Client Alert

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USPTO Issues New Subject Matter Eligibility Examples for Life Sciences

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The United States Patent and Trademark Office (USPTO) recently provided updated guidance regarding the patent eligibility of subject matter related to natural products.[1] The updated guidance may be of interest to companies seeking patent claims to diagnostic methods, biomarker detection, and other life science-based technologies.

The USPTO's May 2016 pronouncement supplements the *2014 Interim Guidance on Subject Matter Eligibility*[2] ("the Guidelines") and the July 2015 Update on Subject Matter Eligibility,[3] which provided guidance and examples for determining patent-eligible subject matter under 35 U.S.C. § 101 ("Section 101"). The USPTO issued these Guidelines in light of various decisions from the Supreme Court, such as *Mayo*[4] and *Myriad,*[5] and to provide a uniform framework for the analysis of subject matter eligibility when a claim is deemed to involve a natural law or product or other judicial exception to patent eligibility.

The latest update provides additional examples illustrating application of the Guidelines for determining patent eligibility in life sciences fields. In particular, the updated examples highlight situations in which patent claims exploiting biomarkers and other natural products may be deemed to be patent eligible.

While the USPTO has, in some cases, been applying a heightened scrutiny on life sciences claims after the *Mayo* and *Myriad* decisions, the new examples suggest opportunities to protect subject matter in this area. Patent applicants should consult the updated examples when amending claims or arguing for the patent eligibility of claims.

BACKGROUND

Together with the previously issued Guidelines the new examples seek to provide guidance for subject matter eligibility under Section 101. Under that section, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

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[1] May 2016 Subject Matter Eligibility Update, 88 Fed. Reg. 27381 (May 6, 2016).

[2] 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618 (Dec. 16, 2014).

[3] July 2015 Update on Subject Matter Eligibility, 80 Fed. Reg. 45429 (Jul. 30, 2015).

[4] M*ayo Collaborative Serv. v. Prometheus Labs*., Inc., 566 U.S. ___, 132 S. Ct. 1289 (2012).

[5] *Association for Molecular Pathology v. Myriad Genetics*, Inc., 569 U.S. ___, 133 S. Ct. 2107 (2013).

Under the USPTO Guidelines, claims that are directed to a statutorily recognized category of subject matter under Section 101 (processes, machines, manufactures, or compositions of matter) are further assessed for subject matter eligibility. First, the claims are reviewed to determine if they are precluded from patent eligibility for being directed to a judicially recognized exception, which includes subject matter involving an abstract idea, law of nature, natural phenomena, or natural product. If the claim as a whole does not fall into a judicially recognized exception, then the claim is patent eligible. If the claim does encompass a nature-based product limitation, the claim is deemed to be patent eligible only if "markedly different characteristics" exist from the product as it exists in nature.

Following issuance of the 2014 Guidelines, supplemental Guidelines were issued in July 2015 with further explanations and examples to illustrate their implementation.

UPDATED EXAMPLES

In the May 2016 update, the USPTO has provided further examples illustrating the subject matter eligibility analysis for various aspects of life sciences-related technologies. The updated examples provide hypothetical patent claims that either meet or do not meet subject matter eligibility in accordance with the Guidelines. Interestingly, in the updated examples, the majority of the sample claims are considered to be directed to patent-eligible subject matter.

One particular example is directed to patent eligibility of claims directed to methods of diagnosis or detection. For instance, Example 29 presents a sample set of claims directed to methods of diagnosis and treatment of a hypothetical disease, julitis, involving the detection of a biomarker, JUL-1. Of the seven claims presented, six are deemed to be patent-eligible, while only one is deemed patent-ineligible. Citing *Mayo*, the USPTO explains that the subject matter eligible claims as a whole recite steps of administering a drug to a patient or determining the resultant level of a product in a patient. According to the USPTO, these steps "are not themselves natural laws."[6]

Specifically, patent-eligible claim 1 recites:

> "1. A method of detecting JUL-1 in a patient, said method comprising:
>
> a. obtaining a plasma sample from a human patient; and
>
> b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody."

The USPTO explains that hypothetical claim 1 is patent eligible because, "although nature-based product limitations are recited in the claim (e.g., the plasma sample and JUL-1), analysis of the claim as a whole indicates that the claim is focused on a process of detecting whether JUL-1 is present in a plasma sample, and is not

[6] The Guidelines state the steps of hypothetical claim 1 "do not recite or describe any recognized exception." See, e.g., *Mayo Collaborative Svcs. v. Prometheus Labs*., 566 U.S. __, 132 S. Ct. 1289, 1297 (2012) (recited steps of administering a drug to a patient and determining the resultant level of 6-thioguanine in the patient "are not themselves natural laws").

focused on the products *per se*." Since the process steps "do not recite or describe any recognized exception," the markedly different characteristics analysis need not be performed.

By contrast, patent-ineligible claim 2 recites:

> "2. A method of diagnosing julitis in a patient, said method comprising:
>
> a. obtaining a plasma sample from a human patient;
>
> b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
>
> c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected."

Claim 2 was deemed to be patent-ineligible because the limitation of "diagnosing the patient" involves "a correlation or relationship between the presence of JUL-1 in a patient's plasma and the presence of julitis in the patient." The USPTO reasons that this hypothetical claim "sets forth a judicial exception, because this type of correlation is a consequence of natural processes, similar to the naturally occurring correlation found to be a law of nature by the Supreme Court in *Mayo*."

Because a judicial exception exists, hypothetical claim 2 is next "analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception." The example explains that "there is no meaningful limitation, such as a particular or unconventional machine or a transformation of a particular article, in this step that distinguishes it from well understood, routine, and conventional data gathering activity engaged in by scientists prior to applicant's invention, and at the time the application was filed." Thus, the explanation concludes that claim 2 is not patent-eligible.

On the other hand, hypothetical claims 3-6, while also directed to the same judicial exception as claim 2, are deemed patent eligible "because they recite specific and unconventional reagents and/or treatments that amount to significantly more than the exception."

Additional examples in the current update are directed to vaccines and dietary sweeteners. These examples further illustrate how the patent eligibility Guidelines may be applied to claims involving natural products and processes. As with the example to methods of diagnosis and detection of biomarkers, these examples outline various scenarios in which patent claims may be subject matter eligible.

The updated examples are not binding law, and federal courts will continue to further define the scope of eligible subject matter. Nevertheless, they offer encouragement that some subject matter remains patent eligible in the life sciences –particularly in the diagnostics space. The *Sequenom v. Ariosa*[7] case may present the next opportunity for courts to shape the parameters to patent eligibility. In March 2016, Sequenom filed a petition for a

[7] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *petition for cert. filed.*

writ of certiorari that presented the following issue: "Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery."

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