VENABLE LLP

white paper

JULY 2014

The USPTO Issues Guidelines for Subject Matter Eligibility Analysis:

How the Supreme Court's Decisions in *Pathology v. Myriad* and *Mayo v. Prometheus* Could Change the Rules

VENABLE LLP ON PATENT LAW

AUTHORS

Miguel A. Lopez, Ph.D.
malopez@Venable.com
310.229.9904

Stefan J. Kirchanski, Ph.D.
sjkirchanski@Venable.com
310.229.9928

The USPTO Issues Guidelines for Subject Matter Eligibility Analysis:

How the Supreme Court's Decisions in *Pathology v. Myriad* and *Mayo v. Prometheus* Could Change the Rules

VENABLE LLP ON PATENT LAW

On March 4th, 2014, the United States Patent and Trademark Office issued a guidance advising examiners and the public of the factors for determining whether an invention satisfies the provisions of 35 U.S.C. §101, as applied to patent eligibility in view of the U.S. Supreme Court's decisions in ***Molecular Pathology v. Myriad Genetics, Inc.*** (*Myriad*) and ***Mayo Collaborative Services v. Prometheus Laboratories, Inc.*** (*Prometheus*). In this issue, we summarize and highlight key "take home" points of the guide. Next month, we will discuss the guide's potential implications for inventors and legal service providers.

The guide issued by the USPTO, ***Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products*** (*Guidance*), contains four sections. The first section summarizes the overall process to be followed by examiners when assessing subject matter eligibility under 35 U.S.C. §101. The second section provides guidance on how to determine if a claim as a whole recites eligible subject matter and is "significantly different" from any of four judicial exemptions recited in the first section. The third section provides several example claims and analyses of their eligibility in view of the points raised in the first two sections. Finally, the fourth section provides examiners with language to be used when making a rejection in accordance with the *Guidance*.

The first section of the *Guidance* presents three questions that must be answered to determine whether a claim is drawn to patent-eligible subject matter:

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 (*e.g.* abstract ideas, laws of nature/natural principles, natural phenomena, or natural products)?

3) Does the claim as a whole recite something "significantly different" than the judicial exception(s)?

If the answer to the first questions is "no," then the claim is not eligible for patent protection. If the answer to the first question is "yes," then one must analyze the claim in view of the second question. Then, if the answer to the second question is "no," the claim is patent eligible and the analysis is complete. If, however, the answer to the second question is "yes" or "perhaps," then one

must evaluate the claim in view of the third question. It is also important to note that the *Guidance* states that if a claim recites an abstract idea, it should be analyzed for subject matter eligibility using only the existing guidance in MPEP 2106(II).

The second section of the *Guidance* notes six factors that weigh *towards* eligibility as well as six factors that weigh *against* eligibility when one is analyzing a claim in view of the third question presented in the first section.

When taken into account, these 12 factors are meant to determine whether or not a claim recites something "significantly different" from the judicial exceptions, respectively.

The six factors that would indicate that the claimed subject matter is "significantly different" from a judicial exception and therefor weigh *in favor of* patent eligibility are:

1) the claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products;

2) the claim recites elements/steps in addition to the item falling within one or more judicial exception(s) that impose meaningful limits on claim scope, *i.e.*, the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the item in all possible ways;

3) the claim recites elements/steps in addition to the item falling within one or more judicial exception(s) that relate to the judicial exception in a significant way, *i.e.*, the elements/steps are more than nominally, insignificantly, or tangentially related to the item;

4) the claim recites elements/steps in addition to the item falling within one or more judicial exception(s) that do more than describe the item with general instructions to apply or use the item;

5) the claim recites elements/steps in addition to the item falling within one or more judicial exception(s) that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more items or integrates the item into a particular practical application; and

6) the claim recites one or more elements/steps in addition to the item falling into one of more judicial exception(s) that add a (non-obvious) feature.

Conversely, six factors that would indicate that the claimed subject matter is not "significantly different" from a judicial exception and therefor weigh *against* patent eligibility are:

1) the claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products;

2) the claim recites elements/steps in addition to the item falling within one or more judicial exception(s) at a high level of generality such that substantially all practical applications of the item are covered;

3) the claim recites elements/steps in addition to the item falling within one or more judicial exception(s) that necessarily must be used/taken by others to apply item;

4) the claim recites elements/steps in addition to the item falling within one or more judicial exception(s) that are well-understood, purely conventional or routine in the relevant field (*i.e.*, totally obvious);

5) the claim recites elements/steps in addition to the item falling within one or more judicial exception(s) that are insignificant extra-solution activity, *e.g.*, are merely appended to item; and

6) the claim recites elements/steps in addition to the item falling within one or more judicial exception(s) that add nothing more than a mere field of use.

The third section of the *Guidance* provides eight examples of composition, manufacture, methods, or process claims containing patent-eligible or non-eligible subject matter.

Sample claim sets as well as brief summaries of the analyses provided by the *Guidance* for each claim set follow below.

