

Report to Congress

Patent eligible subject matter: Public views on the current jurisprudence in the United States

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UNITED STATES
PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office

June 24, 2022

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Ranking Member Subcommittee on Intellectual Property
United States Senate
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The Honorable Chris Coons
United States Senate
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The Honorable Mazie Hirono
United States Senate
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The Honorable Tom Cotton
United States Senate
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Washington, DC 20510

Dear Senators Tillis, Coons, Hirono, and Cotton:

Thank you for your March 5, 2021, letter expressing concern that, “[s]ince the Supreme Court’s landmark decisions in *Alice Corp. v. CLS Bank International* and *Mayo Collaborative Services Inc. v. Prometheus Laboratories Inc.*, there has been a lack of consistency and clarity in our nation’s patent eligibility laws.” As you point out, current eligibility jurisprudence has a direct impact on investment, research, and innovation. Getting back to first principles, we need clear intellectual property laws that incentivize innovation, especially in key and emerging technology areas and from small to medium-sized enterprises, protect that innovation, and bring that innovation to impact including by incentivizing and protecting investment. This is critical for job creation, opportunity, economic prosperity and U.S. competitiveness. It is also necessary to incentivize our brightest minds and greatest companies to solve world problems.

In response to your request, the USPTO conducted a study on the current state of patent eligibility jurisprudence in the United States. The USPTO solicited public comments through a Federal Register Notice published on July 9, 2021, and a subsequent September 3, 2021, Notice extending the deadline for submissions to October 15, 2021. The Federal Register Notices invited interested parties to submit written comments on several questions under two broad sections: (1) observations and experiences and (2) the impact of current subject matter eligibility on the general marketplace. The USPTO received 141 different comments (available at www.regulations.gov/docket/PTO-P-2021-0032/comments) from a variety of stakeholders, including legal associations, industry organizations, advocacy groups, nonprofit entities, businesses, law firms, practitioners, academics, and inventors.

On behalf of the USPTO, I am pleased to deliver this report titled “Patent eligible subject matter: Public views on the current jurisprudence in the United States.” At a high level, the report found that:

- Across the spectrum, stakeholders generally agreed that the law on patent eligibility needs to be clear, predictable, and consistently applied.
- Those in support of the current state of the law on eligibility tended to be companies faced with abusive and costly litigation involving “overbroad,” mostly software, patents. Those companies noted that the current law allows them to avoid or more efficiently resolve abusive, costly litigation. Certain life sciences and patient advocacy organizations also favored the current law, noting its role in enhancing access to medical technologies.
- Those critical of the current state of the law included many patent practitioners and innovative companies, especially companies involved in life sciences. Those stakeholders noted that making patents less available and rights less predictable, inhibits investment in new technologies and companies. Several startups and small and medium-sized enterprises also noted that the current law undermines innovation by decreasing the availability of private risk capital and works to concentrate markets in the hands of a few large, well-resourced incumbents.
- Though these results were not surprising, the USPTO will continue to solicit feedback from stakeholders, including through listening sessions. The USPTO has also reached out to a broader array of stakeholders, including industry groups in critical and emerging technologies, those who fund startups and small and medium-sized enterprises, and organizations focused on economic growth. In addition, the USPTO is providing all stakeholders the opportunity to submit additional feedback and suggestions to 101@uspto.gov.

We look forward to continuing our discussions on this critically important topic and finding a path forward that will optimize our intellectual property laws for the benefit of all by finding ways to better incentivize innovation and investment while curbing abuses and supporting access to technology.

Please do not hesitate to let me know how we can be of any further assistance.

Respectfully,

Katherine K. Vidal

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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Finally, I would like to extend my gratitude to all the members of the public who provided written comments in response to the Federal Register Notices. Their wide-ranging experiences and thoughtful submissions provided critical insights into the effects of the current subject matter eligibility jurisprudence on a variety of industries and technologies.

Katherine K. Vidal

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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I. Introduction

Subject matter eligibility has long been considered a threshold requirement for patentability that is separate from the other patentability requirements, such as utility, novelty, non-obviousness, written description, and enablement. Although the statutory limits on patent subject matter eligibility have largely remained unaltered, the judiciary has wrestled with defining the boundaries.

Between 2010 and 2014, the Supreme Court issued four decisions that have significantly impacted patent eligibility law. Since then, as the courts have struggled to apply these precedents, the jurisprudence has continued to evolve.

A number of stakeholders have raised concerns that there is now a heightened bar for patent subject matter eligibility that is undermining the ability of innovators to secure rights for and investments in their innovations. These stakeholders contend that the Supreme Court decisions have created inconsistencies, uncertainty, and unpredictability in the issuance and enforcement of patent rights. At the same time, other stakeholders view the current jurisprudence as a useful tool for addressing broad patents and improving access to technologies beneficial to the public.

In a letter to the United States Patent and Trademark Office (USPTO) dated March 5, 2021, Senators Thom Tillis, Christopher Coons, Mazie Hirono, and Tom Cotton expressed concern about the “lack of consistency and clarity” in patent

subject matter eligibility jurisprudence in the United States and the effect of that uncertainty on American leadership in innovation.¹ Believing that legislative action was required to address the situation, the Senators asked the USPTO to “publish a request for information on the current state of patent eligibility jurisprudence in the United States, evaluate the responses, and provide [them] with a detailed summary of [its] findings” in order to assist them in that endeavor.² The Senators expressed a particular interest in learning how current eligibility jurisprudence “has adversely impacted investment and innovation” in several key technologies, including quantum computing, artificial intelligence, precision medicine, and diagnostic methods and pharmaceutical treatments.³

In response, the USPTO published a Federal Register Notice on July 9, 2021, soliciting the requested information and setting an initial deadline for responses of September 7, 2021.⁴ In a subsequent Notice, published September 3, 2021, the USPTO extended the deadline for responses to October 15, 2021.⁵ The two Federal Register Notices are collectively referred to herein as the “Notices.”

The Notices invited members of the public to submit written comments on questions directed to two broad topics: (1) observations and experiences and (2) impact of subject matter eligibility on the general marketplace.⁶ Many of the questions in section I of the Notices focused on how the

1 Letter from Thom Tillis, Christopher A. Coons, Mazie K. Hirono, & Tom Cotton, Sens., U.S. Senate, to Drew Hirshfeld, Comm’r for Pats., U.S. Pat. & Trademark Off. 1 (Mar. 5, 2021), www.tillis.senate.gov/services/files/04D9DCF2-B699-41AC-BE62-9DCA9460EDDA; see appendix A.

2 *Id.* at 1–2.

3 *Id.* at 2.

4 Patent Eligibility Jurisprudence Study, 86 Fed. Reg. 36,257 (July 9, 2021), www.federalregister.gov/documents/2021/07/09/2021-14628/patent-eligibility-jurisprudence-study; see appendix B.

5 Patent Eligibility Jurisprudence Study, 86 Fed. Reg. 49,521 (Sept. 3, 2021), www.federalregister.gov/documents/2021/09/03/2021-19112/patent-eligibility-jurisprudence-study; see appendix B.

6 Patent Eligibility Jurisprudence Study, *supra* note 4.

conduct of business is affected by the current state of patent eligibility jurisprudence in the United States.⁷ Questions in section II focused on how the global strength of U.S. intellectual property and the U.S. economy are impacted by the current state of patent eligibility jurisprudence in the United States.⁸

In response to the Notices, 141 different comments were submitted to the USPTO from a wide range of stakeholders including: legal associations, industry organizations, advocacy groups, nonprofit entities, businesses, law firms, practitioners, academics, and inventors.⁹

This report is intended to provide a comprehensive review of the public views on the impacts of the current jurisprudence on subject matter eligibility. Starting with an overview of patent eligibility law in the United States, section II summarizes relevant Supreme Court jurisprudence and the interpretation by the U.S.

Court of Appeals for the Federal Circuit of that precedent. Section III provides an overview of USPTO efforts over the past decade, beginning with a summary of guidance for patent subject matter eligibility for USPTO personnel, then a description of various stakeholder engagements, and finally a discussion of reports assessing trends in key sectors affected by subject matter eligibility developments. Based on the the comments, section IV summarizes public views on the impacts of the current jurisprudence. This section documents views critical of and favorable to the current common law and includes a description of the impacts of the current law on innovation and investment, as well as the effects of the law on most-affected technologies, i.e., life sciences and computer-related technologies. Section V provides a brief summary of the views expressed by the public.

II. Legal background

The statutory basis for patent eligible subject matter in the United States is set forth in 35 U.S.C. section 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.¹⁰

This language has remained substantially unchanged for more than 200 years.¹¹

Though section 101 defines patent eligible subject matter in terms of broad categories of innovation (processes, machines, manufactures, and compositions of matter), the Supreme Court has long recognized certain implicit limits on eligibility in view of the history and context of the statutory text. Specifically, the Court has held that abstract ideas, natural laws, and natural

⁷ *Id.* at 36,259.

⁸ *Id.* at 36,259–60.

⁹ Public comments are available at www.regulations.gov/docket/PTO-P-2021-0032/comments; see appendix C for a list of parties that submitted written comments.

¹⁰ In addition to being patent eligible, an invention must also satisfy the other statutory requirements for patentability to qualify for patent protection: 35 U.S.C. § 102 (novelty), § 103 (non-obviousness), § 112 (written description, enablement, definiteness). Furthermore, a separate requirement for utility is grounded in the term “useful” in 35 U.S.C. § 101.

¹¹ See Patent Act of 1790, ch. 7, 1 Stat. 109 (1790); Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (1793); and 66 Stat. 797, ch. 10, § 101 (1952).

phenomena are not patent eligible.¹² These judicially created exceptions to patent eligibility have long been applied and interpreted by the lower courts. But in recent years, the Supreme Court issued a series of decisions—*Bilski*,¹³ *Mayo*,¹⁴ *Myriad*,¹⁵ and *Alice*¹⁶—that have affected the reach and breadth of these judicially created exceptions. In *Mayo* and *Alice*, the Court enunciated a two-step framework for distinguishing subject matter falling within one of the exceptions from patent eligible subject matter, which has significantly altered patent eligibility law and generated considerable public debate.¹⁷

Bilski, decided in 2010, involved a patent on a business method for hedging risk.¹⁸ The Supreme Court held that the claims at issue were invalid because they were directed to an unpatentable abstract idea—hedging risk—and added only token post-solution activity, namely, the use of well-known random analysis techniques to establish inputs.¹⁹ The Court observed that risk hedging is a long prevalent, fundamental economic practice and that allowing the patent claims “would pre-empt use of [risk hedging] in all fields” and “effectively grant a monopoly over an abstract idea.”²⁰ In rejecting the view of the U.S. Court of Appeals for the Federal Circuit that the “machine or transformation test” is the exclusive test for assessing patent eligibility of a process, the Court explained that the test “is a useful and

important clue,” but it is “not the sole test for deciding whether an invention is a patent-eligible ‘process.’”²¹ The Court, however, left open the possibility that some business methods remain patent eligible.²²

Following *Bilski*, the Supreme Court in *Mayo* addressed a method for optimizing drug dosages for treatment of autoimmune diseases in humans.²³ The inventors obtained a patent claiming a method of determining whether a given dosage level is too low or too high, depending on the concentration level of a metabolite in the blood.²⁴ The Court held the claims to be patent ineligible.²⁵

In analyzing the claims in *Mayo*, the Supreme Court introduced a two-step framework for distinguishing patent ineligible concepts from patent eligible applications of those concepts.²⁶ The first step, according to the Court, is to consider whether the claims are “directed to” a judicially recognized exception to patentability (abstract ideas, laws of nature, or natural phenomena).²⁷ If so, then the second step is to determine “whether the claims do significantly more than simply describe these natural relations,” that is, whether the additional claim elements considered separately or as an ordered combination “transform the nature of the claim” into “a patent-eligible application” of the judicial exception.²⁸ Applying the first step of this framework to the claims at issue,

12 See e.g., *Diamond v. Diehr*, 450 U.S. 175 (1981); *Parker v. Flook*, 437 U.S. 584, 598 (1978) (Stewart, J., dissenting); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175, 14 L. Ed. 367 (1852).

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

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

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

16 *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208 (2014).

17 *Mayo*, 566 U.S. at 77–79; *Alice*, 573 U.S. at 217–18.

18 *Bilski*, 561 U.S. at 599.

19 *Id.* at 612.

20 *Id.* at 611–12.

21 *Id.* at 604.

22 *Id.* at 606–07.

23 *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 73–74 (2012).

24 *Id.*

25 *Id.* at 91–92.

26 *Id.* at 77–79; see also *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217–18 (2014) (summarizing two-part test in *Mayo*).

27 *Mayo*, 566 U.S. at 77–79, 70; see also *Alice*, 573 U.S. at 217.

28 *Mayo*, 566 U.S. at 77–79; see also *Alice*, 573 U.S. at 217–18.

the Court found that the claims were directed to laws of nature: the relationships between the concentration of a particular metabolite in the blood and the likelihood that a dosage of a drug will be ineffective or harmful.²⁹ Assessing the second step, the Court determined that the claims did not do “significantly more” than describe these natural relationships, that is, the additional elements considered separately and as an ordered combination did not “transform the nature of the claim” into “a patent-eligible application” of the judicial exceptions.³⁰

At issue in *Myriad* was the patent eligibility of claims to isolated DNA molecules (genes) associated with an increased risk of breast cancer and to synthetic DNA molecules created from RNA known as complementary DNA (cDNA).³¹ The Supreme Court held that the isolated genes “fell squarely within the law of nature exception.”³² The Court explained that discovering the location of the genes does not render the genes patent eligible, nor does the act of separating them from their surrounding genetic material.³³ While acknowledging that claims to a product “with markedly different characteristics from any found in nature” may be patent eligible,³⁴ the Court explained that *Myriad*’s claims to isolated genes lacked such characteristics because they do not rely on any chemical changes resulting from isolation and are not even expressed in terms of chemical composition.³⁵ The Court did, however, rule that the claimed cDNA molecules were patent eligible because they differed from naturally

occurring DNA by the absence of intron regions (i.e., non-coding nucleotide sequences).³⁶

Finally, in *Alice*, the Supreme Court reaffirmed the *Mayo* two-step framework and applied it to claims reciting a computer-implemented process, computer system, and computer readable medium for mitigating settlement risk.³⁷ Under step one of the framework, the Court concluded that the claims were directed to the abstract idea of intermediated settlement.³⁸ In applying step two, the Court considered whether the claim elements, individually or as an ordered combination, “transform the nature of the claim” into a patent-eligible application.”³⁹ The Court referred to step two as “a search for an inventive concept—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.”⁴⁰ Analyzing the claims at issue, the Court concluded that mere generic computer implementation does not transform the abstract idea into a patent eligible invention.⁴¹ Thus, the Court held the process claims, as well as the claims to the computer system and computer-readable medium, to be patent ineligible.⁴²

Since the Supreme Court’s decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice*, the Federal Circuit has issued over 200 decisions applying the Supreme Court’s two-step framework in a variety of technological contexts, and many petitions for writ of certiorari have been filed. Specific cases that are

29 *Mayo*, 566 U.S. at 75–77.

30 *Id.* at 77–78.

31 *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 583–84 (2013).

32 *Id.* at 591.

33 *Id.* at 591–92.

34 *Id.* at 590–91 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)).

35 *Myriad*, 569 U.S. at 593.

36 *Id.* at 594–95.

37 *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. at 217–18, 212–13 (2014).

38 *Id.* at 218–20.

39 *Id.* at 217–18 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012)).

40 *Alice*, 573 U.S. at 217–18 (internal quotation marks omitted).

41 *Id.* at 221–27.

42 *Id.* at 225–27.

discussed in the public comments are summarized below.

In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the Federal Circuit applied the *Alice* and *Mayo* two-step framework and determined that claims to a prenatal diagnostic method that include step one of amplifying the cell-free fetal DNA (cffDNA) contained in a sample of a plasma or serum from a pregnant female and step two of detecting the paternally inherited cffDNA were patent ineligible.⁴³ The Court based its decision on its finding that the claims begin and end with cffDNA, which is a natural phenomenon, and that the steps of amplifying and detecting were well understood, routine, and conventional.⁴⁴

Similarly, in *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, the Federal Circuit concluded that claims to a method for diagnosing neurological disorders by detecting antibodies to a certain protein, muscle-specific tyrosine kinase (MuSK), were patent ineligible because they were directed to a natural law—the correlation between the presence of naturally occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases such as myasthenia gravis—and the remaining limitations constituted conventional immunological assay techniques.⁴⁵ The court denied rehearing en banc in a sharply fractured decision that included eight separate opinions.⁴⁶

In contrast, in *Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Ltd.*, claims to a method of treating schizophrenia patients

with the compound iloperidone with dosage ranges based on the patient's genotype were found to be patent eligible.⁴⁷ The Federal Circuit determined that the claims were patent eligible because the claims were not directed to the relationships between iloperidone and certain medical phenomena (i.e., CYP2D6 metabolism and QTc prolongation), but to an application of those relationships to treat “specific patients using a specific compound at specific doses to achieve a specific outcome.”⁴⁸

Meanwhile, several decisions issued in the electronic arts. First, in *ChargePoint, Inc. v. SemaConnect, Inc.*, the Federal Circuit held that claims to an apparatus, method, and system for charging electric vehicles over a network were directed to the abstract idea of communicating over a network for device interaction.⁴⁹ Under step two, the court determined that the only possible inventive concept was in the abstract idea itself, which could not supply the inventive concept.⁵⁰ Then, in *Chamberlain Group, Inc. v. Techtronic Industries Co.*, the Federal Circuit held that claims to a garage door opener that wirelessly communicates status information was directed to the abstract idea of wirelessly communicating status information about a system.⁵¹ The remaining limitations in the claims were determined to be well-understood, conventional components recited in a generic way, which did not transform the abstract idea into a patent-eligible application.⁵² Finally, in *Yu v. Apple, Inc.*, the Federal Circuit held that claims to a digital camera were patent ineligible because they were

⁴³ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1378 (Fed. Cir. 2015).

⁴⁴ *Id.*

⁴⁵ *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 750 (Fed. Cir. 2019), *reh'g denied*, 927 F.3d 1333 (Fed. Cir. 2019), *cert. denied*, 140 S. Ct. 855 (2020).

⁴⁶ *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333 (Fed. Cir. 2019).

⁴⁷ *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018).

⁴⁸ *Id.* at 1135–36.

⁴⁹ *ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 765–773 (Fed. Cir. 2019).

⁵⁰ *Id.* at 773–775.

⁵¹ *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1346–1348 (Fed. Cir. 2019).

⁵² *Id.* at 1348–1349.

directed to an abstract idea, that is, taking two pictures, which may be at different exposures, and using one picture to enhance the other.⁵³ The remaining limitations—image sensors, lenses, analog-to-digital converting circuitry, image memory, and digital image processor—were considered well-known and conventional camera components.⁵⁴

In 2019, the Supreme Court issued a call for the views of the Solicitor General (CVSG) in two cases: *HP, Inc. v. Berkheimer* and *Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*⁵⁵ In both cases, the government argued that the Court’s recent decisions had strayed from earlier precedent and fostered uncertainty regarding the patent eligibility standards.⁵⁶ 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.⁵⁷ 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.⁵⁸ Ultimately, the Supreme Court denied writ of certiorari in all three cases.⁵⁹

In 2020, in *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, after a split panel decision concluding that a method for manufacturing vehicle 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.⁶⁰ 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” framework—a claim is ineligible if it “clearly invokes a natural law, and nothing more, to accomplish a desired result.”⁶¹ American Axle petitioned for writ of certiorari on December 28, 2020.⁶² 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?⁶³ In response to the Supreme Court’s CVSG,⁶⁴ the government submitted an amicus brief on May 24 recommending that the Supreme Court grant the petition.⁶⁵ The government contended that industrial techniques, like the claimed method of manufacturing driveshafts, have long been viewed as “processes” that are patent eligible, and the Federal Circuit erred in holding otherwise.⁶⁶ Noting the substantial uncertainty about the proper application of section 101, the government

⁵³ *Yu v. Apple Inc.*, 1 F.4th 1040, 1043 (Fed. Cir. 2021).

⁵⁴ *Id.*

⁵⁵ *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).

⁵⁶ Brief for United States, *HP Inc. v. Berkheimer*, No. 18–415, 2019 WL 6715368, at *10–13 (Dec. 6, 2019) [hereinafter *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) [hereinafter *Vanda CVSG Brief*].

⁵⁷ *Berkheimer CVSG Brief* at *10, *14, *19; *Vanda CVSG Brief* at *8, *22–23.

⁵⁸ *Berkheimer CVSG Brief* at *13, *19; *Vanda CVSG Brief* at *22–23.

⁵⁹ *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).

⁶⁰ *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 966 F.3d 1347 (Fed. Cir. 2020).

⁶¹ *Id.* at 1366 (O’Malley J., dissenting); *id.* at 1361 (Stoll J., dissenting); *id.* at 1359 (Newman J., dissenting).

⁶² *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, No. 20–891, 2019 WL 11611081 (Dec. 28, 2020).

⁶³ *Id.* at *i.

⁶⁴ *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, No. 20–891, 141 S. Ct. 2594 (May 3, 2021).

⁶⁵ Brief for United States, *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, No. 20–891, 2022 WL 1670811 (May 2022).

⁶⁶ *Id.* at *8–9.

urged the Court to provide clarity on how both step one and step two of the framework operate in resolving the ultimate question of patent eligibility.⁶⁷

At the time of this writing, the Supreme Court has not yet decided whether to grant the petition.

III. USPTO response to judicial developments

The USPTO has been monitoring patent eligibility developments in the courts, soliciting input from stakeholders, and assessing examination trends. This section provides an overview of recent USPTO efforts, starting with the USPTO guidance to patent examiners and personnel. Next, this section discusses efforts to engage the public by convening roundtables and soliciting written comments. Finally, this section describes reports issued by the USPTO pertaining to the impact and scope of patent subject matter eligibility, including data and statistics on the effects of patent eligibility jurisprudence.

A. USPTO guidance

The USPTO issued preliminary guidance to the patent examining corps shortly after each of the Supreme Court's decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice* and after passage of the Leahy-Smith America Invents Act in 2011.⁶⁸ Historically, the guidance differed depending on the statutory category and subject matter of the claim. For instance, before the *Myriad* decision in 2013, the USPTO had separate guidance for product claims (machines, manufactures, and compositions of matter), process claims involving abstract ideas,

and process claims involving laws of nature or natural phenomena. However, after the Supreme Court clarified in the *Alice* case that the same eligibility analysis (the two-step framework) applies to all categories of claims (processes, machines, manufactures, and compositions of matter) and for all types of judicial exceptions (abstract ideas, laws of nature, and natural phenomena), the USPTO developed unified guidance.

