Patenting nature-based products in the US

Life science and pharmaceutical companies are more frequently challenged by the strict and complex US practice governing patentability of products containing one or more elements that may be found in nature. It is important to understand the practice to act proactively in prosecution opposite the US patent authority (USPTO).

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Companies seeking patent protection of products, processes or uses, that in some aspects may be related to naturally occurring equivalents, are more frequently met with an objection under 35 USC § 101 when prosecuting their applications opposite the US patent authority (USPTO). This objection relates to *subject-matter* that are excluded for patentability. Here, we will attempt to clarify the rationality and importance of such 35 USC § 101 objections against nature-based products.

The origin to the new practice of the USPTO

Until recently, the bar for patentable *subject-matter* in the US was defined by *"anything under the sun that is made by man"*. Two recent decisions from the US Supreme Court has done away with this mantra. In *Mayo Collaborative Servs. vs. Prometheus Labs. Inc. (2012)*, the court decided that a correlation between a biomarker in a patient and the efficiency of a drug was a natural law and thus excluded from patentability. In the likewise seminal case *Ass. Mol. Pathology vs. Myriad Genetics Inc. (2013)*, the court decided that isolated genomic DNA sequences were naturally occurring products and consequently excluded from patentability.

The two judgments arises from the aspiration of the US Supreme Court to prohibit monopolizing patents that tie up future use and innovation. This concept is known as *pre-emption* and has been the primary motivation for the USPTO to, in an iterative process starting March 2014, draw up new guidelines for their Examiners to follow when deciding whether a patent claim related to a nature-based product is patent eligible or amounts to a judicial exception. The applicable guidelines are described in *Interim Guidance on Patent Subject Matter Eligibility* from December 2014. These guidelines has been updated as of July 2015 and latest of May 2016.

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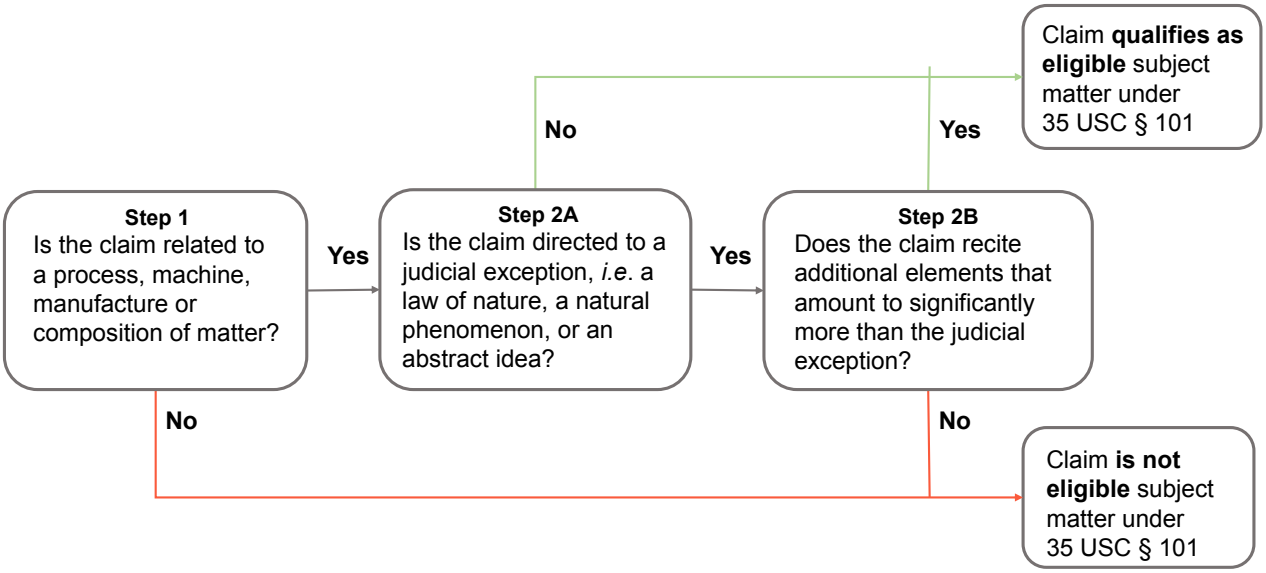

Note
The flowchart illustrate how USPTO assess patentability under 35 USC § 101.

The Mayo-test

The new guidelines come down to a principal set of questions determining if a patent claim to a nature-based product is deemed patent eligible or not. The analysis is schematically illustrated in the flow chart.

Step 2A-B is known as the Mayo-test and is currently utilized by the USPTO for rejecting applications directed to products, processes or uses, which remotely contain an element of a natural aspect. These include compounds from natural extracts, food products, organisms such as bacteria and plants, and proteins and peptides. It is worth noting that recombinant variants of the latter also are subject to the same type of objection.

Although the Examiner according to the guidelines are obliged to present *prima facie* evidence (such as a court decision) to justify a 35 USC § 101 objection, the reality is that these objections are often intangible and the burden of proof to pass the Mayo-test for patentability thus lies with the applicant. Consequently, it is important to understand the motive behind the new type of 35 USC § 101 objections to act proactively in prosecution opposite the USPTO.

Step 2A – "Markedly different" from the naturally occurring equivalent?

