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Practice Group:
Intellectual Property

U.S. Patent Office Issues Extensive Subject Matter Eligibility Guidelines

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Introduction

The United States Patent Office periodically issues guidance for examiners (“Examiners”), often in response to a recent court decision or new statute. These guidelines do not have the force of law, but nevertheless establish the specific procedures that the Examiners apply during examination of patent applications. Consequently, such guidelines are worth considering when preparing new patent applications and advancing pending patent applications.

Examination guidelines were issued on March 4, 2014 (the “Guidance”) to address recent court decisions¹ related to the subject-matter eligibility of claims related to laws of nature, natural phenomena, and natural products. The Guidance supersedes previous guidelines that were not as restrictive², and the broader applicability of these guidelines is worthy of attention from applicants in the life sciences field as well as other subject-matter areas.

The New Subject-Matter Eligibility Guidance

The recent court decisions on which the Guidance is based, *Prometheus* and *Myriad*, both addressed the scope of patentable subject matter. *Myriad* focused on the narrow question of the patentability of isolated DNA. In turn, *Prometheus* addressed the patentability of a personalized medicine dosing process.

From these cases, the Patent Office developed the Guidance. However, the Guidance is not limited to cases involving isolated DNA or personalized medical dosing. Examiners will use tests detailed in the Guidance to determine the patent eligibility of any claim involving nature and natural principles, natural phenomena, and natural products. The goal of such tests is to determine “whether a claim reflects a significant difference from what exists in nature and thus is eligible, or whether a claim is effectively drawn to something that is naturally occurring, like the claims found ineligible by the Supreme Court in *Myriad*.”

To do so, the Guidance articulates a test with three key questions: (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?³ and (3) Does the claim as a whole recite something significantly different than the judicial exception(s)? *Guidance* at 2.

If the answer to the first question is no, then the claim is not directed to patentable subject matter. If the answer to the second question is yes, then the Examiner must proceed to the third question to determine whether the claim is directed to patent-eligible subject matter.

The rest of the Guidance explains in greater detail how to apply the analysis under the questions. Given the ambiguity and subjectivity of the phrase “significantly different” in the

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third question, the explanation in the Guidance relating to this phrase is likely to be of particular interest to applicants.

The Guidance states that “a significant difference can be shown in multiple ways, such as: (1) the claim includes elements or steps in addition to the judicial exception that practically apply the judicial exception in a significant way, e.g., by adding significantly more to the judicial exception; and/or (2) the claim includes features or steps that demonstrate that the claimed subject matter is markedly different from what exists in nature.” *Guidance* at 3-4. The Guidance also provides a list of factors to consider in the analysis. The factors do not provide complete clarity though, as they are interpreted as part of a balancing test, and not all factors or supporting evidence will be applicable in all cases. The nature of the test may lead to decreased predictability in determining whether the Patent Office is likely to find a claim to be patent-eligible. Some examples of the factors include whether a product has markedly different structure from naturally occurring products;⁴ whether the claim recites elements/steps that are more than nominally, insignificantly, or tangentially related to the judicial exception; whether the claims add a feature that is more than well-understood, purely conventional, or routine in the relevant field; whether the claim recites a machine or a transformation, etc.⁵ *Guidance* at 4-5.

The majority of the Guidance is directed to examples applying the various factors, which help to provide some context as to how Examiners may use them when determining patent eligibility. However, unless a particular patent application has a claim that closely mirrors an example, there will still be a great deal of uncertainty as to how the Patent Office will interpret the factors and ultimately determine whether a claim is directed to patentable subject matter. Accordingly, applicants and patent practitioners should give some thought as to how they will explain that a claim is “significantly different” from, for example, a natural product.

Consequences for Patent Practice

The cover letter to the Patent Examiners that accompanies the Guidance indicates that the guidelines apply to “all claims (*i.e.* machine, composition, manufacture and process claims) reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products” (emphasis in original). Not only does the Patent Office specify that the Guidance applies to “all claims,” it proceeds to state that it applies to all claims “reciting or involving” the listed categories. “Reciting or involving” is not defined, and may permit a broad application of the Guidance, as many patent applications in different technical areas may include a claim that arguably “recites or involves” a law of nature, natural phenomenon, or natural product. As a result, Examiners may attempt to apply the Guidance to other types of claims in addition to those at issue in the *Prometheus* and *Myriad* cases.

