3510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO-P-2021-0032]

Patent Eligibility Jurisprudence Study

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Request for information.

SUMMARY: At the request of Senators Tillis, Hirono, Cotton, and Coons, the United States Patent and Trademark Office (USPTO) is undertaking a study on the current state of patent eligibility jurisprudence in the United States, and how the current jurisprudence has impacted investment and innovation, particularly in critical technologies like quantum computing, artificial intelligence, precision medicine, diagnostic methods, and pharmaceutical treatments. The USPTO seeks public input on these matters to assist in preparing the study.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at www.regulations.gov. To submit comments via the portal, enter docket number PTO-P-2021-0032 on the homepage and click “Search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this request for information and click on the “Comment Now!” icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included.

Visit the Federal eRulemaking Portal (www.regulations.gov) for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions on how to submit comments by other means.

Submissions of Business Confidential Information: Any submissions containing business confidential information must be marked "confidential treatment requested" and submitted through www.regulations.gov. Submitters should provide an index listing the document(s) or information they would like the USPTO to withhold. The index should identify the confidential document(s) by document number(s) and document title(s) and should identify the confidential information by description(s) and relevant page numbers and/or section numbers within a document. Submitters should also provide a statement explaining their grounds for requesting non-disclosure of the information to the public. The USPTO also requests that submitters of business confidential information include a non-confidential version (either redacted or summarized) that will be posted on www.regulations.gov and available for public viewing. In the event that the submitter cannot provide a non-confidential version of their submission, the USPTO requests that the submitter post a notice in the docket stating that they have provided the USPTO with business confidential information. Should a submitter fail either to docket a non-confidential version of their submission or to post a notice that business confidential information has been provided, the USPTO will note the receipt of the submission on the docket with the submitter's organization or name (to the degree permitted by law) and the date of submission.

Anonymous submissions: The USPTO will accept anonymous submissions. Enter "N/A" in the required fields if you wish to remain anonymous.

FOR FURTHER INFORMATION CONTACT: Elizabeth Shaw, USPTO, Office of Policy and International Affairs, at Elizabeth.Shaw2@uspto.gov or 571-272-9300. Please direct media inquiries to the USPTO's Office of the Chief Communications Officer at 571-272-8400.

SUPPLEMENTARY INFORMATION:

In 2016, following the Supreme Court's decisions in *Bilski*,[1] *Mayo*,[2] *Myriad*,[3] and *Alice*,[4] the USPTO held two public roundtables and invited written comments from the public on the state of the law of patent subject matter eligibility and the Court's legal framework for evaluating eligibility. Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility, 81 FR 71485 (Oct. 17, 2016). The first roundtable focused on the then-current USPTO eligibility guidance for patent examiners. *Id*. at 71487.[5] The second roundtable explored the legal contours of patent eligibility, including the impact of the current law, if/how the law should be revised, and whether a legislative solution should be sought. *Id*. at 71486-71487. In July 2017, the USPTO published a report summarizing patent eligibility law, public views on the impact of the recent Supreme Court patent eligibility jurisprudence, and public recommendations for a path forward. USPTO, Patent Eligible Subject Matter: Report on Views and Recommendations from the Public (July 2017), available at www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf.

Since 2017, the Federal Circuit has issued numerous decisions applying the Supreme Court's legal framework in a variety of contexts, and many petitions for writ of certiorari have been filed. In 2019, the Supreme Court called for the views of the Solicitor General. *HP Inc.* v. *Berkheimer*, No. 18-415, 139 S. Ct. 860 (Jan. 7, 2019); *Hikma Pharms. USA Inc.* v. *Vanda Pharms. Inc.*, No. 18-817, 139 S. Ct. 1368 (Mar. 18, 2019). In both cases, the Government argued that the Court's recent decisions have strayed from earlier precedent and have fostered uncertainty regarding the patent eligibility standards. Brief for United States, *HP Inc.* v. *Berkheimer*, No. 18-415, 2019

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[1] *Bilski* v. *Kappos*, 561 U.S. 593 (2010).
[2] *Mayo Collaborative Servs.* v. *Prometheus Labs., Inc.*, 566 U.S. 66 (2012).
[3] *Ass'n for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576 (2013).
[4] *Alice Corp.* v. *CLS Bank Int'l*, 573 U.S. 208 (2014).
[5] The USPTO issued revised patent subject matter eligibility guidance for examiners in 2019. USPTO, 2019 Revised Patent Subject Matter Eligibility Guidance, 84 FR 50 (Jan. 7, 2019); USPTO, October 2019 Patent Eligibility Guidance Update, 84 FR 55942-55943 (Oct. 18, 2019). That guidance has since been incorporated into the Manual of Patent Examining Procedure, sections 2103 to 2106.07(c) (9th ed., rev. 10.2019) (June 2020). *See* www.uspto.gov/PatentEligibility.

