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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 promote innovation in certain fields, especially in emerging technologies like artificial intelligence (AI) and biotechnology. This In Focus 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 that is made by man" that meets all of the other requirements for patentability, 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.

The Supreme Court's 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 invalidated patents on the following claimed inventions as 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 (*Ass'n 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 decisions, 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.

Under the second step of the *Alice/Mayo* test, if the claims are directed to an ineligible concept, then the invention is not patentable unless the patent claims have an *inventive concept*. Step 2 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 the *Alice/Mayo* Framework

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 promote innovation. In June 2022, the U.S. Patent and Trademark Office (USPTO) submitted a report to Congress that reviewed public comments on subject matter eligibility from a wide range of stakeholders, including industry organizations, nonprofits, businesses, law firms, practitioners, academics, and inventors. The variability in stakeholder views underscores that changes to patent policy often affect innovation differently depending on many factors, including, among other things, the economic sector, industry, and firm size.

Several groups reported that recent interpretations of subject matter eligibility standards are having positive effects on innovation. For example, civil liberty 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 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 subject matter eligibility 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 worry that AI inventions may be at risk 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 evaluated whether the Supreme Court's 2014 decision in *Alice*, which rejected a patent on a financial transaction method implemented on a computer, impacted AI patents. Following an analysis of patent examination data in 2020, USPTO reported that the agency's allowance rates for patent applications containing AI decreased relative to rates for non-AI applications following *Alice*: that is, USPTO was less likely to grant AI patent applications after *Alice*.

Post-*Alice* Jurisprudence

Citing concern over the effects of 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.

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 (the "2019 Guidance") to patent examiners to clarify how to apply the *Alice/Mayo* framework. USPTO later incorporated 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, offsetting (in part) the increased rejection rates seen immediately following *Alice*.

In 2024, USPTO issued updated guidance (the "2024 Guidance"), which reaffirmed the 2019 Guidance while providing additional details to guide examiners in applying the *Alice/Mayo* framework. In particular, the 2024 Guidance provided specific examples to illustrate how eligibility requirements apply to AI inventions. While some stakeholders appreciated USPTO's efforts to provide more clarity on how it will approach AI patent eligibility issues, others asserted that the 2024 Guidance could have done more to clarify the application of the *Alice/Mayo* framework to AI inventions.

Although USPTO's guidance changes how examiners review new patent applications, it is not binding in court when issued patents are challenged in litigation.

Options for Congress

Congress has a range of potential options to consider. In light of the Supreme Court's apparent reluctance to revisit Section 101, and the limits of the changes that USPTO can make through guidance, some stakeholders have called for Congress to enact legislation on the issue. Several bills have been introduced in recent Congresses, such as the Patent Eligibility Restoration Act in the 118th Congress (S. 2140 and H.R. 9474).

If Congress decided to provide statutory clarification on subject matter eligibility requirements, one potential legislative approach would be to abrogate the *Alice/Mayo* framework and replace it with a closed list of statutorily defined ineligible categories. Past introduced legislation has followed that approach, with proposed statutory exceptions that vary in scope and specificity. For example, some legislative proposals have included only narrow statutory exceptions for inventions that either exist solely in the human mind or exist independently of any human activity. Other proposals have included a broader list of ineligible categories, including mathematical formulas, purely mental processes, substantially economic or cultural processes, purely natural processes, and unmodified natural material. Congress may consider the scope and specificity of proposed statutory exceptions and how they might impact the types of inventions that would be eligible for patents.

Alternatively, Congress could decide to codify the *Alice/Mayo* test or to replace that framework with some different legal standard. Congress may choose not to pursue legislation on subject matter eligibility at all if it concludes that the current patent-eligible subject matter jurisprudence and USPTO guidance effectively promotes innovation or if it wishes to allow the courts to continue to develop patent eligibility doctrine in future cases.

Finally, Congress may also continue monitoring what effects, if any, USPTO's guidance to patent examiners (and any future changes to it) may have, as well as potential changes to the *Alice/Mayo* framework that could emerge in future judicial decisions.

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