

REVISED USPTO PATENT ELIGIBILITY (101) GUIDANCE

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In our previous newsletter (Newsletter No. 41), we reported on the (mostly negative) reception met by the USPTO's March, 2014 Myriad/Mayo Guidance¹, and noted the Office's repeated indication of imminent revision. On December 14, the USPTO issued the revised guidance² and a detailed set of examples of their implementation³, significantly overhauling the criteria set forth in March 2014 guidelines and examples, and raising expectations of fewer and more reasonable 101 rejections, particularly regarding natural-based products.

The Guidance

The updated Guidance offers a decision tree for determining eligibility which differs from the analysis outlined in the March, 2014 Myriad/Mayo guidance.

The flow chart below emphasizes some important revisions in the Eligibility Analysis. For one, the test for determining whether a claim is directed to a "product of nature" exception (Step 2A) is now separated from the analysis of whether the claim includes significantly more than the exception (Step 2B). Further, the analysis is now based on claims directed to judicial exceptions (defined as claims reciting the exception, i.e., set forth or described), rather than claims merely "involving" an exception, a recurrent theme in recent 101 rejections based on the March 2014 Guidance.

For instance, process claims that merely use a nature-based product are now not necessarily subject to an analysis for markedly different characteristics (see "*Streamlined Eligibility*", below). Additionally, whereas the previous test for "markedly different" was limited to structural differences, the "markedly different" analysis now focuses on broader characteristics that can include a product's *structure, function, and/or other properties*, as compared to its naturally occurring counterpart in its natural state. In general terms, the Guidance lists criteria for "markedly different":

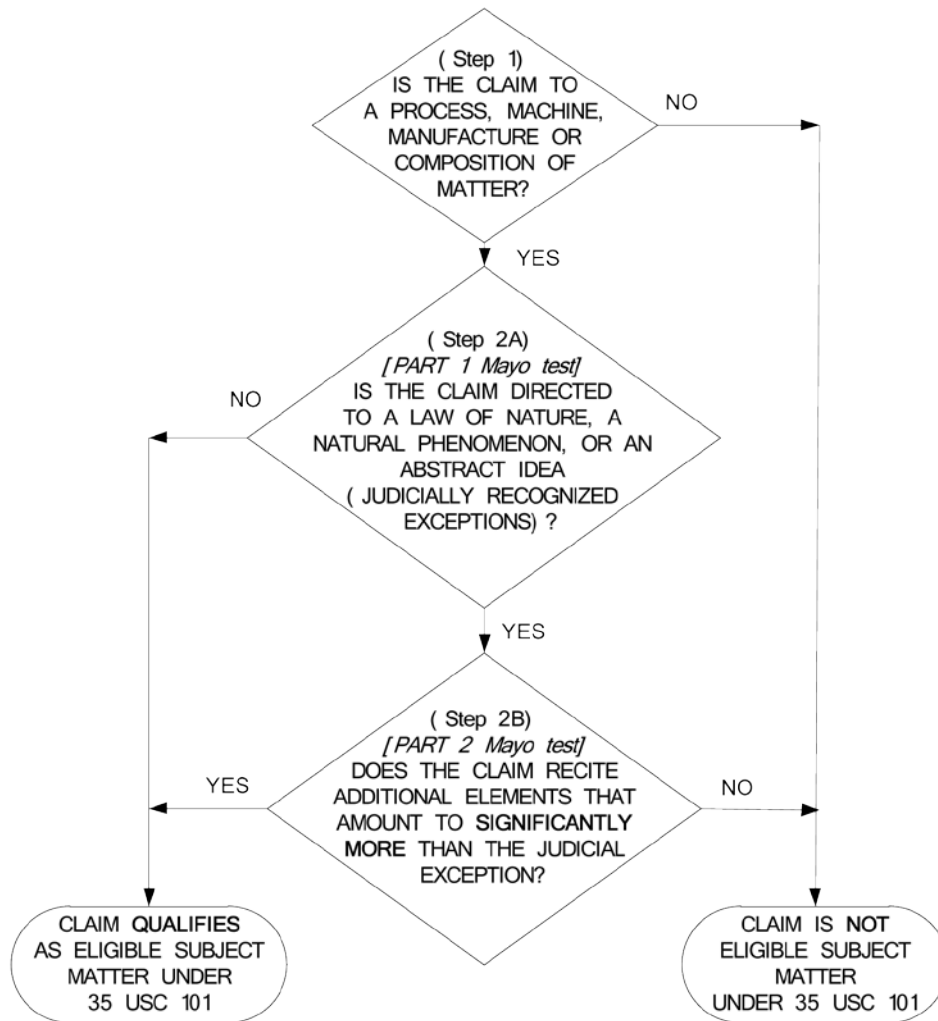
- Biological or pharmacological functions or activities;
- Chemical and physical properties;
- Phenotype, including functional and structural characteristics; and
- Structure and form, whether chemical, genetic or physical.

