

PATENT ELIGIBLE SUBJECT MATTER: USPTO ISSUES INTERIM GUIDANCE POST-PROMETHEUS

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On July 3, 2012, the U.S. Patent and Trademark Office (USPTO) issued a memorandum setting forth its interim procedures for examination of process claims involving so-called “laws of nature.” The guidance is “interim” while at least two pending cases are decided in the wake of the U.S. Supreme Court’s ruling in *Mayo v. Prometheus*. In *Prometheus*, the justices unanimously found that a method for personalizing a medical dosing process was not eligible for patent protection because its claims effectively encompassed a “law of nature,” but did not include additional elements that provide for a practical application of the “law of nature.”

The USPTO’s guidance now requires patent examiners to perform a three-question analysis:

1. Is the claimed invention directed to a process, defined as an act, or a series of acts or steps?
2. If yes, does the claim focus on a use of a natural principle (i.e., is the natural principle a limiting feature of the claim)?
3. If yes, does the claim include additional elements or a combination of elements that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and that are sufficient to ensure that the claim amounts to significantly more than the natural principle itself (i.e., is the invention more than a law of nature plus the general instruction to simply “apply it”)? If yes, the claim is patent-eligible, and the analysis is complete.

Answering the first question is straightforward. Until the interpretations of “natural principle” and “additional elements” are clarified, the remaining two questions will continue to complicate examination of patent applications. Presently, with respect to natural principles, the guidance states:

[a] natural principle is the handiwork of nature and occurs without the hand of man. For example, the disinfecting property of sunlight and the relationship between blood glucose levels and diabetes is a natural principle. A correlation that occurs naturally when a man-made product, such as a drug interacts with a naturally occurring substance, such as blood, is also considered a natural principle, because, while it takes a human action to trigger a manifestation of the correlation, the correlation exists in principle apart from any human action.

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With regard to “additional elements,” the guidance provides some explanation of what would be inadequate, such as patent claim elements that amount to instructions that are well-understood, routine, conventional activity previously engaged in by those in the field and add nothing specific to the natural principle. Some specific, biotechnology-related examples are also provided, but it is clear from the examples that the USPTO has followed the rationale in *Prometheus*, which arguably conflates the requirements for novelty and non-obviousness (35 U.S.C. §§ 102 and 103) with subject matter criteria under 35 U.S.C. § 101.

The “interim” procedures could be modified by two cases that are currently under remand to the Federal Circuit for reconsideration in view of the *Prometheus* decision. In particular, *Ass’n for Molecular Pathology v. Myriad Genetics, et al* involves reconsideration of a decision that, in part, held isolated DNA to be patentable subject matter. The Supreme Court’s remand instructs the Federal Circuit to reconsider the question:

What is the applicability of the Supreme Court’s decision in *Mayo to Myriad’s* isolated DNA claims and to method claim 20 of the ’282 patent?

This is intriguing because the USPTO’s interim guidance appears to be in conflict with this question. Claim 20 in the U.S. Pat. No. 5,747,282 is a process claim, and the USPTO’s interim guidance requires answering question one in the negative for composition claims (i.e., claims to isolated DNA). So, according to the USPTO’s interim guidance, Myriad’s isolated DNA claims should not be subject to a *Prometheus* analysis at all.

In the other case, the Federal Circuit decided in *Ultramercial v. Hula* that the software claims in question did encompass patentable subject matter because they involved “complex programming.” *Ultramercial* will be of great interest to gauge the reach of *Prometheus* beyond the life-sciences area of patent law.

The interim guidance, in connection with the pending cases on remand, suggests that the future for patent claims that involve natural phenomena is uncertain. We look forward to further clarification as the federal courts and the USPTO address patentable subject matter under the *Prometheus* analysis.

We will issue further client alerts when these cases are decided.