This unified guidance was issued in December 2014 as the Interim Guidance on Patent Subject Matter Eligibility (IEG).⁶⁹ The IEG offered a comprehensive view of subject matter eligibility in line with *Bilski*, *Mayo*, *Myriad*, and *Alice* and the related body of case law. The unified guidance combines the criteria for eligibility into a single analysis that applies to all categories of claims and all types of judicial exceptions.⁷⁰ Step 1 of the analysis addresses whether the claimed invention falls into one of the four categories recited in 35 U.S.C. 101.⁷¹ Step 2 applies the Supreme Court's two-step framework as steps 2A and 2B.⁷² Examiners use step 2A to evaluate whether a claim is directed to a judicial exception,

⁶⁷ *Id.* at *9.

⁶⁸ USPTO Memorandum of June 25, 2014, "Preliminary Examination Instructions in view of the Supreme Court Decision in *Alice Corporation Pty. Ltd. v. CLS Bank International, et al.*"; USPTO Memorandum of June 13, 2013, "Supreme Court Decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*"; USPTO Memorandum of March 21, 2012, "Supreme Court Decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*"; USPTO Memorandum of June 28, 2010, "Supreme Court Decision in *Bilski v. Kappos*"; USPTO Memorandum of September 20, 2011, "Claims Directed to or Encompassing a Human Organism" (discussing Section 33(a) of the Leahy-Smith America Invents Act and how it codified existing USPTO policy that human organisms are not eligible subject matter). These memoranda are available at www.uspto.gov/patents/laws/examination-policy/memoranda-examining-corps.

⁶⁹ 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618 (Dec. 16, 2014), www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility-examination-guidance-date.

⁷⁰ See Manual of Patent Examining Procedure (MPEP) § 2106(III); see appendix D for a more detailed explanation of the USPTO's unified patent subject eligibility guidance.

⁷¹ MPEP § 2106.03.

⁷² *Id.* §§ 2106.04, 2106.05.

and if so, proceed to step 2B to evaluate whether the additional elements of the claim amount to significantly more than the judicial exception (also known as providing an inventive concept).⁷³

Over the next five years, the IEG was revised and supplemented several times, for example by memoranda addressing key decisions of the U.S. Court of Appeals for the Federal Circuit impacting patent examination practice on eligibility and by supplemental guidance updates clarifying issues raised through public feedback.⁷⁴ These memoranda included guidance on (1) a decision finding method of treatment claims to be eligible; (2) several decisions applying the Supreme Court’s “improvements to the functioning of a computer or to any other technology or technical field” consideration to various patent claims; and (3) a decision stating that whether a claim element or combination of elements is well understood, routine, and conventional to a skilled artisan in the relevant field is a factual determination.⁷⁵

In 2019, the USPTO published two eligibility guidance documents—the 2019 Revised Patent Subject Matter Eligibility Guidance (2019 PEG)⁷⁶ and the October 2019 Patent Eligibility Guidance Update (October 2019 Update).⁷⁷ The 2019 PEG

and the October 2019 Update revised USPTO procedures for identifying abstract ideas and for determining whether a patent claim or patent application claim is directed to a judicial exception (laws of nature, natural phenomena, and abstract ideas) under step 2A of the USPTO’s current subject matter eligibility guidance.⁷⁸

The USPTO’s guidance development process culminated in June 2020 with the incorporation of the 2019 PEG and the October 2019 Update into chapter 2100 of the MPEP.⁷⁹

B. USPTO roundtables and requests for comments

As Federal Circuit jurisprudence on subject matter eligibility continued to evolve, members of the intellectual property (IP) community expressed concerns over the confusing state of the law, even urging Congress to clarify the law. In fall 2016, the USPTO convened two roundtables and issued a request for public comments on the evolving landscape of subject matter eligibility in the United States.⁸⁰

The first roundtable, “USPTO Subject Matter Eligibility Guidelines,” was held November 14, 2016, at USPTO headquarters in Alexandria,

⁷³ *Id.*

⁷⁴ The IEG and subsequent guidance documents issued through November 2019 are archived on the USPTO website at www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility-examination-guidance-date. Pre-IEG guidance is archived on the USPTO website at www.uspto.gov/patents/laws/examination-policy/memoranda-examining-corps.

⁷⁵ USPTO Memorandum of June 7, 2018, “Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*” (discussing a judicial decision holding method of treatment claims eligible); USPTO Memorandum of May 19, 2016, “Recent Subject Matter Eligibility Decisions (*Enfish, LLC v. Microsoft Corp.* and *TLI Communications LLC v. A.V. Automotive, LLC*)”; USPTO Memorandum of November 2, 2016, “Recent Subject Matter Eligibility Decisions” (both discussing judicial decisions applying the Supreme Court’s “improvements to the functioning of a computer or to any other technology or technical field” consideration to software claims); USPTO Memorandum of April 19, 2018, “Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*)” (discussing the Federal Circuit’s decision in *Berkheimer*, and requiring examiners to support a finding that claim elements or combination of claim elements are well understood, routine, and conventional with a factual determination). These memoranda are available at www.uspto.gov/patents/laws/examination-policy/memoranda-examining-corps.

⁷⁶ 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019), www.federalregister.gov/documents/2019/01/07/2018-28282/2019-revised-patent-subject-matter-eligibility-guidance.

⁷⁷ October 2019 Patent Eligibility Guidance Update, 84 Fed. Reg. 55,942 (Oct. 11, 2019), www.federalregister.gov/documents/2019/10/18/2019-22782/october-2019-patent-eligibility-guidance-update.

⁷⁸ *Id.*

⁷⁹ The USPTO’s eligibility guidance is set forth in sections 2103–06 (MPEP, 9th Ed., Rev. 10.2019, June 2020). The current and prior versions of the MPEP are available at www.uspto.gov/MPEP. Additional information and supplementary materials are available at www.uspto.gov/PatentEligibility.

⁸⁰ Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility, 81 Fed. Reg. 71,485 (Oct. 17, 2016), www.federalregister.gov/documents/2016/10/17/2016-24888/notice-of-roundtables-and-request-for-comments-related-to-patent-subject-matter-eligibility.

Virginia.⁸¹ It focused on the training and guidance provided by the USPTO to patent examiners on how to faithfully apply the statute and case law.

The second roundtable, “Exploring the Legal Contours of Patent Eligible Subject Matter,” was held December 5, 2016, in Stanford, California.⁸² It focused on stakeholder feedback on larger questions concerning the appropriate scope of patent eligible subject matter. This roundtable consisted of seven interactive panels and was attended by more than 250 participants from across the country, representing a broad cross-section of stakeholder views, including industry, private practice, academia, associations, inventors, and small businesses.

In July 2017, the USPTO issued a report titled “Patent Eligible Subject Matter: Report on Views and Recommendations from the Public.”⁸³ The report synthesized stakeholder input from the second roundtable and put it into context in terms of relevant developments in U.S. law and comparative practices in other jurisdictions around the world.⁸⁴

The discussions at the roundtables, together with the written submissions, highlighted the complexities of determining the appropriate boundaries of patent eligible subject matter. The comments confirmed that the recent Supreme Court cases have significantly changed the standards for determining patent eligibility.⁸⁵

As noted in the report, stakeholders were divided as to the state of the law on eligibility.⁸⁶ Many commenters disagreed with the Court’s decisions, arguing that the decisions were legally flawed and that the judicially created exceptions to eligibility had become too broad.⁸⁷ These commenters also asserted that the Court’s two-step framework was difficult to apply, led to inconsistent decisions and unpredictability, and conflated section 101 eligibility with other patentability requirements.⁸⁸ Finally, these critics argued that the Court’s jurisprudence stifles innovation, hurts businesses, and undermines American competitiveness to the extent that the patent systems of other countries allow for a broader scope of patent protection.⁸⁹

Other commenters supported the Court’s decisions and subsequent lower court case law developments, viewing them as simply the common law process at work. These commenters asserted that the two-step framework provided a beneficial way to challenge overly broad patents and helped by requiring that claims be directed to a specific implementation of an inventive solution instead of a vaguely claimed functional result.⁹⁰ These supporters also argued that the two-step framework provides a useful tool to defend against abusive lawsuits by patent assertion entities.

The report also looked at the public comments through the lens of various technology sectors and found that the impacts of the jurisprudence were felt differently across sectors, such as life sciences versus computer-related technologies.⁹¹ Representatives from the life sciences industry

81 The webcast of the first roundtable is available at www.uspto.gov/patents/patent-subject-matter-eligibility-roundtable-1.

82 The transcript of the second roundtable is available at www.uspto.gov/sites/default/files/documents/RT2%20Transcript%20FINAL.pdf.

83 USPTO, PATENT ELIGIBLE SUBJECT MATTER: REPORT ON VIEWS AND RECOMMENDATIONS FROM THE PUBLIC, 1 (2017), www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf.

84 *Id.*

85 *Id.* at 23–38.

86 *Id.*

87 *Id.* at 27–29.

88 *Id.* at 29–32.

89 *Id.* at 32–34.

90 *Id.*

91 *Id.* at 34–38.

almost uniformly disagreed with the Court's recent decisions.⁹² They asserted that the Court had effectively rendered many life sciences inventions ineligible, being derived from natural products or processes.⁹³

Representatives of computer-related industries, especially the software sector, had divided views.⁹⁴ Some argued that the two-step framework addressed the problem of abusive patent litigation and had little impact on deterring software innovation.⁹⁵ This group cautioned against legislative redress and instead recommended that the common law should be allowed to evolve further, before legislative reform is considered.⁹⁶ Others in the computer industries asserted that patents are important to foster investment and that the framework devalued patent portfolios and injected uncertainty into their business practices, hurting innovation.⁹⁷

A majority of commenters, including representatives from academia, industry groups, life sciences companies, law firms, and legal associations, recommended legislative changes aimed at reversing the recent trend in the law and restoring, in their view, a more appropriate dividing line between eligible and ineligible subject matter.⁹⁸ A call for a legislative fix was particularly strong from commenters from the life sciences industry, but many supporters also came from computer-related industries.⁹⁹

Other commenters recommended administrative actions to address the impact of the Court's decisions.¹⁰⁰ For example, some suggested that the USPTO take steps to increase consistency among examiners in the application of the two-step framework and ensure clarity of section 101 rejections in office actions.¹⁰¹ Others urged the USPTO to provide better guidance, with more examples and thorough analyses.¹⁰² Following the publication of the 2017 report, the USPTO developed the guidelines described in the previous part; which in turn were commented on as part of the current report.

C. USPTO studies on patent eligibility examination trends

In addition to continued dialogues with stakeholders on the changing landscape of patent eligible subject matter, the USPTO has undertaken several studies to analyze the impacts of these changes through multiple lenses. These studies illustrate the effectiveness of USPTO practices and aid in informing policy decisions regarding patentable subject matter.

1. Examination outcomes in *Alice*-affected technologies¹⁰³

One area of concern to the USPTO is the impact of the eligibility guidance on the examination process. To better inform the ongoing debate about the breadth and clarity of subject matter eligibility jurisprudence, the USPTO studied

92 *Id.* at 35–36.

93 *Id.*

94 *Id.* at 37–38.

95 *Id.* at 37.

96 *Id.* at 39.

97 *Id.* at 37–38.

98 *Id.* at 41–46.

99 *Id.*

100 *Id.* at 40–41.

101 *Id.*

102 *Id.*

103 Patent litigation cases from the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court that involved patent subject matter eligibility were used to identify *Alice*-affected technologies. More details are available in the report (ANDREW A. TOOLE & NICHOLAS A. PAIROLERO, ADJUSTING TO *ALICE*: USPTO PATENT EXAMINATION OUTCOMES AFTER *ALICE CORP. V. CLS BANK INTERNATIONAL* (2020), www.uspto.gov/sites/default/files/documents/OCE-DH_AdjustingtoAlice.pdf).

examination outcomes in response to the *Alice* decision and to USPTO guidance for personnel. In May 2020, the USPTO published its report, “Adjusting to *Alice*,”¹⁰⁴ which explores examination outcomes in the USPTO since the *Alice* decision.

As an initial matter, the findings show that the *Alice* decision increased the likelihood of receiving a first office action with a rejection for patent ineligible subject matter by 31% in the 18 months following the decision.¹⁰⁵ Further, uncertainty in patent examination, defined as the variation in decision-making on subject matter eligibility among examiners within a technology area, increased by 26%.¹⁰⁶

At the same time, the report determined that USPTO guidance issued in 2018 and 2019 largely reversed the upward trend of the *Alice* decision in examination by reducing both the percentage of first action eligibility rejections and examination uncertainty.¹⁰⁷ One year after the USPTO’s 2019 PEG guidance update, the likelihood of *Alice*-affected technologies receiving a first office action with a rejection for patent ineligible subject matter had decreased by 25%.¹⁰⁸ Additionally, uncertainty in patent examination for such technologies decreased by 44%.¹⁰⁹

Although the USPTO study narrowly focused on uncertainty in the patent examination process, it provided systematic evidence that the *Alice* decision increased uncertainty for innovators

using the patent system. Greater uncertainty in any part of the innovative process can dampen economic activity. Higher levels of uncertainty may reduce investments for new or existing technologies: namely, they lower the economic value of patents in force, reduce patent purchases and licensing transactions, and limit opportunities to obtain entrepreneurial financing.¹¹⁰

2. Patent eligibility outcomes for AI-related technologies

During the past several years, considerable public debate has focused on the intersection of artificial intelligence (AI) and patent eligible subject matter. Throughout 2019 and 2020, the USPTO engaged with stakeholders on their views of AI and IP policy through various forums and Federal Register Notices.¹¹¹ Although the focus was on AI and IP policy in general, the topic of patent eligible subject matter was specifically addressed.

In October 2020, the USPTO published a report titled “Public Views on Artificial Intelligence and Intellectual Property Policy” (Public Views Report).¹¹² The Public Views Report noted that stakeholders viewed many AI-related inventions as being at risk of patent ineligibility under the current two-step framework because they may be characterized as methods of organizing human activity, mental processes, or mathematical concepts, and thus may be ineligible if they fail to recite “significantly more” than those judicial

104 *Id.*

105 *Id.* at 1.

106 *Id.*

107 *Id.* at 16–17. As the ADJUSTING TO *ALICE* report shows, uncertainty in the first action stage of patent examination started to decrease following the release of the *Berkheimer* memorandum (USPTO Memorandum of April 19, 2018, “Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*)”). The 2019 PEG had an even larger statistically significant effect on reducing examination uncertainty, particularly in *Alice*-affected technologies.

108 TOOLE & PAIROLERO, *supra* note 103, at 16–17.

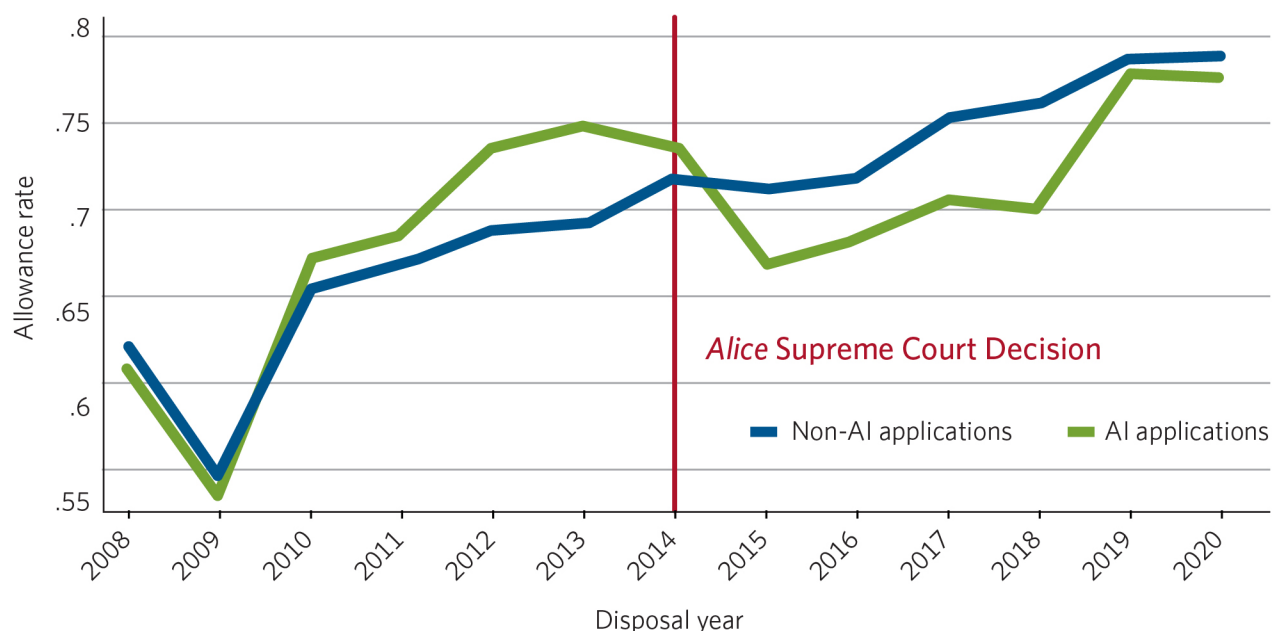
109 *Id.*

110 See, e.g., Andrew Abel et al., *Options, the Value of Capital, and Investment*, 111 QUAR. J. ECON. 753 (1996); Edward Sherry and D. Teece, *Royalties, Evolving Patent Rights, and the Value of Innovation*, 33 Res. Policy 2 (2004); Joshua Gans et al., *The Impact of Uncertain Intellectual Property Rights on the Market for Ideas: Evidence from Patent Grant Delays*, 54 Manage. Sci. 5 (2008).

111 Request for Comments on Patenting Artificial Intelligence Inventions, 84 Fed. Reg. 44,889 (Aug. 27, 2019), www.govinfo.gov/content/pkg/FR-2019-08-27/pdf/2019-18443.pdf; Request for Comments on Intellectual Property Protection for Artificial Intelligence Innovation, 84 Fed. Reg. 58,141 (Oct. 30, 2019), www.federalregister.gov/documents/2019/10/30/2019-23638/request-for-comments-on-intellectual-property-protection-for-artificial-intelligence-innovation.

112 USPTO, PUBLIC VIEWS ON ARTIFICIAL INTELLIGENCE AND INTELLECTUAL PROPERTY POLICY (2020), www.uspto.gov/sites/default/files/documents/USPTO_AI-Report_2020-10-07.pdf.

Figure 1: Allowance rates, 2009–2020: Patent applications containing AI and not containing AI



The allowance rate was calculated as the number of allowances over the number of disposals by disposal year. An application is classified as AI if the patent is AI, or if not patented, the latest PGPub is AI.

exceptions.¹¹³ In light of various concerns raised by users in the Public Views Report, the USPTO’s Office of the Chief Economist analyzed patenting activity in the field of AI and, in October 2020, published a report titled “Inventing AI: Tracing the diffusion of artificial intelligence with U.S. patents” (Inventing AI Report).¹¹⁴

The Inventing AI Report demonstrated the increasing geographic diffusion of AI across the United States.¹¹⁵ Initially, for the period from 1976 to 2000, inventors named on AI patents tended to be concentrated in larger cities and established technology hubs, such as Silicon

Valley, California.¹¹⁶ These locations have resource advantages that make early adoption easier.¹¹⁷ More recently, however, the patent data make clear that AI technologies have diffused widely across the United States.¹¹⁸ For instance, Maine and South Carolina are active in digital data processing and data processing adapted for business. Inventor-patentees in Oregon are using AI in fitness training and equipment. In Montana, AI is incorporated into inventions for analyzing the chemical and physical properties of materials. Wisconsin leads in medical instruments and processes for diagnosis, surgery, and identification, followed by Ohio and Kansas.¹¹⁹

¹¹³ *Id.*

¹¹⁴ ANDREW TOOLE ET AL., INVENTING AI: TRACING THE DIFFUSION OF ARTIFICIAL INTELLIGENCE WITH U.S. PATENTS (2020), www.uspto.gov/sites/default/files/documents/OCE-DH-AI.pdf.

¹¹⁵ *Id.* at 10–11.

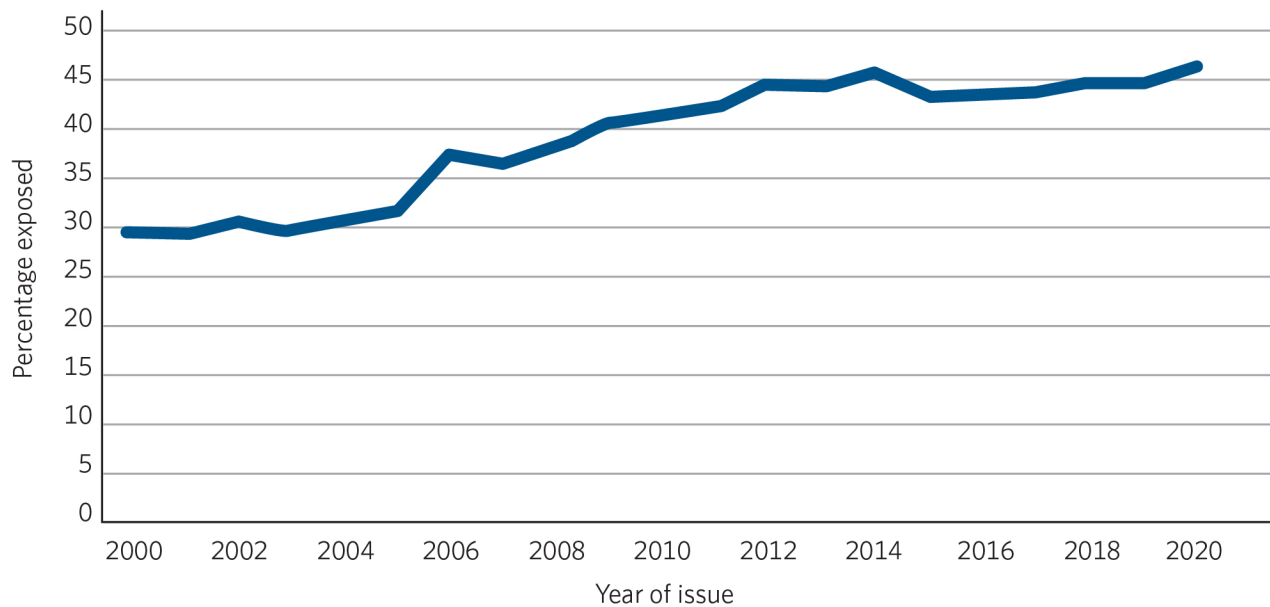
¹¹⁶ *Id.* at 10.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 10–11; figure 7b (illustrating the geographic dispersion of AI inventor patentees for the period 2001–2018).

¹¹⁹ *Id.* at 10–11.

