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 September 7, 2021.

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. BecauseStart Printed Page 36258comments 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 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 Start Printed Page 36259publish 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 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. My business was innovating to solve problems in the area of retirement savings. My partner, Brian Tarbox, died pursuing our innovations. His work, cited by Nobel Prize winner Richard Thaler, was instrumental in increasing retirement savings. Financial service firms made hundreds of millions of dollars practicing our inventions, but Brian died insolvent. Further, even though his innovations were patented, his family has received nothing. He was effectively the victim of a bait and switch as the promise of patent protection, which motivated his innovations, was a false promise and patent protection was withdrawn. Consequently, I have not filed any patent application, or published any innovations since the Alice Bank decision and do not plan on doing so in the United States.

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; I understand that Patent Examiners and the ALJs on the PTAB are measured and rated, at least in part, on the number of cases processed. The adverse publicity concerning "business method patents" largely promoted by financial service firms makes them gun shy concerning finding patents in this area valid. These pressures lead to inappropriate actions taken against those perceived as least likely to be able to defend themselves, small inventors. I will provide three egregious examples from my experience.

In a case before the Patent Trial and Appeals Board (Appel 2017-002346) the ALJs, at page 5, cited the concurrence in the Bilski Supreme Court case as the controlling law in ruling against me. The language cited was inconsistent with the controlling majority decision which held that some business methods may be patentable. The Board declined to revisit its conclusion even after I pointed this out.

Perhaps the most benign explanation is an extreme bias against small inventors, causing the ALJs in this case to misread the law which they would otherwise read correctly. This may be based on the premise that small inventors cannot invent anything of significance and that small inventors have less resources to challenge errors. An alternative explanation that three ALJs exhibited a lack of understanding of the nature of concurring opinions and substantive supreme court jurisprudence in the area of patent law, even absent bias, would perhaps be even more troubling.

Second, the Federal Circuit premised June 10, 2019 decision in **IN RE: MARK ALFRED GREENSTEIN, Appellant 2019-1117,** at least in part on the premise that "We agree with the PTO that the claims are ineligible for patenting under § 101. First, as the Board concluded, the claims are directed to the abstract idea of allocating returns to different investors in an investment fund, a fundamental business practice that long predates computer technology." This omits a critical element/limitation of the claims, which included providing at least one investor a return that is different from that of other investor, despite the fact that the Court recited claim language which included this limitation "assign[] an investment return to the investor which assigned return is

different from the investment return assigned to at least one other investor in the collective investment vehicle;" Omitting and/or not correcting a critical limitation when communicating to the Federal Circuit is egregious, particularly when that Court's opinion is based upon erroneous information. Again, the most benign explanation may be that the PTO employees did not believe that small inventors can invent anything significant and therefore this warped their understanding of, and subsequent communication of, critical facts.

Third, one of the ways to ensure consistency and fairness is to provide a set of procedures that examiners must follow. However, such procedures are of little value and are not protective of disfavored groups when examiners are free to ignore them. This is the case in an ongoing patent prosecution, 16/503,799. The patent examiner declined to follow a number of procedural safeguards, including provisions of the MPEP and declining to consider the factual record. In one example, the MPEP states, at **§ 2106.05(d)** that in order to find that the claims are conventional "**A factual determination is required to support a conclusion that an additional element(or combination of additional elements) is well-understood, routine, conventional activity.** *Berkheimer v. HP, Inc.,* 881 F.3d 1360,1368, 125 USPQ2d 1649, 1654 (Fed. Cir. 2018)." However, the examiner provided his own exception to this requirement, without stating any basis for it. He concluded that he can ignore this requirement in the MPEP because, according to him, it only applies to that portion of the claims that the examiner concludes are not abstract. He did not cite any provision in, nor language from the MPEP which would permit such an analysis. The examiner is likely emboldened to ignore procedural safeguards by a lack of accountability. In this connection I have been informed by counsel that certain art units decline to follow the MPEP. Examiners are further emboldened by the fact that the Patent Trial and Appeals Board is very unlikely reverse examiners per a July 20, article in Patently O where the author estimates as follows: "Applicants rarely win appeals based upon Section 101 — Eligibility rejections are affirmed in 90%+ of cases."

Further, even in the unlikely event the examiner is reversed, I have been informed that certain art units will continue to make the same rejections despite such reversals. The lack of procedural safeguards coupled with the fact the appeals are not likely to be successful and are expensive combine to make the process hostile for small inventors. I respectfully suggest that the Patent and Trademark Office provide a process which can be initiated at a level above those of art unit head, when appropriate procedures are not followed. Further, adding complying with the MPEP absent an

express and written waiver which is part of the record, from a level above art unit heads, as part of the standards for examiners and their supervisors would help address this issue.

b. patent enforcement and litigation;

A lack of consistency within the same opinion in Federal Court is atypical, in my experience. Therefore, the inconsistency noted above supports that there is an explicit or subconscious bias against small inventors, even in the case of Federal Judges.

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, Start Printed Page 36260computer 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.

Footnotes

1. *Bilski v. Kappos, 561 U.S. 593 (2010).*

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2. *Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).*

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3. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).*

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4. Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014).

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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.

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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.

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