AIPLA

American Intellectual Property Law Association

October 15, 2021

The Honorable Andrew Hirshfeld,
Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Via Federal eRulemaking Portal

Re: AIPLA Comments on USPTO Request for Information to Assist Preparation of Patent Eligibility Jurisprudence Study, 86 Fed. Reg. 36257 (9 July 2021) and 37316 (15 July 2021).

Dear Commissioner Hirshfeld:

The American Intellectual Property Law Association ("AIPLA") is pleased to have the opportunity to present its views to assist the preparation of the Patent Eligibility Jurisprudence Study [Docket No. PTO-P-2021-0032].

Established in 1897, the American Intellectual Property Law Association is a national bar association of approximately 8,500 members who are engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent (utility and design), trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping to establish and maintain fair and effective laws and policies that stimulate and reward invention but that also balance the public's interest in healthy competition, reasonable costs, and basic fairness.

AIPLA values its long, constructive relationship working with the United States Patent and Trademark Office ("USPTO" or the "Office") to foster innovation. Based on its members' experiences, AIPLA believes that incentivizing innovation—investment in research and development, commercialization, and investment in licensing and other IP transactions—requires a high level of certainty and predictability, which the courts are not providing. Our member surveys going back to 2012 identified Section 101 as the most important issue facing our members as they try to advise their clients on how to best invest their limited resources. Our members have been unable to advise their clients with enough certainty about what inventions would be deemed patent eligible by patent examiners and later by the courts.

For these reasons, AIPLA welcomes the USPTO's study and looks forward to continued collaboration with the Office and with Congress to ensure a sound patent system that nurtures an innovation ecosystem.

Responses

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.

Response:

In our view, the current state of patent eligibility jurisprudence has had a negative impact on the predictability and reliability of patent protection, particularly in the life sciences and software industries. The Supreme Court has invoked a variety of non-statutory policy concerns to narrow the scope of patent-eligible subject matter, developing the *Alice-Mayo* test to implement these non-statutory criteria.[1] The Court's distortion of patent eligibility has endangered the patentability of important and, in some cases, critical innovations.

The harm done to important life sciences innovations is demonstrated in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *en banc review denied*, 809 F.3d 1282 Fed. Cir. (2015). The patent in this case claims a process for detecting paternally inherited fetal DNA in maternal blood samples, which permits a prenatal diagnosis of possible birth defects in a non-invasive manner. The Federal Circuit held that the claimed invention is ineligible for patent protection under *Mayo* because it is directed to well-understood, routine, and conventional steps that act on a natural phenomenon, even though the invention as a whole was acknowledged to be "groundbreaking."

The *Ariosa* decision disregards the Supreme Court's admonition in *Diehr* that "a new combination of steps in a process may be patentable even though all the constituents of the combination were well-known and in common use before the combination was made."[2] In a concurrence to the denial of *en banc* review of the *Ariosa* decision, Judge Lourie suggested that the Supreme Court rules may have put the whole category of diagnostic claims at risk, creating a crisis of patent law and medical innovation.

Likewise, software-implemented inventions are frequently deemed ineligible as being directed to abstract ideas. This category of subject matter has its roots in attempts to claim different types of mathematical algorithms. But current law has dissolved the boundary between a claim to an algorithm itself and a legitimate claim to a system that uses an algorithm. Software-implemented innovations, which power our modern world, are no less deserving of patent protection than any other type of innovation. Software is the enabling technology for improving the way we provide healthcare (*e.g.*, surgical robots), drive automobiles (*e.g.*, automatic parallel

[1] The *Alice-Mayo* test is the two-step framework for assessing patent eligibility, established by the Supreme Court in two cases, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012), and *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014).
[2] *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

parking systems), and communicate with people around the world (*e.g.*, video conferencing). Failure to provide adequate patent protection in the life sciences and software industries could weaken competition and hamper innovation.

