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The Uncertain Future of Section 101: Patent Eligibility in the Wake of Recent Supreme Court (In)Action

The Patent Playbook on **April 8, 2025**

Patent eligibility under 35 U.S.C. § 101 remains one of the most hotly contested and unpredictable areas of U.S. patent law. In the years following the Supreme Court's landmark decisions in *Alice Corp. v. CLS Bank Int'l* (2014) and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (2012), lower courts, the USPTO, and the Federal Circuit have wrestled with the proper application of the two-step framework for determining whether an invention is directed to an abstract idea, law of nature, or natural phenomenon—and, if so, whether it includes an inventive concept sufficient to transform it into patent-eligible subject matter.

For years, stakeholders across industries have looked to the Supreme Court for further guidance, yet the Court has consistently declined to intervene. The denial of certiorari in *Tropp v. Travel Sentry, Inc.* (2023), *CareDx, Inc. v. Natera, Inc.* (2023), *Eolas Technologies v. Amazon.com* (2024), for example, has left businesses and patent practitioners with little hope that clarity is forthcoming. As a result, companies in technology, life sciences, and medical devices must continue to navigate a legal landscape marked by uncertainty and evolving interpretations.

The State of Section 101: The Federal Circuit's Approach

The Federal Circuit has been the primary forum for interpreting and applying the Supreme Court's eligibility framework. Its rulings, however, have been criticized for inconsistency, leading to unpredictability in patent litigation. In some cases, the court has applied a broad view of *Alice/Mayo*, striking down patents covering software and diagnostic methods as abstract ideas or natural laws. In others, such as *CardioNet, LLC v. InfoBionic, Inc.* (2022), the court has found certain medical device-related innovations patent-eligible, suggesting that eligibility may turn on nuanced factual distinctions.

For companies in AI, fintech, and biotechnology, the Federal Circuit's inconsistent rulings have made it increasingly difficult to predict how courts will assess patent eligibility. This uncertainty complicates both prosecution and enforcement, as applicants struggle to draft claims that can withstand judicial scrutiny while still capturing commercially valuable inventions. The lack of a consistent standard means that patent holders must grapple with the risk of invalidation under § 101, even after successfully demonstrating novelty (§ 102) and non-obviousness (§ 103). As a result, companies in these rapidly evolving industries often face significant hurdles in securing and defending their intellectual property, creating an unpredictable legal landscape that can stifle innovation and deter investment.

Legislative Reform: A Possible Solution?

Given the Supreme Court's reluctance to take up a case, Congress remains the only other viable avenue for reform. In recent years, there have been efforts to clarify or overhaul § 101, most notably through proposed legislation such as the *Patent Eligibility Restoration Act of 2023* introduced by Senator Thom Tillis. The bill aimed to roll back the *Alice/Mayo* framework by expressly stating that judicial exceptions like abstract ideas and laws of nature should not bar eligibility if a claim is directed to a "useful process, machine, manufacture, or composition of matter."

Industry reactions to such legislative proposals have been mixed. The technology sector, particularly companies that frequently face patent infringement lawsuits from non-practicing entities (NPEs), has largely opposed broadening eligibility. Meanwhile, the life sciences industry, particularly diagnostic and biotech firms, has pushed for reform, arguing that the current state of the law discourages investment in new life science technologies and applications.

Practical Considerations for Patent Owners and Litigants

In the absence of Supreme Court guidance or legislative change, companies must take a strategic approach to patent prosecution and litigation. Some best practices include:

- **Drafting Applications with Eligibility in Mind:** Patent applicants should focus on drafting claims that emphasize specific, concrete technical improvements rather than broad functional descriptions. Consider having claims reviewed by litigation counsel during prosecution.

- **Leveraging Prior Art in § 101 Challenges:** In litigation, parties should consider how factual evidence related to novelty and non-obviousness may also bolster arguments that a claimed invention is not merely an abstract idea or natural law.
- **Considering Alternative IP Strategies:** Given the risks associated with § 101 challenges, companies should explore complementary IP protections, such as trade secrets and copyright, particularly for software-based innovations.

Conclusion

With the Supreme Court continuing to sidestep Section 101 issues, uncertainty in patent eligibility is likely to persist for the foreseeable future. While legislative reform remains a possibility, businesses must proactively adjust their IP strategies to navigate the evolving legal landscape. Patent owners and litigants should stay attuned to Federal Circuit decisions and USPTO guidance to refine their approaches and mitigate the risks of invalidation under § 101.

If you have questions about patent eligibility or how best to protect your company's innovations, our team is here to help.

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