

Client Alert

Intellectual Property Practice Group

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USPTO Issues New Guidelines for Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products

On March 4, 2014, the United States Patent and Trademark Office (USPTO) issued final guidance to the Examining Corps regarding patent eligibility of claims involving laws of nature, natural phenomena and natural products. The 18 page memorandum, entitled “Guidance For Determining Subject Matter Eligibility Of Claims” (the “Guidelines”), interprets and extends the Supreme Court’s holdings in *Association for Mayo Collaborative Services v. Prometheus Laboratories, Inc.*¹ (*Prometheus*) and *Molecular Pathology v. Myriad Genetics, Inc.*² (*Myriad*). The Guidelines provide an analytical rubric and detailed examples that Examiners will use to assess whether claims involving laws of nature/natural principles, natural phenomena, and/or natural products are patent eligible subject matter. Notably, the Guidelines extend the holding of *Myriad* beyond isolated nucleic acids and instruct Examiners that isolated natural products are not patentable subject matter. While these Guidelines are not legally binding and the courts will ultimately interpret *Prometheus* and *Myriad* and clarify what subject matter is patent eligible, the Guidelines will at this time significantly impact the scope of claims relating to laws of nature and natural products the USPTO is willing to grant. In this client alert, we will briefly review the *Prometheus* and *Myriad* holdings, provide a summary of the Guidelines, and finally offer some forward looking considerations flowing from these new examination criteria.

Overview of *Prometheus* and *Myriad*

In its unanimous *Prometheus* opinion, the Supreme Court held that a “law of nature” relationship exists between metabolite levels and the likelihood that a given dosage of a drug will be ineffective or cause harm. Although the appellate court below had held that “administering” and “determining” steps in the method claim were sufficiently transformative to be patentable, the Supreme Court in *Prometheus* held that these steps failed to transform the law of nature into patentable subject matter. The Court explained that a claim to a natural law is not patentable unless it has additional features that add significantly more to the natural law itself. Routine, well known steps, such as “administering” a drug and then “determining” levels of a metabolite, which physicians had routinely carried out prior to the invention, could not make the law of nature into patentable subject matter.

For more information, contact:

Kenneth H. Sonnenfeld, Ph.D.
+1 212 556 2324
ksonnenfeld@kslaw.com

Margaret B. Brivanlou, Ph.D.
+1 212 556 2270
pbrivanlou@kslaw.com

Rebecca J. Kaufman
+1 404 572 3567
bkaufman@kslaw.com

King & Spalding

New York

1185 Avenue of the Americas
New York, New York 10036-4003
Tel: +1 212 556 2100
Fax: +1 212 556 2222

Atlanta

1180 Peachtree Street, NE
Atlanta, Georgia 30309-3521
Tel: +1 404 572 4600
Fax: +1 404 572 5100

www.kslaw.com

Justice Breyer summarized the Court's reasoning: "if a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction 'apply the law.'"

In *Myriad*, the Supreme Court, in another unanimous decision, held that a naturally occurring DNA segment was a product of nature and not patent eligible even when isolated from its source. The patents in *Myriad* claimed the BRCA1 and BRCA2 genes, and mutations of these genes associated with an increased risk of breast and ovarian cancers. Rejecting the long accepted practice of claiming DNA as an isolated and purified molecule, the Supreme Court held that separating a naturally occurring gene from its surrounding genetic material is not an invention. However, the Court found synthetic cDNA to be generally patentable as it does not exist in nature. Notably, the Supreme Court expressly stated that *Myriad* does not relate to claims to methods of using the isolated DNA or to claims in which the nucleotide sequence of the isolated DNA had been altered.

I. Summary of the USPTO's Guidance Memorandum

a. Factors For and Against Patent Eligibility

Against the backdrop of the holdings in *Prometheus* and *Myriad*, the Guidelines outline a three step analysis for Examiners to follow in determining whether claims involving naturally occurring products and laws of nature qualify as patentable subject matter under 35 USC § 101. The first two steps of the analysis are straightforward, requiring the Examiner to determine whether: (1) the claimed invention is directed to one of the four statutory categories of patent eligible subject matter, namely process, machine, manufacture or composition of matter; and, (2) if so, whether the claim includes a judicial exception, namely an abstract idea, a law of nature or a naturally occurring product.

If the answer to the second question is positive, the Examiner is to engage in the third step, to determine whether: (3) the claim as a whole recites "something *significantly different* than the judicial exception" and is, therefore, patentable subject matter. The Guidelines provide examples of products that *must* be analyzed under step 3, including "chemicals derived from natural sources (*e.g.*, antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (*e.g.*, fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (*e.g.*, rocks, sands soils); nucleic acids; organisms (*e.g.*, bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature."

