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Client Alert

Intellectual Property Practice Group

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Patentable Subject Matter in the Life Sciences: New USPTO Guidance Impacts Diagnostic Methods and Natural Products

The United States Patent and Trademark Office issued on May 6, 2016, updated guidance to its patent Examiners that would have an impact on patent applications covering diagnostic methods and natural products. The new guidance includes a memorandum to the examining corps detailing best practices for examining claims for subject matter eligibility and new Examples in the life sciences of what should be considered patent eligible and ineligible.

The Examples clarify the USPTO's position on what is and is not patentable subject matter. These guidelines are not binding on the courts and, thus, claims issued in accordance with the guidance are subject to challenge in federal court. However, for those seeking patent protection, the USPTO Examiners rely on these statements of the USPTO's interpretation of the Supreme Court and Court of Appeals for the Federal Circuit decisions to reject or allow claims in pending patent applications based upon subject matter eligibility. Failure of the USPTO to grant claims based on the reasoning in the guidance may also be appealed to the Federal Circuit.

Two-Part Test: Patentability According to the USPTO

Based on its interpretation of the *Mayo*, *Myriad* and *Alice* trio of Supreme Court cases, the USPTO has developed a two-part test for assessing whether claims are eligible for patent protection or not.

First, the Examiner considers whether the claim is drawn to one of the exceptions of subject matter eligibility - an abstract idea, a law of nature or natural phenomenon, or a natural product. In this first step, the Examiner is to consider whether additional claim elements make the claimed composition containing or derived from the naturally occurring product "markedly different" from the product as it exists in nature and therefore leading to a conclusion of patent eligibility.

Second, if the claim is not markedly different and is therefore drawn to one of these exceptions, then the Examiner must consider whether the claim, either in its component parts or read as a whole, provides significantly more than the exception. For example, if the aspects of the claims other than the natural phenomenon or natural product relate to well understood, routine and conventional activities, then they do not add significantly more to the

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exception, and the claim is found not to be patent eligible. What "markedly different" and "significantly more" mean in practice still requires clarification by the courts - in particular, whether the other aspects of the claims must be inventive, that is novel and non-obvious, when taken in the absence of the exception. The new Examples that the USPTO issued reflect the agency's view that the other claimed aspects need not be independently inventive.

New Examples: Diagnostic Methods and Natural Products

The Examples pertain to vaccines, methods of diagnosing and treating a disease, methods identifying mutations associated with predisposition to a disease, and purified natural products. The USPTO's new guidance provides clarity and some hope for stakeholders seeking patent protection for innovations in diagnostics and products based upon naturally occurring substances.

Applying the Supreme Court's *Myriad* decision, the Examples indicate that vaccine compositions made from a live attenuated virus (having one or more mutations relative to the naturally occurring virus) or inactivated virus (for example, inactivated using formalin) can be patented. Both the mutation and the formalin change the structure and function of the wild type virus sufficiently to be "markedly different" from the virus found in nature—making claims to the live attenuated virus and the inactivated virus patent eligible even if the method of altering the viruses are well known. A further Example of a purified natural product (in this case a dietary sweetener isolated from a plant sap) confirms that, while the purified product itself is not considered patentable subject matter, formulations of the product, such as granulated forms or controlled release forms, may be patentable if the formulation structurally or functionally alters the product, even if in a very conventional manner.

The Supreme Court's *Mayo* decision has dramatically impacted the patent protection available for diagnostic methods. The Examples provide stakeholders encouragement and certain ways forward for protecting diagnostic innovation. The USPTO finds methods of identifying a novel biomarker to be patent eligible (while, interestingly, finding that methods of diagnosis using the new biomarker as an indication of disease are not because such claims relate to a natural phenomenon). For diagnostics relying upon detection of a known biomarker for diagnosing a disease not previously associated with the biomarker, patent eligibility depends upon the use of new and/or specific reagents, such as a new monoclonal antibody, or incorporation of a specific method of treatment for the disease if diagnosed. The Examples also, in accordance with the *Myriad* decision, confirm that methods of detecting a mutation associated with a risk of disease are not patentable unless unconventional methods are used to detect the mutation.

Although it still remains to be seen whether patents issued following these Examples will withstand court scrutiny and they may be at odds with how the courts will ultimately rule, these Examples provide an opening for patent protection for certain innovations at least from the USPTO.

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