Figure 2: The share of patents in exposed technologies issued to U.S. companies, 2000–2020



In addition to noting the widespread geographic diffusion within the United States, the Inventing AI Report went on to show that from 2002 to 2018, USPTO patent applications from the United States and abroad that contain AI increased by more than 100%, rising from 30,000 to more than 60,000 annually.¹²⁰ During the same period, the share of all patent applications containing AI grew from 9% to nearly 16%.¹²¹ Additionally, patents containing AI appeared in about 9% of all technology subclasses used by the USPTO in 1976 and spread to more than 42% by 2018.¹²²

Given the increased reliance on AI technologies across so many sectors and geographies, the USPTO decided to study the potential impact of the *Alice* decision on allowance rates. For instance, directly following the *Alice* decision, an observed decrease in the USPTO allowance rate for patent

applications containing AI relative to non-AI applications provides suggestive evidence that *Alice* impacted AI technologies differentially.¹²³ Figure 1 shows a substantial decrease in allowance rate for patent applications containing AI following the *Alice* decision in June 2014. Further, the allowance rate stayed below the non-AI application rate until 2019, when the allowance rate for applications containing AI increased by about 8%. This increase is consistent with the finding in the “Adjusting to *Alice*” report that the 2019 USPTO patent examiner guidance substantially reduced the rate of subject matter eligibility rejections in *Alice*-affected technologies.¹²⁴

3. Patent eligibility landscape of industrial sectors

The USPTO also examined domestic companies¹²⁵ listed on issued patents to help shed light on

¹²⁰ *Id.* at 4–5.

¹²¹ *Id.* at 5.

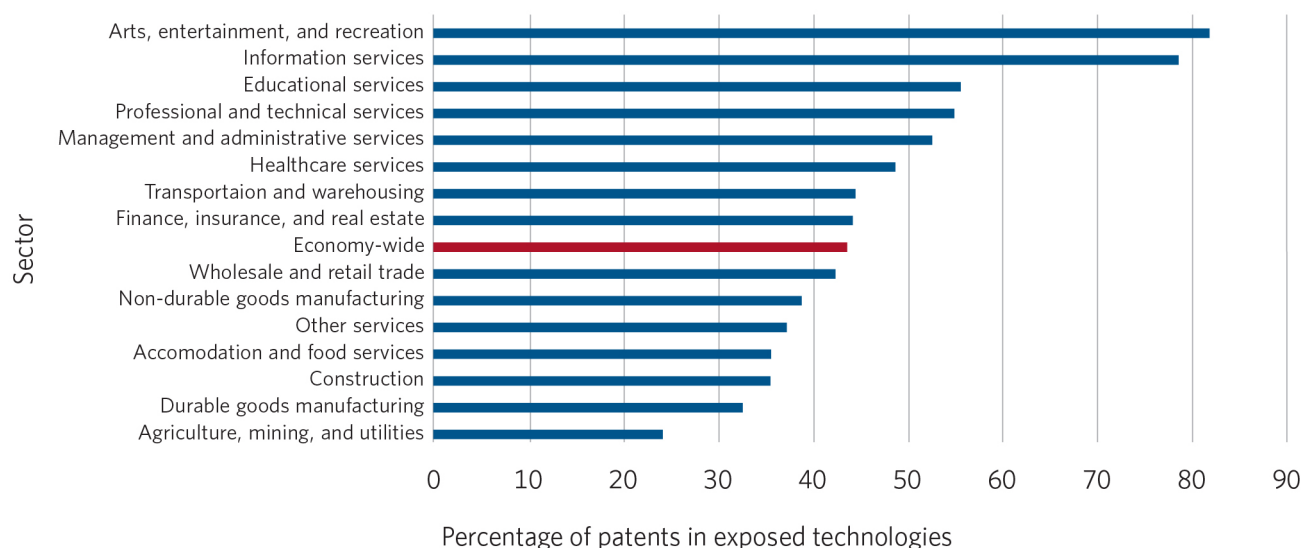
¹²² *Id.* at 7.

¹²³ The allowance rate is the fraction of patent applications allowed relative to all applications with disposals in the year under consideration. A patent application is considered disposed when it is either allowed by the examiner or abandoned by the applicant.

¹²⁴ TOOLE & PAIROLERO, *supra* note 103, at 6.

¹²⁵ For this analysis, the USPTO’s Office of the Chief Economist defined domestic companies as patent assignees with establishments in the United States.

Figure 3: The percentage of patents in exposed technologies issued to U.S. companies, by industry sector, 2012–2016



whether U.S. industrial sectors are exposed to greater uncertainty from changing jurisprudence on subject matter eligibility. Exposure to greater uncertainty is measured using the percentage of patents in “exposed technologies.”¹²⁶

Figure 2 illustrates that for patents owned by U.S. companies, the share of patents in the exposed technologies has increased by 50% during the past two decades. Notably, as of 2020, 46% of all patents issued that year to U.S. companies were in exposed technologies.

Grouping all companies into industries, figure 3 indicates that companies operating in a broad swath of U.S. industries were issued patents in the exposed technologies—totaling about 44% of all USPTO patents issued to U.S. companies between 2012 and 2016.¹²⁷

Domestic companies in nine industry sectors of the U.S. economy had at least 40% of their patents granted in exposed technologies.¹²⁸ These sectors cover areas such as education, managerial and administrative services, transportation and logistics, health care, and financial services.

Patents are considered to have been granted to a domestic company if the assignee’s address is in the United States. Such assignees can include subsidiaries of foreign companies or companies with a presence in the United States but that are owned and/or controlled by a foreign interest.

126 For this analysis, the USPTO’s Office of the Chief Economist defined exposed technologies as U.S. patent classifications appearing in Court of Appeals for the Federal Circuit and U.S. Supreme Court cases involving abstract ideas, laws of nature, or natural phenomena.

127 This is the most recent five-year period for which the Office of the Chief Economist has complete matched data on the industry of patent owners.

128 The number of total patents granted annually to U.S. establishments in these sectors ranged from 185 in the transportation and warehousing sector to more than 17,700 in the professional and technical services sector. Combined, the nine sectors accounted for roughly 46,000 total patent grants per year. The patent counts include patents that the Office of the Chief Economist matched to U.S.-based establishments for 2012–2016. Overall, the Office of the Chief Economist was able to match roughly 90% of patents issued to U.S.-based assignees to establishments. For more details, see Ryan Hughes, Charles deGrazia & Julian Kolev, *Technical Documentation for Matching Patents and Trademarks to the 2017 National Establishment Time Series Database* (USPTO, Economic Working Paper No. 2021-4, 2021), www.uspto.gov/sites/default/files/documents/oce-wp-ip-to-nets.pdf.

IV. Discussion of public views on the impacts of subject matter eligibility jurisprudence

In response to the USPTO's request of July 9, 2021, for public comments on the current state of patent eligibility jurisprudence, the USPTO received 141 different written submissions, including 15 anonymous submissions.¹²⁹ The comments, which provide a variety of different views from a diverse range of stakeholders, include the following:

- 43 comments from associations, nonprofit entities, and other advocacy groups;
- 21 comments from companies and businesses;
- 16 comments from law firms and practitioners;
- 9 comments from academics, healthcare institutions, and universities; and
- 34 comments from individuals, including inventors and patent applicants, and other entities that did not fit one of the aforementioned categories.

The written remarks made clear that the jurisprudence had a substantial impact on the scope of patent eligible subject matter. Commenters, however, disagreed as to whether the impacts of the jurisprudence on businesses, the economy, and innovation were positive or negative. This section summarizes arguments, observations, and evidence submitted by members of the public addressing the impacts of the evolving subject matter eligibility jurisprudence.

In addition, this section highlights effects on technology-specific sectors, specifically life sciences and computer-related technologies. In preparing this summary report, the USPTO carefully considered the written comments to ensure that all views were adequately represented. The USPTO attempted to reference in the citations, to the extent possible, members of the public that addressed a particular topic.

A. Views on the current state of patent eligibility law

Although stakeholders expressed differing views on the impacts of the current jurisprudence for determining patent subject matter eligibility, respondents nonetheless agreed that whatever the standard for determining whether an invention is eligible for patenting, it should be clear, predictable, and consistently applied by the USPTO and the courts.¹³⁰ A key point of contention, however, was whether the current state of the law achieves these objectives.

1. Current law is sufficiently clear

Numerous respondents claimed that the current law is sufficiently clear, predictable, and consistent.¹³¹ Some pointed to the fact that the Federal Circuit affirms ineligibility decisions by district courts and the USPTO at a high

¹²⁹ See appendix C.

¹³⁰ See Business Law Section of the Florida Bar Intellectual Property Committee (hereinafter Business Law Section of the Florida Bar) at 3 (“[W]hether the clarification [of current law] comes by broadening the patent eligible subject matter or narrowing it, is not as important as is *clarifying it* and making the application of the rules more uniform.”); Coalition for the Life Sciences, second submission (hereinafter CLS #2) at 1 (stated that “existing prohibitions against patenting laws of nature, products of nature, and abstract ideas are essential for fostering scientific research and innovation, and the Supreme Court’s recent decisions in this area have demonstrably clarified essential boundaries on subject matter eligibility”); Dell Technologies at 5–6 (indicated that “[m]odern case law sets forth a clear and predictable set of patent-eligibility tests for software-based inventions,” but goes on to state that “[t]o the extent some believe the current case [law] remains unpredictable, Dell welcomes efforts to identify legislative or administrative solutions, provided that the critical benefits of section 101 are not lost in the process”); IBM at 2 (advocated for “a more principled and certain eligibility standard that allows innovators to obtain and benefit from patents without enabling abusive behaviors”); Johnson & Johnson at 2 (“A predictable patent system encourages pharmaceutical companies to take on the significant risks associated with solving the world’s greatest healthcare challenges.”). See also Computer & Communications Industry Association (hereinafter CCLIA) at 1; Google at 8; Juniper Networks at 5.

¹³¹ See generally American Civil Liberties Union (hereinafter ACLU); High Tech Inventors Alliance (hereinafter HTIA); Intellectual Property Owners Association (hereinafter IPO); Software & Information Industry Association (hereinafter SIIA).

rate,¹³² with one civil liberties organization concluding that “district courts, the PTAB, and patent examiners clearly and consistently apply Supreme Court jurisprudence.”¹³³ Other commenters pointed to findings in the USPTO report “Adjusting to *Alice*,”¹³⁴ which shows that applications are rejected for lack of eligibility at generally the same rate after the Supreme Court’s decision in *Alice* as prior to it.¹³⁵ One high-tech advocacy group further noted that an artificial intelligence system had been successfully trained to predict with reasonable accuracy whether patent claims were eligible under *Alice*, which refutes “[c]laims about the impossibility of predicting such outcomes.”¹³⁶

In addition to providing clarity and stability, many respondents claimed the current law also represents a general improvement to the patent system.¹³⁷ One computer industry association, for instance, stated that, “[t]he current state of patentable subject matter jurisprudence is working well and should be retained.”¹³⁸ Another industry association said its members “believe that current 101 jurisprudence has resulted in a healthier patent system.”¹³⁹ A computer company likewise asserted that “the state of the law [is] amply predictable” and noted that it had not encountered a situation “where the viability of a commercial transaction [had] been significantly hampered by uncertainty” caused by the current law.¹⁴⁰

Other groups focused on innovation benefits. A life sciences organization claimed that the Supreme Court’s decisions are “essential for fostering scientific research and innovation” and “have demonstrably clarified essential boundaries on subject matter eligibility.”¹⁴¹ A public interest group praised the Supreme Court’s decisions, stating that the “[c]urrent patent eligibility jurisprudence is faithful to the Constitution, the Patent Act, and the public’s interest in a patent system that promotes more innovation than it deters.”¹⁴²

Other commenters expressed support for the current law as improving the quality of patents and the level of information they convey to the public. One computer industry association claimed that the current jurisprudence “has resulted in patent applicants improving the quality of their patents, better defining their inventions.”¹⁴³ A high-tech company asserted that the Supreme Court’s eligibility test “act[s] as a ‘forcing function’ to bring about greater detail and clarity in patent applications, thereby resulting in more useful information being shared with the public, and a clearer definition of the rights being claimed.”¹⁴⁴

A few commenters took issue with the questions the USPTO posed in the Notices, claiming they were biased against the current state of the law.¹⁴⁵ For example, one life sciences organization

132 ACLU at 1–2 (referencing Robert Sachs, *Alice: Benevolent Despot or Tyrant? Analyzing Five Years of Case Law Since Alice v. CLS Bank: Part I*, IPWATCHDOG (Aug. 29, 2019), <https://www.ipwatchdog.com/2019/08/29/alice-benevolent-despot-or-tyrant-analyzing-five-years-of-case-law-since-alice-v-clsbank-part-i/id=112722/>); see also Richard Gruner at 17; IPO at 4.

133 ACLU at 2.

134 TOOLE & PAIROLERO, *supra* note 103, at 6.

135 See HTIA at 7; IPO at 4; SIIA at 5.

136 HTIA at 8.

137 See United for Patent Reform (hereinafter UFPR) at 2 (“Eligibility law, when properly enforced as in recent years, plays a critical role in keeping patents within their proper lanes and protecting American businesses and consumers from unjustified and abusive litigation.”). See also CCIA at 8; Dell Technologies at 2; Engine at 25; Google at 7–8. See generally Electronic Frontier Foundation (hereinafter EFF); HTIA; Timothy O’Leary; Public Interest Patent Law Institute (hereinafter PIPLI); SIIA; Ted Wang; Wikimedia Foundation (hereinafter Wikimedia).

138 CCIA at 8.

139 SIIA at 6.

140 Dell Technologies at 2.

141 Coalition for the Life Sciences, first submission (hereinafter CLS #1) at 1; CLS #2 at 1.

142 PIPLI at 1.

143 CCIA at 1.

144 Google at 8.

145 See generally ACLU; CLS #1; CLS #2; Google; Robert Rutkowski; UFPR.

asserted “that both the [Federal Register Notice] and proposed study ... appear to presuppose that [the current state of the law] lacks clarity and consistent application and that this lack of clarity is harming innovation. This is not the case.”¹⁴⁶ A life sciences company criticized the questions as being “posed with the underlying assumption that recent jurisprudence has resulted in negative outcomes for industry, competitive disadvantages for the United States, and consequences for patient care,” which the company said is inaccurate.¹⁴⁷

2. Current law is unclear and unpredictable

In contrast, many other commenters expressed their concerns that the current law on eligibility is unclear and unpredictable.¹⁴⁸ Those commenters primarily focused on court decisions and USPTO guidance.

a. Court decisions

Many respondents argued that the current jurisprudence is fundamentally flawed.¹⁴⁹ One law professor stated that “patent eligibility jurisprudence continues to remain fundamentally unsettled” and the “doctrine is marked by unpredictability and indeterminacy.”¹⁵⁰ Other commenters asserted that the test is unworkable because it relies on subjective reasoning.¹⁵¹ One computer company, for instance, said the “current jurisprudence asks courts to make a

subjective judgment of whether developments are just *too* abstract, with the only guideposts being prior judicial decisions that themselves were fact-specific, subjective judgments.”¹⁵² An organization representing research-based technology companies added that “[g]iven that all patent claims at some level rely upon the judicial exceptions, the determination of which claims are ‘directed to’ a judicial exception—and which claims are not—is a very difficult, subjective, and frankly often arbitrary, determination.”¹⁵³

Other commenters referred to statements and outcomes from the courts as evidence that the current law lacks clarity and predictability.¹⁵⁴ One technology transfer association, for instance, cited public remarks from Federal Circuit Chief Judge Kimberly Moore recognizing that the Federal Circuit judges are “‘at a loss’ as to how to apply section 101.”¹⁵⁵ The association further observed that other judges, notably Judge Todd Hughes, have “‘begged the Supreme Court and Congress to provide more clarity, pointing out that ‘uncertainty’ is a major problem.”¹⁵⁶ An IP advisory firm also cited critical remarks by other Federal Circuit judges noting that the current state of the law is “incoherent” and “makes it near impossible to know with any certainty whether the invention is or is not patent eligible” (Judge Jay Plager); the abstract idea test is “indeterminate and often leads

¹⁴⁶ CLS #2 at 1.

¹⁴⁷ *Invitae* at 1.

¹⁴⁸ See IBM at 2 (advocating for “a more principled and certain eligibility standard that allows innovators to obtain and benefit from patents without enabling abusive behaviors”); Johnson & Johnson at 2 (“[A] predictable patent system encourages pharmaceutical companies to take on the significant risks associated with solving the world’s greatest healthcare challenges.”). See generally ACT|The App Association (hereinafter App Association); Alliance for U.S. Startups & Inventors for Jobs (hereinafter USIJ); American Intellectual Property Law Association (hereinafter AIPLA); Association of Amicus Counsel (hereinafter AAC); Business Law Section of the Florida Bar; Dominion Harbor Group; Richard Gruner; IBM; Innovation Alliance; Adam Mossoff; New York Intellectual Property Law Association (hereinafter NYIPLA); Mark Tornetta; TrackTime.

¹⁴⁹ See generally AAC; AIPLA; App Association; Business Law Section of the Florida Bar; Dominion Harbor Group; Richard Gruner; IBM; Innovation Alliance; Adam Mossoff; NYIPLA; Mark Tornetta; TrackTime; USIJ.

¹⁵⁰ Adam Mossoff at 3.

¹⁵¹ See generally AAC; AIPLA; App Association; Business Law Section of the Florida Bar; Dominion Harbor Group; Richard Gruner; IBM; Innovation Alliance; Adam Mossoff; NYIPLA; Mark Tornetta; TrackTime; USIJ.

¹⁵² IBM at 4 (“Courts have never adequately defined what is meant by ‘abstract’ (due to the difficulty of the task). Without such a foundation, determining if a claim is something more than the (undefined) abstract idea is even more subjective.”). See also Adam Mossoff at 5.

¹⁵³ Innovation Alliance at 2.

¹⁵⁴ See AAC at 17–18; Association of University Technology Managers (hereinafter AUTM) at 2; Business Law Section of the Florida Bar at 6; Conservatives for Property Rights (hereinafter CPR) at 1; Dominion Harbor Group at 2–4; Richard Gruner at 7; IGT at 8; Novartis at 3; TrackTime at 3..

¹⁵⁵ AUTM at 2.

¹⁵⁶ *Id.*

to arbitrary results” (Judge Richard Linn); the current law is “inconsisten[t] and unpredictab[le]” and has “destabilized technologic development in ... all fields” (Judge Pauline Newman).¹⁵⁷ The same commenter also suggested that the large variance among district courts in rates of granting of motions to dismiss for ineligibility is further evidence of uncertainty in the law.¹⁵⁸

Finally, numerous commenters raised concerns about the uncertain trajectory of the current jurisprudence, which, in view of recent cases such as *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*¹⁵⁹ and *Yu v. Apple Inc.*,¹⁶⁰ appears to be threatening the eligibility of basic mechanical technologies that had heretofore been unquestioned.¹⁶¹ As stated by one patent law association, “[i]n light of the recent holdings in *American Axle* and *Yu*, there is apparently no technical field in which an applicant for a patent can have reasonable certainty that their claimed invention will be deemed concrete and not abstract.”¹⁶² This sentiment was echoed by a computer company, which observed that “a logical extension of the current patent eligibility jurisprudence, [has] even led courts to find inventions lacking eligible subject matter in cases involving mechanical devices and processes such as an electric car charger, a garage door opener, a method for tuning driveshaft liners, and most

recently the design of a digital camera.”¹⁶³ These cases were also referenced by a golf equipment manufacturer as “signs that the whirlwind of § 101 is beginning to encroach on mechanical systems and processes where subject matter eligibility generally had not been in question.”¹⁶⁴

b. USPTO guidance

Although several commenters expressed appreciation to the USPTO for issuing and updating guidelines and examples to assist USPTO personnel and applicants in applying the current jurisprudence, many remarked that the effort did not produce the desired consistency or predictability in determining patentable subject matter.¹⁶⁵ Commenters cited two main reasons for this perceived failure.

First, various commenters noted that however helpful the USPTO guidance had been to applicants and examiners, its “overall impact ha[d] been largely negated because it is not binding on the courts.”¹⁶⁶ One organization representing IP owners further explained that “[b]ecause the examination guidance is not binding on the federal courts, patents granted by the USPTO under the revised guidance remain open to challenge and invalidation in the courts.”¹⁶⁷ Likewise, a coalition of research-based technology companies remarked that even when “a patent

157 *Dominion Harbor Group* at 2–3 (quoting *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1353–54 (Fed. Cir. 2018) (Plager, J., concurring in part and dissenting in part); *Smart Systems Innovations v. Chicago Transit Auth.*, 873 F.3d 1364, 1377 (Fed. Cir. 2017) (Linn, J., dissenting in part and concurring in part); *Yu v. Apple Inc.*, 1 F.4th 1040, 1049 (Fed. Cir. 2021) (Newman, J., dissenting)).

158 *Dominion Harbor Group* at 4.

159 *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 966 F.3d 1347 (Fed. Cir. 2020).

160 *Yu v. Apple Inc.*, 1 F.4th 1040, 1043 (Fed. Cir. 2021).

161 *See* *Acushnet Company* at 3; *Boston Patent Law Association* (hereinafter *BPLA*) at 3; *IBM* at 5; *IPO* at 5; *Adam Mossoff* at 2; *Lori Pressman* at 5.

162 *BPLA* at 3.

163 *IBM* at 5.

164 *Acushnet Company* at 3.

165 *See* *Holby Abern* at 1; *Acushnet Company* at 2; *AIPLA* at 3; *Anonymous #13* at 2; *BPLA* at 8–9; *Business Law Section of the Florida Bar* at 6; *Ericsson* at 3; *Richard Gruner* at 12; *IBM* at 3; *IGT* at 2; *Innovation Alliance* at 4; *IPO* at 4; *Schwegman Lundberg & Woessner* at 3; *Dana Stangel* at 2.

166 *Innovation Alliance* at 4. *See also* *AIPLA* at 3 (“While AIPLA greatly appreciates the efforts of the USPTO to provide guidance to examiners and applicants to navigate the ambiguities of section 101 jurisprudence, including its 2019 revised guidance, this guidance cannot solve the problems caused by the *Alice-Mayo* test.”); *AUTM* at 5 (“The problem we run into in the US, as compared to the other major offices, however, is that the courts here flat out ignore or are downright hostile to the [2019 Revised Patent Subject Matter Eligibility Guidance].”); *Peter Cheng* at 3; *Eagle Forum Education & Legal Defense Fund* (hereinafter *Eagle Forum*) at 2; *Ericsson* at 3; *IBM* at 3; *IGT* at 2; *IPO* at 4; *Adam Mossoff* at 7; *Novartis* at 7; *Schwegman Lundberg & Woessner* at 3.

