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Patent-Eligible Subject Matter Reform: An Overview

The U.S. patent system is designed to encourage innovation. The types of inventions that can be patented, however, may affect the patent system's ability to incentivize innovation in certain fields, especially in emerging technology sectors like artificial intelligence (AI) and biotechnology. This In Focus summarizes and analyzes recent judicial, administrative, and legislative developments related to the standards for determining patent-eligible subject matter.

Section 101 of the Patent Act

Patent-eligible subject matter generally refers to the types of inventions that may be patented. Section 101 of the Patent Act (35 U.S.C. §101) sets out four categories of patentable inventions: “any new and useful [1] process, [2] machine, [3] manufacture, or [4] composition of matter.” Through Section 101, Congress sought to ensure the patentability of “anything under the sun made by man” that meets all of the other requirements for patentability found in the Patent Act, such as novelty, enablement, and nonobviousness.

The statutory definition of patent-eligible subject matter under Section 101 has remained essentially unchanged for more than two centuries. Nonetheless, the scope of patent-eligible subject matter has waxed and waned over time, depending on the trends in judicial decisions.

Recent Supreme Court Jurisprudence on Patent-Eligible Subject Matter

The Supreme Court has long held that Section 101 contains implicit exceptions. Specifically, the Court's 19th- and 20th-century cases established that “laws of nature, natural phenomena, and abstract ideas,” when claimed as such, are not patentable. These three types of nonpatentable discoveries are sometimes called the *judicially developed exceptions* to patent-eligible subject matter.

Decisions of the U.S. Court of Appeals for the Federal Circuit in the 1990s had construed the judicially developed exceptions narrowly, such that Section 101 rarely presented a barrier to patentability. Beginning in 2010, the Supreme Court issued a series of decisions that narrowed patent-eligible subject matter by broadening the scope of the judicially developed exceptions. In this series of decisions, the Supreme Court held that patents on the following claimed inventions were all ineligible under Section 101:

- a business method for hedging price-fluctuation risk (*Bilski v. Kappos*, 2010);
- a method for calibrating the dosage of a particular drug (*Mayo Collaborative Servs. v. Prometheus Labs.*, 2012);
- isolated human DNA segments (*Association for Molecular Pathology v. Myriad Genetics*, 2013); and

- a method of mitigating settlement risk in financial transactions using a computer (*Alice Corp. Pty. v. CLS Bank*, 2014).

As a result of these cases, fewer inventions are patentable, particularly in areas such as computer software, business methods, and biotechnology.

The *Alice/Mayo* Framework

The Supreme Court decisions referenced above established what has come to be known as the two-step *Alice/Mayo* test for patentable subject matter. The first step of the *Alice/Mayo* test addresses whether the patent claims are “directed to” an ineligible concept (i.e., a law of nature, a natural phenomenon, or an abstract idea). To be directed to an ineligible concept, the focus of the claims must be a patent-ineligible concept, as opposed to a technological process. If the patent claims are not directed to an ineligible concept, then the claims are patent-eligible.

If the claims are directed to an ineligible concept, then the invention is not patentable unless the patent claims have an *inventive concept* under the second step of the *Alice/Mayo* test. Step two considers the elements of each patent claim, both individually and as an ordered combination, in determining whether they contain additional aspects that “transform the nature of the claim” into a patent-eligible application of an ineligible concept. Claim limitations that are conventional, routine and well understood, such as implementing an abstract idea on a generic computer, cannot supply an inventive concept.

Stakeholder Views on Patent-Eligible Subject Matter Jurisprudence

Stakeholder views vary on whether the *Alice/Mayo* framework has positively or negatively affected the patent system's ability to encourage investment in technology and encourage innovation. In June 2022, the U.S. Patent and Trademark Office (USPTO) submitted a report to Congress that reviewed public comments on patent subject matter eligibility from stakeholders, including legal associations, industry organizations, advocacy groups, nonprofit entities, businesses, law firms, practitioners, academics, and inventors. The variability in stakeholder views underscores an important aspect of patent and innovation policy: changes to patent policy often affect innovation differently depending on many factors, including, among other things, the economic sector, industry, and firm size in question.

Several groups reported that recent interpretations of patent subject matter eligibility standards are having positive effects on innovation. For example, civil liberties and nonprofit organizations generally supported the current legal exclusions on patentability, which they asserted help

foster invention and innovation by preventing monopolies on basic research tools and concepts.

Other respondents reported negative effects on innovation as a result of the expansion of ineligible subject matter, especially in the life sciences sector. Some of these groups further warned of potential negative implications for the United States' position as a global leader in innovation. For example, one representative of the biotechnology industry stated that current interpretations of patent subject matter eligibility standards had jeopardized the industry's ability to develop and deliver "precision medicine, pharmaceutical treatments, and diagnostics" to patients.