The Guidelines set forth a number of factors that an Examiner should consider in the step 3 analysis. The Examiner is to apply the factors and weigh them in their totality to determine whether, on balance, the claimed subject matter is eligible for patenting. The Guidelines set forth 12 factors—6 supporting and 6 against assessing a claim as patentable subject matter. These factors essentially include evaluating whether (1) a product is "markedly different in structure from naturally occurring products;" (2) the claim includes additional meaningful limitations or steps such that others are not preempted from practicing the natural law or using the natural product; (3) the claim does more than just describe the natural law and actually applies it; (4) the additional steps are more than routine and well understood steps in the field or are more than nominally or tangentially related to the natural law or product; and (5) the additional steps include a machine or transformation. Not all of the factors may be relevant to a particular claim and not all need to be satisfied for subject matter to be patent eligible.

b. Examples

The Guidelines provide examples with model claims and analysis using the factors to assist Examiners in applying the Guidelines. Several examples present claims from Supreme Court precedents and find the subject matter

patentable or unpatentable in line with the holdings of those cases. Other examples go beyond the specific holdings of the existing case law and current USPTO practice. Four of the examples are particularly instructive:

Of particular note is an example of claims to a natural product—an acid purified from leaves that has anti-cancer activity. The Guidelines expressly state that Examiners should no longer consider claims to this purified natural product to be patentable subject matter, highlighting the absence of any “structural difference between the purified acid in the claim and the acid in the leaves.” Claims to a structurally modified compound would be patent eligible according to the Guidelines. The Guidelines also find patentable subject matter claims to treating a specific form of cancer. However, the exemplified claim includes limitations to the amount and timing of dosage, which the Guidelines highlight as meaningfully limiting the use of the natural product. The USPTO has not previously discriminated between method of treatment claims with isolated natural products and method of treatment claims with synthetic products. The Guidelines do not expressly state the extent to which Examiners will now require claims to specify details of the administration of the product beyond the particular indication in method of treatment claims involving compounds isolated from natural sources.

Analyzing claims to nucleic acid primers with specified sequences found in naturally occurring DNA, the Guidelines advise that claims to the primers themselves are not patentable subject matter. Citing *Myriad*, the Guidelines note that although isolation structurally alters a nucleic acid from its natural state by “breaking bonds,” the essential structure and sequence of the nucleic acid is not altered or changed. Such primers are naturally occurring as the substrates for DNA synthesis within a cell according to the Guidelines. The Guidelines do deem a method of amplifying DNA using the primers is patentable subject matter, so long as the claim is sufficiently limited so as not to preempt use of the naturally occurring product. In the example, even though the steps for carrying out PCR are well understood and routine, the recitation of cooling and heating the reaction mixture to “predetermined temperature[s]” and use of a specific enzyme in the reaction are found to sufficiently narrow the scope of the claim to make it patent eligible.

Example six is a method of diagnosis. The claim in question is to a method for testing whether a patient has a disease characterized by a misfolded protein using a particular antibody that selectively binds to the misfolded protein and using flow cytometry to detect binding. The antibody is not naturally occurring. According to the guidelines, the subject matter of the claim is patent eligible. Although the correlation between the misfolded protein and the disease is a natural law, the Guidelines state that use of a specific antibody and method of detection do not preempt the application of the correlation. The Guidelines do not address whether the claim would present patentable subject matter if it did not specify the particular antibody or method of detection or if the antibody were a naturally occurring antibody.

The final example is based on claim 1 of U.S. Patent No. 6,033,857, one of the patents at issue in the *Myriad* litigation (found by the Court of Appeals for the Federal Circuit to be not patentable subject matter), although not involved in the Supreme Court appeal. This claim recites a method of identifying a BRCA2 mutant by “comparing” a suspected mutant BRCA2 nucleotide sequence with a wildtype BRCA2 nucleotide sequence. Asserting that the claim contains both an abstract idea and a natural product, the Guidelines state that the claim does not present eligible subject matter and points the Examiner to previous Examiner guidance for determining whether a claim to an algorithm or abstract idea constitutes patent eligible subject matter.

II. Practice Comments

While prompted by *Prometheus* and *Myriad*, the Guidelines extend beyond the specific holdings of either case and will significantly impact the types of claims the USPTO will consider as patentable subject matter, going forward. As a result, Examiners may rely on these Guidelines to reject claims to purified proteins, antibiotics and other

substances previously determined to be patentable subject matter. We expect that either the application of these Guidelines will be challenged in appeals to the Court of Appeals for the Federal Circuit (CAFC) of rejected patent claims or clarified by district courts and the CAFC in challenges to the validity of issued patents.

As we await judicial clarification, strategic drafting and prosecution of patent applications related to laws of nature and naturally occurring products may maximize the ability to obtain meaningful patent coverage in this field. In particular, applications should be drafted to include disclosure of aspects of the invention that might distinguish as much as possible claimed subject matter from a natural product or law of nature. A review of pending applications is also recommended to determine if currently pending claims are at risk of rejection in view of the Guidelines and to assess what amendments may be advisable to avoid such rejections or what strategies should be put in place to challenge the rejections.

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¹ 566 U.S. ___, 132 S. Ct. 1289 (2012)

² 569 U.S. ___, 133 S. Ct. 2107 (2013)