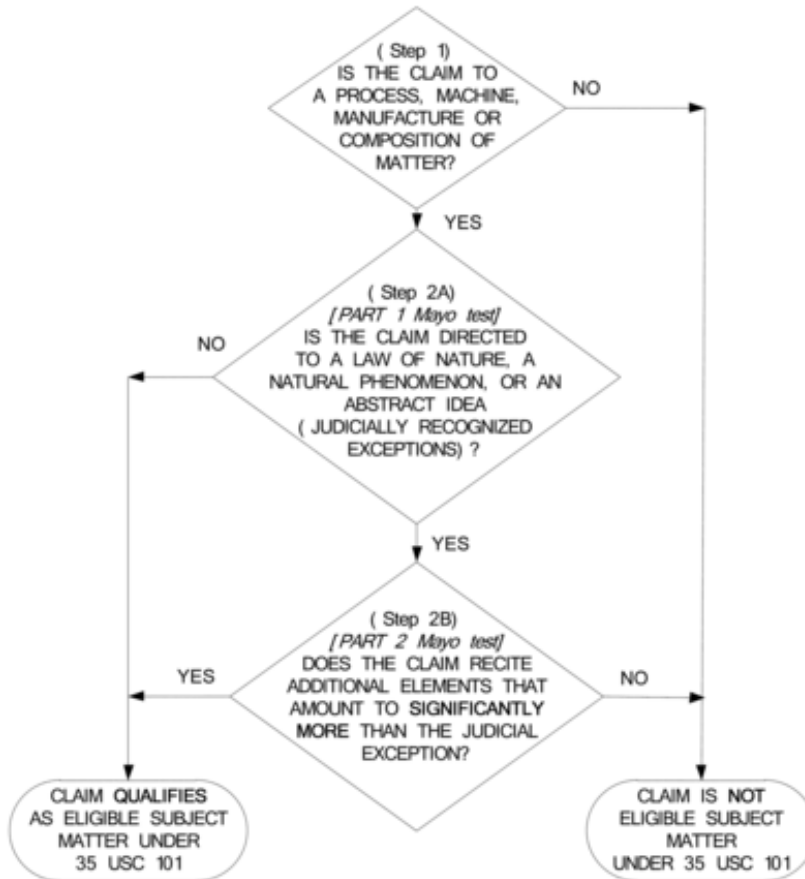
The Guidance did not add much clarity to the subject matter eligibility of claims that are directed to computer-based technologies or those that are directed to business method applications. It, however, reiterated that none of these two types of claims are categorically ineligible, and that they do not invite any special requirement for eligibility.

Practice Tip: The Guidance includes analyses and summaries of some cases in which these types of claims were not invalidated. These cases may offer characteristics that help a claim pass the Mayo test; characteristics such as satisfying the machine-or-transformation test, or being rooted in or improving an existing technology, such as the computer technology.

If you have any questions, or would like to discuss any of these issues, please contact the authors of this alert, [Dan Lev Ph.D.](#) and [Reza Sadr, Ph.D.](#) You can reach Dan at dlev@pierceatwood.com or 617.488.8112, and Reza at rsadr@pierceatwood.com or 617.488.8163.

**SUBJECT MATTER ELIGIBILITY TEST FOR
PRODUCTS AND PROCESSES**

*PRIOR TO EVALUATING A CLAIM FOR PATENTABILITY, ESTABLISH THE
BROADEST REASONABLE INTERPRETATION OF THE CLAIM.
ANALYZE THE CLAIM AS A WHOLE WHEN EVALUATING FOR PATENTABILITY.*



IN ACCORDANCE WITH COMPACT PROSECUTION, ALONG WITH DETERMINING ELIGIBILITY, ALL CLAIMS ARE TO BE FULLY EXAMINED UNDER EACH OF THE OTHER PATENTABILITY REQUIREMENTS: 35 USC §§ 102, 103, 112, and 101 (UTILITY, INVENTORSHIP, DOUBLE PATENTING) AND NON-STATUTORY DOUBLE PATENTING.

Notable changes from prior guidance:

- All claims (product and process) with a judicial exception (any type) are subject to the same steps.
- Claims including a nature-based product are analyzed in Step 2A to identify whether the claim is directed to (recites) a "product of nature" exception. This analysis compares the nature-based product in the claim to its naturally occurring counterpart to identify markedly different characteristics based on structure, function, and/ or properties. The analysis proceeds to Step 2B only when the claim is directed to an exception (when no markedly different characteristics are shown) .