EVOLVING STANDARDS FOR THE PATENTABILITY OF LIFE SCIENCES INVENTIONS

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As the life sciences industry continues to emerge as a major source of innovation and catalyst for economic growth, many biotechnology companies are encountering significant challenges in building and maintaining a strong patent portfolio. The spectre of a "patent cliff" looms over many blockbuster drug patents set to expire in the coming years, whilst generic products continue their surge onto the market, forcing companies to invest heavily in the research and development of new products. Complicating companies' efforts to obtain patent protection on these innovations, however, are the evolving guidelines dictating which discoveries are even eligible for patentability.

Since the Supreme Court's landmark 1980 decision in *Diamond v. Chakrabarty* — which noted that Congress intended for "anything under the sun that is made by man" to be patent eligible — businesses generally viewed the law's subject matter eligibility requirement as a filter that very seldom restricted patentability. This understanding was called into doubt by two recent decisions from the high court which found that naturally-occurring gene sequences, and methods for giving a drug to a patient which relied heavily on naturally-occurring correlations, were ineligible for patent protection because they were merely natural phenomena or laws of nature. *See Association for Molecular Pathology v. Myriad Genetics; Mayo Collaborative Services v. Prometheus Laboratories.* A third Supreme Court decision, *Alice Corp. v. CLS Bank Int'l,* provided further explanation on the legal test for determining whether an invention is an unpatentable abstract idea or law of nature, and, in late 2014, the United States Patent and Trademark Office released its Interim Guidance on Patent Subject Matter Eligibility ("Interim Eligibility Guidance") to provide patent examiners with revised instructions on how to evaluate inventions concerning naturally-occurring principles or substances.

The Interim Eligibility Guidance defines laws of nature and natural phenomena, in accordance with judicial precedent, to include "naturally-occurring principles/substances that do not have markedly different characteristics compared to what occurs in nature." Importantly, in a departure from previous examination guidelines, the new test requires consideration of both structural *and* functional differences to determine whether a product is markedly different from its naturally-occurring counterpart, a change in examination protocol that may give biotech companies greater leeway to obtain a patent because of the biological or pharmacological effects of their products or treatment methods. Although it may be too early to determine the precise impact of *Myriad/Mayo/Alice*, life sciences companies are surely hopeful that the Interim Eligibility Guidance standards will provide a more predictable framework for pursuing patent protection for their valuable innovations.

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