Further, the current state of patent eligibility law has had an adverse effect on the ability to obtain patent protection needed to advance new technologies. The judiciary has created uncertainty surrounding Section 101 law that presents obstacles for patent applications claiming innovative and emerging technologies. This uncertainty has led to rejections by the U.S. Patent and Trademark Office that either delay or preclude consideration of the invention on the merits.

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. The Federal Circuit has made this abundantly clear in recent decisions rejecting the reasoning and application of the USPTO's guidance, explaining: "[w]e are not, however, bound by the Office Guidance, which cannot modify or supplant the Supreme Court's law regarding patent eligibility, or our interpretation and application thereof. *In re Rudy*, 956 F.3d 1379, 1383 (Fed. Cir. 2020); *see also Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App'x 1013, 1020 (Fed. Cir. 2019) ("While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law.").

The *Alice-Mayo* test is causing these detrimental results. A 2017 study of datasets of USPTO rejections and issuances between 2013 and 2015, analyzed Section 101 rejections before and after the *Alice Corp. v. CLS Bank*.[3] This Madigan-Mossoff study points out that USPTO subject matter rejections of patent applications doubled in the chemical engineering field (from 1.5% to 3.2%), nearly doubled in the mechanical arts space (from 3.7% to 6.1%), and increased by more than one-third (from 10.2% to 15.5%) for patent applications directed to networks and video technology.

Concomitantly, the current jurisprudence has narrowed the pipeline for inventions that are patent eligible under U.S. law, while applicants in other key jurisdictions, specifically China and Europe, are obtaining patent protection on applications claiming the same inventions.

The Madigan-Mossoff study reports that 17,743 U.S. patent applications received a final rejection on Section 101 grounds and the applications were later abandoned between August 1, 2014 and September 27, 2017.[4] No patent was granted on these applications or on any related

[3] *See* Kevin Madigan & Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 Geo. Mason L. Rev. 939 (analyzing a database compiled by Robert Sachs, a Partner at Fenwick & West, and David Kappos, a Partner at Cravath, Swaine & Moore LLP and former Director of the USPTO, using USPTO datasets of patent rejections and issuances from 2013-2015).
[4] *See* Madigan & Mossoff, 955-959.

application in the United States. By comparison, 1,694 patent applications claiming the same or similar inventions as claimed in U.S. applications were granted by either the European Patent Office and/or the Chinese Patent Office. Some of those applications rejected by the USPTO on eligibility grounds but issued by the European and Chinese Patent Offices were directed to diagnostic inventions, including methods and compositions for diagnosing cancer, apparatuses and methods for user interactions during ultrasound imaging, and a medical device for peritoneal dialysis.

These setbacks in the U.S. patent system have also been noticed by those who finance technological innovations. A recent study by David O. Taylor surveyed 475 venture capital and private equity investors to analyze the impact of the Supreme Court's eligibility rulings on decisions to invest in companies developing technologies across a range of fields.[5] ("Taylor Survey") The survey reported that 74% of investors agreed that patent eligibility is an important consideration for deciding whether to invest in companies that are developing particular technologies. On average, according to the survey, investment in a wide range of industries would decrease with reduced patent eligibility. Moreover, the survey revealed that decreased patent eligibility has a differential impact on investment in various industries. For example, 77% of investors responded that reduced patent eligibility would decrease their investment in biotechnology, 79% would decrease their investment in medical devices, and 73% would reduce their investment in the pharmaceuticals.

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.

[5] David O. Taylor, *Patent Eligibility and Investment*, 41 Cardozo L. Rev. 2019 (2020). http://cardozolawreview.com/wp-content/uploads/2020/10/6.-Taylor.41.5.3.FINAL-1.pdf (describing results of a survey of venture capital and private equity investors revealing reduced investment in research and development due to the Supreme Court's recent eligibility decisions).