167 *IPO* at 4. *See also* *Ericsson* at 3 (“While the evolving USPTO guidance to examiners ... has proved very helpful, the unpredictability of eligibility challenges in litigation remains.”).

applicant follows the direction provided by the USPTO in applying for and obtaining a patent, significant uncertainty remains where the courts may take a materially different view” of the claimed invention’s eligibility.¹⁶⁸

Second, other commenters said that the USPTO’s own examiners were not applying the guidance consistently.¹⁶⁹ One patent practitioner observed that despite the USPTO guidance, “different sets of examiners (even within the same art unit [that] report to the same [supervisory patent examiner]) have vastly different viewpoints on the current state of the law.”¹⁷⁰ Another commenter suggested that inconsistent examination approaches “mak[e] the assignment of a patent application for review by one technology art unit ... versus another a significant determinant of patent review outcomes.”¹⁷¹ Likewise, a law firm pointed out that “the amount of prosecution difficulty faced by [its] clients appears to depend more on the art unit to which the patent application is assigned than recent developments in the law.”¹⁷²

In addition, a few commenters expressed concerns that the USPTO guidance exceeded the reach of the Supreme Court’s precedent.¹⁷³ One interest group suggested that “[t]here is ... evidence that the revised guidance is leading to the allowance of patent claims that are ineligible under *Alice*.”¹⁷⁴ One professor argued that the USPTO guidance

has resulted in thousands of improperly issued patents that “can now only be corrected by very expensive post-grant reviews (because there is no legislated third-party right to challenge the grant of a patent directly by appeal on the administrative record).”¹⁷⁵ Another commenter added that “PTO also risks compromising the credibility of the U.S. patent system and the foundations of a patent’s entitlement to a presumption of validity.”¹⁷⁶

B. Impacts on innovation, investment, and competition

The impact of 101 jurisprudence on investment and innovation is of particular importance and policy interest. In response to the USPTO’s request, commenters generally agreed that a healthy, robust patent system promotes economic development through incentivizing innovation and investment and fostering competition. However, views differed considerably on whether and how the current state of the law on eligibility is furthering those objectives.

1. Impacts on innovation

Numerous commenters expressed the view that the current jurisprudence is beneficial to innovation and technological development.¹⁷⁷ A civil liberties organization, for example, stated that the exclusions from patentability recognized

168 Innovation Alliance at 4; *see also* Askeladden at 8–9 (citing seven cases and concluding “that the courts will continue to follow their own jurisprudence rather than the [USPTO] guidance when interpreting and applying the law of subject matter eligibility”).

169 *See* Holby Abern at 1; Acushnet Company at 2; Anonymous #13 at 2; BPLA at 8–9; Business Law Section of the Florida Bar at 6; Richard Gruner at 12; IGT at 2; Schwegman Lundberg & Woessner at 3.

170 Holby Abern at 1. *See also* Acushnet Company at 2; Anonymous #13 at 2 (“Different Group Art Units, as well as examiners within an individual GAU, have vastly different interpretations as to what technology is properly eligible under the law.”); BPLA at 8–9; Business Law Section of the Florida Bar at 6; IBM at 3 (prosecution often requires “extensive dialogue with examiners ... which can resemble a philosophical debate. Even patent examiners have a difficult time applying the eligibility jurisprudence, and this can result in variability between examiners”); IGT at 2.

171 Richard Gruner at 13.

172 Schwegman Lundberg & Woessner at 3.

173 *See* Askeladden at 3; PIPLI at 8 (“*Alice* remains the Supreme Court’s most recent patent eligibility decision. Despite the lack of intervening Supreme Court precedent, the USPTO abandoned the 2014 IEG and July 2015 update to adopt entirely new patent eligibility guidance in 2019. When the USPTO issued its new guidance, public commenters objected that the changes were inconsistent with *Alice* and thus contrary to governing law.”); Joshua Sarnoff at 4.

174 PIPLI at 9.

175 Joshua Sarnoff at 4.

176 Askeladden at 3.

177 *See generally* ACLU; CCIA; CLS #1; CLS #2; Dell Technologies; Developers Alliance; EFF; Engine; HTIA; Internet Association; Invitae; Juniper Networks; Laboratory for Clinical Genomics and Advanced Technology at Dartmouth-Hitchcock Medical Center (hereinafter Dartmouth-Hitchcock Medical Center); Ted Wang; Wikimedia.

under current law “play a crucial role in fostering technological invention that benefits the public interest.”¹⁷⁸ Similarly, a nonprofit organization that supports collaborative knowledge projects added, “[E]xpanding patent-eligibility to include the basic tools of technological work would impede innovation more than it would promote it,” and cited as an example the free access to certain genomic information researchers have enjoyed in the fight against COVID-19.¹⁷⁹ One investor further asserted that allowing patents to be obtained and enforced on “basic ideas,” particularly by nonpracticing entities (NPEs),¹⁸⁰ causes otherwise productive businesses to spend limited money defending against infringement suits rather than on innovation and business growth.¹⁸¹

Many other commenters, however, viewed the current jurisprudence as detrimental to innovation, especially in certain technologies, notably life sciences.¹⁸² One national bar association stated that current law “undermines the U.S. patent system.”¹⁸³ Another national IP bar association agreed, adding that the recent jurisprudence also undermines U.S. leadership in global innovation and “will have serious negative implications for our economy in the

future.”¹⁸⁴ An organization representing the biotechnology industry pronounced that the industry’s “ability to develop and deliver precision medicine, pharmaceutical treatments, and diagnostics to patients has been jeopardized” by the current jurisprudence.¹⁸⁵ This view was shared by several other commenters focused on life sciences technologies.¹⁸⁶ Other commenters cited a decrease in patent applications filed in certain technologies or a lowering of the United States’ ranking as a global innovation leader as evidence of the negative impact of the current jurisprudence on innovation.¹⁸⁷

Still, other commenters suggested that it is not possible to determine the impact that the current jurisprudence has had on innovation. Academics, for example, argued that “[a]nswering the question of whether limits on patent eligibility increase or decrease innovation requires specifying a counterfactual of how innovation would have evolved in the absence of these caselaw changes.”¹⁸⁸ They explained that “[a]necdotes and descriptive data are unable to provide such a counterfactual, and related empirical studies that do develop a rigorous counterfactual framework do not purport to answer the broad policy question of whether

178 ACLU at 6.

179 Wikimedia at 2.

180 Nonpracticing entities (NPEs) are defined as entities that do not make or sell products that embody their patented technologies. Some NPEs are also labeled patent assertion entities (PAEs), which are generally defined as entities that acquire patents for the purpose of asserting them against alleged infringers.

181 Ted Wang at 1.

182 See AIPLA at 12; American Bar Association Intellectual Property Law Section (hereinafter ABA-IPL) at 2; IPO at 9; Johnson & Johnson at 2; John Storella at 1. See generally Biotechnology Innovation Organization (hereinafter BIO); Genentech; Novartis; Pharmaceutical Research and Manufacturers of America (hereinafter PhRMA).

183 ABA-IPL at 3.

184 AIPLA at 12.

185 BIO at 2.

186 See IPO at 9 (“It is impossible to quantify the cost to society if medicines cannot be developed because the current section 101 jurisprudence is too restrictive.”); Johnson & Johnson at 2 (“A predictable patent system encourages pharmaceutical companies to take on the significant risks associated with solving the world’s greatest healthcare challenges. Unfortunately, the current state of patent eligibility law in the United States is anything but predictable.”); John Storella at 1 (“Since the Supreme Court’s [*Mayo*] decision ... it has been increasingly difficult for companies to obtain U.S. patents on diagnostic tests. This difficulty has had a negative impact on the development and commercialization of such tests.”).

187 See CPR at 3; Eagle Forum at 3; Adam Mossoff at 9. Observing that the United States had fallen from the top 10 in global innovation economies for the first time, these three commenters relied on Michelle Jamrisko, Wei Lu & Alexandre Tanzi, *South Korea Leads World in Innovation as US Exits Top Ten*, BLOOMBERG (Feb. 3, 2021), <https://www.bloomberg.com/news/articles/2021-02-03/south-korea-leads-world-in-innovation-u-s-drops-out-of-top-10>. See also Chad Rafetto at 29 (noting a decline in applications filed in bioinformatics, business methods, and software technologies).

188 Maya Durvasula, Lisa Larrimore Ouellette & Heidi Williams at 1.

limits on patent eligibility increase or decrease innovation.”¹⁸⁹

2. Impacts on investment

Many commenters either explicitly or implicitly acknowledged a link between innovation and investment, which can be summarized as follows: innovation requires investment, which, in turn, requires certainty and predictability in patent protection and enforcement, without which capital will not be risked, thus leading to decreased innovation.¹⁹⁰ The views diverged largely over the question of whether and how the current jurisprudence is affecting investment.

Numerous commenters were of the view that the current jurisprudence is having little or no effect on investment, at least in certain computer-related technologies.¹⁹¹ One computer company, for instance, stated that “investment in startups is booming,” and that “[f]ar from being discouraged [by the current jurisprudence], investors have dedicated ever-larger pools of funds to startups over recent years.”¹⁹² The same commenter added that “in Q2 of calendar year 2021, funding for artificial intelligence firms reached a record high of \$20 billion, up from \$9 billion in the same quarter two years earlier,” with the highest number

of such deals being for applications in the health care field.¹⁹³ Another high-tech company noted that its investment and innovation in some of these same new and emerging technologies has actually continued an upward trend since the Supreme Court’s *Alice* decision.¹⁹⁴

Other commenters contended that the current jurisprudence is having a negative effect on investment, particularly in the area of life sciences.¹⁹⁵ Several commenters noted that the development of biologics and pharmaceuticals is both high risk and high cost, requiring \$2 billion or more and 8–12 years of clinical testing to bring a single drug to market,¹⁹⁶ and approximately \$100 million and 7–10 years of testing to develop new diagnostic products.¹⁹⁷ In the view of many of these commenters, the uncertainty in the current jurisprudence is significantly diminishing present investment in these areas and disincentivizing future investment and innovation because of the increasingly uncertain prospects of obtaining and enforcing patent rights on these technologies.¹⁹⁸ The concern shared by several commenters is that, if left uncorrected, the current jurisprudence could jeopardize the “industry’s ability to develop and deliver precision medicine, pharmaceutical treatments, and diagnostics to patients.”¹⁹⁹

189 *Id.*

190 See ABA-IPL at 3; AIPLA at 12 (“[T]he erosion of the scope of what is considered patent eligible (and the attendant uncertainty as to boundaries of patent eligibility) has discouraged investment in certain technologies by investors as well as companies (big and small).”; AUTM at 5; BIO at 2 (“Nothing could be worse for investment in innovation than changing the rules of patentability after ... large investments have been made in reliance on properly examined and issued patents.”); BPLA at 2; David Crowther at 1 (“[W]ith the current uncertainty surrounding the patent-eligibility issue, many investors simply refuse to risk their capital on such uncertain outcomes. And many inventors with world-improving ideas, are impeded.”); Genentech at 4; IGT at 5; Innovation Alliance at 3; IPO at 6; Johnson & Johnson at 4; Adam Mossoff at 2 (“[I]n a global economy in which R&D investments and the venture capital financing that are the lifeblood of innovation can easily move from one country to another in search of more reliable legal security in the fruits of inventive labors.”); Novartis at 2; Chad Rafetto at 31; Joshua Sarnoff at Attachment B (Testimony of Judge Paul R. Michel (retired)); The Coalition for 21st Century Patent Reform (hereinafter 21C) at 3; USIJ at 2; Wisconsin Alumni Research Foundation (hereinafter WARF) at 2–3.

191 See CCIA at 2; Dell Technologies at 3; Engine at 7–10, 13–17; Google at 6; HTIA at 5; Internet Association at 15; SIIA at 2–4.

192 Dell Technologies at 7.

193 *Id.*

194 See Google at 6.

195 See BIO at 2; BPLA at 3; Genentech at 2–3; IPO at 9; Johnson & Johnson at 4; John Storella at 1; 21C at 3–4. See generally Novartis; PhRMA.

196 BIO at 2 (providing estimated costs and testing time, and adding: “Research and development within the biotechnology industry is time and capital intensive. The likelihood of failure is significantly higher than of success.”); see also Genentech at 2–3; Johnson & Johnson at 4.

197 BIO at 3.

198 See, e.g., *id.* at 2. See also BPLA at 3; Johnson & Johnson at 2; John Storella at 1; 21C at 3–4.

199 BIO at 2, 3 (asserting that “[w]ithout the ability to protect ... diagnostic tools once introduced into the market, large sustained investment in this area may not be maintained and, consequently, innovation will diminish”). See also Novartis at 2–3; PhRMA at 3; John Storella at 1 (“Without patent protection, these [diagnostics] companies are more likely to fail, and any investment in them to be wasted. The long-term impact will be a diminished number of new diagnostic tests on the market.”); WARF at 5 (“The current state of patent eligibility, however, requires an additional step, such as a manipulation of some sort or the addition of a second chemical, to render the underlying invention patentable. This significantly limits the scope of invention and

According to one association representing IP owners, the combination of legal uncertainty leading to diminished investment in this area “is likely to have a long-term impact on whether new technologies are developed at all, leaving the public without access to new and important medicines, treatments, and diagnostics at any price.”²⁰⁰

3. Impacts on competition

Many commenters, though representing diverse views, focused on the effects of the current jurisprudence on competition, with a particular spotlight on startups and small and medium-sized enterprises (SMEs).²⁰¹ Commenters indicated that throughout U.S. history, startups and SMEs have been “disproportionately responsible for ‘breakthrough’ inventions”²⁰² and have been viewed as especially sensitive to changes in the legal and investment climate and thus something of a bellwether for healthy competition in innovation.²⁰³

Several commenters asserted that the current jurisprudence promotes competition in various

ways.²⁰⁴ One high-tech company suggested that the current law on eligibility has “democratized” AI by allowing greater participation in the space by a broader range of actors, including SMEs.²⁰⁵ Organizations active in software and internet technologies argued that the current jurisprudence is pro-competitive in that it protects less-resourced entities from abusive litigation practices or assertions of “overbroad” patents covering little more than abstract ideas, defending against which would divert limited resources away from enterprise and industry growth.²⁰⁶

Other commenters, however, argued that the current jurisprudence is actually stifling competition by making it harder for startups and SMEs to attract much-needed investment, which has led to increased concentration of key technologies in the hands of a few large, well-resourced incumbents.²⁰⁷ One telecommunications company stated that a “pro-competitive feature of patent rights is that they often serve as a check on significant market power held by incumbents. A strong patent system allows innovators of all sizes to compete.”²⁰⁸ An organization that represents

hinders the potential for commercial development.”).

200 IPO at 9.

201 See USIJ at 1. See also Centre for Law, Medicine and Life Sciences, University of Cambridge (hereinafter University of Cambridge) at 13; CCIA at 1–2; Developers Alliance at 1; Ericsson at 4–5; Google at 6–7; Innovation Alliance at 5; Robert Osann, Jr. at 2–3; Todd Van Thomme at 1; 21C at 3–4.

202 USIJ at 1.

203 See University of Cambridge at 13 (relying on Nature Biotechnology, 36, 1146–1149 (2018), they stated that “[S]trong, reliable patents are particularly important for SMEs. These firms are important providers of disruptive innovation (e.g., new ventures, substitute and new entrant products), which often require a period of market protection to challenge incumbents.”).

204 See CCIA at 3; Developers Alliance at 1; Engine at 2; Google at 6–7.

205 Google at 6–7.

206 See CCIA at 2 (“The current jurisprudence works. Litigation, especially in the arena of nonpracticing entities asserting broad and vague software patents, has been generally reduced in cost and frequency.”); Developers Alliance at 1 (The current jurisprudence “provide[s] a critical floor that protects startups from over-broad lawsuits on account of abusive patent assertion entities. ... Removing or revising these laws could put many tech startups out of business, or disincentivize growth in an otherwise flourishing industry by again exposing our industry to patent trolls and nuisance lawsuits.”); Engine at 2 (“[C]urrent patent eligibility jurisprudence promotes startup innovation and competition by preventing patents that cover abstract ideas ... patents that would improperly stand in the way of broad swaths of standard business activities or innovative new technologies.”).

207 See Ericsson at 4–5; Innovation Alliance at 5 (citing Mark A. Lemley & Samantha Zyontz, *Does Alice Target Patent Trolls?*, 18 J. EMPIRICAL LEGAL STUD. 47 (2021)) (“These risks are all the harder to justify for smaller inventors, with recent studies showing that post-*Alice*, individual inventors and inventor-started companies are the most likely to lose their patents on the basis of patent subject matter eligibility.”); Robert Osann, Jr., at 2–3; 21C at 3–4 (“21C members have traditionally partnered with startups after these have reached a certain milestone in the development of promising patent-protected technology. But uncertainty and unpredictability in section 101 jurisprudence disincentivizes these startups from pursuing technologies for which eligibility is an obstacle to patentability.”); USIJ at 3 (“Thirty-three decisions by the Court over the last 16 years have left an indelible stamp on the U.S. patent system that will last for decades unless corrected by Congress. The aggregate impact of these rulings ... has made it far more difficult—indeed, effectively impossible in some cases—for small companies and inventors to enforce their patent rights against larger incumbents.”); Todd Van Thomme at 1 (“The current judicially created uncertainty resulting from the Supreme Court’s change in subject matter jurisprudence unduly restricts protections especially for small companies, start-ups and single inventors. These entities can’t afford to pay the tremendous costs in legal fees and expenses that result from the unequal and uncertain landscape of the law.”); STT WebOS and TS Patents at 1.

208 Ericsson at 4.

startups and companies added that the current state of the law on eligibility has undermined investment in startups, particularly in digital technologies, to such an extent that “a number of the large companies [in this space] today face little or no competition,” and “[f]or anyone seeking to understand just how the major players in digital technology markets have managed to become monopolies and near-monopolies in their respective spaces, it would be a good idea to examine the impact of this neutering of the U.S. patent system.”²⁰⁹

Different commenters pointed out that similar concerns exist in other technologies. For example, an organization representing the biotechnology industry referenced recent business analyses showing that the field of in vitro diagnostics is becoming increasingly concentrated in the hands of a few large key players and marked by lackluster investment.²¹⁰ Relatedly, an organization representing American corporations added that “[s]uch consolidation, spurred in part by patent eligibility jurisprudence, will likely limit competition in the diagnostic market. As such, in the areas of precision medicine and diagnostics, startups and small companies will find it increasingly difficult to engage business partners, which will ultimately result in lost opportunities to advance much needed care for patients.”²¹¹ In addition, one technology transfer association explained: “Without enforceable patents as a source of sustainable competitive advantage, few companies, particularly in the life sciences,

will make the necessary multi-million dollar investments into the development and testing of new products, particularly medical treatments. In other words, no patents mean no licenses, which means no startups, which means no further development, and little or no benefit to the economy or the public. It’s as simple as that.”²¹²

C. Impacts on legal costs

A considerable number of commenters described the impacts of the current jurisprudence on legal costs. Several suggested that the current jurisprudence is beneficial in that it helps curb abusive litigation strategies from NPEs and thus reduces overall legal costs.²¹³ Many commenters, however, including respondents otherwise in favor of the current state of the law, noted that it increases legal costs associated with prosecuting patent applications, sometimes significantly.²¹⁴ Others complained of higher post-issuance litigation costs as well as increased expenditures in developing legal strategies.²¹⁵

1. Reduced litigation costs

Various commenters suggested that the state of the law on eligibility before the Supreme Court’s *Alice* decision encouraged overly broad patents that essentially led to the patenting of abstract ideas.²¹⁶ In their view, this gave rise to the growth in lawsuits by NPEs or patent assertion entities coupled with skyrocketing legal costs associated with defending against such suits.²¹⁷ For example, an advocacy group for startup

209 USIJ at 3–4.

210 BIO at 3 (noting also that between 2016 and 2019, the in vitro diagnostics industry received only about 3% of all biomedical venture dollars.).

211 21C at 4.

212 AUTM at 1–2.

213 See App Association at 2–3; CCIA at 2; Byron Deeter at 1; Developers Alliance at 1; Engine at 20; David Hornik at 1; Internet Association at 13; UFPR at 2.

214 See Acushnet Company at 2; AIPLA at 10–11; Anonymous #13 at 4; BPLA at 4; Business Law Section of the Florida Bar at 3; Ericsson at 2; Nicholas Fratalone at 1; Google at 4; Intellectual Property Law Section of the State Bar of Nevada (Nevada IP Section) at 2; William Morriss at 1; NYIPLA at 5; Rio Tinto at 5; Schwegman Lundberg & Woessner at 2; Steve Seawall at 3; University of Cambridge at 21.

215 See Nevada IP Section at 4; Novartis at 10; TrackTime at 6–7; 21C at 3.

216 See ACLU at 6–7; Acushnet Company at 2; App Association at 2–3; CCIA at 2; Engine at 1; David Hornik at 1; NYIPLA at 3; SIIA at 1–2; Martin Snyder at 9; UFPR at 2.

217 See App Association at 2–3; CCIA at 2; Engine at 20; IPO at 5; NYIPLA at 9; SIIA at 1–2.

companies estimated the median cost of defending against an infringement suit by such entities to be \$1.7 million, which can be “crippling” to a small business and can force the payment of a nuisance settlement “regardless of the merits of the case.”²¹⁸ A high-tech association further noted that this behavior tended to “greatly limit[]” progress in certain areas, such as web application development.²¹⁹ In addition, one venture capitalist contended that the “current law does an excellent job of creating space for innovation while reducing money wasted on legal fees” by “enabl[ing] entrepreneurs, innovators, and start-ups to more efficiently deploy capital—those companies can spend less on legal fees and more on productive activities like research and development and product marketing.”²²⁰

2. Increased costs of obtaining patents

Several commenters complained that the current jurisprudence significantly increases the costs of obtaining a patent from the USPTO.²²¹ Multiple bar associations noted substantial increases in prosecution costs, with several attributing the increase to protracted cycles of USPTO examiner office actions and responses to resolve questions of eligibility.²²² One law firm reported that the increased uncertainty caused by the current jurisprudence forces some clients to make a

difficult choice to either abandon an application or spend substantially more money without any certainty of obtaining a patent.²²³ Independent inventors provided anecdotal evidence of substantially increased costs, complexity, and uncertainty.²²⁴ A university study suggested that the additional prosecution complexity resulting from the current jurisprudence may have a disproportionate adverse effect on startups and small businesses that lack the resources to engage in multiple rounds of prosecution.²²⁵ Even one commenter that otherwise favors the current jurisprudence acknowledged it requires an increased dedication of resources to navigate.²²⁶

Other commenters suggested that the increased prosecution costs and the uncertainty associated with the current jurisprudence are having serious follow-on consequences for U.S.-based innovation.²²⁷ One commenter stated that the situation is actively discouraging its clients from even filing applications in the United States in certain affected technologies, such as life sciences and software.²²⁸ Three multinational companies that are substantial users of the patent system noted that the current state of the law not only increased prosecution costs but also made obtaining a global portfolio of similar patent rights in different countries significantly

218 UFPR at 2 (also noting that NPEs “bring 40% of their suits against small and medium-sized companies”).

219 App Association at 2.

220 David Hornik at 1. *See also* Byron Deeter at 1.

221 *See* Acushnet Company at 2; AIPLA at 10–11; Anonymous #13 at 1; BPLA at 4; Business Law Section of the Florida Bar at 3; Ericsson at 2; Nicholas Frattalone at 1; IBM at 2–3; Nevada IP Section at 2; NYIPLA at 5; Rio Tinto at 5; Schwegman Lundberg & Woessner at 2; Steve Seawall at 3; University of Cambridge at 20–21.