Innovation in emerging technology areas may face unique challenges because of the restricted scope of patent-eligible subject matter, as well as the variability in how such standards are interpreted by patent examiners and the courts. For example, one area of policy concern relates to patent-eligible subject matter standards as they apply to innovations in AI. Though the number of patent applications pertaining to AI has increased over the past 10 years, some stakeholders have reported concern that AI inventions are at risk of patent ineligibility under the current framework because "they may be characterized as methods of organizing human activity, mental processes, or mathematical concepts."

Given the growing importance of AI technologies, USPTO analyzed patent examination data to study the effect of the *Alice/Mayo* framework on AI. USPTO's study evaluated whether the Supreme Court's 2014 decision in *Alice*, which rejected a patent claim on a method of mitigating settlement risk in financial transactions using a computer, impacted the agency's allowance rates for patent applications containing AI. USPTO reported suggestive evidence that *Alice* impacted AI technologies differentially.

Post-*Alice* Changes to Patent Examination Processes by USPTO

USPTO responded to concerns about the patentability of AI-related and other inventions in 2019 by issuing new guidance to patent examiners to clarify how to apply the *Alice/Mayo* framework. USPTO later incorporated this guidance (the "2019 Guidance") into the Manual of Patent Examining Procedure, which guides patent examiners in their review of patent applications. The 2019 Guidance was generally perceived as lowering Section 101 barriers to patentability, especially for computer-related inventions. The 2019 Guidance appears to have led to an increase in the allowance rate for patent applications containing AI.

Although the 2019 Guidance changes how USPTO examiners review new patent applications, it is not binding on the courts when issued patents are challenged in litigation. The 2019 Guidance itself states that it lacks "the force and effect of law." Following its June 2022 report to Congress on patent eligibility, USPTO issued a request for comments on its 2019 Guidance and other patent subject matter eligibility issues. The comment period closed in October 2022. The USPTO Director has explained that the office is "evaluating the comments to determine next steps."

Introduced Legislation on Patent-Eligible Subject Matter in the 117th and 118th Congresses

Citing concern over the effects of patent subject matter eligibility standards on innovation, some patent law stakeholders have called for the Supreme Court to revisit its patent-eligible subject matter jurisprudence. Since its 2014 decision in *Alice*, the Supreme Court has received dozens of petitions for certiorari (i.e., requests that the Court hear an appeal) on Section 101 issues. In some of these cases, the Supreme Court sought the views of the Solicitor General, who urged the Court to hear the cases to provide "much-needed clarification" on *Alice*'s "abstract-idea exception and the proper application" of the *Alice/Mayo* framework. The Supreme Court has declined to hear any of these cases.

In light of the Supreme Court's apparent reluctance to revisit Section 101, some stakeholders have called for Congress to enact legislation on the issue. Two relevant bills were introduced in the 117th Congress. First, the Patent Eligibility Restoration Act of 2022 (PERA 2022; S. 4734) would have abrogated the *Alice/Mayo* framework and replaced it with a closed list of narrower ineligible categories. Second, the Restoring America's Leadership in Innovation Act of 2021 (RALIA; H.R. 5874) contained a provision that would have abrogated the *Alice/Mayo* framework and replaced it with a single, narrow statutory exception for inventions that either exist only in the human mind or exist independently of any human activity.

As of the end of 2023, one bill focusing on patent-eligible subject matter has been introduced during the 118th Congress: S. 2140, the Patent Eligibility Restoration Act of 2023 (PERA 2023). Like PERA 2022, the introduced version of PERA 2023 would replace the *Alice/Mayo* framework with an exclusive statutory list of narrower ineligible categories: mathematical formulas, purely mental processes, purely natural processes, unmodified human genes, and unmodified natural material. PERA 2023 would also exclude from patentability any "substantially economic, financial, business, social, cultural, or artistic" process, even if it involves a machine or manufacture. However, if the process "cannot practically be performed" without the machine or manufacture, then it would be patent-eligible.

PERA 2023 also contains provisions on how to read the exclusions for unmodified human genes or other unmodified natural material. Specifically, PERA 2023 explains that natural material would be considered modified (and thus patentable) if it is "isolated, purified, enriched, or otherwise altered by human activity" or "otherwise employed in a useful invention or discovery." This provision would appear to abrogate the Supreme Court's *Myriad* decision to allow patenting of isolated DNA segments, although unmodified human genes (i.e., genes as they exist in the human body) would remain unpatentable.

Emily G. Blevins, Analyst in Science and Technology Policy

Kevin J. Hickey, Legislative Attorney

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