Response:

In response to question 1, we explained the impacts our members have experienced because of the current state of patent eligibility jurisprudence in the United States, especially in the life sciences and software industries. We also explained the adverse impact of the current state of patent eligibility jurisprudence on the ability of businesses to obtain financing in cutting-edge technologies. Those adverse impacts are directly felt in innovation, research and development, product development, employment, and competition.

We believe that an effective patent system requires predictable and reliable rules in order to "promote the progress of … the useful arts." In our view, once the fog surrounding patent eligibility lifts, an overall increased rate of innovation will follow, resulting in more competition to develop products that improve the quality of life for all. The current state of patent eligibility jurisprudence has interfered with achieving this result by increasing uncertainty and risk. For example, personalized medicine offers the promise of targeted therapies that are more effective and efficient than prior medical treatments. This improves outcomes for individual patients and targets expenditures on therapies that have a higher likelihood of success for a particular patient population. If the exclusive rights conferred by patents are in doubt, these innovations will not advance .

The uncertainty created by the current state of patent eligibility jurisprudence in the United States directly impacts patent enforcement and litigation, patent counselling and opinions, and licensing strategy. In litigation, courts may find an invention ineligible for patent protection as a matter of law and dismiss infringement actions without trial under a Rule 12(b)(6) dismissal or a summary judgment. Aside from the shortcomings of the *Alice-Mayo* test, this short-cut procedure glosses over fact issues underlying that test and prevents the examination of the merits of an invention at trial.[6]

Routine pre-trial determinations of ineligibility are not confined to life sciences and software inventions. The Federal Circuit recently affirmed a summary judgment that a claimed process used in connection with a mechanical device was directed to a law of nature.[7] The decision refused to recognize any dispute of material fact as to whether the use of a law of nature in the claimed process necessarily meant that the claim was "directed to" that law of nature.

This confusion and uncertainty permeates patent prosecution and procurement strategies, portfolio management, and patent counselling and enforcement. One outcome is that businesses faced with uncertain patent protection, coupled with the necessity of public disclosure, increasingly rely on trade-secret protection in lieu of seeking patent protection, depriving the public of disclosure of innovations.

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[6] The Federal Circuit finally recognized the problems with such pre-trial determinations of ineligibility in *Berkheimer v. HP Inc*., 881 F.3d 1360 (Fed. Cir. 2018), *en banc review denied*, 890 F. 3d 1369 (Fed. Cir. 2018)(fact issues on whether a technology was well-understood and routine precluded summary judgment); *AAtrix Software, Inc. v. Green Shades Software, Inc.*, 882 F. 3d 1121 (Fed. Cir. 2018)(patent owner's allegations as to the presence of an inventive concept raise fact issues that precluded dismissal under Rule 12(b)(6)). However, even these decisions fall short of providing sufficient guidance to bring pre-trial determinations of ineligibility under control.

[7] *American Axle & Mfg. Inc. v. Neapco Holdings LLC*, 967 F.3d 1285 (Fed. Cir. 2020).

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).***

Response:

The current state of patent eligibility jurisprudence in the United States has dampened the interest of venture capital and private investment firms in funding particular technological fields. The Taylor survey and analysis discussed above provides empirical evidence of an overwhelming belief that patent eligibility is an important consideration in investment decisions, and that reduced patent eligibility makes it less likely their firms will invest in companies developing technology, particularly in the life-science industry.[8]

Taylor used a database of individual investors and investment firms from across all 50 states who fund a wide range of industries. He sent his survey to 14,641 investors and 3,304 investment firms 475 investors and 422 investment firms responded. The survey questions related only to U.S. patents and only to financing activities in the United States. The Taylor survey demonstrates the negative impact of the Supreme Court's recent patent eligibility decisions on this investment. Specifically, it reveals that investors knowledgeable about those decisions shifted investments out of the pharmaceutical, biotechnology, medical device, software, and Internet industries.

