USPTO ISSUES UPDATED GUIDELINES AFFECTING NATURAL PRODUCTS AND PHENOMENON

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Attorneys

John Lopinski Ph.D.

Practices & Industries

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On December 15, 2014, the United States Patent & Trademark Office (USPTO) released its much-anticipated clarification on subject matter eligibility for patents. The guidelines, titled Interim Guidance on Patent Subject Matter Eligibility (the Interim Guidance), became effective upon publication in the Federal Register on December 16, 2014.[1]

The Interim Guidance establishes a single test for all inventions. This communication provides a summary of the Interim Guidance relevant to laws of nature, natural phenomena, or natural products. A summary relevant to computer-implemented inventions can be found in the Hodgson Russ-issued client alert "USPTO Issues Updated Guidelines Affecting Computer-Implemented Claims."

While the Interim Guidance does not have the power of law, it provides an updated set of instructions for patent examiners to determine patent subject matter eligibility, superseding the preliminary guidelines issued on March 4, 2014. The Interim Guidance continues to follow the Supreme Court's decisions in *Mayo*[2] and *Myriad*.[3]

Updated Test for Eligibility

Under Step 1 of the Interim Guidance, patent examiners are directed to determine if a claim is drawn to a process, machine, manufacture, or composition of matter (the statutory categories of inventions under 35 U.S.C. §101). If the answer is no, the claim is deemed to recite ineligible subject matter. If the answer is yes, the examiner will apply a two-part test in Step 2 to determine if judicial exceptions apply.

In Step 2A, an examiner will determine whether the claim is "*directed*" to a "*judicial exception*." A judicial exception is an abstract idea, a natural phenomenon or law of nature. In contrast to the preliminary guidelines of March 4, 2014, the present Interim Guidance explains the meaning of "directed." A claim is "directed" to a judicial exception when that judicial exception is "recited (i.e., set forth or described) in the claim." In setting forth a rejection, an examiner must identify the judicial exception and where it is recited in the claim, and explain why it is

considered an exception.

"Markedly Different Characteristics" From the Natural Product

Nature-based products may avoid being labeled as a judicial exception if the product exhibits "markedly different characteristics." Such characteristics include biological or pharmacological properties, chemical or physical properties, phenotype, and structure and form. In this analysis, the nature-based product is to be compared to its closest naturally occurring counterpart. The Interim Guidance states that a purified or isolated nature-based product is patent eligible when there is a "resultant change in characteristics sufficient to show a marked difference from the product's naturally occurring counterpart." Examiners are cautioned to not over-extend the markedly different characteristics analysis to products that when viewed as a whole are not nature-based.

If the claim is determined as not directed to a judicial exception, then it is eligible subject matter. If the claim is "directed" to a judicial exception, then the Interim Guidance instructs the examiner to proceed to Step 2B of the analysis.

"Significantly More" Than a Judicial Exception

Step 2B instructs the examiner to determine whether an element or combination of elements in the claim amounts to "significantly more" than the judicial exception. If it does, then the claim is drawn to eligible subject matter. If not, the claim is drawn to ineligible subject matter.

A claim is directed to "significantly more" than a judicial exception if it includes additional features that ensure that the claim does not monopolize the exception – i.e., it does not "tie up" the subject matter such that others are pre-empted from using the judicial exception. If it is determined that the claim adds significantly more than the judicial exception, then the claim is drawn to eligible subject matter. If not, then the claim is drawn to ineligible subject matter.

The Interim Guidance instructs examiners to evaluate claims "as a whole." "Individual elements viewed on their own may not appear to add significantly more to the claim, but when combined may amount to significantly more than the exception." This is in contrast to the earlier preliminary guidelines, under which examiners typically analyzed each element separately.

The Interim Guidance indicates that claims that include specific limitations other than what is "well-understood, routine, and conventional in the field" may satisfy the requirements of Step 2.

Practical Claim Drafting Tips

Many claims in the biotech area will frequently involve a judicial exception (such as natural product or a natural phenomenon). One likely point of contention with examiners will be whether a nature-based product has markedly different characteristics than the product's naturally occurring counterpart. Applicants should describe in the specification how their nature-based product is different from the closest naturally occurring counterpart, thereby minimizing the likelihood of it being labeled as a judicial exception. Further, applicants should also include support in the specification for specific limitations that arguably are not well understood, routine, and conventional in the field, thereby providing support for an argument that the claim does not preclude others from using the exception.

A Step Toward More Clarity

While the Interim Guidance still leaves room for subjectivity in the application of the Two-Step Test, it is a good first step toward providing more clarity. It also indicates the USPTO is willing to listen to the feedback it receives from the public. Toward that end, the USPTO has invited public comment on the Interim Guidance by March 16, 2015, and plans to hold a public forum in mid-January 2015 to discuss the next steps.

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1. The full text of the Interim Guidance can be found here: http://www.gpo.gov/fdsys/pkg/FR-2014-12-16/pdf/2014-29414.pdf

2. *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 566 U.S., 132 S. Ct. 1289 (2012).

3. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S., 133 S. Ct. (2013).