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New Procedures for Determining Patent Eligible Subject Matter

The United States Patent and Trademark Office recently released new guidelines to aid its patent examiners in determining whether or not the subject matter of a patent claim is eligible for patent protection. These new guidelines were issued in light of the recent Supreme Court decisions in two biomedical patent disputes: *Mayo v. Prometheus*, 132 S. Ct. 1289 (2012) and *Association for Molecular Pathology v. Myriad Genetics,* 133 S. Ct. 2107 (2013). In *Mayo*, the Supreme Court held that a method of determining whether to increase or decrease the dosage of a drug based on administering the drug to a patient and measuring how well that particular patient metabolized the drug was not patent eligible. In *Myriad*, the Supreme Court held that a claim to isolated DNA was not patent eligible, but that a claim to man-made cDNA, which does not exist in nature, was patent eligible.

The first step under the new guidelines is for the patent examiner to determine whether the claim recites or involves a law of nature, natural principle, natural phenomenon, and/or natural product ("natural occurrences"). A list of natural products is provided in the guidelines and includes 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. The new guidelines are silent as to the other types of natural occurrences, but a short list of examples includes gravity, lightning, cell division and $E=mc^2$.

In brief, these new guidelines require the patent examiners to balance a list of factors when determining whether claims that recite or involve a natural occurrence are nonetheless patent eligible. The factors all help answer the question of whether or not there is something in the claim beside the natural occurrence that causes the claim as a whole to recite an invention that is *significantly different* than that natural occurrence. As a practical matter, the addition of a limitation in the claim that will allow others to make use of the natural occurrence *outside of the invention* will weigh in favor of the claim being patent eligible. It is also helpful to patent eligibility if there is an additional element or step in the claim that itself is new to the relevant industry and that affects or implements the natural occurrence in a significant way. Finally, as has been true for thirty years or so, it is useful to include a particular machine that uses the natural occurrence and/or transforms or integrates the natural occurrence into a practical use.

In drafting patent claims, we at Wood Phillips work closely with our clients to understand the true subject matter of their invention. If you have questions about whether your invention is patent eligible or what other means you could use to secure your invention please contact an attorney at Wood Phillips.