

## **New Guideline of Subject Matter Eligibility Challenges Patent Applicants in the U.S.**

The United States Patent and Trademark Office (USPTO) issued a memorandum on March 4, 2014, providing a guideline for determining the subject matter eligibility of patent claims related to nature, natural phenomena and natural products. This is in response to U.S. Supreme Court's decisions in *AMP v. Myriad Genetics*, 569 U.S. 12-398 (Jun. 13, 2013) and *Mayo v. Prometheus*, 566 U.S. 10-1150 (March. 20, 2012).

In general, the Supreme Court takes a measured approach that narrows the scope of its decision to the specific facts of the case. In *Myriad*, the Court held that, for gene-related inventions, isolated DNA is not a patent-eligible subject matter, but cDNA, recombinant cell based cancer drug screening method, altered oligonucleotides, primers, probes (such as antisense or siRNA), and gene-manipulating methods in search for specific genes are still patent-eligible. To circumvent this hurdle, patent practitioners have drafted new types of claims in patent applications and reissue applications involving gene-related inventions. However, the USPTO's interpretation of these rulings as reflected in its memorandum is even more far-reaching than the Court's holdings: it provides a new procedure not only for those gene-related inventions, but all claimed inventions. In fact, ever since the publication of the human genome and isolation of genetic sequences are now easily achievable, there are already plenty of challenges for patenting genes and gene-related products. So far, the USPTO has received more than 40,000 applications based on more than 2,000 human genes (these genes constitute 20% of the total human genome).

In practice, most efforts are focused on overcoming obviousness rejections during patent prosecution. Many applications now have the added burden to show that the claimed invention is patent-eligible subject matter. The memorandum guideline includes a three-step analysis: 1. Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture, or composition of matter? 2. Does the claim recite or involve one or more judicial exceptions which include abstract ideas, laws of nature/natural principles, natural phenomena, and natural products (when interpreted broadly, any claimed subject matter could be a target scrutiny because any claimed invention arguably relies on certain laws of nature or principles and phenomena)? If there are any doubts as to whether the claim recites a judicial exception, the claim requires further analysis under step 3. 3. Does the claim as a whole recite something significantly different than the judicial exception(s)? A significant difference exists in the claim as a whole as compared to the judicial exception if the claims include elements or steps that practically apply the judicial exception(s) in a significant way or include features that are markedly different from what exists in nature. The fact that the marked difference comes about as a result of routine activity or via human manipulation of natural processes does not affect patent eligibility.

The memorandum cited eight examples of claimed invention. A summary of what is considered as patent-eligible and the reasoning are summarized below:

1. Composition/manufacture claims reciting natural products: A plasmid, which provides a hydrocarbon degradative pathway (non-eligible claim); A bacterium containing at least two plasmids

providing a separate hydrocarbon degradative pathway (eligible claim). Reasoning: plasmids alone are natural products but the bacterium containing the plasmids are not.

2. Composition vs. Method claims, each reciting a natural product: Purified amazonic acid (non-eligible claim); purified 5-methyl amazonic acid (eligible claim); A method of treating colon cancer comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for 10 days, wherein said daily dose comprises 0.75 teaspoons of amazonic acid (eligible claim). Reasoning: 5-methyl amazonic acid is structurally and functionally different than amazonic acid that occur in nature. Although not necessary, functional difference makes a stronger case for eligibility. The specific dose and treatment time meaningfully limit the scope of the claim to a particular application so that others are not substantially foreclosed from using amazonic acid.

3. Manufacture claims reciting natural products: A firework comprising: (a) a sparking composition, (b) calcium chloride, (c) gunpowder, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder, and (e) a plastic ignition fuse (eligible claim). Reasoning: the addition of elements to calcium chloride and gunpowder amount to a specific practical application of the natural products.

4. Composition claims reciting multiple natural products: An inoculant for leguminous plants comprising a plurality of strains of different species of bacteria of the genus *Rhizobium*, (non-eligible claim). Reasoning: *Rhizobium* bacteria are naturally occurring bacteria that infect leguminous plant. The claim does not include significantly more elements in addition to the judicial exceptions and does not include features that are markedly different from what exists in nature.

5. Composition vs. method claims, each reciting two natural products: A pair of primers having the sequence of SEQ ID NO:1 and SEQ ID NO:2 (non-eligible claim). A method of amplifying a target DNA sequence comprising: providing a reaction mixture comprising a double-stranded target DNA, the pair of primers, Taq polymerase; heating the reaction mixture to a predetermined temperature for a predetermined time; cooling the reaction mixture to a predetermined temperature; repeat the steps for 20 times (eligible claim). Reasoning: The pair of primers is naturally occurring DNA sequences found on a human chromosome. The heating and cooling step contain a number of limitations that narrow the scope of the claim and involve direct manipulation of the natural products in a significant way and does not foreclose others to apply and use the natural products.

6. Process claims involving a natural principle and reciting natural products: A method for determining whether a human patient has disease X comprising: obtaining sample from a human patient; determining whether mutant protein A is present in the sample and detecting whether binding occurs between mutant protein A and antibody X using flow cytometry, wherein antibody X binds to an epitope on the mutant protein A but not on normal protein X; and diagnosing the patient as having disease X if mutant protein A was determined to be present in the sample (eligible claim). Reasoning: the correlation between the mutant protein A and disease X is a natural principle, however, antibody X does not exist in nature. The claim as a whole recites something significantly different than the natural principle and amount to a practical application of the natural principle. The use of flow cytometry

narrows the scope of the claim so that others are not foreclosed from using other means to detect the mutant protein.

7. Process claims involving a natural principle. A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain comprising: exposing the patient to sunlight, wherein the exposure to sunlight alters the neuronal activity in the patient's brain and mitigates the mood disorder (Non-eligible claim). A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising: exposing the patient to a synthetic source of white light, wherein the exposure to white light alters the neuronal activity in the patient's brain and mitigates the mood disorder (Non-eligible claim). A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising: providing a light source that emits white light; filtering the ultra-violet rays from the white light; and positioning the patient adjacent to the light source between 30-60 cm for 30-60 minutes to expose photosensitive regions of the patient's brain to the filtered white light (eligible claim). Reasoning: the natural principle is that Sunlight is a natural source of white light which affects human neuronal activity. In contrast, the steps of positioning the patient at a set distance for a set duration so as to expose photosensitive regions of the patient's brain to the light meaningfully limit the claim to a particular application of the natural principle so that others are not foreclosed from using the natural principle.

8. Process claims reciting an abstract idea and a natural product. A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises comparing the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence, wherein a difference between the suspected mutant and the wild-type sequences identifies a mutant BRCA2 nucleotide sequence (non-eligible claim). Reasoning: same reasoning as presented in Myraid where the claim is a process of comparing (an abstract mental process) the wild-type BRCA2 nucleotide sequence (a natural product) with a suspected mutant BRCA2.

The guidelines certainly encompass more subject matters deemed to be non-patent-eligible than what the Supreme Court decisions have held. As the guidelines are not legal statutes or case law, it is nevertheless a problem to be reckoned with.