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The USPTO Issues New Examination Procedures for Process Claims Relating to Natural Principles

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Patent applications containing process claims directed to laws of nature, natural phenomena or naturally occurring relations or correlations are now being examined differently by the United States Patent and Trademark Office for compliance with 35 U.S.C. § 101. These procedures will affect both the subject matter that will be considered allowable in process claims and how that subject matter needs to be presented.

On July 3, 2012, the USPTO released the 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature (2012 Interim Procedure for Laws of Nature), providing patent examiners with guidance on how to apply the recent Supreme Court opinion in *Mayo Collaborative Services v. Prometheus Inc.*, 132 S.Ct. 1289 (2012). According to the memo, claims will be judged for patent-eligibility under 35 U.S.C. 101 following a three-step process:

Step 1: Is the claimed invention directed to a process?

- If YES, then the examiner proceeds to step 2.
- If NO, then claimed invention must be evaluated under the 2009 Interim Guidance.

For the purposes of this step, a process is defined as "an act, or a series of acts or steps."

Step 2: **Does the claim focus on use of a law of nature, a natural phenomenon or naturally occurring relation or correlation (collectively referred to as a natural principle)?**

- If YES, then the examiner then proceeds to step 3.
- If NO, the claim should be analyzed using the 2010 Interim Bilski Gudance to determine if an abstract idea is claimed.

For the purposes of this step, "[a] natural principle is the handiwork of nature and occurs without the hand of man." It thus encompasses anything that "exists in principle apart from any human action." A claim "focus[es] on use of a [natural principle]" when the natural principle is a limitation of the claim.

Step 3: Does the claim include additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself? (Is it more than a law of nature + the general instruction to simply "apply it"?)

- If YES, the claim is patent-eligible.
- If NO, the claim is not patent-eligible and should be rejected.

For the purposes of this step, the claims must: be limited to a practical application of a natural principle and provide sufficient assurance that the claim will not preempt all use of the natural principle. For the first prong, the critical question is whether the natural principle is sufficiently "integrated" with additional steps or elements so as to meaningfully limit the scope of the claim. For the second prong, the additional steps or elements must

be significant enough to "provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." Examples of claims that would fail this test include:

- Claims having a limitation that describes a law of nature and additional steps that must be taken in order to apply the law of nature by establishing the conditions under which the law of nature occurs such as a step of taking a sample recited at a high level of generality to test for a naturally occurring correlation;
- Claims adding steps to a natural biological process that only recite well-understood, routine, conventional activity previously engaged in by researchers in the field; and
- Claims having a combination of steps that amounts to nothing significantly more than an instruction to doctors to "apply" applicable natural laws when treating their patients.

Patent applicants should carefully consider how these new guidelines affect their pending patent applications. If you would like guidance on how this affects you, please contact one of our experienced Patent Attorneys.