# Patent Subject-Matter Eligibility in Light of the Revised USPTO Guidance and the Latest Myriad Decision

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As previously reported (here), after much consultation from the legal, academic, science and industry communities, the U.S. Patent and Trademark Office ("USPTO") issued earlier this week the Interim Guidance on Patent Subject Matter Eligibility ("Interim Guidance") pursuant to 35 U.S.C. § 101. Effective as of December 16, 2014, the Interim Guidance supplements the June 25, 2014 Preliminary Examination Instructions in view of *Alice*[1], and supersedes the 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 issued in view of *Myriad*[2] and Mayo[3]. In conjunction with the Interim Guidance, new examples relating to nature-based products have replaced the examples in the previous Guidance.

The Interim Guidance provides some long-awaited positive departure from the previous Guidance; however, this departure is short-lived in light of the latest *Myriad* decision before the Federal Circuit, *In re BRCA1- and BRCA2-based Hereditary Cancer Test Patent Litigation*, which may unfortunately bring significant restrictions to diagnostic type method claims (as discussed below).

The Interim Guidance provides steps for determining subject matter eligibility. Once the Examiner determines that the claim is to a process, machine, manufacture or composition of matter (Step 1), the following two-part analysis for subject matter eligibility ("*Mayo* test") which was applied in *Alice* is conducted.

In Step 2A, the Examiner determines whether the claim is directed to a judicially recognized exception. A first notable departure from the previous Guidance is that the analysis applies to all types of judicial exceptions: laws of nature, natural phenomena and natural products and abstract ideas[4] (including software and business methods).

A second notable departure is that a narrower interpretation of a “judicial exception” is adopted in the Interim Guidance and it is no longer required that a claim merely “recite or involve judicial exceptions”. To be considered a judicial exception, a claim must be “directed to” a judicial exception, which is a more stringent criterion.

The Interim Guidance provides insight on how to determine whether the claim is "directed to" a judicial exception in the context of nature-based products. In the March 2014 Guidance examples, only claims presenting structural differences were considered markedly different from products of nature and therefore did not recite or involve a judicial exception. The Interim Guidance now clarifies that "markedly different characteristics" in a product can be expressed as the product’s structure, function and/or other properties. If the product is shown to be markedly different by this expanded method, then it is not directed to a judicial exception.

The USPTO's new position is clearly illustrated in its examples of combinations of nature-based products for gunpowder and for a beverage comprising pomelo juice and a preservative. Both mixtures were previously considered non-patent-eligible since combining the substances did not confer a structural difference and therefore had no marked difference from what exists in nature. The USPTO now considers both mixtures patent-eligible, as combining the substances confers a functional difference (i.e. explosiveness and preservative property, respectively) that makes them markedly different from what exists in nature, and therefore not directed to a judicial exception.

Interestingly, the Interim Guidance specifies that the "marked difference" analysis does not apply to a process claim unless it is

drafted in such a way that there is no difference in substance from a product claim (e.g. method of providing an apple). This may have a positive effect of broadening the interpretation of patent eligibility in process claims, including method of treatment claims. This is demonstrated in one example where a method of treatment comprised administering an effective amount of purified amazonic acid to a patient suffering from cancer. This method was found to be patent-eligible on the basis that "[a]lthough the claim recites a nature-based product […], analysis of the claim as a whole indicates that the claim is focused on a process of practically applying the product to treat a particular disease […], and not on the product *per se*".

If the claim is directed to a judicial exception, i.e. no "marked difference" can be found in a nature-based product, the Examiner will then go on to consider whether the claim recites additional elements that amount to “significantly more” than the judicial exception (Step 2B). The previous redundant 12-factor balancing test to determine if the claim recites something "significantly different" has been replaced with a simpler test, where the Examiner will look for limitations that qualify as "significantly more" than the judicial exception. The Interim Guidance lists examples of sufficient limitations, such as: improvements to another technology or technical field; adding a specific limitation other than what is well-understood, routine and conventional in the field, or adding unconventional steps that confine the claim to a particular useful application; and other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment.

The new examples provide a patent eligibility analysis of claims directed to products, processes, methods of treatment, purified proteins, genetically modified bacterium, bacterial mixtures, nucleic acids, antibodies, cells and food products. However, the USPTO held off on providing examples on diagnostic method claims possibly because of other pending decisions, including the latest *Myriad* decision.

Recently, the Federal Circuit rendered its latest decision in the Myriad saga, affirming the District Court’s decision to deny Myriad’s motion for a preliminary injunction. The Federal Circuit reviewed the claims and found none of them to be patent-eligible. The Court first considered the claims directed to DNA primers. Looking at their structure, it held that they are structurally identical to what is found in nature and rejected the argument that the primers are synthetically replicated or are single stranded. The Court further held that there was no functional difference between primers when extracted and when part of the DNA strand, rejecting the argument that as primers they "have a fundamentally different function than when they are part of the DNA strand".

Next, the Court looked at the diagnostic method claims. Strangely, instead of analyzing the method claims as a law of nature exception, the Court opined that the claims recite abstract ideas and applied the two-step test used in *Alice*. In the second step asking "whether the remaining elements, either in isolation or combination with the other non-patent-ineligible elements, are sufficient to "'transform the nature of the claim' into a patent-eligible application"", the Court held that the comparison steps (between wild-type and subject genetic sequences) and the techniques used in making the comparison (hybridizing, detecting, amplification and sequencing steps) "do not add 'enough' to make the claims as a whole patent-eligible" and that further "those comparison techniques were the well-understood, routine, and conventional techniques that a scientist would have thought of when instructed to compare two gene sequences".

Are primers and diagnostic methods still patentable? Possibly, but drafters will have to be mindful to introduce meaningful limitations that are considered "enough" to make the claim as a whole patent-eligible (e.g. claiming primers with labels or tags to distinguish them from what exists in nature). One example of a possible meaningful limitation is to identify the specific mutations that can be detected by the diagnostic test. This limitation was discussed by the Court at the end of the *Myriad* case, stating that a claim directed to a method of detecting alterations in which the alterations are expressly identified as specific predisposing mutations of the BRCA1 gene sequence might be patent-eligible (although it refused to decide at this time).

The Interim Guidance is a step forward for patentability and for the biotech industry; however, the *Myriad* decision takes two steps backward. In light of the evolving case law, and in particular, the latest *Myriad* decision, the USPTO guidelines and claim examples may undergo further revisions, and the IP and life science communities will be surely quick to provide feedback. Written comments on the Interim Guidance as well as additional suggestions on claim examples are currently being accepted, and can be sent to: 2014_interim_guidance@uspto.gov until March 16, 2015.

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1 *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. __, 134 S. Ct. 2347 (2014).

2 *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S. Ct. 2107 (2013).

3 *Mayo Collaborative Serv. v. Prometheus Labs., Inc.*, 566 U.S. __, 132 S. Ct. 1289 (2012).

4 The USPTO has noted on its website that it will soon publish examples of subject-matter eligibility analysis of abstract ideas, similar to the nature-based product examples.