A much clearer understanding of the meaning of "markedly different", in the context of Eligibility Analysis, is provided in the Nature-Based Product Examples (see below).

1 Guidance for Determining Patent Eligibility for Patent Examiners http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf
2 2014 Interim Guidance on Patent Subject Matter Eligibility <http://www.gpo.gov/fdsys/pkg/FR-2014-12-16/pdf/2014-29414.pdf>
3 2014 Interim Guidance-Examples of Nature-Based Products http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf

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) .

Another welcome change is the explicit directive not to employ the eligibility analysis for claims which, as a whole, do not “tie up” any judicial exception (e.g. law of nature, natural phenomenon, abstract idea or nature-based product) such that others cannot practice it. Dubbed “Streamlined Eligibility”, this aspect of the updated Guidance relates to recitation of the judicial exception in an “ancillary” capacity, as in “an artificial hip prosthesis coated with a naturally occurring mineral” or “a cellphone with an electrical contact made of gold”. Seemingly obvious, the USPTO evidently felt the need to clarify this distinction to its Examiners.

Gone, as promised, is the awkward 12 factor test (see March 2014 Guidance, section II) for analyzing eligibility, based on six factors ([a]-[f]) weighing toward eligibility and six ([g]-[l]) weighing against eligibility which practically forced Examiners to issue 101 rejections, and confounded Attorney’s attempts to put forth a rational argument in rebuttal. Although the lists of what constitutes patent ineligible “laws of nature and natural phenomena” (“isolated DNA; a correlation of how a compound is metabolized by the body; electromagnetism to transmit signals; the chemical principle underlying the union between fatty elements and water”) and “abstract ideas” (“mitigating settlement risk; hedging; creating contractual relationship; using advertising as an exchange or currency; processing information through a clearinghouse; managing a game of bingo; the Arrhenius equation for calculating the cure time of rubber; a formula for updating alarm limits; a mathematical formula relating to standing wave phenomena”, etc) do little to delineate eligibility, Applicants and Attorneys alike are now hoping for a more reasonable dialogue with Examiners regarding eligibility rejections, particularly regarding nature-based products.

Examples of Analyses for Nature-Based Products

Since publication of the March 2014 Guidance, the USPTO has conducted a lively public forum for discussion, inviting prominent members of the IP, Life Science, Biotechnology, Software and Academic communities to comment and offer suggestions for improvement. One indication of the Office’s commendable consideration of comments reflecting the IP, Life Science and Biotechnology communities widespread dissatisfaction with the sample analyses put forth in the March 2014 Guidance is the revised Examples now provided in a separate document accessible on the USPTO website⁴. The USPTO has undertaken to soon publish a similar set of Examples for evaluating eligibility of natural processes and abstract ideas, particularly software and business methods, according to recent Supreme Court decisions such as *Alice Corp. v CLS Bank Intr’l* and *Wildtangent v Ultramercial*.