222 *See* AIPLA at 10–11; BPLA at 4 (“[P]rosecution of individual applications has become more costly. Rather than rapidly traversing the question of eligibility and dealing with anticipation and obviousness, repeated cycles of office actions and responses that address substantially the same eligibility issues result in additional cost and delay. In some cases, separate applications are filed to carve out subject matter more likely to be found patent eligible (e.g., method claims) from that less likely to do so.”); Business Law Section of the Florida Bar at 3 (estimating a 150% increase in post-filing prosecution costs for computer-related patent applications since 2016); Nevada IP Section at 2 (“The need to deal with subject matter eligibility rejection during patent prosecution has dramatically driven up the cost of patent prosecution and time to procurement of patents.”).

223 *See* Schwegman Lundberg & Woessner at 2.

224 *See* Nicholas Frattalone at 1 (noting that while two patents were obtained, the process involved 15–20 years of back and forth with the USPTO, multiple court decisions, and frequent payment of fees); Steve Seawall at 3 (claiming to have invested approximately \$80,000 in the patent prosecution process, only for the application to be rejected as drawn to an abstract idea, and stating that counsel were out of ideas on how to move prosecution forward).

225 University of Cambridge at 13.

226 *See* Google at 4 (noting the addition of “foreign outside counsel in the preparation process, where before it was typically just U.S.-based counsel who drafted [their] patent applications”).

227 *See* Anonymous #13 at 1; Ericsson at 2; IBM at 2–3; NYIPLA at 3; Rio Tinto at 5.

228 Anonymous #13 at 1.

more difficult.²²⁹ Expanding on the impacts, one state bar association submitted information and anecdotal evidence suggesting that in addition to increased prosecution costs, the current jurisprudence is resulting in narrower claims; more frequent abandonment of applications; discouragement of disclosure of new innovations; and flight of innovation from the United States to other markets, such as China.²³⁰

3. Increased post-grant litigation costs

Many commenters asserted that, in addition to an increase in the cost of procuring a patent, the cost of defending a patent once it has been issued has also increased as a function of several factors attributable to the current jurisprudence.²³¹ One factor cited is the sheer increase in the frequency of litigation over patent eligibility. One state bar association, for instance, reported that patent invalidations by district courts for lack of eligibility had increased by more than 141% following the Supreme Court's 2014 *Alice* decision.²³²

A second factor referenced by some of the commenters is the increasing use of certain litigation procedures driven by the evolving law on patent eligibility.²³³ One IP bar association cited “[a]dditional motion practice specific to section 101 issues (including motions to dismiss, motions to bifurcate (or stay) certain discovery,

and motions for summary judgment)” as the reason for increased litigation costs.²³⁴ Relatedly, one company argued that defending such motions to dismiss, in addition to increasing litigation costs for briefings and arguments, also effectively and unfairly placed the burden on patent owners to prove the patent is valid, rather than on the infringer to prove the patent is not.²³⁵

Another factor mentioned for increased post-grant costs is the willingness by some parties to exploit the uncertainty created by the current jurisprudence by engaging in questionable litigation tactics.²³⁶ Commenters claimed that such uncertainty had emboldened defendants to advance spurious arguments, which has added unnecessarily to the cost of the litigation.²³⁷ One global health care company likened the situation to what litigation regarding “best mode” had become before its elimination as a litigation defense in the America Invents Act, saying that “[w]henever policy doctrine crosses the line into litigation strategy, lawmakers should be concerned.”²³⁸

4. Increased costs for patent counseling

Several commenters asserted that they are also incurring significant additional costs in developing patenting strategies, costs that detract from further innovation or business

229 See *Ericsson* at 2 (“In many instances, we have seen patent applications proceed to grant in multiple foreign jurisdictions, only to see the corresponding U.S. application take significantly longer in prosecution, grant with different, amended claims due to § 101 rejections, or even be abandoned over § 101 rejections.”); *IBM* at 3 (“The additional prosecution efforts needed to overcome examiner’s eligibility concerns increase costs, slows our ability to obtain patents, and sometimes results in legally unwarranted changes to the definition of the invention as recited in our claims.”); *Rio Tinto* at 5 (“[P]rosecution costs have increased substantially due to a rise in the frequency of patent ineligibility rejections, multiple rounds of rejections, and continuing revisions of prosecution strategy.”).

230 See NYIPLA at 3.

231 See AIPLA at 11; BPLA at 3–4; *Dominion Harbor Group* at 3–4; *Nevada IP Section* at 4; *Novartis* at 10; *TrackTime* at 6–7; 21C at 3.

232 *Nevada IP Section* at 4 (“[I]n the six years prior to *Alice* (from June 19, 2008, to June 19, 2014), approximately 2,104 patent cases were filed in federal district courts, of which 874 cases resulted in findings of patent invalidity. 179 (or 20.5%) of those findings of patent invalidity were based on section 101. In contrast, in the six years after *Alice* (from June 20, 2014, to June 20, 2020), approximately 1,891 patent cases were filed in federal district courts, of which 941 cases resulted in findings of patent invalidity. 432 (or 45.9%) of those findings of patent invalidity were based on section 101. In other words, the number of cases resulting in findings of patent invalidity increased by 141.3%.”)

233 See AIPLA at 5; *Dominion Harbor Group* at 3–4; NYIPLA at 5; *TrackTime* at 6–7.

234 NYIPLA at 5.

235 *TrackTime* at 6–7.

236 See *Acushnet Company* at 5; *Novartis* at 10; *TrackTime* at 12; 21C at 3.

237 See *TrackTime* at 12; 21C at 3 (citing a case where the issue of eligibility was improperly first raised on appeal to the Federal Circuit).

238 *Novartis* at 10.

opportunities.²³⁹ One state bar association, for instance, noted that “[t]he state of subject matter eligibility has driven up the complexity and cost of patent counseling (including licensing transactions and other patent transactions) and opinions.”²⁴⁰ An organization representing American corporations complained that its members “have been forced to spend time and resources developing patent strategies in the face of significant uncertainty [that] could be better spent if focused on research, product development, and improved services to ultimately help customers.”²⁴¹ A manufacturing company added that “[t]he uncertainty regarding § 101 adds to the potential for unrelated lawsuits to be brought ... forcing the legal team to spend resources obtaining patent advice and drafting legal opinions.”²⁴²

D. Impacts on access to technical information

Numerous commenters provided perspectives on how technical information is disseminated in light of the current jurisprudence and how the dissemination of and access to information influences economic and innovative development.²⁴³ A coalition of high-tech companies explained that patents are intended to represent a balance of “knowledge and innovation shared with the public, in exchange for limited protections granted to incentivize future discoveries,” and that “[w]here secrecy is encouraged, iterative and incremental progress of established technology is made difficult to impossible.”²⁴⁴

Noting the integral role patents play in fostering the dissemination and advancement

of technologies, one association representing IP owners explained that patents allow “others to stand on the shoulders of those who have invented before them.”²⁴⁵ A university’s patenting and licensing organization further explained that patents “are the best method to balance the public dissemination of information that academic freedom demands with the scientific controls that successful technology commercialization requires.”²⁴⁶ One nonprofit organization dedicated to natural products expounded that not only do patents provide technical data that are often used as the basis for incremental improvements but also “[w]ithout patents and the possibility of their enforcement, knockoff dietary supplements can (and will) proliferate the market” such that patent rights can facilitate product quality control, public health, and safety measures.²⁴⁷ In addition, a national IP bar association noted that the data provided in patents facilitate faster developments and commercialization of new innovative products: “Patent protection has always been essential to encouraging earlier and broader disclosure of innovations, which not only helps to accelerate innovation by incentivizing alternatives but also makes it easier to commercialize innovation through investment and business transactions.”²⁴⁸

1. Improved patent disclosures

Various commenters expressed the view that the current jurisprudence has made technical information more readily available and reliable.²⁴⁹ Specifically, a high-tech advocacy group stated

239 See Acushnet Company at 5; Nevada IP Section at 4; NYIPLA at 5; 21C at 3.

240 Nevada IP Section at 4.

241 21C at 3.

242 Acushnet Company at 5.

243 See AIPLA at 10; Association for Molecular Pathology (hereinafter AMP) at 7; Google at 4; HTIA at 14; Innovation Alliance at 5; IPO at 9; Natural Products Association (hereinafter NPA) at 5; SIIA at 5–6; WARF at 2–3.

244 Innovation Alliance at 5–6.

245 IPO at 9.

246 WARF at 3.

247 NPA at 3.

248 AIPLA at 10.

249 See AMP at 7; Google at 4 (“Alice was a ‘forcing function’ for Google and others to include more detail in patent applications.”); HTIA at 14; SIIA at 6.

that “[t]he increased incentives to more fully disclose the invention and to seek marginally narrower claims are the most notable effects with respect to prosecution practice and strategy,” and that “this has resulted in clearer patents that more fully support the disclosure function of the patent system.”²⁵⁰ A scientific organization that promotes molecular diagnostics supported the current jurisprudence regarding genetic data because “information that underpins health-care service delivery should be treated neither as intellectual property nor as a trade secret when other patients may benefit from the knowledge being widely available” and such data should be shared outside the patent context.²⁵¹

2. Enhanced reliance on trade secrets

Although patent applications may be more detailed, commenters contended that researchers and innovators frustrated with the state of patent eligibility are turning to trade secrets to protect their innovations in lieu of seeking patent protection.²⁵² Specifically, a national IP bar association commented that “[m]ost innovators rely on a combination of trade secrets and patents to protect investments in innovations and new products.”²⁵³ A patent law association also indicated that “companies in the critical business of isolating genetic components for treatment and diagnostic purposes are declining to file patent applications and sometimes keeping their innovations as trade secrets instead.”²⁵⁴

Some commenters asserted that attorneys have begun counseling that trade secrets are less risky compared with patents in light of the current jurisprudence, with one commenter noting that its lawyers “counsel holding inventions as trade secrets if we think there will be significant eligibility challenges.”²⁵⁵ A patent practitioner similarly commented: “We now encourage our clients with medical treatment inventions, biotech inventions, and software-related inventions to rely on trade secrets when possible and to file patent applications only in the US and with non-publication requests, so our clients will not divulge their inventions if they never get patent protection.”²⁵⁶

Several commenters discussed the claimed shift to trade secrets and its impacts on innovation and investment.²⁵⁷ In particular, a coalition of technology companies stated that by limiting access to innovative information, “trade secret protection injects slowness of discovery into industry-wide innovation,” and that “industries that are otherwise nimble and quick to innovate—effectively all digital technologies—are encouraged to adopt a policy of isolation, discouraging the sharing of information and slowing progress.”²⁵⁸ Likewise, a biotechnology corporation stated that if “patent protection is unavailable, it may force companies seeking to advance this field to protect their intellectual property through trade secrets,” which “will inevitably steer investment away from ground-breaking and novel medicines and therapies as well as potentially slow the progress

(“*Alice* and subsequent cases have required more detail in the claims and description, but that specificity has resulted in higher-quality patents and better disclosure to the public.”).

250 HTIA at 14.

251 AMP at 7 (quoting Board of Directors, American College of Medical Genetics and Genomics, *Laboratory and Clinical Genomic Data Sharing Is Crucial to Improving Genetic Health Care: A Position Statement of the American College of Medical Genetics and Genomics*, 19 GENETICS MED. 721–22 (2017)).

252 See AIPLA at 9–10; Anonymous #13 at 12; AUTM at 8; BPLA at 8; Genentech at 3, 11; IBM at 2, 7; Innovation Alliance at 5–6; Seth Nehrbass at 7; NYIPLA at 9; Lori Pressman at 6; WARF at 4.

253 AIPLA at 9.

254 BPLA at 8.

255 Anonymous #13 at 12.

256 Seth Nehrbass at 7.

257 See AUTM at 8; Genentech at 3, 11; IBM at 2, 7; Innovation Alliance at 5–6; NYIPLA at 9; Lori Pressman at 6; WARF at 4. See also Anonymous #6.

258 Innovation Alliance at 6.

of science.”²⁵⁹ Commenters also recognized that, unlike patents, there is no expiration date on proprietary data, and the data may never become available for public use.²⁶⁰ In addition, a state IP law association suggested that the use of trade secrets rather than patents leads to higher long-term prices of new products because “knowledge is hoarded” and “[s]uch ‘know how’ becomes more expensive and is priced into licenses, diagnostic tests, etc.”²⁶¹

Some commenters noted concerns that maintaining innovative technologies as trade secrets could prevent meaningful peer review on their underlying data and put patients and consumers at risk.²⁶² For example, one university’s patenting and licensing organization stated that “[a] lack of patent protection allows, and even encourages, proprietary trade secrets that prevent anyone not employed at the company (such as our university-employed scientists) from accessing information related to the invention,” and that “[t]hese circumstances have the potential to increase the likelihood of low-quality, ineffective, and dangerous products making it to market.”²⁶³ Another commenter pointed out that when a company keeps certain genetic data as a trade secret, there is no peer review, and the company expects medical providers and patients to take its conclusions on faith.²⁶⁴

E. U.S. global leadership and national security implications

Several commenters opined on the impact of the jurisprudence on the overall competitiveness of the United States.²⁶⁵ As noted by one organization: “The United States is in a technology race, if not a war. Without a strong patent system and first-to-market process, the United States will lose that race—with profound implications for our standard of living, industrial competitiveness, and national security.”²⁶⁶ Other commenters were specifically concerned with boosting American competitiveness with China. A coalition of technology companies explained that “[w]hile U.S. innovators have struggled to adjust to the recent changes in patent subject matter eligibility, other countries such as China have invested heavily in strengthening patent rights.”²⁶⁷

Some commenters equated the loss of innovation with the loss of U.S. leadership as an innovative economy and an advocate for robust IP systems.²⁶⁸ A national IP bar association agreed, stating that “[t]he recent jurisprudence eroding the scope of patent eligibility has undermined the U.S. patent system’s ability to maintain this leadership position protecting today’s innovations as well as its ability to secure patent protection for future, currently unforeseeable innovation.”²⁶⁹ An advocacy group echoing remarks from retired Federal Circuit Chief Judge Paul R. Michel stated that “[u]nless

259 Genentech at 11.

260 See generally Anonymous #6, attachment 2 at 6 (quoting Sharon Levy, *Our Shared Code: The Myriad Decision and the Future of Genetic Research*, 121 ENVIRON. HEALTH PERSP. a250 (2013): “‘Myriad has more data on BRCA mutations than anyone else,’ [and] that proprietary databases like Myriad’s could hinder the progress of genetic medicine [because] ‘[d]atabases and trade secrets ... don’t expire like patents do.’”). See also NYIPLA at 2, 9; 21C at 8.

261 NYIPLA at 9.

262 See Anonymous #6, attachment 2 at 6; WARF at 4.

263 WARF at 4. See also AUTM at 8; Lori Pressman at 6.

264 Anonymous #6, attachment 2 at 6.

265 See AAC at 20; Business Law Section of the Florida Bar at 5–6; CPR at 4; Eagle Forum at 3; Innovation Alliance at 6–9.

266 Eagle Forum at 3.

267 Innovation Alliance at 6.

268 See AAC at 8; ABA-IPL Section at 13 ([T]he uncertainty and unpredictability in patent eligibility appears to be weakening U.S. leadership, and importantly signals to other countries that subject matter that was globally accepted as patent eligible subject matter now can be denied protection in the U.S. without violating Trade-Related Aspects of Intellectual Property Rights (TRIPS).); AIPLA at 12; Innovation Alliance at 7; Adam Mossoff at 9; Novartis at 10–12; Chad Rafetto at 29–30; TrackTime at 12; 21C at 5 (“21C is concerned that the United States’ leadership position as a strong advocate for robust intellectual property rights is weakened by the current uncertainty in patent eligibility jurisprudence.”).

269 AIPLA at 12.

this problem is resolved, our nation's innovation economy will weaken and our world leadership in science and technology will decline.”²⁷⁰ Other commenters cited a decrease in patent applications filed in certain technologies or a lowering of the United States' ranking as a global innovation leader as evidence of the negative impact of the current jurisprudence on innovation.²⁷¹

Similarly, an organization concerned with private property rights warned of “legal uncertainties created by current U.S. patent eligibility and patentability doctrine, the lack of an effective response to China's domestic and geopolitical strategies centered on its IP institutions, and the lack of effective data protection policies.”²⁷² The organization went on to note that “by strengthening its IP regimes, China is poised to ‘fill the void’ left by weakened U.S. IP protections, particularly for patents, as the U.S. has lost its ‘comparative advantage in securing stable and effective property rights in new technological innovation.’”²⁷³ Another organization representing research-based technology companies noted that “[t]o maintain U.S. leadership in essential and emerging technologies—including artificial intelligence—the U.S. must address the uncertainty of post-*Alice* § 101 jurisprudence and at the very least match its foreign counterparts such as the [European Patent Office] and [China National Intellectual Property Administration] with respect to ‘eligible’ technology.”²⁷⁴

Others also raised the lack of patentability for certain technologies as a potential national security risk.²⁷⁵ A national IP bar association pointed out that “[t]he National Security Commission on Artificial Intelligence's Final Report recommends that ‘[t]he United States must recognize IP policy as a national security priority critical for preserving America's leadership in AI and emerging technologies.’”²⁷⁶ Relying on the report, the association referenced that “the United States lacks the comprehensive IP policies it needs for the AI era and is hindered by legal uncertainties in current U.S. patent eligibility and patentability doctrine.”²⁷⁷

A coalition representing research-based technology companies synopsisized the national security issue, remarking that “[p]rotecting U.S. economic and national security has always gone hand-in-hand with ensuring U.S. technological leadership.”²⁷⁸ The coalition specifically highlighted the potential detriments to national security if the United States were no longer to be a leader in developing telecommunication technologies: “If the United States were to lose leadership in the underlying foundational technology and standards, foreign governments and businesses, including adversaries, could gain unprecedented control over all aspects of a wireless communications system that will connect every part of our economy, infrastructure, and daily lives.”²⁷⁹

270 Innovation Alliance at 8 (quoting *The State of Patent Eligibility in America: Part I, Hearing Before the Subcomm. on Intellectual Property of the S. Comm. of the Judiciary*, 116th Cong. (2019) (statement of Judge Paul R. Michel)).

271 See CPR at 3; Eagle Forum at 3; Adam Mossoff at 9. Observing that the United States had fallen from the top 10 in global innovation economies for the first time, these references relied on Michelle Jamrisko, Wei Lu & Alexandre Tanzi, *South Korea Leads World in Innovation as US Exits Top Ten*, BLOOMBERG (Feb. 3, 2021), <https://www.bloomberg.com/news/articles/2021-02-03/south-korea-leads-world-in-innovation-u-s-drops-out-of-top-10>). Chad Rafetto at 29 (noting a decline in applications filed in bioinformatics, business methods, and software technologies). See also ABA-IPL at 16; Anonymous #13 at 6; BPLA at 4, 8; IBM at 6; IPO at 6; Nevada IP Section at 2; NYIPLA at 3.

272 CPR at 4 (quoting NATIONAL SECURITY COMMISSION FOR ARTIFICIAL INTELLIGENCE, FINAL REPORT 201 (March 1, 2021)).

273 *Id.*

274 Innovation Alliance at 7.

275 See AAC at 20; AIPLA at 13; Business Law Section of the Florida Bar at 5; CPR at 4 (noting “the fraught situation concerning computer-implemented inventions, medical diagnostics, and biopharmaceutical therapeutics”); Eagle Forum at 3; Innovation Alliance at 6.

276 AIPLA at 13.

277 *Id.* (quoting NATIONAL SECURITY COMMISSION, *supra* note 272, at 12.)

278 Innovation Alliance at 9.

279 *Id.*

F. Impacts on technology-specific sectors

The evolving Supreme Court and Federal Circuit precedent on patent eligibility has had a significant impact on certain areas of technology, in part because the exceptions to eligibility as articulated by the Court—abstract ideas, laws of nature, and natural phenomena—seem to implicate those technologies more than others. Specifically, the life sciences and computer-related technologies have been greatly affected by the recent jurisprudence. This section describes the comments relating to these technology sectors.

1. Life sciences technologies

A significant number of commenters discussed how the changing patent eligibility landscape has affected the life sciences industries, especially the impact of patenting innovations on pharmaceuticals, biologics, medical diagnostics, precision medicine, bioinformatics, and gene-based technologies. The comments were largely split between patent owners and companies that market and manufacture medical treatments and diagnostics, on the one hand, and the research community and patient advocacy groups, on the other.

The life sciences industries emphasized their heavy reliance on patent protection to recoup investment, noting that the cost of researching and developing a new medicine is substantial both in time and money. For example, several companies acknowledged that it costs approximately \$2.6 billion to bring one medicine to market and that it takes approximately 12 years for a medicine to

move from research and development to market, which includes several years of research and clinical studies involving hundreds or thousands of failures.²⁸⁰

Conversely, the research community and patient rights groups applauded the Supreme Court's two-step framework. In their views, the recent patent eligibility case law plays a crucial role in fostering scientific research and innovation, which benefits the public interest.²⁸¹ In particular, one patient advocacy group asserted that “scientific researchers, health care providers, and patients depend on access to abstract ideas, laws of nature, and natural phenomena,” and that changing patent eligibility law “would threaten future innovation, healthy competition, and affordable access to quality health care.”²⁸²

a. Diagnostic innovations

In general, medical diagnostic tests are used in clinical medicine to identify a patient's condition and provide for early and effective treatments. These diagnostic tests can be used to confirm or exclude that a patient has a particular disease, to monitor a treatment's effectiveness, or to assess the progression of a particular disease.

Many commenters contended that innovation in medical diagnostics has been curtailed in recent years because of the current jurisprudence.²⁸³ Commenters asserted that the approach in recent case law has all but eliminated certain categories of patent protection in the life sciences, including medical diagnostics and precision medicine, causing innovators not to

280 See *Genentech* at 2–3; *Johnson & Johnson* at 2 (stating that “[m]illions of compounds [must] be screened, developed, or tested for each one that meets safety and efficacy standards for use in patients” and for the “very few compounds that are subject to clinical testing . . . just 9.6% of these candidates ultimately receive regulatory approval”); *Novartis* at 2 (stating that “less than 12% of medicines succeed even once clinical trials begin” and that one approval requires about 10 to 15 years).

281 See generally ACLU; Association of American Medical Colleges (hereinafter AAMC); AMP; Breast Cancer Action (hereinafter BCAction); Coalition Against Patent Abuse (CAPA); CLS #1; CLS #2; College of American Pathologists (hereinafter CAP); Invitae; Dartmouth-Hitchcock Medical Center; My Gene Counsel; PIPLI; Lunenfeld-Tanenbaum Research Institute of Sinai Health System hereinafter (hereinafter Sinai Health System); The Breasties.