Taylor's conclusions are consistent with our members' experiences. For example, one member who is part of an angel investment group reported that intellectual property is a key consideration as to whether their group invests. If there are no patents, or if the patents are vulnerable to a Section 101 challenge, the group will often pass on the investment. For example, the investment group decided not to invest in a medical diagnostic company with a promising technology for the early detection of a particular type of cancer because it was unlikely that the company could prevent others from using the same diagnostic method. This member reported that similar situations have arisen with software companies, explaining that potential investors believe that the "first mover" advantage is often not enough for a small company that does not have patent protection where there are dominant companies in the same space that could easily pivot if the small company gains traction. The erosion of the scope of what is considered patent eligible (and the attendant uncertainty as to boundaries of patent eligibility) has a direct impact on companies (especially small businesses) by impacting their access to early-stage funding.

[8] *See* footnote 5, *supra*.

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.

Response:

Our members observe that compliance with subject-matter eligibility requirements in other jurisdictions is more predictable because the requirements are clearer and more consistently applied in examination and enforcement.[9] The predictability of outcomes is an important factor in deciding whether to seek patent protection in another country due to the high costs of obtaining patents outside the United States.

For example, in Europe, any invention in any field of technology can be patented if novel and inventive; certain types of inventions are categorically excluded, but only "as such." The means they claim no other feature. Thus, a computer program—meaning, literally, a listing of program instructions—is not patentable as such. A method implemented using the programmed computer, however, is not excluded and is eligible. In March 2021, the Enlarged Board of Appeal of the European Patent Office issued a decision spelling out this distinction with the following propositions:[10]

> 1. A computer-implemented simulation of a technical system or process that is claimed as such can, for the purpose of assessing inventive step, solve a technical problem by producing a technical effect going beyond the simulation's implementation on a computer.
>
> 2. For that assessment it is not a sufficient condition that the simulation is based, in whole or in part, on technical principles underlying the simulated system or process.
>
> 3. The answers to the first and second questions are no different if the computer-implemented simulation is claimed as part of a design process, in particular for verifying a design.

Some U.S. businesses and innovators express concern with this categorical list of exclusions. Yet, this clear eligibility standard can be easily met by reciting at least one technical feature in the claim.

Because non-technical features or limitations in claims cannot be relied upon to meet novelty and inventiveness requirements, drafting claims that would meet the inventiveness requirement presents a challenge for some types of subject matter. From an eligibility perspective, however, the impact of this on the outcome of an inventiveness determination is relatively predictable.

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[9] This is not to say that the requirements of the different countries are consistent with each other, or that they give, for any given type of subject matter, broader protection. For example, it is well known that certain jurisdictions categorically exclude patents for certain types of subject matter, such as pharmaceuticals and medical treatments.

[10] G_1_19_decision_of_the_Enlarged_Board_of_Appeal_of_10_March_2021_en.pdf (epo.org).

In China, the availability of patent protection for computer-implemented inventions is becoming more permissive. China is now one of the global leaders in patent filings. Chapter 1, Article 2 of the Patent Law of the People's Republic of China defines "inventions" to "mean new technical solutions proposed for a product, a process or the improvement thereof." Article 25 provides that patent rights are excluded for certain categories, including "rules and methods for intellectual activities," and computer programs may fall into this category of exclusion. While computer programs per se are not patent eligible, that same exclusion does not apply to all inventions that are computer-implemented.

Under revised guidelines, which took effect in 2017, computer-implemented inventions that involve a technical feature may be protectable under patent laws in China.[11] Under the guidelines, "[i]f a claim merely relates to an algorithm, or mathematical computing rules, or computer programs per se, or computer programs per se recorded in mediums (such as tapes, discs, optical discs, magnetic optical discs, ROM, PROM, VCD, DVD, or other computer-readable mediums), or rules or methods for games, etc., it falls into the scope of the rules and methods for mental activities and does not constitute the subject matter for which patent protection may be sought." This amendment was "intended to distinguish a sequence of machine-readable code which should be protected by copyright from the technical solution based wholly or partially on process flow of computer programs."