Prominent in the analyses offered in the Examples is the two-step analysis distinguishing between determining whether or not claims are directed to features or products directed to judicial exceptions (*Step 2A*) and determining whether or not the claim amounts to “significantly more than the judicial exception” (*Step 2B*). Some of the Examples are actually reversals of analyses provided as Examples in the March 2014 Guidance. Others provide reasoning which should be useful for Patent Attorneys and clients in strategizing and formulating eligibility defenses.

For example, whereas gunpowder was previously deemed a judicial exception for consisting of naturally occurring potassium nitrate, charcoal and sulfur, the current Examples exempt the mixture from eligibility analysis (*Step 2A:NO*) since: “the components do not occur together in nature” and

⁴ <http://www.uspto.gov/patents/law/exam/examguide.jsp>

“none of the three claimed substances are explosive in nature”. Thus, the claimed composition not only lacks a naturally occurring counterpart, but exhibits a markedly different property (explosiveness) and is not “a product of nature” (see Examples, Example 1).

Pomelo juice, clearly a naturally occurring and ineligible composition (*Step 2A: YES and 2B:NO*), qualifies as patent eligible when mixed with “an effective amount of an added preservative”, since “the claimed combination has markedly different characteristics (slower spoiling)” and is deemed not a product of nature (*Step 2A: NO*)(see Examples, Example 2). In Example 4, peptides 90% identical to a naturally occurring Antibiotic L with at least one substitution modification qualify as eligible under 101, due to “different structural characteristics”, which “ensure that the claim is not tying up future use of the naturally occurring Antibiotic L” (*Step 2A: NO*)

While some examples indicate that structural or functional differences alone may qualify nature-based product claims for eligibility, the winning combination of structural and related functional differences from naturally occurring products receives much attention in the Office’s Examples. In Example 3, a composition of amazonic acid and a surrounding layer of natural polymeric material (claim 5) qualifies as eligible due to structural differences resulting in different functional characteristics (delayed release upon ingestion) (*Step 2A:NO*). In Example 6, the ineligible mixture of unspecified bacterial species becomes eligible when limited to two specific species, not described together in nature, which as a mixture can infect previously unsusceptible leguminous plants (“markedly different function”) (*Step 2A:NO*).

Here the Examples note, citing *Myriad*, that the burden of proof for demonstrating “existence in nature” rests on the Examiner.

Surprisingly, Example 7 explains that the ineligible isolated nucleic acid comprising a sequence from naturally occurring Gene W (*Step 2A: YES and 2B:NO*) becomes eligible when broadened to sequences 90% identical and having at least one substitution modification (claim 2), and also when comprising a fluorescent label attached thereto (claim 3). In both cases, structural differences from the naturally occurring sequence of the Gene W fragment, and the resultant functional differences (modified sequences may encode different proteins, and the property of fluorescence) combine to qualify the claimed compositions as not a “product of nature exception” (*Step 2A: NO*). In Example 8, a human or humanized antibody to a known protein not known to be immunogenic in humans (claim 2) is deemed eligible by virtue of different structural (CDRs, three dimensional configuration) and functional (binds to different antigens, altered affinities) characteristics relative to the naturally occurring murine and coyote antibodies.

While it is too early to predict, the theme of the nature-based products Examples (structural + functional differences = eligibility under 101) signals the possibility of fewer 101 rejections, and a clearer framework within which claims can now be analyzed. This is certainly a welcome change. However, until provision of similar exemplary analyses for process claims, the criteria for eligibility of process and method claims, including software and diagnostic claims, remain unclear and problematic.

That said, it is important to recall that claimed subject matter, having been deemed eligible, must still qualify under 35 U.S.C. 112 (Written Description and Enablement), 102 (Novelty) and 103 (Non-Obviousness) before it can be deemed allowable subject matter. Hopefully, the new Guidance and Examples will serve to untangle these frequently confounded criteria.

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