Example 1: Composition/Manufacture Claim Reciting a Natural Product

Claim 1. *A stable energy-generating plasmid, which provides a hydrocarbon degradative pathway*

Claim 2. *A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway*

Analysis: In applying the six factors that would indicate that the claimed subject matter is "significantly different" from a judicial exception and therefor weigh *toward* eligibility, Claim 1 is rejected under Section 101 because there are no structural differences recited between the claimed plasmid and the naturally occurring plasmid. Claim 2, on the other hand, contains patent eligible subject matter. Specifically, the recitation of the limitation "*at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway"* provides a significant difference over a judicial exemption. Specifically, the bacterium is structurally modified over naturally occurring bacterium to carry at least two plasmids. Further, the modified bacterium is functionally different from natural isolates as it is has been engineered to degrade at least two different hydrocarbons.

Example 2: Composition vs. Method Claims, Each Reciting a Natural Product

Claim 1. *Purified amazonic acid*

Claim 2. *Purified 5-methyl amazonic acid*

Claim 3. *A method of treating colon cancer, comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for a period of time from 10 days to 20 days, wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid.*

Analysis: In this example, 5-methyl amazonic acid represents a compound designed and synthesized by the inventor and has some distinct properties from amazonic acid. Also, amazonic acid was known in

the art to be effective against breast cancer. According to the *Guidance,* Claim 1 does not contain patent eligible subject matter because it does not contain structural differences from the compound found in nature. Claim 2 does contain patent-eligible subject matter because it contains a structural difference not found in nature. In addition, although the *Guidance* states that a functional difference is not necessary to find a marked difference from a naturally occurring product, the presence of a functional difference strengthens the argument in favor of patent-eligibility. Finally, Claim 3 also contains patent-eligible subject matter because the limitations regarding the dosage schedule and amount limit the scope of the claim. Also, the application of the compound for the treatment of colon cancer is novel.

Example 3: Manufacture Claim Reciting Natural Products

Claim 1. *A fountain-style 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 having one end extending into the second compartment and the other end extending out of the cardboard body.*

Analysis: In this example, the claim is found to contain patent eligible subject matter. The reason is that the claim includes elements (the sparking composition, cardboard body and ignition fuse) in addition to the natural products (calcium chloride and gunpowder) that amount to a specific practical application of the natural products. As such, the scope of the claim is limited thus not foreclosing others from using the natural products in other ways. (Of course, most of us would also not find gunpowder to be a natural product.)

Example 4: Composition Claim Reciting Multiple Natural Products

Claim 1. *An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.*

Analysis: In this example, it was believed in the field that *Rhizobium* strains were mutually inhibitive. The inventor, however, discovered that particular strains of *Rhizobium* do not inhibit each other and thus could be used in mixed culture. According to the *Guidance*, this claim does not contain patent-eligible subject matter because the claim as a whole does not recite any limitations that alter the

organisms in any way and as such what is claimed is not significantly different from the natural product. (The claim is also very open-ended because it could be applied to many combinations of strains of which the inventor has no knowledge.)

Example 5: Composition vs. Method Claims, Each Reciting Two Natural Products

Claim 1. *A pair of primers, the first primer having the sequence of SEQ ID NO: 1 and the second primer having the sequence of SEQ ID NO: 2.*

Claim 2. *A method of amplifying a target DNA sequence comprising:*

(a) *providing a reaction mixture comprising a double-stranded target DNA, the pair of primers of claim 1 wherein the first primer is complementary to a sequence on the first strand of the target DNA and the second primer is complementary to a sequence on the second strand of the target DNA, Taq polymerase, and a plurality of free nucleotides comprising adenine, thymine, cytosine and guanine;*

(b) *heating the reaction mixture to a first predetermined temperature for a first predetermined time to separate the strands of the target DNA from each other;*

(c) *cooling the reaction mixture to a second predetermined temperature for a second predetermined time under conditions to allow the first and second primers to hybridize with their complementary sequences on the first and second strands of the target DNA, and to allow the Taq polymerase to extend the primers; and*

(d) *repeating steps (b) and (c) at least 20 times.*

Analysis: According to the *Guidance,* Claim 1 case does not contain patent-eligible subject matter as the claim as a whole does not recite something significantly different than the natural products. Regarding Claim 2, the *Guidance* holds that this claim does contain patent-eligible subject matter because it contains claim elements that narrow the scope of the claim and involve manipulation of the natural products (in this case, the SEQ IDs). More specifically, the *Guidance* indicates that the claim includes very specific limitations that limit the scope of the claim including: the fact that the DNA must be heated and cooled to very specific temperatures for very specific periods of time, and that the combination of natural products that is limited to amplification using Taq polymerase in thermal cycling. (This analysis would seem to be at odds with *Myriad* because that decision indicates that cDNA is patent eligible because it is not naturally occurring and must be made by man. In the same way, primers are not naturally occurring but must be made by man. As for claim 2, it is no surprise that PCR (Polymerase Chain Reaction) is patentable since that was one of the most clever and innovative inventions in molecular biology.)