For patent claims concerned with nature-based products, step 2A of the Mayo-test boils down to whether the nature-based product can be categorized as *markedly different* from the closest naturally occurring equivalent. Only those limitations of the patent claim relating to the naturally occurring equivalent is evaluated in step 2A. For patent claims composed of a combination of nature-based products, the resulting product must be evaluated as a single entity and not as the separate components.

Product-by-process patent claims are treated as a normal patent claim to a product. On the contrary, patent claims to processes are not evaluated by the *markedly different* criteria, unless the claim is constructed so that no substantial difference from a product claim can be identified, i.e. the process does not contain any innovative elements.

Practice of the USPTO is largely formed by the jurisprudence of the courts, where *markedly differences* may for instance be found in:

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

The USPTO has developed a string of explanatory fictive examples that Examiners are to use as a guideline when trying to identify *markedly differences* in patent claims comprising nature-based products. New examples has continuously been added since December 2014 and it is thus important to monitor updates from the USPTO.

It is not necessary to advance the analysis to step 2B if the Applicant successfully demonstrates a *markedly difference* since the patent claim thus is not deemed to contain a naturally occurring product. If no *markedly difference* is identified, the nature-based product is further evaluated in step 2B.

Step 2B – "Significant more" than the naturally occurring equivalent?

In step 2B the Examiner evaluates if further element or combinations of elements are sufficient for the patent claim to constitute *significant more* than a judicial exception according to step 2A.

In contrast to the *markedly different*-analysis of step 2A, the patent claim is evaluated as a whole in the *significant more*-analysis of step 2B. This part of the Mayo-test is relative vague, but the USPTO provides the following non-limiting examples from the Supreme Court that suffice to qualify as *significant* more:

- Improvements to another technology or technical field
- Effecting a transformation or reduction of a particular article to a different state or thing
- 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
- Other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment

The additional features of a patent claim must be evaluated both individually and in combination with each other. It is not uncommon that individual elements, which does not amount to significant more, in combination represent *significant more* than a judicial exception.

Legal validity of *Interim Guidance*

The USPTO has gone a long way to explain that the new guidelines are only their interpretation of case law, but that they by no means are binding to the US courts. It is therefore relevant to consider whether patents granted under the new guidelines are valid when subsequently challenged in court.

Especially the part of the new guidelines, which deals with *streamlined analysis*, may be a cause of concern. According to the USPTO, patent claims related nature-based products that clearly do not tie up future use and innovation will not be evaluated by the Mayo-test.

While this at first sight appears to be good news for applicants, future opponents will challenge the validity of patents granted under the *streamlined analysis* at the *USPTO Patent Trial and Appeal Board* or *in district court* with the argument that the patent claims are not valid under a complete Mayo-test. Indeed, in *Sequenom vs. Ariosa* (2016) the US Court of Appeals for the Federal Circuit specifically stated *"while preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility".*

Patent claims in the US prospectively

Objections under 35 USC § 101 are to a great extent formed by case law and the outcome of future proceedings at the US courts will continue to shape and define the interpretation of 35 USC § 101.

With *Interim Guidance* on *Patent Subject Matter Eligibility*, the associated examples and especially their subsequent updates, the USPTO has relaxed the criteria for obtaining patent protection of nature-based products as compared to the original reaction to *Mayo* and *Myriad* back in March 2014.

The Mayo-test and the explanatory examples has made it easier for applicants to figure out the, at times, incomprehensible objections raised under 35 USC § 101. Companies seeking to patent a nature-based product should be prepared to demonstrate or argue that the product is *markedly different* from the naturally occurring equivalent according to step 2A. The assessment of whether a product amount to *significant more* than a judicial exception under step 2B, is still shrouded in too much uncertainty for it to be recommendable to rely on this part of the Mayo-test.

Since the Examiners do not always accept functional differences, it is recommended to focus on patent claims with solid fallback options containing structural limitations. This recommendation is corroborated by the fact that the courts appear also to prefer structural limitations. At Plougmann Vingtoft we already have great experience with the new generation of objections under 35 USC § 101 and recommend all companies that work with nature-based products and have interest in the enormous US market to monitor the development of the erratic US practice carefully.

Outline of USPTO examples concerning nature-based products

1. A purified natural product that does not differ structurally or functionally from the naturally occurring equivalent is not patentable. It is worth noting that even minor structural modifications may qualify the natural product as patent eligible, also in the absence of any related functional difference.

   Such a structural modification may be the exchange of a single nucleotide in a nucleic acid sequence or a single amino acid in a protein. It may also be a different glycosylation pattern of a purified protein. However, the Examiner may typically request that data demonstrating the alleged difference is provided by the applicant.

2. A purified natural product that does not differ structurally or functionally from the naturally occurring equivalent may be rendered paten eligible by including an additional component. For example, an isolated nucleic acid attached to a fluorescence marker or incorporated in a vector may be patent eligible.

   When comparing the nature-based product to the closest naturally occurring equivalent, the USPTO uses the broadest reasonable interpretation of the patent claim. Therefore, a pharmaceutically acceptable carrier may encompass water and will consequently not necessarily constitute a component that are not found in nature.

3 Compositions that are functionally distinct from the individual naturally occurring components are patent eligible. This appear to be the case even if the new function is arguably obvious as exemplified by the combination of a fruit juice with a preservative having the new characteristic of a longer shelf life than a juice without the preservative.

4. Methods of treating a specific disease with a product of nature are patent eligible as long as the methods do not tie up all practical uses of the product of nature.