282 The Breasties at 1.

283 See generally ABA-IPL Section; AIPLA; AUTM; BIO; BPLA; Alexandra Sasha Hoyt; IPO; Johnson & Johnson; NYIPLA; PhRMA; 21C; USIJ; WARE.

pursue patent protection.²⁸⁴ As an organization representing American corporations explained, “[s]ome member companies are not pursuing medical diagnostic claims because they are widely considered patent ineligible under current law.”²⁸⁵

While recognizing that methods of treatment are generally patent eligible, pursuant to the Federal Circuit’s *Vanda*²⁸⁶ decision, several commenters observed the lack of benefit from that ruling on medical diagnostics.²⁸⁷ As one patent law association explained:

Current §101 jurisprudence generally requires that claims to diagnostic tests be linked to affirmative steps reciting methods of treatment. As an initial matter, this is counterintuitive, as companies in the business of discovering and developing diagnostic tools are generally not in the business of treating patients. This dilutes the value of the IP these companies are able to secure by implicating divided infringement issues.²⁸⁸

Many commenters also expressed concern about the divergence in patent eligibility standards between the United States and other countries, asserting that other countries provide more protection for medical diagnostics.²⁸⁹ Observing that China, Japan, Korea, and Europe view diagnostic methods as patent eligible under certain circumstances, a large pharmaceutical association provided a summary of eligibility standards in those jurisdictions:

- In China, claims directed to diagnostic methods are patent eligible so long as the method does not lead to a diagnosis or health assessment—regardless if it is carried out separately from the body or performed on the body.
- In Korea, methods of diagnosis are patentable in some forms, namely where the claims do not require the human body to carry out the invention.
- A method of diagnosis may be patent eligible in Japan if the method is performed outside the human body, does not include the steps of medical doctors judging the physical condition of a human body for medical purposes, or is used to collect information from a human body.
- The [European Patent Office] will not grant patents covering diagnostic methods practiced on the human or animal body. But a known substance or composition may still be patented for use in diagnostic methods if the known substance or composition has not previously been disclosed for use in any such method. A subsequent diagnostic method employing a known substance or composition that has previously been used in a method may still be deemed patent eligible if the subsequent use of the substance in these methods is novel and inventive.²⁹⁰

284 See AUTM at 2; NYIPLA at 9; 21C at 8.

285 21C at 2.

286 *Vanda Pharms. Inc. v. West-Ward Pharms. Int’l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018).

287 See ABA-IPL Section at 7; BPLA at 7; Novartis at 6; PhRMA at 5.

288 BPLA at 7. See also ABA-IPL Section at 7.

289 See AAC at 21; ABA-IPL Section at 13–14; AIPLA at 3–4, 7–9; AUTM at 4–5; BPLA at 8–9; CPR at 2–3; Genentech at 8–9; Innovation Alliance at 7–8; International Association for the Protection of Intellectual Property (AIPPI) at 4; IPO at 7; Johnson & Johnson at 4; Adam Mossoff at 3, 6–7, 9–10; Novartis at 10–12; NYIPLA at 3, 7–8; PhRMA at 10; Chad Rafetto at 29–30; 21C at 2, 5; University of Cambridge at 129 (enclosed article by Johnathon Liddicoat, Kathleen Liddell & Mateo Aboy, *The Effects of Myriad and Mayo on Molecular-Test Development in the United States and Europe: Interviews from the Frontline*, 22 VAND. J. ENT. & TECH. L. 785 (2020)).

290 PhRMA at 10. See AIPPI at 3 (noting that in the European Patent Office, “there is a prohibition on patenting ‘methods for treatment of the human or animal body by surgery or therapy and diagnostic methods [practiced] on the human or animal body.’ However, applicants can obtain claims that cover diagnostic inventions, but do not recite treatment or interaction with the human or animal body”).

An international IP association also provided several examples of patent application families²⁹¹ for which diagnostic claims have been granted outside the United States. However, claims in counterpart U.S. applications remain rejected on patent eligibility grounds.²⁹²

Although the biopharmaceutical industry largely faulted the current patent eligibility jurisprudence for limiting patent protection on diagnostic-related innovations, a number of commenters applauded this impact for public policy reasons.²⁹³ For example, one patient advocacy group asserted that the current jurisprudence ensures “that innovative treatments and diagnostic tests remain affordable and accessible to the people who need them.”²⁹⁴ Referring to the ongoing pandemic as an example, another patient advocacy group contended that “public access to the genetic sequence of the virus responsible for COVID-19 made it possible for researchers and companies to develop and commercialize a wide variety of diagnostic tests and vaccines at unprecedented speed,” which, in turn, led to “more access, more competition, and more innovation.”²⁹⁵ In contrast, a scientific organization that promotes molecular diagnostics maintained that during the 2003 SARS outbreak, which occurred before the Supreme Court’s recent patent eligibility decisions, “biotechnology and pharmaceutical companies raced to patent everything from the genetic

sequences within the virus’ genome to the virus itself,” and the Centers for Disease Control and Prevention “sought to defensively patent the virus and its entire genetic content ‘to make sure access to the virus remains available to anyone.’”²⁹⁶ Other commenters echoed these views.²⁹⁷ One university, although acknowledging the adverse effects of the current patent eligibility jurisprudence on the development of molecular diagnostics and the potential disadvantages for U.S.-headquartered companies, argued that because the law may provide overall benefits, such as “unshackling” the “basic tools of scientific and technological work,” reform is premature until those positive effects are better understood.²⁹⁸

b. Precision medicine and gene-based technologies

According to the National Cancer Institute, precision medicine, or personalized medicine, is a form of medicine that uses information about a person’s own genes to prevent, diagnose, or treat disease or assess the likelihood of future disease.²⁹⁹ Coupled with the rise in the development of emerging medical diagnostic technologies, precision medicine allows physicians to formulate therapeutic strategies tailored to an individual, for treatment or prevention purposes, on the basis of that individual’s genomic profile. As explained by a biotechnology company, personalized medicine research is generally interdisciplinary and includes

291 Patent families are composed of patents and patent applications that claim the benefit to one *priority* application. A priority application is a patent application that is first filed in one jurisdiction and then serves as the basis for patent filings in other jurisdictions. Patent treaties allow applicants to claim the benefit of the filing date in the first filed jurisdiction when filing in other jurisdictions. Patent applications on the same subject matter filed in multiple jurisdictions are called patent families because they are all related to the first-filed application.

292 See AIPPI at 5–10.

293 See ACLU at 5–7; AMP at 1, 10–11; BCAction at 1; CAP at 1–5; CLS #2 at 1–3; Dartmouth-Hitchcock Medical Center at 1–2; Helen Fernandes, Susan Hsiao & Mahesh Mansukhani at 1–2; Invitae at 1–2, 10–14; My Gene Counsel at 1; PIPLI at 4–6; Sinai Health System at 1–2; The Breasties at 1.

294 The Breasties at 1.

295 BCAction at 1.

296 AMP at 8.

297 See ACLU at 5–6; Dartmouth-Hitchcock Medical Center at 2; My Gene Counsel at 1; PIPLI at 4; Sinai Health System at 1; The Breasties at 1.

298 University of Cambridge at 30–31 (drawing on the results of empirical research assessing the impact of the *Myriad*, *Mayo*, and *Alice* decisions on biotech, precision medicine, diagnostics, artificial intelligence, and other computer-related inventions affecting digital health).

299 See the National Cancer Institute’s dictionary of cancer terms at <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/precision-medicine>. The NCI Dictionary defines precision medicine as “A form of medicine that uses information about a person’s own genes or proteins to prevent, diagnose, or treat disease. In cancer, precision medicine uses specific information about a person’s tumor to help make a diagnosis, plan treatment, find out how well treatment is working, or make a prognosis. Examples of precision medicine include using targeted therapies to treat specific types of cancer cells, such as HER2-positive breast cancer cells, or using tumor marker testing to help diagnose cancer. Also called personalized medicine.”

research in diagnostics, genomic profiling, imaging analytics, and bioinformatics, as well as other scientific disciplines.³⁰⁰

Highlighting the adverse impact on precision medicine and gene-based technologies, numerous commenters were critical of the current patent eligibility jurisprudence.³⁰¹ One patent law association said that “[t]he blanket exclusion of isolated genes from patent eligible subject matter is technically misplaced.”³⁰² According to the association, “[w]hile the gene itself literally exists in nature (i.e., as part of DNA), it does not retain the same functioning when isolated that it would exhibit in nature as part of an overall genome.”³⁰³ Furthermore, the association asserted that the “[e]xclusion of an identified gene sequence primarily responsible for a particular disorder denies the reward of patent protection to inventions that are otherwise useful, novel, and nonobvious, and also dissuades a public-benefitting disclosure.”³⁰⁴

Regarding the impact of the Court’s precedent, one global health care company contended that “precision medicine, cell & gene therapies, certain types of biologics, and digital health—appear to lie directly in the expansion path” of the recent case law, which “foreclosed the possibility of patents for the entire field of medical diagnostics, cloned organisms, certain modified proteins, biomarkers, and DNA primers, to name but a few.”³⁰⁵ The company further asserted that “in fields like precision medicine ... the difference between eligible and ineligible subject matter

now apparently *sometimes* (though not always) comes down not to the actual substance of the claimed invention, but to whether a court will ultimately construe it as a ‘diagnostic,’ a ‘method of treatment,’ or a ‘method of preparation.’”³⁰⁶ Another company argued that “[p]ersonalized medicine relies on the ability to identify the right medicine for the right patient, and current patent eligibility case law frustrates this research by foreclosing the patentability of advances in diagnostic testing and by the impact on technology that lies at the intersection of biology and AI.”³⁰⁷ According to the company, this foreclosure “decreases the likelihood of research that will lead to earlier detection, personalized treatment, and better health outcomes.”³⁰⁸ Likewise, one technology transfer association detailed several real-world examples of problems in gene patenting and diagnostics that its members have encountered that have significantly impeded development of new technologies.³⁰⁹

In contrast, several commenters asserted that when it comes to IP protection for gene technologies and precision medicine, less is more.³¹⁰ For example, a medical advocacy group asserted that “[i]f gene sequences and other natural phenomena can be considered intellectual property, a company with monopoly rights over the related disease can significantly hinder critical research, make the healthcare industry less productive and less competitive domestically and globally as well as significantly increase the cost of care for patients and society.”³¹¹ The group

300 See Genentech at 5.

301 See ABA-IPL Section at 7; AUTM at 2–4; BIO at 2–4; BPLA at 8; Genentech at 5–6; IPO at 6–8; Novartis at 2–3; PhRMA at 7–9; 21C at 2, 6.

302 BPLA at 8.

303 *Id.*

304 *Id.*

305 Novartis at 2.

306 *Id.* at 3.

307 Genentech at 5–6.

308 *Id.* at 6.

309 AUTM at 2–4.

310 See AMP at 8; CAP at 3; CLS #2 at 3; Dartmouth-Hitchcock Medical Center at 1–2; Helen Fernandes, Susan Hsiao & Mahesh Mansukhani at 1–2; Invitae at 1–2; My Gene Counsel at 3; PIPLI at 2; Sinai Health System at 1–2; The Breasties at 1.

311 CAP at 3. See also CLS #2 at 2 (warning that “[a] patent holder that is granted exclusive rights over all uses of a gene can preempt scientific access and

went on to argue that “[i]t is not in the public’s interest for [a] single entity to hold ownership over the means to diagnose certain diseases or serve as the sole gatekeeper for targeted therapeutics.”³¹² A life sciences organization reported that “a major analysis undertaken by The Secretary’s Advisory Committee on Genetics, Health and Society in 2010 ... concluded that patents on genes undermined the development of new and promising testing technologies and documented multiple cases where gene patents directly interfered with patient access to testing and care.”³¹³ The organization urged that “[r]eturning to the days of gene patents would create barriers to genomic tests, eliminate access to confirmatory testing, and likely increase the cost of testing,” and that “[r]esearch is considerably slowed when scientists need to license or pay for patented technologies.”³¹⁴

In addition, several commenters highlighted the benefits of recent jurisprudence on competition in gene technology as it relates to public health. Specifically, two organizations relied on data showing that “since the Supreme Court’s decision [in *Myriad*], there has been a proliferation of innovation and healthy competition in genetic testing, and overall investment in genomics increased from \$6.21 billion in 2013 to over \$17 billion in 2018.”³¹⁵ Moreover, another commenter contended that the *Myriad* decision has led to

greater access to medicines and therapeutics at a lower cost, estimating that since the ruling, “the cost of genetic testing for BRCA1 and BRCA2 alone has decreased substantially (was \$4,400 and is now less than \$300 at some laboratories) and continues to fall as technology improves and competition increases.”³¹⁶

2. Computer-related technologies

A substantial number of commenters identified the impacts of the current patent eligibility jurisprudence on emerging computer technologies and areas reliant on computer-related innovations.³¹⁷ Many commenters noted that the Supreme Court’s two-step framework is unworkable and detrimental to innovation.³¹⁸ Some commenters submitted relevant data, including declining patent application filings, lower relative investments in research and development, and diminishing GDP.³¹⁹ Others expressed concern with the expanding scope of patent ineligible subject matter in recent court decisions and the impacts going forward.³²⁰ In contrast, several stakeholders shared data showing that investments in emerging technologies, especially AI and quantum computing, are still strong and continuing to grow.³²¹ That group of stakeholders indicated that the current jurisprudence is promoting the type of innovation and growth intended by the patent system.³²²

use of those genes in research, diagnostic testing, and care”).

312 CAP at 3.

313 CLS #2 at 3.

314 *Id.*

315 *Id.* at 2 (relied on a statement of Sean George, CEO, Invitae Corporation, *The State of Patent Eligibility in America: Part II Before the S. Subcomm. on Intellectual Property: Hearing before the Subcommittee on Intellectual Property of the Committee of the Judiciary*, 116th Cong. (2019), <https://www.judiciary.senate.gov/imo/media/doc/George%20Testimony.pdf>). See also ACLU at 6–7.

316 My Gene Counsel at 1. See also Invitae at 10–12.

317 See generally Gregory Aharonian; AIPLA; Anonymous #13; App Association; AUTM; Business Law Section of the Florida Bar; CCIA; Tara Chand; Dell Technologies; Dominion Harbor Group; Eagle Forum; Engine; Ericsson; Genentech; Google; Richard Gruner; Alexandra Sasha Hoyt; HTIA; IBM; IGT; Ilija Ilijovski; Innovation Alliance; IPO; Juniper Networks; Adam Mossoff; Robert Osann, Jr.; Lori Pressman; Chad Rafetto; Rio Tinto; Rutman IP; Joshua Sarnoff; SIIA; John Storella; USIJ.

318 See AAC at 5; Gregory Aharonian at 1; AIPLA at 2–3; Anonymous #13 at 1; Business Law Section of the Florida Bar at 6; Tara Chand at 13; Dominion Harbor Group at 2; Richard Gruner at 12; IBM at 3; IGT at 2; Innovation Alliance at 2–3; Lori Pressman at 5; Chad Rafetto at 28; Joshua Sarnoff at 13–14; TrackTime at 4; USIJ at 8.

319 See generally AIPLA; Alexandra Sasha Hoyt; Innovation Alliance; Adam Mossoff; Chad Rafetto.

320 See generally Gregory Aharonian; Anonymous #13; App Association; IPO; Lori Pressman.

321 See generally CCIA; Dell Technologies; Engine; Google; HTIA; Juniper Networks; SIIA.

322 See CCIA at 2; Dell Technologies at 6; Developers Alliance at 1; Engine at 5; Google at 6; HTIA at 4; Juniper Networks at 3; SIIA at 2.

As an initial matter, many commenters contended that the jurisprudence is detrimental to innovation in computer-related technologies because it is unsettled and drives uncertainty.³²³ These commenters described the Supreme Court’s two-step framework as unworkable, highlighting the lack of a uniform definition for an “abstract idea” and the ambiguity of what constitutes “significantly more” as drivers of uncertainty.³²⁴ In addition, some of them focused on the high level of abstraction that is inherent in computing, calculations, and algorithms as the fundamental flaw in the current test.³²⁵ Other stakeholders pointed to a more international approach, as an alternative, to bring more consistency to the U.S. patent system.³²⁶

First, numerous commenters expressed concern with the application of the *Mayo* and *Alice* framework because there is no uniform definition of an abstract idea.³²⁷ Quoting Judge Jay Plager of the Federal Circuit, these stakeholders emphasized, “[t]here is almost universal criticism among commentators and academicians that the ‘abstract idea’ has created havoc in the patent law.”³²⁸ Many commenters specifically expressed

their frustrations with the subjectivity and lack of definition of what constitutes an abstract idea.³²⁹ In addition, one attorney advocacy group noted that without a clear understanding of the term “abstract idea,” courts, practitioners, innovators, and agencies do not have sufficient guidance to determine the scope of the abstract idea exception.³³⁰

Commenters also focused on the difficulties in applying the abstract idea test to computer-related inventions.³³¹ As noted by one commenter, computer-implemented inventions are often a series of calculations, simulations, models, instruction sets, etc., which are not patentable themselves.³³² For this reason, one commenter described the *Mayo–Alice* eligibility test as “biased against computer-related inventions because abstraction is a foundational characteristic of computer science.”³³³ On this point, a national IP bar association pointed out that the “current law has dissolved the boundary between a claim to an algorithm itself and a legitimate claim to a system that uses an algorithm.”³³⁴ That organization recognized that “[s]oftware is the enabling technology for improving the way we provide healthcare (e.g., surgical robots), drive automobiles

323 See App Association at 3; IBM at 3; Innovation Alliance at 3 (“Because the application of *Alice* is so fraught with uncertainty and unpredictability, a cloud of uncertainty hangs over these patents, threatening incentives to innovate in this key technology area.”); Chad Rafetto at 28 (stating that “the recent changes to patentable subject matter have raised doubts about whether patents will continue to be available for cutting edge advances such as ‘artificial intelligence, blockchain technology, quantum computing, and personalized medicine’”).

324 See generally AAC; AIPLA; App Association; Business Law Section of the Florida Bar; Dominion Harbor Group; Richard Gruner; IBM; Innovation Alliance; Adam Mossoff; NYIPLA; Mark Tornetta; TrackTime; USIJ.

325 See generally IBM; Martin Snyder. See also Tara Chand at 13; Richard Gruner at 18; Internet Promise Group at 8; Adam Mossoff at 4; Mark Tornetta at 3–4.

326 See generally Genentech; Google; Ilija Ilijovski; Internet Association; Rio Tinto; Rutman IP; SIIA.

327 See generally AAC; Dominion Harbor Group; Richard Gruner; Innovation Alliance; Mark Tornetta; TrackTime; USIJ.

328 Richard Gruner at 7 (quoting *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1353–54 (Fed. Cir. 2018) (Plager, J., concurring in part and dissenting in part)). See also Innovation Alliance at 2; TrackTime.

329 See Dominion Harbor Group at 2 (“[T]he [Supreme] Court refused ‘to delimit the precise contours’ of the judicially-created abstract idea exception, and that lack of guidance has sent lower courts into a tailspin.”); Innovation Alliance at 2 (“The subjectivity and unpredictability of this test has only been compounded by the fact that the judicial exceptions themselves are ambiguous.”); Mark Tornetta at 3–4; TrackTime at 4 (“There is no definition for that which is an ‘abstract idea’ and that which is not.”); USIJ at 8 (“When fundamental and settled principles of law are undermined by the use of vague and imprecise language or are abandoned altogether, the predictable result is that the lower courts feel free to adopt whatever subjective interpretation they choose as to the meaning of the statutory language.”).

330 See AAC at 5 (noting that “its contours and boundary conditions remain ill-defined in U.S. Supreme Court patent jurisprudence where it has become a controversial focus of attention and concern among members of the patent bar, patent applicants and the PTO, litigants and tribunals, and the commentariat”).

331 See AAC at 5 (asserting that “[a]mong the four categories of exceptions, abstract ideas are outliers in that some of them may be new, beneficially useful, and can be called into existence through acts of invention”); App Association at 5 (explaining that “[c]omputer related inventions combine numerous abstract ideas to create the applications that consumers use on a daily basis”).

332 Martin Snyder at 8.

333 IBM at 3.

334 AIPLA at 2.

(e.g., automatic parallel parking systems), and communicate with people around the world (e.g., video conferencing).³³⁵

Second, several commenters also identified numerous challenges with the second part of the *Mayo–Alice* eligibility test, that is, whether the claimed invention is “significantly more” than an abstract idea.³³⁶ These commenters relied on personal observations and examples to demonstrate when it was not possible to overcome the second part of the inquiry.³³⁷ In addition, some commenters noted a lack of consistency on what constitutes “significantly more.”³³⁸ Finally, a few commenters raised concerns regarding how computer-related inventions are being treated by the courts and examiners at the USPTO, specifically noting that they are often generalized by their components, without the courts and examiners understanding the complexity of the components needed to complete the claimed functions.³³⁹

Setting aside the aforementioned challenges in applying the jurisprudence to computer-related innovations, stakeholders shared observations of successful outcomes in meeting the current eligibility test by showing that a claimed invention

provides a technical solution to a technical problem.³⁴⁰ For example, one high-tech company reported that it is able to meet the *Mayo* and *Alice* requirements for eligibility by “going into depth on the technological problem we are addressing and our technological solution to that problem.”³⁴¹ Other industry associations agreed that this approach is the key to avoiding the abstract idea exception.³⁴² Finally, some commenters noted that relying on this approach could help overcome the obstacles of defining an abstract idea³⁴³ and also better align U.S. practices with other major jurisdictions.³⁴⁴

a. Artificial intelligence, quantum computing, and machine learning

A sizable number of commenters addressed the impacts of the current jurisprudence on transformative innovations, including AI, quantum computing, and machine learning.³⁴⁵ This group raised concerns that uncertainty and unpredictability in the law are undermining U.S. economic and innovative development.

Most notably, many from the group argued that the complete lack of protection for some innovations and the loss of claim scope to overcome subject matter eligibility rejections are impacting the research, growth, and development

335 *Id.* at 2–3.

336 See Business Law Section of the Florida Bar at 6 (stating that “the ‘significantly more’ inquiry is ambiguous and conflates the issue of subject matter eligibility with the issue of patentability pursuant to 35 USC §102 (novelty); 35 USC §103(a) (obviousness) or 35 USC §112 (enablement)”; Richard Gruner at 8, 12; Adam Mossoff at 7; NYIPLA at 4; Daniel Thomson.

337 See Anonymous #13 at 9, 12 (observing that the USPTO determined that “a substantial improvement in the speed and accuracy for detecting a disease outbreak is not eligible because it does not improve the operation of the processor that is receiving the data” and questioning “[o]n what objective basis does the Office quantify ‘significant?’ [sic] to determine whether the improvement is ‘enough’ to overcome the eligibility hurdle?”); Internet Promise Group at Attachment C; Steve Seawall at 25–26.

338 See Richard Gruner at 12; IGT at 2 (“IGT has encountered severe differences among examiners on what inventions are considered abstract, what constitutes an improvement or a practical application, and what constitutes ‘significantly more.’”); Michael Mazza at 1; Joshua Sarnoff at 13–14.

