USPTO Issues New Subject Matter Guidance Post-*Myriad* and *Prometheus*

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The United States Patent and Trademark Office (USPTO) issued a new guidance document for Examiners on March 4, 2014, effective immediately, describing revised procedures for assessing subject matter eligibility of claims involving or reciting laws of nature, natural principles, natural phenomena, and/or natural products (hereinafter "*2014 Guidelines*"). The *2014 Guidelines* are *intended* to reflect changes to the law arising from recent Supreme Court decisions in *Association for Molecular Pathology v. Myriad Genetics*, Inc., 569 U.S. _, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013) ("*Myriad*"), and *Mayo Collaborative Services v. Prometheus Laboratories*, Inc., 566 U.S. _,132 S. Ct. 1289, 101 USPQ2d 1961 (2012) ("*Prometheus*"). The *Myriad* decision, which we have previously discussed, was limited to the patent-eligibility of human DNA sequences. While acknowledging the limitations of the *Myriad* decision, the USPTO argues that: "[…] while the holding in Myriad was limited to nucleic acids, Myriad is a reminder that claims reciting or involving natural products should be examined for a marked difference under *Chakrabarty*" (*Diamond v. Chakrabarty*, 447 U.S. 303 (1980) ("*Chakrabarty*")) (*2014 Guidelines*, pg. 1).

Under the new *2014 Guidelines*, all claims (whether directed to a machine, composition, manufacture or process) which recite or involve laws of nature/natural principles, natural phenomena, and/or natural products will be examined for subject matter eligibility according to the framework provided in the *2014 Guidelines*. These guidelines supersede previous guidance issued by the USPTO on June 13, 2013 in response to *Myriad*, which singled out claims involving nucleic acid molecules for greater scrutiny with respect to subject matter eligibility. Accordingly, the *2014 Guidelines* represent a departure from both the *Myriad* decision and the USPTO's previous guidance.

The *2014 Guidelines* suggest a 3-step approach for assessing subject matter eligibility of a claim. The steps comprise asking the questions:

1. Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture, or composition of matter?
2. Does the claim recite or involve one or more judicial exceptions, for example, abstract ideas, laws of nature/natural principles, natural phenomena, and natural products?
3. Does the claim as a whole recite something significantly different than the judicial exception(s)?

Steps 1 and 2 are directed to determining the threshold question of whether the claims in any way recite or involve a judicial exception. In situations where there is uncertainty whether this threshold has been met, Examiners are required to nevertheless proceed to the next inquiry. The core of the analysis occurs at Step 3, which assesses whether the claim as a whole recites something that renders it "significantly different" from the excluded subject matter.

Importantly the *2014 Guidelines* identify "claimed subject matter that must be analyzed under Question 3" as including but "not limited to: chemicals derived from natural sources (e.g. antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods […]; metals and metallic compounds that exist in nature; minerals; natural materials […]; nucleic acids; organisms (bacteria, plants and multicellular animals); proteins and peptides; and other substance found in or derived from nature" [emphasis added] (pg. 3) [emphasis added].

In assessing Step 3, the *2014 Guidelines* encourage Examiner's to consider all relevant factors and to reach a determination by weighing the factors in favor of eligibility against those factors against eligibility. A non-exhaustive and non-exclusive list of factors to be considered by Examiners is provided in the guidelines and reproduced **here**.

The factors are applied in a series of Examples which in some instances provide for tempered optimism that not everything will be rejected. Example A suggests that a claim directed to a naturally occurring organism comprising a combination of naturally occurring plasmids is patent eligible since "the claimed bacterium is markedly different". It is both "structurally different" since it is genetically modified to include more plasmids than are found in a single naturally occurring *Pseudomonas* bacterium and "functionally different" as it is able to degrade at least two different hydrocarbons compared to the naturally occurring *Pseudomonas* bacteria that can only degrade a single hydrocarbon. Example B confirms that method of treatment claims using a natural product (amazonic acid in the Example) will continue to be allowed, although it appears that additional limitations may be needed as "a general instruction to use amazonic acid" may be insufficient. Example E unfortunately suggests that a pair of primers having specified sequences, which consist of sequences naturally occurring in human DNA, will not be considered patentable subject matter but methods of amplifying a target DNA using the pair of primers will pass the test.

The *2014 Guidelines* also clarify that the fact that "a marked difference came about as a result of routine activity or via human manipulation of natural process does not prevent the marked difference from weighing in favour patent eligibility" (at pg. 5) and confirm that a hybrid plant that "is markedly different from naturally occurring plants is eligible subject matter, even though it was created via routine manipulation of natural processes such as pollination and fertilization" (at pg. 5).

As should be clear from the foregoing, the *2014 Guidelines* represent a marked departure from traditional Office practice in relation to subject matter eligibility analysis. As a result of these guidelines, claims reciting or involving any natural products found in or derived from natural sources, not just "naturally-occurring nucleic acids", will be subject to an analysis to determine if a "significant difference" from the naturally occurring product exists. Echoing the caution suggested in *Myriad* with respect to nucleic acids, according to the *2014 Guidelines*, the use of terms like "isolated", "recombinant", or even "synthetic" will not shield a claim reciting or involving any natural product from being subjected to a full subject matter analysis under the new guidelines.

One significant concern is the lack of clarity on when a product becomes "significantly different" or "markedly different" from a natural occurring form, so as to be patent eligible. *Myriad* and *Chakrabarty* offer some guidance.

In *Myriad* the court suggested that mere isolation of a naturally occurring nucleic acid, where the isolation does not result in chemical changes to the nucleic acid, is insufficient to confer patentability (at 14). However, the Court held that a nucleic acid which does not naturally occur, such as certain cDNAs, are sufficiently distinct from the natural products to be patent-eligible subject matter (at 16-17). In *Chakrabarty*, a genetically engineered microorganism was held to be patent eligible on the basis that the engineered bacteria was non-naturally occurring. While the case law is helpful, much will depend on how expansively the definition of substances "found in or derived from nature" is interpreted. Also, many complicated questions remain unresolved, such as, whether a therapeutic protein derived from a transgenic animal is "naturally occurring", or what change in a cell strain that has been lab adapted to show beneficial properties, will be sufficient for the strain to be considered "significantly different" from the parent strain.

Patent professionals and prospective patentees will need to be mindful of these concerns when applying for patents in the United States, particularly in fields related to biotechnology.