

USPTO Guidance on Natural Product Development

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To be eligible for patent protection, an invention must meet several requirements under U.S. patent law. One of those requirements – whether the patent claims eligible subject matter (35 U.S.C. § 101) – has been front and center in several recent Supreme Court cases. Two of those cases directly concern life science inventions—the Mayo and Myriad cases—while a third—Alice Corp.—is likely to have broad applicability to any patentable method.

In light of these cases, the United States Patent and Trademark Office (USPTO) recently issued guidelines to patent examiners on how to analyze claims reciting or involving “Laws of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products.”

(http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf) (Mayo/Myriad guidance). The analytical framework of the guidance involves a “decision tree” with three sequentially addressed questions:

- 1. Is the claimed invention directed to a process, machine, manufacture, or composition of matter? (If no, the claim is ineligible.)
- 2. If yes, does the claim “recite or involve” one or more judicial exception(s)? Exceptions include laws of nature/natural principles, natural phenomena, natural products, and abstract ideas, which are examined under a different guidance. (If no, the claim is eligible.)
- 3. If yes, or if there is any doubt, does the claim as a whole recite something significantly different than the judicial exception(s)?

After meeting much hostility from the life sciences patent community—unlike similar guidance on high tech related inventions, which was generally well-received—the USPTO has stated that it will revise the Mayo/Myriad guidance, already committing to change Questions 2 and 3 to more closely track Supreme Court law. For example, Question 2 will ask whether the claim is “directed to” one or more judicial exceptions, after commentators pointed out that almost all life sciences inventions may be said to “involve” a natural product or phenomenon. Similarly, Question 3’s “significantly different” standard—which was the USPTO’s effort to apply simultaneously the Mayo and Chakrabarty decisions—will likely be changed to use a formulation directly from the Supreme Court’s cases.

Understanding the Guidelines

Nonetheless, the guidelines are instructive on how the USPTO is struggling to apply Mayo, Myriad and Alice. And while the new guidance will use different language, it is likely that the later guidance will not appreciably differ in substance from the prior guidance.

With that in mind, let’s look at a few of the examples the USPTO employed to explain the guidance: one on gunpowder, which the USPTO has said it will abandon, and two, on the use of DNA primers for PCR, which may be inconsistent with current law.

The gunpowder example was actually not an example at all – rather, it was hidden in a comment to another example where gunpowder was one of the ingredients in an otherwise patentable

firework. But, in that comment, the USPTO stated that “gunpowder [is] not markedly different from what occurs in nature,” and then went on to explain that under a broad claim construction, in the USPTO’s view, gunpowder included a mere mixture of the three natural ingredients, which the USPTO stated was not changed from nature and was not patentable.

This example demonstrates how easy it is to misapply Supreme Court law on Section 101 if one is not careful. While the Supreme Court in the *Myriad* case focused on the lack of significant structural difference between an isolated nucleic acid and the intact gene, the Court did not dispense with an analysis of new utility where relevant. In fact, *Myriad* argued that the Court should recognize its claim because isolated DNA could be used in ways that the intact gene could not, as primers and probes, for example – i.e., there was a new utility to that isolated DNA. However, that utility was not claimed in the patent. Accordingly, the claim simply covered the isolated gene no matter how one might use it, even, hypothetically, if one didn’t use it at all. As such, it was unpatentable as not markedly different from the product of nature – i.e., the gene.

By contrast, a claim to “gunpowder” requires the utility of gunpowder – i.e., blowing things up. Such a claim has a new utility that does not exist in the natural ingredients of which gunpowder is made and it would not cover a non-useful “mixture” of the three ingredients that did not function as gunpowder. This utility was created by man, and does not exist in nature. As such, it should be clearly patentable under Section 101.

The two examples regarding DNA primers also are inconsistent with Supreme Court caselaw for the same reason. In those examples, the USPTO simultaneously stated that a claim to a pair of DNA primers with specific sequences (presumably for a novel gene) was not patentable, while a method claim of amplifying the same gene using PCR with the new primers (and the various “conventional” steps of PCR) was patentable. According to the USPTO, the former is not patentable because the primers are not structurally changed from fragments of genomic DNA, while the latter is patentable despite the only difference between the method and the prior art being the novel primers.

Again, these examples demonstrate a fundamental misconception about the Supreme Court’s 101 jurisprudence. A claim to a pair of DNA primers should not be interpreted to cover the identical fragments of DNA sitting on the table, as the USPTO appears to have concluded – rather, those fragments of DNA must be being utilized for priming an artificial reaction that man has created. Otherwise, they have no meaning. Instead, the USPTO conflated how primers operate – through the naturally occurring Watson-Crick base pairing—with the non-natural utility of the claimed product (priming of PCR). While the USPTO was correct to say that the method claim was patentable, for the same reason, the composition claim is patentable as well.

In short, when it issues its new guidance, the USPTO should be careful to make sure it considers utility in the Section 101 analysis. While the Supreme Court has emphasized that structural differences are important in the 101 analysis, new utility matters as well and perhaps even more. Indeed, at the *Myriad* oral argument, there appeared to be no question that a new use of a natural product was considered patentable by the Supreme Court. Accordingly, a natural product that has new utility—where that utility is claimed in the patent—should be eligible for patent protection. This is the direction that the USPTO needs to move with its new guidance.

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