For example, many practitioners assumed that the *Myriad* decision would only affect the patentability of isolated DNA. However, the Guidance specifically notes that while *Myriad* may have been stated to be limited to nucleic acids, “claims reciting or involving natural products should be examined for a marked difference” from nature and can be examined based on the test in the Guidance. Additionally, *Myriad* was directed only to product claims, but the Guidance applies the teachings of *Myriad* to method claims as well.

Accordingly, the Guidance may result in changes to the examination of other categories of applications at the Patent Office, even applications that may seem at first glance to clearly contain patent-eligible subject matter. The broad scope of the Guidance and the vagaries of the factor-based test may lead to more rejections under 35 U.S.C. § 101.

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However, given the recent issuance of the Guidance, it will take some time to fully gauge its impact. As the Patent Office applies the Guidance, further insight will become available as to how the tests will be applied in practice. We will provide further updates as the practical application of the Guidance develops.

Nevertheless, certain insights follow from the language of the Guidance itself. Going forward, based on the Guidance, mere recitation of the words “purified” or “isolated” will be insufficient to bring a claim into the realm of patentable subject matter. Looking at the examples in the Guidance found to be patent-eligible and drafting some claims that track such examples is likely to be helpful as a hedge should the Guidance remain in effect without further changes in the laws of patentability. For example, based on the examples provided, claims reciting certain details, such as explicit concentrations, are more likely to be found to contain patent-eligible subject matter. Accordingly, including such details in a claim that may fall within a non-patentable judicial exception may be worthwhile. Concentrations, dosages and timing of administration, ratios for combinations of naturally occurring elements, etc., are all some exemplary claim details that may help demonstrate that a claim recites patent-eligible subject matter under the new Guidance. Drafting detailed specifications with respect to these claim details may also help navigate examination of a patent application through the Patent Office in light of the Guidance.

Conclusion

More frequent non-statutory subject-matter rejections may result from the Guidance—time will tell. However, preventing or overcoming these rejections may be possible using a forward-thinking approach that includes certain features and examples from the Guidance.

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¹ *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013); and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. __, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012).

² Guidelines dated March 13, 2013: “Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101.” Other claims, such as method claims, that involve naturally occurring nucleic acids “should be examined under the existing guidance in MPEP 2106.” Thus, these superseded guidelines were clearly limited to product claims directed to nucleic acids.

³ The judicial exceptions include abstract ideas, laws of nature/natural principles, natural phenomena, and natural products. The Guidance notes that the following are examples of natural products: 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. *Guidance* at 3.

⁴ The “marked difference” test is explained further as requiring that mere isolation of a naturally occurring product will be insufficient to confer patent subject-matter eligibility. “Not all differences rise to the level of marked differences, e.g., merely isolating a nucleic acid changes its structure (by breaking bonds) but that change does not create a marked difference in structure between the isolated nucleic acid and its naturally occurring counterpart.” *Guidance* at 5.

⁵ The full list of factors is as follows:

Factors that weigh toward eligibility (significantly different):

- a) 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.
- b) Claim recites elements/steps in addition to the 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 judicial exception(s).
- c) Claim recites elements/steps in addition to the 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 judicial exception(s).
- d) Claim recites elements/steps in addition to the judicial exception(s) that do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s).
- e) Claim recites elements/steps in addition to the judicial exception(s) that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application. (See MPEP 2106(II)(B)(1) for an explanation of the machine or transformation factors.)
- f) Claim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional, or routine in the relevant field.

Factors that weigh against eligibility (not significantly different):

- g) 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.
- h) Claim recites elements/steps in addition to the judicial exception(s) at a high level of generality such that substantially all practical applications of the judicial exception(s) are covered.

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- i) Claim recites elements/steps in addition to the judicial exception(s) that must be used/taken by others to apply the judicial exception(s).
 - j) Claim recites elements/steps in addition to the judicial exception(s) that are well-understood, purely conventional, or routine in the relevant field.
 - k) Claim recites elements/steps in addition to the judicial exception(s) that are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s).
 - l) Claim recites elements/steps in addition to the judicial exception(s) that amount to nothing more than a mere field of use.