WL 6715368, at *10-13 (Dec. 6, 2019) (Berkheimer CVSG Brief); Brief for United States, *Hikma Pharms. USA Inc.* v. *Vanda Pharms. Inc.*, No. 18-817, 2019 WL 6699397, at *13-21 (Dec. 6, 2019) (Vanda CVSG Brief). While the Government contended that neither of the cases was an optimal vehicle to consider those standards, it urged the Court to grant certiorari in an appropriate case. Berkheimer CVSG Brief at *10, *14, *19; Vanda CVSG Brief at *8, *22-23. In particular, the Government highlighted the then-pending certiorari petition in *Athena Diagnostics, Inc.* v. *Mayo Collaborative Services, LLC*, a case involving medical diagnostic methods in which the Federal Circuit, in denying rehearing en banc, issued multiple separate opinions asking the Supreme Court for further guidance in the area. Berkheimer CVSG Brief at *13, *19; Vanda CVSG Brief at *22-23. Ultimately, the Supreme Court denied writ of certiorari in all three cases. *HP Inc.* v. *Berkheimer*, No. 18-415, 140 S. Ct. 911 (Jan. 13, 2020); *Hikma Pharms. USA Inc.* v. *Vanda Pharms. Inc.*, No. 18-817, 140 S. Ct. 911 (Jan. 13, 2020); *Athena Diagnostics, Inc.* v. *Mayo Collaborative Servs., LLC*, No. 19-430, 140 S. Ct. 855 (Jan. 13, 2020).

Last year, after a split panel decision concluding that a method for manufacturing drive shafts was patent ineligible, the Federal Circuit again issued a decision denying rehearing en banc that included multiple separate opinions with differing views on the scope of patent eligible subject matter. *Am. Axle & Mfg., Inc.* v. *Neapco Holdings LLC*, 966 F.3d 1347 (Fed. Cir. 2020). Like the dissenting judge on the panel, several of the opinions denying rehearing en banc faulted the panel majority for establishing a new "nothing more" test—if the claimed invention "clearly invokes a natural law, and nothing more, to accomplish a desired result"—for patent ineligibility. *Id*. at 1366 (O'Malley J., dissenting); *id*. at 1361 (Stoll J., dissenting); *id*. at 1359 (Newman J., dissenting). American Axle petitioned for writ of certiorari on December 28, 2020, and the Supreme Court called for the views of the Solicitor General on May 3, 2021. *Am. Axle & Mfg., Inc.* v. *Neapco Holdings LLC*, No. 20-891, 2021 WL 1725166 (May 3, 2021). The questions presented in the petition are: (1) What is the appropriate standard for determining whether a

claim is directed to a patent-ineligible concept under step one of the *Alice* two-step framework?; and (2) Is patent eligibility a question of law for the court or a question of fact for the jury?

On March 5, 2021, Senators Thom Tillis, Mazie Hirono, Tom Cotton, and Christopher Coons sent a letter to Mr. Drew Hirshfeld, Performing the functions and duties of the Director of the USPTO, asking that the USPTO publish a request for information on the current state of patent eligibility jurisprudence in the United States (since the Supreme Court's decisions in *Mayo* and *Alice*), evaluate the responses, and provide a detailed summary of its findings by March 5, 2022. The Senators indicated a particular interest in learning how the current jurisprudence has adversely impacted investment and innovation in critical technologies like quantum computing, artificial intelligence,[6] precision medicine, diagnostic methods, and pharmaceutical treatments.

Request for Information: To aid in the study that Senators Tillis, Hirono, Cotton, and Coons requested, the USPTO invites stakeholders to submit written comments on the questions below. In the questions, the phrase "the current state of patent eligibility jurisprudence in the United States" should be understood as referring to the body of patent subject matter eligibility decisions issued by the U.S. Federal Judiciary.

When responding to the questions, please identify yourself and your interest in the U.S. patent system. If applicable, please indicate whether you fall within one or more of the following categories: (1) inventors, patent owners, or investors (e.g., venture capital, investment bank, fund, etc.); (2) licensees or users of patented technology; (3) entities that represent inventors or patent owners (e.g., law firms); (4) recipients of demand letters concerning alleged patent

[6] On October 6, 2020, the USPTO released a report titled "Public Views on Artificial Intelligence and Intellectual Property Policy." The report takes a comprehensive look at a wide variety of stakeholder views on the impact of artificial intelligence across the intellectual property landscape. *See generally* "Public Views on Artificial Intelligence and Intellectual Property Policy," available at www.uspto.gov/sites/default/files/documents/USPTO_AI-Report_2020-10-07.pdf.

infringement or accused infringers in a patent lawsuit; (5) entities that represent accused infringers; (6) government agencies or officials; (7) academic or research institutions; (8) intellectual property organizations or associations; and (9) nonprofit organizations or advocacy groups. Additionally, if you are a patent owner or inventor, please include the number of U.S. and foreign patent applications you have filed; the number of U.S. and foreign patents you hold; the number of patents you have licensed or sold; and the number of patent cases you have been involved in since the Supreme Court's decision in *Bilski* in 2010.

Commenters need not respond to every question and may provide relevant information even if not responsive to a particular question.

Topics for Public Comment

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?

Andrew Hirshfeld,
Commissioner for Patents,
Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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