339 See Tara Chand at 14 (“USPTO and CAFC have a gross misunderstanding and have used that to create a new test of ‘conventional use of computers’ in isolation and devoid of the context it was used in *Alice*.”); Internet Promise Group at 8; Mark Tornetta at 3–4.

340 See AUTM at 4; Google at 4, 8.

341 Google at 4.

342 See Internet Association at 3; SIIA at 1 (“The case law correctly focuses on requiring a software patent (and other computer-implemented inventions) to claim an improvement in computer technology or recite a technical solution to a technical problem supports innovation in software.”).

343 See IBM at 5 (“Determining whether an invention has a technical character is not always easy, and may lead to some uncertainty, but this test is easier to apply and more predictable than the ‘abstract ideas’ jurisprudence we must wrestle with in the United States.”). See also Google at 4, 8; Internet Association at 3, 10; SIIA at 1.

344 See AUTM at 4 (“While certain differences in the assessment of computer-implemented inventions between the patent offices still persist, it can be generally said that claims providing a technical solution to a technical problem are patentable throughout the world—if claimed properly and provided that the requirements for patentability (i.e., novelty and nonobviousness/inventive step) are fulfilled.”). See also Genentech at 9.

345 See generally App Association; Eagle Forum; Ericsson; IBM; Innovation Alliance; Robert Osann, Jr.; Chad Rafetto; Rio Tinto; John Storella.

of critical areas of technology.³⁴⁶ Others emphasized how the current eligibility analysis is biased and unworkable for computer innovations.³⁴⁷ Some stakeholders, including many companies, acknowledged that robust protections for software are more important than ever because of the ever-increasing reliance on software and AI in medical fields and precision medicine.³⁴⁸

According to several commenters, the uncertainty and lack of protection for AI inventions is affecting the United States' innovative edge and leadership in the world.³⁴⁹ One commenter shared statistics noting that “the United States received 77% of capital investments for software driven industries, such as Artificial Intelligence, in 2013, but only 50% in 2017.”³⁵⁰ The same commenter observed that “in 2017, 48% of the funding for Artificial Intelligence startup companies went to China whereas the United States received only 38%.”³⁵¹ This commenter concluded that

“[b]ecause investment is crucial to developing certain technologies, less investment is likely to result in less innovation.”³⁵² On a global level, it was also noted that “[t]he combination of other countries' patent systems allowing more protection coupled with the increasing funding they are receiving suggests that the two are correlated and thus the uncertainty in America's patent system is reducing funding and therefore reducing innovation.”³⁵³

Though all commenters recognized the importance of fostering AI and quantum computing technologies, not all commenters held the view that stronger or more robust patent rights for these areas would achieve such results.³⁵⁴ Specifically, some commenters advocated that AI innovations should be excluded from eligibility.³⁵⁵ A few commenters pointed out that because patent law remained unchanged for many historical technologies that are considered disruptive, the

346 See App Association at 4 (“The uncertainty around both the ability to get a valid patent on AI inventions, and the threat of lawsuits from issued but potentially invalid patents on various aspects of AI, reduces inventive activity in this space.”); Ericsson at 6; IBM at 5; Mertzluft Law at 3 (“The rejections seen by applicants in such applications can be gratuitously difficult to overcome, and sometimes result in the need to add otherwise extraneous limitations to claims for the sole purpose of satisfying an undefined standard.”); Robert Osann, Jr., at 6 (“[M]any AI applications currently involve a heavy amount of software running on general purpose processors. As such, inventions claiming how the software operates are subject to uncertain eligibility standards, with the resultant rejections and in many cases the inability to protect unique AI inventions in the courts.”); Rio Tinto at 5; Dana Stangel at 2 (“As a practical matter, the patent examiners try to box in the invention with specific, but sometimes irrelevant, details on how the invention is made or performed.”); John Storella at 1 (“[T]he value of patents that do issue tend to be of narrow scope, and there is uncertainty as to whether these patents will provide meaningful exclusion of competitors in the market.”).

347 See AAC at 5; Gregory Aharonian at 1; AIPLA at 2–3; Anonymous #13 at 1; Business Law Section of the Florida Bar at 1–3, 6; Tara Chand at 13; Dominion Harbor Group at 2, 6; Richard Gruner at 12; IBM at 4; IGT at 2; Innovation Alliance at 2–3; Lori Pressman at 5; Chad Rafetto at 28; Joshua Sarnoff at 13–14; TrackTime at 4; USIJ at 8.

348 See AIPLA at 2–3; Genentech at 7 (“The ‘use of bioinformatics to inform serious patient treatment decisions or to design personalized medicines requires extreme precision and more upfront investment from the beginning of the process so that it can perform with stability, accuracy, and predictability at the time of launch. In order to secure this type of investment, there must be no question that such innovations are patent eligible.”); IBM at 5; John Storella at 2 (“In a diagnostic discovery phase, large amounts of data may be collected. This could be measurements of thousands of proteins in [a] sample of blood, or thousands of nucleic acid sequences from a tissue sample [or] thousands of microbes in a feces sample. ... The algorithms that perform this processing can, themselves, may [sic] be novel and useful inventions. ... Under current patent eligibility jurisprudence, the very activity that produces a new, useful, and unobvious diagnostic test is not patent eligible because the process of diagnosis involves the execution of an algorithm.”).

349 See Eagle Forum at 5 (“The state of [section] 101 jurisprudence exposes the United States to a steadily weakened position relative to China and other foreign competitors in critical, emerging technologies' leadership.”); IBM at 8 (“[T]he current U.S. patent eligibility law has an outsized impact on patents for inventions in AI, quantum, and other computer-related inventions, which by nature involve abstractions.”); Innovation Alliance at 7 (“To maintain U.S. leadership in essential and emerging technologies—including artificial intelligence—the U.S. must address the uncertainty of post-*Alice* § 101 jurisprudence.”).

350 Chad Rafetto at 31.

351 *Id.*

352 *Id.*

353 *Id.*

354 See HTIA at 11 (“Put simply, the evidence suggests that seeking to ‘strengthen’ the U.S. patent system by abrogating the Supreme Court's eligibility precedents to expand the scope of patent eligibility would not enhance U.S. competitiveness or increase domestic innovation as many stakeholders have argued. Such a course of action is dramatically more likely to have the opposite effect and reduce competitiveness, impair economic efficiency, deter inventive activities, weaken national security, and impose unnecessary costs and legal risk on domestic businesses.”). See also Robert Crockett at 1; Developers Alliance at 1; EFF at 3–4; Engine at 26.

355 See Robert Crockett at 1; Developers Alliance at 1; EFF at 3–4; Engine at 26 (“AI software inventions should not be any more patentable than typical software. If anything, AI patent claims are more likely to be directed towards abstract ideas under *Alice* and subsequent case law than other software inventions.”).

same reasoning should apply to AI and emerging technologies.³⁵⁶ Finally, a high-tech advocacy group cautioned that the USPTO must continue to evaluate these new and fast-evolving technologies consistent with the current law and ensure proper application of all relevant patentability statutes.³⁵⁷

Relatedly, stakeholders highlighted that the data do not support the inference that the current subject matter jurisprudence is having a negative impact on investment in innovation.³⁵⁸ One software industry organization reported that “[s]ince *Alice*, investment and innovation in the information industries have thrived.”³⁵⁹ The organization noted that “[a]ccording to the Bureau of Economic Analysis, for example, the ‘digital economy’—which includes high-tech goods and services, technological infrastructure, e-commerce transactions, and digital media—accounts for about 9.6% of U.S. GDP, and grew at 6.5% per year on average between 2005 and 2019.”³⁶⁰

Several commenters also pointed to more granular evidence of the post-*Alice* health of the technology sector.³⁶¹ For example, in examining startup and venture capital activity, an industry association pointed out that \$70.4 billion in U.S. venture funding was raised for technology-related activities with global investing at record levels.³⁶² In comparison, this organization noted that China experienced a drop in venture funding during the same period.³⁶³

Moreover, some commenters contended that the United States remains the preferred destination for investment in AI.³⁶⁴ One software association referenced a robust 39% increase year over year of U.S. AI deals.³⁶⁵ This association noted that investment in AI in the United States was approximately \$23.6 billion for the second quarter of 2021, more than double the investment in AI in the next two leading countries, that is, China and the United Kingdom.³⁶⁶

Another high-tech association asserted that investment in research and development has been particularly strong in the *Alice*-affected technologies, citing continued growth in venture capital and investments in startup companies, “with 2021 on track to be ‘another consecutive record-setting year.’”³⁶⁷ This association also referenced impressive growth in investment in startups involving affected technologies like AI, in which “funding for artificial intelligence firms reached a record high of \$20 billion in 2021, up from \$9 billion two years earlier.”³⁶⁸

Likewise, a large high-tech company noted that “[a]rtificial intelligence (AI) and quantum computing (QC) technologies are expected to drive substantial economic growth, with one report estimating that AI could contribute up to \$15.7 trillion to the global economy by 2030, with approximately \$3.7 trillion of that growth in North America.”³⁶⁹ This company highlighted that IP

356 See Robert Crockett at 1; Developers Alliance at 1; EFF at 3–4; Engine at 25 (“[D]espite its transformative tendencies, AI does not need to disrupt the U.S. patent system. Patents have adapted to accommodate revolutionary technologies in the past, such as computer software and genetic engineering. While our patent policies should account for the value of emerging AI technologies—and we commend the Patent Office for seeking public input—the U.S. patent system does not now need substantial changes to accommodate AI.”).

357 See HTIA at 14.

358 See CCIA at 4–6; Dell Technologies at 6–7; Engine at 5, 7–10; HTIA at 5; Internet Association at 15–16; Juniper Networks at 3–4; SIIA at 2–4.

359 SIIA at 2.

360 *Id.* at 2–3.

361 See CCIA at 4–6; Engine at 7–10; HTIA at 4, SIIA at 2–3.

362 SIIA at 2–4.

363 *Id.* at 3.

364 See CCIA at 4–6; Engine at 7–10; HTIA at 4–5, 18; SIIA at 2–4.

365 See SIIA at 4.

366 *Id.* at 3.

367 HTIA at 5.

368 *Id.*

369 See Google at 2.

is not a likely consideration in the development and investment of AI technologies and that the current jurisprudence would not be a factor in the economic impacts of AI development.³⁷⁰

Other commenters relied on increases in patents granted to support the proposition that AI and computing technologies have not been harmed by the current jurisprudence. One commenter provided evidence that there has been an “explosion in artificial intelligence patenting” by citing a recent study by the Institute of Electrical and Electronics Engineers (IEEE), which found that the USPTO granted nearly five times as many AI-related patents in 2018 compared with 2008.³⁷¹ This commenter noted that the IEEE study revealed that “the percentage of AI-related patent grants has more than doubled during these years.”³⁷²

With respect to innovations in quantum computing, commenters advised the USPTO, judiciary, and other decision makers to take time to learn about the technology before determining the impacts of the current jurisprudence.³⁷³ One quantum industry group encouraged the USPTO

to engage in the promotion of small and medium enterprises in quantum innovation.³⁷⁴

3. Mechanical and future technologies

Although the majority of comments were directed to innovations in the life sciences and computer-related technologies, some commenters opined not only on the impacts of the jurisprudence on future innovations, particularly on unknown technologies,³⁷⁵ but also on more traditional industries.³⁷⁶ Some commenters raised concerns that decisions like *American Axle* and *Yu* are just the beginning of a gradual expansion that will effectively swallow future computer-based inventions.³⁷⁷ These commenters noted that certain technologies like quantum computing could easily be reduced to a judicial exception, and they suggested those technologies may be classified as a natural phenomenon or product of nature.³⁷⁸ Commenters explained that companies active in traditional, mechanical-based industries are reevaluating their patenting and investment strategies out of concern that they can no longer rely on patent rights to protect their innovations.³⁷⁹

370 *Id.*

371 Internet Association at 12 (citing Hamidreza Habibollahi, Najaf Abadi & Michael Pecht, *Artificial Intelligence Trends Based on the Patents Granted by the United States Patent and Trademark Office*, 8 IEEE ACCESS 81633, 81634 (2020)).

372 Internet Association at 12. *See also* Dell Technologies at 8 (providing additional data that “[p]atent applications directed to quantum computers grew at a compound annual growth rate (CAGR) of 41.75% between 2016 and 2020. Machine learning applications increased at a rate of 46.01%. And applications on computer systems based on biological models (which includes, for example, an application directed to “[o]ptimizing patient treatment recommendations”), grew at a CAGR of 67.28%”).

373 *See* Anonymous comment #14 at 2 (“Patents may both aid and hinder innovation, and intellectual property policy (and government policy writ large) will undoubtedly shape this industry. Even though this is a nascent industry, patents are being filed and granted in quantum technologies at rapidly increasing rates—the current pace of issued patents related to quantum industries is more than double that of 2018.”); Quantum Industry Coalition (hereinafter QIC) at 2 (“[O]btaining predictable and enforceable patent rights for inventions solving quantum computing technical challenges is crucial ... to help the U.S. maintain and build America’s leadership in quantum computing.”).

374 *See* QIC at 2.

375 *See* Acushnet Company at 4; BPLA at 3 (“In light of the recent holdings in *American Axle* and *Yu*, there is apparently no technical field in which an applicant for a patent can have reasonable certainty that their claimed invention will be deemed concrete and not abstract.”); IBM at 5; IPO at 5.

376 *See* Acushnet Company at 4; BPLA at 3; IBM at 5; IPO at 5; Adam Mossoff at 2.

377 *See* IBM at 5 (“[T]he reach of computer enabled innovation, and a logical extension of the current patent eligibility jurisprudence, have even led courts to find inventions lacking eligible subject matter in cases involving mechanical devices and processes such as an electric car charger, a garage door opener, a method for tuning driveshaft liners, and most recently the design of a digital camera.”); Lori Pressman at 5 (“In view of [the] *American Axle* decision, these concerns are real, and impact other leading edge hardware designs and material innovations inspired by an understanding of the underlying physics.”).

378 *See* Gregory Aharonian at 1 (noting the issues that may arise under 101/102/103 because of the semantics used in quantum physics (“Most of the major terms of quantum physics: ‘wavefunction,’ ‘particle,’ ‘system,’ ‘time,’ ‘set’ and more, have no clear definition in standard physics semantics.”)); Lori Pressman at 5 (explaining that “[q]uantum computing depends on quantum entanglement which is a natural phenomenon, and uses qubits, which could be considered products of nature”).

379 *See* App Association at 3; Acushnet Company at 4 (“Patent eligibility of claimed subject matter is not generally an issue to consider when drafting claims to an article of manufacture such as a golf club. However, *American Axle* clearly changed that dynamic.”); IBM at 5; Rio Tinto at 4.

One organization representing IP owners expressed caution that “this creep will negatively affect the strength of U.S. patents and the U.S. economy because it will drag out the resulting uncertainty and begin to disincentivize investment in new areas

of technology.”³⁸⁰ Opining on the potential impacts, another commenter concluded that without knowing how far the jurisprudence is going to expand, it is not possible to determine how far the economic and innovative impacts will go.³⁸¹

V. Conclusions

The public comments confirmed that the current jurisprudence has altered the landscape for determining patent subject matter eligibility, with particular, though quite different, impacts on the life sciences and computer-related industries. Although the comments demonstrate a continuing divide, respondents agreed that the standard for determining whether an invention is eligible for patenting should be clear, predictable, and consistently applied.

Supporters of the current jurisprudence, primarily from computer-related industries, asserted that the new eligibility standard provides a useful tool for addressing overly broad patents and defending against abusive lawsuits by patent assertion entities. Many commenters expressed the view that by avoiding the need to defend against assertions of such patents, the current jurisprudence is beneficial to innovation and technological development because more resources can be devoted to innovation and enterprise growth instead of to unnecessary legal costs. Representatives from the high-tech industry have even noted that their investments and innovations, including in emerging fields such as AI and quantum computing, have trended upward during the course of the Supreme Court’s evolving eligibility jurisprudence. Members of the life sciences research community and patient advocacy groups also applauded the current

jurisprudence, suggesting that it has made more key scientific information and advancements freely available for scientific research and innovation, which benefits the public at large.

In contrast, critics expressed concern that the jurisprudence has unreasonably and improperly expanded the scope and application of the judicially created exceptions to eligibility, resulting in significant inconsistencies, uncertainty, and unpredictability in the issuance and enforcement of patents. These stakeholders, especially innovators working in life science technologies, argued that the jurisprudence stifles innovation and hurts businesses, particularly startups and SMEs that are most dependent on outside sources of funding, because without reliable patent rights, investors are unwilling to risk capital on these new enterprises. Many stakeholders, including several from other industry sectors, also pointed out that by deterring private investment in startups and SMEs, the current law is having the effect of decreasing competition in several fields and concentrating the market in the hands of a few large, well-funded incumbents. In the fields of diagnostics and precision medicine, some innovators stated that they are no longer seeking patents and are turning to other forms of IP protection, such as trade secrets, at the cost of decreased disclosure of new technological information to the public.

³⁸⁰ IPO at 5.

³⁸¹ Adam Mossoff at 2 (“Applying the *Alice-Mayo* framework, courts have invalidated patents covering classic nineteenth-century technologies, such as new methods for operating oil derricks and for constructing automobile axles. Courts have invalidated twentieth-century innovations, such as holding that a claim ‘directed to’ a wireless electric garage door opener is an abstract idea. This is an alarming shift from the historical approach of the U.S. in securing reliable and effective patent rights in new innovations, which has been a key driver of economic growth in the U.S.”). See also IPO at 5.

Appendix A: Congressional request letter

United States Senate

WASHINGTON, DC 20510

VIA ELECTRONIC TRANSMISSION

March 5, 2021

Mr. Drew Hirshfeld
Commissioner for Patents
Performing the functions and duties of the Director
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Dear Mr. Hirshfeld:

We write you today regarding the state of patent eligibility jurisprudence in the United States. Since the Supreme Court's landmark decisions in *Alice Corp. v. CLS Bank International* and *Mayo Collaborative Services Inc. v. Prometheus Laboratories Inc.*, there has been a lack of consistency and clarity in our nation's patent eligibility laws. Our nation has the world's strongest innovation economy, and 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.

As you are well aware, the United States consistently leads the world in innovation across multiple sectors, including quantum computing, artificial intelligence, 5G, the internet of things, biopharmaceuticals, precision medicine, and life sciences. Our robust innovation economy ensures American citizens not only receive early access to revolutionary and groundbreaking technology, cures, and treatments, but also retain good, sound jobs and economic growth in these industries.

If the United States is going to continue leading in all of these technology sectors, we can no longer continue to ignore the fact that current eligibility jurisprudence has had a dramatic negative impact on investment, research, and innovation. The lack of clarity has not only discouraged investment in critical emerging technologies, but also led the courts to foreclose protection entirely for certain important inventions in the diagnostics, biopharmaceutical, and life sciences industries. At a time when the United States is struggling to contain and treat the worst global pandemic in more than one hundred years, it is simply astounding that current jurisprudence makes it virtually impossible to obtain many patents in the diagnostic methods and precision medicine sectors.

It is past time that Congress act to address this issue. To assist us as we consider what legislative action should be taken to reform our eligibility laws, we ask that you publish a request for information on the current state of patent eligibility jurisprudence in the United States, evaluate

the responses, and provide us with a detailed summary of your findings. We are particularly interested in learning how the current jurisprudence has adversely impacted investment and innovation in critical technologies like quantum computing, artificial intelligence, precision medicine, diagnostic methods, and pharmaceutical treatments. We ask that you provide your findings no later than March 5, 2022.

Thank you for your attention to this matter. If you have any questions, please do not hesitate to contact us. We stand ready and willing to work with you to provide long-term certainty in the area of patent eligibility to ensure our role as the world's leading innovation economy continues for years to come.

Sincerely,



Thom Tillis
United States Senator



Mazie K. Hirono
United States Senator



Tom Cotton
United States Senator



Christopher A. Coons
United States Senator



prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permits was based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the MMPA of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: July 6, 2021.

Julia Marie Harrison,
Chief, Permits and Conservation Division,
Office of Protected Resources, National
Marine Fisheries Service.

[FR Doc. 2021–14658 Filed 7–8–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB207]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of its Scientific and Statistical Committee (SSC) via webinar. See **SUPPLEMENTARY INFORMATION**.

DATES: The SSC meeting will take place July 28, 2021, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held via webinar.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: The meeting is open to the public via webinar as it occurs. Webinar registration is required. Information regarding webinar registration will be posted to the Council's website at: <http://safmc.net/safmc-meetings/scientific-and-statistical-committee-meetings/> as it becomes available. The meeting agenda, briefing book materials, and online comment form will be posted to the Council's website two weeks prior to the meeting. Written comment on SSC agenda topics is to be distributed to the Committee through the Council office, similar to all other briefing materials. For this meeting, the deadline for submission of written comment is 5 p.m. July 28, 2021.

Agenda Items

The SSC will review projections from the SEDAR (Southeast Data Assessment and Review) 73 South Atlantic Red Snapper stock assessment and provide fishing level recommendations; provide comments on a National Marine Fisheries Service draft technical memo entitled “Managing the Annual Catch Limits (ACLs) for data-limited stocks in federal fishery management plans”; and develop a workplan and workgroup for catch level projections best practices for stocks assessed in the South Atlantic region. The SSC will provide guidance to staff and make recommendations for Council consideration as appropriate.

Multiple opportunities for comment on agenda items will be provided during SSC meetings. Open comment periods will be provided at the start of the meeting and near the conclusion. Those interested in providing comment should indicate such in the manner requested by the Chair, who will then recognize individuals to provide comment. Additional opportunities for comment on specific agenda items will be provided, as each item is discussed, between initial presentations and SSC discussion. Those interested in providing comment should indicate such in the manner requested by the Chair, who will then recognize individuals to provide comment. All comments are part of the record of the meeting.

Although non-emergency issues not contained in the meeting agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act,

provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SAFMC office (see **ADDRESSES**) at least (5) business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 2, 2021.

Diane M. DeJames-Daly,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–14604 Filed 7–8–21; 8:45 am]

BILLING CODE 3510–22–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 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. 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 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

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.

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 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,

⁶On 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.

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.

[FR Doc. 2021-14628 Filed 7-8-21; 8:45 am]

BILLING CODE 3510-16-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) and service(s) previously furnished by such agencies.

DATES: Comments must be received on or before: August 8, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202-4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785-6404, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the

service(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following service(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Service Type: Fourth-Party Logistics (4PL) of Personal Protective Equipment Safety Stock

Mandatory for: Department of Homeland Security, Departmental Operations Acquisition Division

Designated y Source of Supply: National Industries for the Blind, Alexandria, VA
Contracting Activity: Department of Homeland Security, Departmental Operations Acquisition Division

Deletions

The following product(s) and service(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s): 7520-01-383-7929—Marker, Tube Type, Highlighter, Chisel Tip, Magenta
Designated Source of Supply: Dallas Lighthouse for the Blind, Inc., Dallas, TX
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

Service(s)

Service Type: Document Destruction
Mandatory for: Defense Logistics Agency, Defense Supply Center, Columbus, OH, 3990 East Broad Street, Columbus, OH
Mandatory Source of Supply: Greene, Inc., Xenia, OH
Contracting Activity: DEFENSE LOGISTICS AGENCY, DCSO COLUMBUS

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2021-14635 Filed 7-8-21; 8:45 am]

BILLING CODE 6353-01-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes product(s) and service(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Date added to and deleted from the Procurement List: August 8, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely

Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202-4149.

