

## USPTO Issues Guidance in View of *Myriad* and *Prometheus*

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*Advisory*

On March 4, 2014, the U.S. Patent and Trademark Office (USPTO) published the long-awaited *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products*. The Guidance implements new examination procedures to address the recent Supreme Court decisions in *Association for Molecular Pathology v. Myriad Genetics* (holding that isolated natural DNA sequences are not patent eligible) and *Mayo Collaborative Services v. Prometheus Laboratories* (holding that application of a law of nature, using only known steps, is not patent eligible). Since those decisions issued in June 2013 and March 2012, respectively, the patent community has eagerly anticipated the USPTO guidelines.

The 19-page Guidance has now arrived. The Guidance states that the use of traditional descriptors such as “isolated,” “recombinant,” or “synthetic,” or the addition of routine or conventional elements, will not suffice for patent eligibility. Rather, patent examiners must now conduct a more probing analysis, on a claim by claim basis, if the invention is “significantly different” from what is found in nature. The guidelines will impact many applications currently pending in the USPTO, particularly, those pertaining to the life sciences and chemistry, since patent examiners must now apply that analysis to all claims that recite or involve, even *arguably*, a “judicial exception” (i.e., an abstract idea, a law of nature or a natural principle, a natural phenomenon, or a natural product). Determining whether a claimed invention is “significantly different” will require weighing 12 factors (such as claim scope, the magnitude of differences, the presence or absence of unique features, etc.). The Guidance also offers several detailed examples of how those factors are to be applied in analyzing claims to modified bacteria, purified natural anti-cancer compounds, bacterial mixture compositions, DNA primers and methods of conducting a PCR reaction, methods of diagnosing a disease using a biomarker, and even a fountain-style firework that utilizes calcium chloride.

The Guidance will have the greatest impact on the internal USPTO examination procedures – the effects will be seen immediately. Although the guidelines are not binding or precedential for the courts, the document will still be cited and weighed considerably in litigation at District Courts and the Federal Circuit. Nutter attorneys will continue to keep you updated and provide you with insight on subject matter eligibility under 35 U.S.C. § 101, *Myriad*, and *Prometheus*.

**This advisory was prepared by the Intellectual Property practice group at Nutter McClennen & Fish LLP. For more information, please contact your Nutter attorney at 617-439-2000.**

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