

July 12, 2021

USPTO Soliciting Input for Study on Patent Eligibility

On July 9, 2021, the USPTO published a [notice in the Federal Register](#) seeking comments on the current state of U.S. patent eligibility jurisprudence. These comments will be used to prepare a study on patent eligibility under 35 U.S.C. § 101, focusing on how the jurisprudence has impacted investment and innovation, particularly in technologies such as quantum computing, artificial intelligence, precision medicine, diagnostic methods, and pharmaceutical treatments.

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Patent eligibility has been a topic of much debate and confusion over the past decade-plus, with the Supreme Court weighing in through its decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice*. The USPTO’s study comes at the request of a bipartisan group of Senators: Thom Tillis, R-N.C., Mazie Hirono, D-Hawaii, Tom Cotton, R-Ark, and Chris Coons, D-Del. In a [March 2021 letter](#) to USPTO Acting Director Drew Hirshfeld, the Senators requested that the USPTO prepare a study on patent eligibility and submit it to Congress by March 2022, writing that “unless we take steps to provide clarity in the area of patent eligibility, we risk losing our place as the global innovation leader in the twenty-first century.” Congress has been considering the issue of patent eligibility reform for the last few years: for example, in 2019, dozens of witnesses appeared before Congress to testify about patentable subject matter, and Senators Tillis and Coons proposed a draft bill that would have explicitly abrogated decisions such as *Alice* and *Myriad* and removed the judicial exceptions to patent eligibility. However, no action has been taken on the draft bill since late 2019, and no other legislative fixes on the issue of § 101 reform have since been forthcoming.

Notably, the USPTO’s Federal Register notice and request for comment acknowledges that multiple Federal Circuit judges have repeatedly asked the Supreme Court for further patent eligibility guidance, including in the recent cases of *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC* and *American Axle v. Neapco*. Specifically, the USPTO is requesting interested parties to submit written comments on the following topics:

Section I—Observations and Experiences

1. Please explain how the current state of patent eligibility jurisprudence affects the conduct of business in your technology area(s). Please identify the technology area(s) in your response.
2. Please explain what impacts, if any, you have experienced as a result of the current state of patent eligibility jurisprudence in the United States. Please include impacts on as many of the following areas as you can, identifying concrete examples and supporting facts when possible:
 - a. patent prosecution strategy and portfolio management;
 - b. patent enforcement and litigation;
 - c. patent counseling and opinions;
 - d. research and development;
 - e. employment;
 - f. procurement;
 - g. marketing;

- h. ability to obtain financing from investors or financial institutions;
 - i. investment strategy;
 - j. licensing of patents and patent applications;
 - k. product development;
 - l. sales, including downstream and upstream sales;
 - m. innovation; and
 - n. competition.
3. Please explain how the current state of patent eligibility jurisprudence in the United States impacts particular technological fields, including investment and innovation in any of the following technological areas:
 - a. quantum computing;
 - b. artificial intelligence;
 - c. precision medicine;
 - d. diagnostic methods;
 - e. pharmaceutical treatments; and
 - f. other computer-related inventions (e.g., software, business methods, computer security, databases and data structures, computer networking, and graphical user interfaces).
 4. Please explain how your experiences with the application of subject matter eligibility requirements in other jurisdictions, including China, Japan, Korea, and Europe, differ from your experiences in the United States.
 5. Please identify instances where you have been denied patent protection for an invention in the United States solely on the basis of patent subject matter ineligibility, but obtained protection for the same invention in a foreign jurisdiction, or vice versa. Please provide specific examples, such as the technology(ies) and jurisdiction(s) involved, and the reason the invention was held ineligible in the United States or other jurisdiction.
 6. Please explain whether the state of patent eligibility jurisprudence in the United States has caused you to modify or shift investment, research and development activities, or jobs from the United States to other jurisdictions, or to the United States from other jurisdictions. If so, please identify the relevant modifications and their associated impacts.
 7. Please explain whether the state of patent eligibility jurisprudence in the United States has caused you to change business strategies for protecting your intellectual property (e.g., shifting from patents to trade secrets, or vice versa). If so, please identify the changes and their associated impacts.

8. Please explain whether you have changed your behavior with regard to filing, purchasing, licensing, selling, or maintaining patent applications and patents in the United States as a result of the current state of patent eligibility jurisprudence in the United States. If so, please describe how you changed your behavior.
9. Please explain how, in your experience, the status of patent eligibility jurisprudence in the United States has affected any litigation for patent infringement in the United States in which you been involved as a party, as legal counsel, or as another participant (e.g., an expert witness). For example, please explain whether this jurisprudence has affected the cost or duration of such litigation, the ability to defend against claims of patent infringement, the certainty/uncertainty of litigation outcomes, or the likelihood of settlement.

Section II—Impact of Subject Matter Eligibility on the General Marketplace

10. Please identify how the current state of patent eligibility jurisprudence in the United States impacts the global strength of U.S. intellectual property.
11. Please identify how the current state of patent eligibility jurisprudence in the United States impacts the U.S. economy as a whole.
12. Please identify how the current state of subject matter eligibility jurisprudence in the United States impacts the global strength of U.S. intellectual property and the U.S. economy in any of the following areas:
 - a. quantum computing;
 - b. artificial intelligence;
 - c. precision medicine;
 - d. diagnostic methods;
 - e. pharmaceutical treatments; and
 - f. other computer-related inventions (e.g., software, business methods, computer security, databases and data structures, computer networking, and graphical user interfaces).

In responding to this question, please provide concrete examples and supporting facts when possible.

13. Please identify how the current state of patent eligibility jurisprudence in the United States affects the public. For example, does the jurisprudence affect, either positively or negatively, the availability, effectiveness, or cost of personalized medicine, diagnostics, pharmaceutical treatments, software, or computer-implemented inventions?

In addition to these 13 separate questions, the public and any stakeholders are also encouraged to submit any additional information that the USPTO may find useful in preparing the forthcoming study. Comments and submissions in response to the Federal Register notice are due by September 7, 2021. If you have any questions about this Alert or the Federal Register notice, please contact [Matthew Rizzolo](#), [Brendan McLaughlin](#), or [Nicole Pobre](#).