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USPTO Issues Patentability Guidelines Under *Mayo v. Prometheus*

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Advisory

On July 5, 2012, the United States Patent and Trademark Office issued a memorandum to all patent examiners providing guidelines for examining process claims for patent eligibility in view of the Supreme Court decision *Mayo v. Prometheus*. Entitled "*2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature*," the much-anticipated guidance is intended to apply to process claims focused on a law of nature, natural phenomenon, or naturally occurring relation or correlation ("natural principle"). Although it is expected this guidance will predominantly impact claims examined in Technology Center 1600 (Biotechnology), the guidelines will be applicable to any process claim that refers to a natural principle. Process claims directed to abstract ideas, such as the claims in *Bilski* will continue to be examined using the previously issued guidance for determining subject matter eligibility under *Bilski v. Kappos*.

In summary, the new guidelines provide that a process claim relying on a natural principle should be evaluated by determining whether the claim includes elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that (a) the natural principle is practically applied, and (b) the recited elements/steps are sufficient to ensure that the claim "amounts to significantly more than the natural principle itself." If the claim as a whole satisfies this inquiry, the claimed subject matter is patent-eligible. If the claim does not satisfy this inquiry, it will be rejected under 35 USC § 101 as being directed to non-statutory subject matter. To streamline prosecution, examiners are instructed to evaluate claims for all other patentability requirements, in addition to § 101, in the same office action.

In dealing with *Mayo*-type § 101 rejections, an applicant should present persuasive arguments that the claim includes steps that add something significantly more to the claim than merely describing the natural principle. According to the guidelines, another course of action would be a claim amendment adding or amending steps/features so that they a) integrate the natural principle into the process (by practically applying or making use of the principle), and b) are sufficient to limit the application of the natural principle to more than just "the principle itself plus steps that do more than simply "apply it" at a high level of generality." A showing that such steps are not routine, well-known or conventional could be persuasive.

The full 12-page memorandum details the analytical framework, relevant factors, as well as provides specific examples of claims and illustrates the application of the guidelines.
The Patent Office expects to further refine the guidelines as the Federal Circuit resolves relevant pending cases, the most notable of which are *Myriad* and *Ultramercial*. Patent applicants and patent owners with affected inventions and/or applications should carefully consider the recent guidelines and monitor ongoing developments in the courts. In many cases, corrective action will be necessary to salvage patent claims from the scathing reach of *Mayo v. Prometheus*.

This advisory was prepared by Nutter's Intellectual Property practice. For more information, please contact your Nutter attorney at 617-439-2000.

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