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USPTO Issues New Patent Subject Matter Eligibility Guidelines under Myriad and Mayo Decisions

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On March 4, 2014, the U.S. Patent and Trademark Office issued a long-awaited guidance memo for evaluating subject matter eligibility under 35 U.S.C § 101 in the wake of two recent Supreme Court decisions: *Association for Molecular Pathology, et. al*. v. *Myriad Genetics, Inc., et. al*.[i] and *Mayo Collaborative Services, et. al.* v. *Prometheus Laboratories, Inc*.[ii] This memorandum can be found **here**.

The guidance memo broadly applies to all claims reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products. According to the guidance memo, if a claim recites a law of nature/natural principle, a natural phenomenon, or a natural product, patent eligibility is determined by whether the claim as a whole recites something "significantly different" from the law of nature/natural principle, natural phenomena, or natural product. To assist examiners in making this determination, the guidance memo provides a multi-factor balancing test and a number of examples that demonstrate how to apply the factors for or against patent eligibility.

In situations where a claim is to a "natural" product, factors that weigh toward eligibility include whether the product as claimed is non-naturally occurring and markedly different in structure from the naturally-occurring product. For example, the guidance memo states that a claim directed to a purified, naturally-occurring chemical that is useful in treating breast cancer is not patent-eligible subject matter even though many may have tried and failed to isolate the cancer-fighting chemical from its natural surroundings. In addition, for example, the guidance memo states that a claim to a composition of a pair of synthetic oligonucleotide primers is not patent-eligible subject matter if the nucleotide sequence of the primers is not substantially different from the naturally occurring genomic DNA sequences found in a human chromosome. In contrast, the guidance memo states that a claim to an amplification process employing the pair of oligonucleotide primers and reciting some heating and cooling steps may be patent eligible.

In situations where a claim recites elements or steps in addition to laws of nature/natural principle, or natural phenomena, factors that weigh toward eligibility include (1) whether the elements or steps narrow the scope of the claim so that others are not substantially foreclosed from using the laws of nature/natural principle, or natural phenomena; (2) whether the elements or steps do more than generally instruct to apply or use the law of nature; and (3) whether the elements or steps add a feature that is more than a well-understood, purely conventional or routine feature in the relevant field. The guidance memo, for example, states that it is a well-known natural principal that sunlight is a natural source of white light and exposure to white light changes neuronal activity and affects a person's mood. Accordingly, the guidance memo states that a method claim for treating a mood disorder by exposing an individual to a synthetic source of white light is not patent-eligible subject matter even if the source of white light is synthetic and not natural. On the other hand, the guidance memo states that a method claim that recites additional steps, such as filtering ultraviolet rays from a white light source or positioning the individual a certain distance from the white light source, may be significantly different

from the natural principle and qualify as eligible subject matter.

The guidance memo has sparked controversy among the patent field. Many practitioners have raised a concern that the guidance memo imposes a test for patent eligibility that is stricter than required by the applicable law. Although the guidance memo will likely significantly impact patent prosecution in the chemical, pharmaceutical, and biotechnology fields in the near term, we expect that the standards laid out in the memo will be challenged going forward.

If you have any questions or wish to discuss how this guidance memo may impact your business, please contact an attorney in the **Biopharma Group** at Brinks Gilson & Lione.

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i 133 S. Ct. 2107 (2013).
ii 132 S. Ct. 1289 (2012).