Example 6: Process Claim Involving a Natural Principle and Reciting Natural Products

Claim 1. *A method for determining whether a human patient has degenerative disease X, comprising:*

(a) *obtaining a blood sample from a human patient;*

(b) *determining whether misfolded protein ABC is present in the blood sample, wherein said determining is performed by contacting the blood sample with antibody XYZ and detecting whether binding occurs between misfolded protein ABC and antibody XYZ using flow cytometry, wherein antibody XYZ binds to an epitope that is present on misfolded protein ABC but not on normal protein ABC; and*

(c) *diagnosing the patient as having degenerative disease X if misfolded protein ABC was determined to be present in the blood sample.*

Analysis: In the example above, Antibody XYZ does not exist in nature and was created by the inventors. According to the *Guidance*, this claim does contain patent-eligible subject matter. Specifically, the facts that the antibody is novel and that the scope of the claim is narrowed to detection of binding to the misfolded protein via flow cytometry (thus not preventing others from detecting the misfolded protein via other means) weigh in favor of patentability.

Example 7: Process Claims Involving a Natural Principle

Claim 1. *A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising:*

(a) *exposing the patient to sunlight, wherein the exposure to sunlight alters the neuronal activity in the patient's brain and mitigates the mood disorder.*

Claim 2. *A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising:*

(a) *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.*

Claim 3. *A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising:*

(a) *providing a light source that emits white light;*

(b) *filtering the ultra-violet (UV) rays from the white light; and*

(c) *positioning the patient adjacent to the light source at a distance between 30-60 cm for a predetermined period ranging from 30-60 minutes to expose photosensitive regions of the patient's brain to the filtered white light, wherein the exposure to the filtered white light alters the neuronal activity in the patient's brain and mitigates the mood disorder.*

Analysis: In the example above, it was well-known in the art that exposure to white light changes neuronal activity in the brain and can change a person's mood. In addition, it was also well-known that sunlight is a natural source of white light. According to the *Guidance*, Claims 1 and 2 do not contain patent-eligible subject matter. In the case of Claim 1, the claim does not recite something significantly different from the natural principle and the natural phenomenon. Furthermore, the claim as written prevents others from using or applying sunlight. Regarding Claim 2, the *Guidance* indicates that the step of exposing a patient to white light is no more than a general instruction to apply or use the natural principle. According to the *Guidance*, Claim 3 does contain patent-eligible subject matter as the claim as a whole recites something significantly different than the natural principle. More specifically, the filtering and positioning steps meaningfully limit the claim to a particular application of the natural principle and because it is not routine in the art position a patient at the recited distance from a filtered light source for the specified length of time.

Example 8: Process Claim Reciting an Abstract Idea and a Natural Product

Claim 1. *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.*

Analysis: According to the *Guidance*, the claim above contains an abstract idea and thus should be analyzed using only the existing guidance in MPEP § 2106(II). This claim is copied from claim 1 of *Myriad's* U.S. Patent No. 6,033,857, which was held to be patent ineligible by the Supreme Court.

Venable office locations

BALTIMORE, MD
750 E. PRATT STREET
SUITE 900
BALTIMORE, MD 21201
t 410.244.7400
f 410.244.7742

LOS ANGELES, CA
2049 CENTURY PARK EAST
SUITE 2100
LOS ANGELES, CA 90067
t 310.229.9900
f 310.229.9901

NEW YORK, NY
ROCKEFELLER CENTER
1270 AVENUE OF THE AMERICAS
25TH FLOOR
NEW YORK, NY 10020
t 212.307.5500
f 212.307.5598

ROCKVILLE, MD
ONE CHURCH STREET
FIFTH FLOOR
ROCKVILLE, MD 20850
t 301.217.5600
f 301.217.5617

SAN FRANCISCO, CA
SPEAR TOWER, 40TH FLOOR
ONE MARKET PLAZA
1 MARKET STREET
SAN FRANCISCO, CA 94105
t 415.653.3750
f 415.653.3755

TOWSON, MD
210 W. PENNSYLVANIA AVE.
SUITE 500
TOWSON, MD 21204
t 410.494.6200
f 410.821.0147

TYSONS CORNER, VA
8010 TOWERS CRESCENT DRIVE
SUITE 300
VIENNA, VA 22182
t 703.760.1600
f 703.821.8949

WASHINGTON, DC
575 7TH STREET NW
WASHINGTON, DC 20004
t 202.344.4000
f 202.344.8300

WILMINGTON, DE
1201 NORTH MARKET STREET
SUITE 1400
WILMINGTON, DE 19801
t 302.298.3535
f 302.298.3550

CALIFORNIA | DELAWARE | MARYLAND | NEW YORK | VIRGINIA | WASHINGTON, DC

1.888.VENABLE | www.Venable.com