The Attack on Life Sciences Patents - Subject Matter Eligibility

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In recent years, there has been an increasing effort to restrict and control the number and scope of patents in the life sciences sector. While these efforts may address certain concerns related to affordability and access, they have the potential to inhibit innovation in critical areas of healthcare and biotechnology, where massive investment is intimately tied to strong patent protection. IP professionals and their clients await the promulgation of rules, further jurisprudence or legislation that may address these conflicting interests.

In this first in a series of articles to address actions which may further limit the number and scope of patents in the life sciences, the focus will be on patentable subject matter eligibility.

The *Mayo/Myriad/Alice* line of Supreme Court cases has imposed stringent restrictions on what constitutes patent-eligible subject matter and have been particularly detrimental in the areas of diagnostics, isolated natural products, and related computer-implemented methods such as those involving artificial intelligence (AI). These Supreme Court decisions have made it more difficult for inventors to secure patents on innovations in personalized medicine, gene sequencing, bioinformatics and diagnostics, where discovering the relationship between genes or proteins and diseases is central.

Since these decisions, the United States Patent and Trademark Office, the lower courts, and applicants, have struggled to decipher the metes and bounds of what can and cannot be patented in the United States, while such inventions can often be patented in key competitive jurisdictions like Europe and China. The result is a stifling of innovation and an inability for technology companies to compete with entities that can obtain patent protection abroad. Adding insult to injury, the Supreme Court has denied *certiorari* on petitions for review of all cases being appealed on § 101 grounds.

After several years of negotiations amongst stakeholder groups, the *Patent Eligibility Reform Act* of 2023 (PERA) was introduced by Senators Tillis (R-NC) and Coons (D-DE) in June of 2023. The intent of the bill was to clarify the scope of what Congress intended to constitute patent eligible subject matter under 35 USC § 101. PERA seeks to abrogate the Supreme Court precedent and to modify 35 USC § 101 to specify only certain narrow exceptions to subject matter eligibility, including natural substances and processes that are wholly independent of human activity (including unmodified human genes as they exist in the human body), purely mathematical formulae that are not otherwise part of a useful process, machine, manufacture, or composition and purely mental processes that can be performed solely in the human mind.

On January 23, 2024, Congress heard testimony regarding PERA from two panels of witnesses. PERA was scheduled for mark-up in an Executive Business Meeting on Thursday, September 26, 2024. Statements were submitted in opposition to the mark-up, including by many high-tech organizations, as well as the generic drug industry and drug price reform advocates, and the meeting has since been canceled. It remains to be seen whether § 101 federal legislation will pass

to clear up the abyss created by the above-mentioned Supreme Court decisions, or whether the upcoming change in the U.S. administration could impact this important area of patent law.