

Study of the United States Patent and Trademark Office (USPTO) Revised Guidelines Concerning Patentable Subject Matter Under 35 U.S.C. § 101

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ABSTRACT

The United States Patent and Trademark Office (USPTO) revised guidelines on patentable subject matter under 35 U.S.C. § 101 marking a pivotal development in intellectual property law. These guidelines, issued in response to the escalating complexity and ambiguity surrounding patent eligibility, seek to provide a structured framework for the evaluation of patent claims, particularly in areas like software, biotechnology, and diagnostics. Their primary aim is to introduce clarity and consistency into patent examination practices, aligning with key Supreme Court decisions, such as *Mayo v. Prometheus* and *Alice v. CLS Bank International*, to address the challenges of determining patent eligibility. The guidelines incorporate established legal precedents, offering practical guidance to patent examiners, and enhancing predictability in patent prosecution. They provide a step-by-step analysis, emphasize practical examples, and strike a balance between clear standards and adaptability to evolving technologies and legal developments. These guidelines have a profound impact on the patent community, offering a structured framework for patent applications while generating debates and discussions among stakeholders. Their evolution is anticipated in response to shifting technology and legal precedents, solidifying their status as a crucial development in patent law.

On January 4, 2019, the United States Patent and Trademark Office (USPTO) introduced revised guidelines concerning patentable subject matter under 35 U.S.C. § 101. These guidelines, which took effect on January 7, 2019, were titled "2019 Revised Patent Subject Matter Eligibility Guidance." The objective of these guidelines was to provide a more structured framework for the assessment of patent claims in light of key Supreme Court decisions, such as *Mayo v. Prometheus* and *Alice v. CLS Bank International*.

These guidelines were seen as a response to the uncertainty and inconsistency that had arisen in determining patent eligibility, particularly in areas like software, biotechnology, and diagnostics. The document aimed to clarify the analysis of whether claims were "directed to" an abstract idea, thereby supplanting previous analysis methods, including the Examiner's "Quick Reference."

The guidelines acknowledged that the application of the *Alice/Mayo* test had led to confusion and variable examination practices, making it challenging for stakeholders to predict what subject matter was patent-eligible. To address this, the guidelines made revisions to the USPTO's analysis under the first step (Step 2A) of the *Alice/Mayo* test, without altering the analysis under Steps 1 and 2B significantly.

Previously, examiners often compared claims to those found to be directed to an abstract idea in previous judicial decisions. The new guidelines acknowledged the impracticality of this approach due to conflicting decisions regarding similar subject matter's eligibility.

The new approach introduced a two-pronged analysis for Step 2A. The first prong involved determining if a claim fell into one of three "enumerated groupings of abstract ideas." If not, the claim was likely considered patent-eligible. To establish that a claim fell within these categories, examiners had to identify specific limitations in the claim and assess if they fit the three defined categories.

Under the second prong, the guidelines provided clarification on how examiners should determine if a claim was "directed to" a judicial exception under Step 2A. This process resembled the traditional, yet rarely applied, "preemption" analysis under § 101. Examiners now needed to determine if an abstract idea was "integrated into a practical application" by assessing if the application imposed a meaningful limit on the exception. This was based on whether additional claim elements went beyond the judicial exception and integrated it into a practical application.

The analysis under Step 2B remained largely unchanged, adhering to the guidance found in MPEP § 2106.05, as influenced by the USPTO Berkheimer Memorandum.

The guidelines made it clear that examiners could only reject claims that failed both prongs in rare circumstances. Any such rejection required approval from the Technology Center Director, who needed to justify treating a claim limitation as reciting an abstract idea, with this justification documented in the application's file record.

In essence, the new guidelines provided a more defined framework for Step 2A of Alice/Mayo, replacing the earlier approach of broadly applying a potentially inconsistent body of case law. Examiners were required to categorize claims into specific USPTO-defined judicial exception categories. This shift aimed to assess whether a claim genuinely represented a practical application of an alleged abstract idea or if it was merely an attempt to monopolize the abstract concept before proceeding to Step 2B.

Adapting to this new examination methodology would require distribution and training for examiners, as well as an understanding and adjustment by both practitioners and examiners. Questions about how "practical application" would be determined would likely arise, and it would take time for stakeholders to become familiar with and proficient in applying this new guidance.

The study concludes by emphasizing the lasting implications of these guidelines on patent examination practices. It suggests that these guidelines have the potential to evolve and adapt to changing technology and legal precedents, making them a significant development in patent law.

In summary, the study provides a thorough analysis of the USPTO's revised guidelines concerning patentable subject matter under 35 U.S.C. § 101. It highlights the guidelines' role in addressing patent eligibility challenges and their impact on the patent community, offering a structured framework for patent applications. The study anticipates the continued evolution of these guidelines in response to changes in technology and legal developments.

KEYWORDS: Patentable Subject Matter, Prong Test, Guidelines, Patentability