FOR FURTHER INFORMATION CONTACT:

Michael R. Jurkowski, Telephone: (703) 785-6404, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Deletions

On 6/4/2021, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51-2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501-8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s): 7930-00-NIB-0213—Finish Remover, Concentrate, 2 Liter

Designated Source of Supply: Beacon Lighthouse, Inc., Wichita Falls, TX
Contracting Activity: STRATEGIC ACQUISITION CENTER, FREDERICKSBURG, VA

NSN(s)—Product Name(s):

7520-01-618-9917—Portable Desktop Clipboard, 9½" W x 1½" D x 13½" H, Black
7520-01-653-5889—Clipboard, Desktop, Reflective Yellow, 9½" W x 1½" D x 13½" H

Designated Source of Supply: LC Industries, Inc., Durham, NC
Contracting Activity: GSA/FAS ADMIN

Agenda

Friday, September 17, 2021

The PCFMAC agenda will include: (a) Reviewing the draft 2022 Annual Deployment Plan and budget update; (b) status update on the partial coverage integrated analysis work plan; (c) an update on observer provider labor issues; (d) public comment; and (e) other business. The agenda is subject to change, and the latest version will be posted at <https://meetings.npfmc.org/Meeting/Details/2374> prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smartphone; or by phone only. Connection information will be posted online at: <https://meetings.npfmc.org/Meeting/Details/2374>.

Public Comment

Public comment letters will be accepted and should be submitted electronically to <https://meetings.npfmc.org/Meeting/Details/2374>.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 31, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021-19092 Filed 9-2-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB383]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Scallop Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Wednesday, September 22, 2021, at 9 a.m. Webinar registration URL information: <https://>

attendee.gotowebinar.com/register/6632293038888778251.

ADDRESSES: Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465-0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will review Framework 34, specifically a review of results of 2021 scallop surveys, and preliminary projections. The primary focus of this meeting will be to develop input on the range of potential specification alternatives for FY 2022 and FY 2023. Framework 34 will implement measures approved through Amendment 21 to the FMP. The action will set ABC/ACLs, days-at-sea, access area allocations, total allowable landings for the Northern Gulf of Maine (NGOM) management area, targets for General Category incidental catch, General Category access area trips and trip accounting, and set-asides for the observer and research programs for fishing year 2022 and default specifications for fishing year 2023. They also plan to discuss the 2021 Work Priorities with a focus on Amendment 21 timelines, including final decision and implementation. Receive updates on the progress of the Scallop Survey Working Group and the evaluation of rotational management. Develop input, if needed. The Committee will also provide input on the range of possible 2022 scallop work priorities. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to

Thomas A. Nies, Executive Director, at (978) 465-0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 31, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021-19123 Filed 9-2-21; 8:45 am]

BILLING CODE 3510-22-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; extension of comment period.

SUMMARY: On July 9, 2021, the United States Patent and Trademark Office (USPTO) published a request for public input on a study it is conducting on the current state of patent eligibility jurisprudence in the United States and on how that jurisprudence has impacted investment and innovation. Through this notice, the USPTO is extending the period for public comment until October 15, 2021.

DATES: *Comment date:* Comments must be received by October 15, 2021. Late comments will be considered to the extent practicable.

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 in the comments. Visit the Federal eRulemaking Portal 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 regarding how to submit comments by other means.

FOR FURTHER INFORMATION CONTACT: Courtney L. Stopp, Office of Policy and International Affairs, USPTO, at Courtney.Stopp@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: At the request of Senators Tillis, Hirono, Cotton, and Coons, the USPTO is conducting a study on the current state of patent eligibility jurisprudence in the United States and on how that jurisprudence has impacted investment and innovation. On July 9, 2021, the USPTO published a request for information, seeking public input to assist in the preparation of that study. See Patent Eligibility Jurisprudence Study, 86 FR 36257 (Jul. 9, 2021). The notice requested public comments by September 7, 2021.

Through this notice, the USPTO is extending the period for public comment until October 15, 2021, to give interested members of the public additional time to submit comments. All other information and instructions to commenters provided in the July 9, 2021, notice remain unchanged. Previously submitted comments do not need to be resubmitted.

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.

[FR Doc. 2021-19112 Filed 9-2-21; 8:45 am]

BILLING CODE 3510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO-P-2021-0037]

Modification of COVID-19 Prioritized Examination Pilot Program

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

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is modifying the COVID-19 Prioritized Examination Pilot Program to accept applications until December 31, 2021. Requests that are compliant with the pilot program's requirements and are filed on or before December 31, 2021,

will be accepted, even if more than 500 requests have already been approved. The USPTO will evaluate whether to terminate or further extend the program during this extension.

DATES: The COVID-19 Prioritized Examination Pilot Program is modified as of September 3, 2021 and is extended to run until December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Robert A. Clarke, Editor of the Manual of Patent Examining Procedure (MPEP) (telephone at 571-272-7735; email at robert.clarke@uspto.gov).

SUPPLEMENTARY INFORMATION: On May 14, 2020, the USPTO published a notice for the implementation of the COVID-19 Prioritized Examination Pilot Program. See COVID-19 Prioritized Examination Pilot Program, 85 FR 28932 (May 14, 2020) (COVID-19 Track One Notice). The COVID-19 Track One Notice indicated that an applicant may request prioritized examination without payment of the prioritized examination fee and associated processing fee if: (1) The application's claim(s) covered a product or process related to COVID-19, (2) the product or process was subject to an applicable Food and Drug Administration (FDA) approval for COVID-19 use, and (3) the applicant met other requirements given in the COVID-19 Track One Notice. As of August 2, 2021, 120 patents have issued from applications granted prioritized status under the pilot program. The average total pendency, including time consumed by continued examination, from filing to issue for those applications was 249 days. The shortest pendency from filing date to issue date for those applications was 75 days.

The COVID-19 Track One Notice indicated that the pilot program would expire after the USPTO accepted 500 applications into the program. As of August 16, 2021, the USPTO had accepted 476 applications into the program, and there were 52 requests to participate that had not yet been acted upon. To ensure that applicants are not refused access to the pilot program due to delays in the USPTO's consideration of the requests to participate, the USPTO is modifying the program to consider on the merits any request filed on or before December 31, 2021, even if an applicant's request to participate is not acted upon until after the USPTO has accepted 500 requests. The USPTO will evaluate whether to terminate or further extend the program during this extension. If the USPTO determines that a further extension of the pilot program is appropriate, the USPTO will publish a subsequent notice further extending the program.

Unless the pilot program is further extended by a subsequent notice to the public, following the expiration of this extension, the pilot program will be terminated, and applicants may instead seek to use the Prioritized Examination (Track One) Program. Applications accorded prioritized examination under the pilot program will not lose that status merely because the application is pending after the date the pilot program is terminated. In other words, applications accepted into the pilot program will continue to be examined under prioritized examination status until that status is terminated for one or more reasons, as described in the COVID-19 Track One Notice.

The Prioritized Examination (Track One) Program permits an applicant to have an application advanced out of turn (accorded special status) for examination under 37 CFR 1.102(e) if the applicant timely files a request for prioritized (Track One) examination accompanied by the appropriate fees and meets the other conditions of 37 CFR 1.102(e). See MPEP 708.02(b)(2). The current fee schedule is available at: www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule.

The Track One Program does not have the restrictions of the COVID-19 Track One Program on the types of inventions for which special status may be sought, as the Track One Program does not require a connection to any particular technology. Moreover, delays associated with the determination of whether an application presents a claim that covers a product or process related to COVID-19 and whether the product or process was subject to an applicable FDA approval for COVID-19 use will be avoided under the Track One Program.

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.

[FR Doc. 2021-19114 Filed 9-2-21; 8:45 am]

BILLING CODE 3510-16-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

Appendix C: Commenting parties

Comments are available at www.regulations.gov/docket/PTO-P-2021-0032/comments.

Associations, nonprofit entities, and other organizations	
1	ACT The App Association (App Association)
2	Alliance for Automotive Innovation (Auto Innovators)
3	Alliance for U.S. Startups & Inventors for Jobs (USIJ)
4	American Bar Association Section of Intellectual Property Law (ABA-IPL)
5	American Civil Liberties Union (ACLU)
6	American Intellectual Property Law Association (AIPLA)
7	Askeladden
8	Association for Molecular Pathology (AMP)
9	Association of American Medical Colleges (AAMC)
10	Association of Amicus Counsel (AAC)
11	Association of University Technology Managers (AUTM)
12	Biotechnology Innovation Organization (BIO)
13	Boston Patent Law Association (BPLA)
14	Breast Cancer Action (BCAction)
15	Business Law Section of the Florida Bar Intellectual Property Committee (Business Law Section of the Florida Bar)
16	Coalition Against Patent Abuse (CAPA)
17	Coalition for the Life Sciences (CLS) (two different submissions received on September 8, 2021)
18	College of American Pathologists (CAP)
19	Computer & Communications Industry Association (CCIA)
20	Conservatives for Property Rights (CPR)
21	Developers Alliance
22	Eagle Forum Education & Legal Defense Fund (Eagle Forum)
23	Electronic Frontier Foundation (EFF)
24	Engine
25	High Tech Inventors Alliance (HTIA)
26	Innovation Alliance
27	Intellectual Property Owners Association (IPO)
28	International Association for the Protection of Intellectual Property (AIPPI)
29	Internet Association

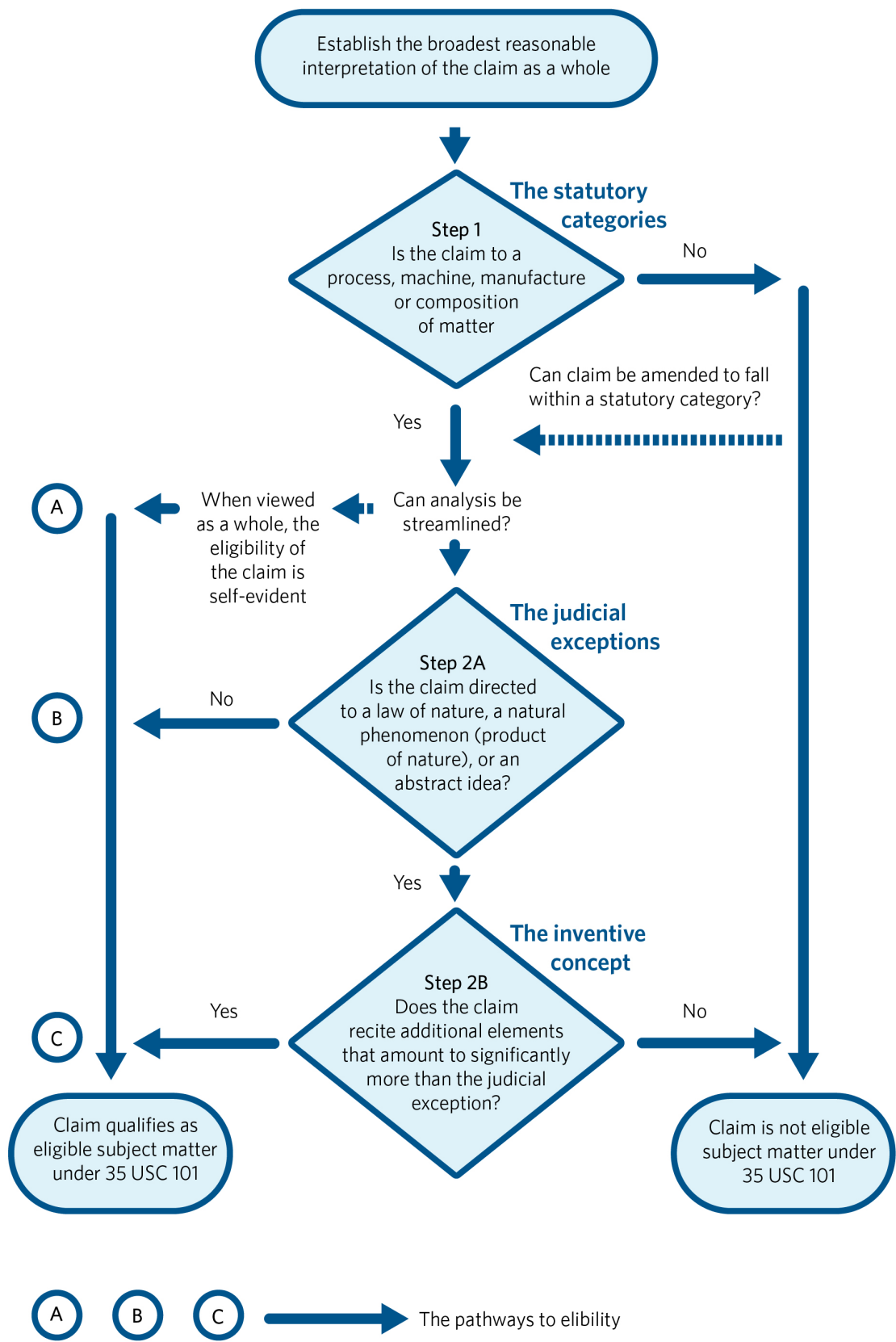
30	Japan Patent Attorneys Association (JPAA)
31	Market Institute
32	Natural Products Association (NPA)
33	New York Intellectual Property Law Association (NYIPLA)
34	Pharmaceutical Research and Manufacturers of America (PhRMA)
35	Public Interest Patent Law Institute (PIPLI)
36	Quantum Industry Coalition (QIC)
37	Software & Information Industry Association (SIIA)
38	State Bar of Nevada Intellectual Property Law Section (Nevada IP Section)
39	The Breasties
40	The Coalition for 21st Century Patent Reform (21C)
41	United for Patent Reform (UFPR)
42	U.S. Chamber of Commerce (U.S. Chamber)
43	Wikimedia Foundation (Wikimedia)
Companies and businesses	
44	Acushnet Company
45	Arrow Antennas
46	Dell Technologies
47	Dominion Harbor Group
48	EasyTracGPS
49	Ericsson
50	Exhaustless
51	Genentech
52	Google
53	IBM
54	IGT
55	Internet Promise Group
56	Invitae
57	Johnson & Johnson
58	Juniper Networks
59	Kraftwürx
60	My Gene Counsel
61	Novartis
62	Rio Tinto

63	STT WebOS and TS Patents
64	TrackTime
Law firms	
65	Mertzlufft Law
66	Rutman IP
67	Saidman Design Law Group
68	Schwegman, Lundberg & Woessner
Healthcare institutions and universities	
69	Laboratory for Clinical Genomics and Advanced Technology at Dartmouth-Hitchcock Medical Center (Dartmouth-Hitchcock Medical Center)
70	Lunenfeld-Tanenbaum Research Institute, Sinai Health System (Sinai Health System)
71	University of Cambridge, Centre for Law, Medicine and Life Sciences (University of Cambridge)
72	Wisconsin Alumni Research Foundation (WARF)
Individuals	
73	Holby Abern
74	Gregory Aharonian
75	Benjamin Broderick
76	Marc Brown
77	Tara Chand
78	Peter Cheng
79	Robert Crockett
80	David Crowther
81	Byron Deeter
82	Nick Desaulniers
83	Charles Duan
84	Maya Durvasula and Heidi Williams, Department of Economics, Stanford University; Lisa Larrimore Ouellette, Stanford Law School
85	Bensefia Faissal
86	Helen Fernandes, Susan Hsiao, and Mahesh Mansukhani
87	Nicholas Frattalone
88	Erik Gottlieb
89	Mark Greenstein (two different submissions received on September 7, 2021)
90	Richard Gruner
91	Will Hairston (two different submissions received on July 9, 2021 and July 10, 2021)
92	David Hornik

93	Alexandra Sasha Hoyt
94	Inas Ibrahim
95	Ilija Ilijovski
96	Ralph Jocke
97	Samuel Johnson
98	Adam Masia
99	Michael Mazza
100	Brandon Mintern
101	William Morriss
102	Stephen Mosher
103	Adam Mossoff, Professor, Antonin Scalia Law School, George Mason University
104	Kent D. Murphy
105	Jacob Nash
106	Seth Nehrbass
107	Timothy O'Leary
108	Robert Osann, Jr.
109	Lori Pressman
110	Chad Rafetto
111	John Richards
112	Robert Rutkowski
113	Joshua D. Sarnoff, Professor, DePaul University College of Law
114	Steven Schneider
115	Steve L. Seawall
116	Anthony Skipper
117	Martin H. Snyder
118	Dana Stangel
119	John Storella
120	Daniel Thomson
121	Mark Tornetta
122	Todd Van Thomme
123	Ted Wang
Anonymous	
Fifteen comments were submitted anonymously	

Appendix D: USPTO guidance on patent subject matter eligibility

Figure D1: Subject matter eligibility test for products and processes



The USPTO guidance on patent subject matter eligibility combines criteria for eligibility into a single analysis that applies to all categories of claims and all types of judicial exceptions (see figure D1).¹ Step 1 of the analysis addresses whether the claimed invention falls into one of the four categories recited in 35 U.S.C. 101. Step 2 applies the Supreme Court’s two-step framework to determine whether an applicant is seeking to patent a judicial exception. USPTO personnel use step 2A to evaluate whether a claim is directed to a judicial exception, and if so, they proceed to step 2B to evaluate whether the additional elements of the claim amount to significantly more than the judicial exception (also known as providing an inventive concept).

Step 2A, which corresponds to the first step of the Court’s two-step framework, is a two-pronged inquiry.² The first prong is a determination of whether a claim recites a judicial exception (i.e., an abstract idea, law of nature, or natural phenomenon). For example, USPTO personnel determine whether a claim recites a law of nature or natural phenomenon by evaluating the claim limitations in connection with scientific principles and natural laws. Examples of these principles include the laws of thermodynamics, Newton’s laws, and the like. USPTO personnel determine whether a claim recites a product of nature (a type of natural phenomenon) by evaluating whether a claimed nature-based product, such as a genetically modified bacterium, has characteristics that are “markedly different” from its naturally occurring counterpart, using considerations derived from judicial precedent including *Myriad*.³

For abstract ideas, the situation is more challenging. The guidance originally required examiners to identify abstract ideas by comparing the claim under examination to concepts previously identified by the courts as “abstract ideas,” but this comparison became impractical over time because of the large number of judicial decisions issued by the courts since *Alice*.⁴ Some stakeholders also criticized the approach as not providing sufficient consistency and predictability. Accordingly, in January 2019, the USPTO revised its guidance to require USPTO personnel to identify abstract ideas by whether a claim limitation falls into one or more groupings of abstract ideas derived from judicial precedent: mathematical concepts, such as math equations; mental processes; and certain methods of organizing human activity, such as fundamental economic practices.⁵

If the claim does not recite a judicial exception, it is considered eligible and the eligibility analysis stops. But if the claim does recite a judicial exception, the eligibility analysis continues to the second prong of step 2A, which was added to the guidance in January 2019. This prong is used to determine whether the claim integrates the recited judicial exception into a practical application of the exception (in which case the claim is eligible), as opposed to being directed to the exception itself (in which case the claim requires further analysis). This determination is made using considerations identified by the courts, such as whether the additional elements improve the functioning of a computer or another technology, whether the claim merely sets the judicial exception in a particular environment or field of use, or whether

1 The flowchart, and an accompanying summary of the analysis, is in MPEP 2106(III).

2 More information about step 2A is provided in MPEP 2106.04 and its subparts.

3 *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013). See also MPEP 2106.04(b) and (c) for more information about laws of nature, natural phenomena, and products of nature.

4 *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208 (2014).

5 The USPTO made this change in January 2019 as part of an effort to “ensure that its more than 8500 patent examiners and administrative patent judges apply the *Alice/Mayo* test in a manner that produces reasonably consistent and predictable results across applications, art units and technology fields.” 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 2019) (2019, 7 PEG); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012). The current guidance on identifying abstract ideas is in MPEP 2106.04(a).

there is a step in the claim that applies or uses the judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition.⁶ If the claim passes the second prong of step 2A, it is considered eligible and the eligibility analysis stops.

If the claim does not pass step 2A, the analysis continues to step 2B, which is an evaluation using similar considerations.⁷ USPTO personnel may also consider in step 2B whether an additional element (or combination of elements) is a well-understood, routine, conventional activity, and if this consideration is relied upon, it must be supported by a written factual determination that the element is widely prevalent or in common use in the relevant industry.⁸ If USPTO personnel determine in step 2B that the additional elements do amount to significantly more than the judicial exception, then the claim is eligible. If the additional elements do not amount to significantly more, then USPTO personnel will reject the claim as lacking eligibility, and the applicant will be given a chance to respond, for example, by amending the claim or by making a showing of why the claim is eligible for patent protection.⁹ Regardless of whether an eligibility rejection is made, the examiner will also evaluate the claim to determine if it meets the other requirements for patentability such as novelty and non-obviousness.

The guidance also includes 46 examples to assist USPTO personnel and stakeholders in applying the guidance to various fact patterns and technologies, including artificial intelligence, biotechnology, business methods, computer-related inventions, diagnostic and treatment methods, pharmaceutical treatments, precision medicine, and software.¹⁰ The USPTO has also conducted extensive training to keep USPTO personnel updated about developments in subject matter eligibility and application of the guidance. The examples, examiner training, and other supplemental materials are all publicly available and posted on the USPTO's subject matter eligibility webpage.¹¹

⁶ The addition of a second prong in step 2A was also made in the 2019 PEG. Current guidance on this prong is in MPEP 2106.04(d).

⁷ See MPEP 2106.05(a).

⁸ The requirement to support a conclusion of well-understood, routine, conventional activity was introduced by the USPTO Memorandum of April 19, 2018, "Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*)," which is available at <https://www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility-examination-guidance-date>. The current guidance on this requirement is in MPEP 2106.07(a)(III).

⁹ For more information on how examiners formulate rejections for lack of subject matter eligibility, and evaluate applicant responses thereto, see MPEP 2106.07 and its subparts.

¹⁰ See, e.g., Examples 36 and 39 (relating to artificial intelligence), Examples 29 and 31 (relating to diagnostic methods), Examples 43 and 46 (relating to precision medicine), and Examples 11, 12, 16, 17, 28, and 44 (relating to pharmaceuticals and pharmaceutical treatments). These examples, and an index providing an overview of the relevance of each example, are available at <https://www.uspto.gov/PatentEligibility>.

¹¹ <https://www.uspto.gov/PatentEligibility>.



U.S. Patent and Trademark Office

600 Dulany Street ▪ Alexandria, Virginia, 22314 ▪ www.uspto.gov