In Japan, eligibility focuses on whether a claimed invention as a whole involves the "creation of a technical idea utilizing a law of nature" and results in more software patents allowed in Japan than in the United States. A two-step inquiry is used for software-related inventions. The first step is to determine whether the claims, setting aside the software aspect, involve the "creation of a technical idea utilizing a law of nature." If this requirement is met, then interplay between software and hardware (i.e., implementation a process on a computer system) is analyzed and may support a patent eligibility determination.

> ***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.***

Response:

The Madigan-Mossoff study offers several examples of subject matter that was deemed ineligible for patenting in the United States, but was granted patent protection in Europe and/or China. The included examples, which were subject to either final or non-final rejections, pertain generally to medical processes and devices, such as:

[11] *See* Revisions of the Patent Examination Guidelines in China, https://www.regimbeau.eu/REGIMBEAU/GST/COM/PUBLICATIONS/2017-03-Revisions-to-the-Patent-Examination-Guidelines-in-China-DAS-b.pdf; see also https://www.ccpit-patent.com.cn/node/4375.

- methods and compositions for diagnostic use in cancer patients;
- apparatuses and methods for user interactions during ultrasound imaging;
- a method for detecting gynecologic cancer;
- a method for early determination of recurrence after therapy for prostate cancer;
- an analyte testing method and system for treating diabetes-related complications;
- methods and kit for the prognosis of breast cancer;
- a medical device for perioneal dialysis;
- method of diagnosis of acute strokes; and
- methods of diagnosing and treating prostate and lung cancer.

The list of examples also includes a method of growing plants, and control apparatus and control method for internal combustion engine.

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.

Response:

Yes, based in our members' experiences, the uncertainty surrounding patent eligibility in the United States has resulted in an inability to protect certain inventions subject to these non-statutory requirements. This has increased costs, decreased the level of protection available, and increased uncertainty regarding enforcement. Each of these effects has caused applicants to modify or shift investment and research and development to activities that are more effective, reliable, and predictable. This, in turn, has shifted resources away from productive activities that would otherwise have occurred as well as reducing U.S. patenting and enforcement activity.

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.

Response:

Most innovators rely on a combination of trade secrets and patents to protect investments in innovations and new products. For any given piece of intellectual property, the advantages and disadvantages of employing trade secret protection must be weighed against the advantages and disadvantages of patenting.

Our members have observed that the choice between trade secret protection and patents has shifted toward trade secrets in at least certain fields and for certain types of subject matter.[12]

[12] *See also* Samuel J. LaRoque, Comment, Reverse Engineering and Trade Secrets in the Post-Alice World, 66 U. KAN. L. REV. 427, 431–35 (2017); Sonia K. Katyal, The Pardadox of Source Code Secrecy, 104 CORNELL L. REV. 1183, 1191–1236 (2019).

This shift deprives the public of disclosure, and later use, of information that would otherwise have been made public, enriching the public domain.

Where there is a lack of certainty around patent-eligibility, the likely return on investment, measured in terms of the loss of trade secret status of the invention, has decreased. In short, if trade secret protection is a viable alternative, there is much less reason to take on the risk associated with filing a patent application, i.e., publication of the detailed description of the invention 18 months after filing the application.

In addition, a recent study has shown that, in technical fields where subject matter rejections are common, it costs more to prosecute patent applications and the outcomes are poorer and less predictable.[13] Therefore, even where trade secret protection is risky, there is good reason not to pursue patent protection. As a result, fewer patent applications are being filed in these fields.[14]

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. Having to keep information secret slows the flow of information and impedes formation of business relationships and transactions involving intellectual property. Although such information could be shared using non-disclosure agreements, parties are often justifiably reluctant to sign one. Furthermore, the best way to keep something secret is to disclose it to as few people as possible, even if they have agreed to keep it secret.

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.

Response:

The recent empirical study of the influence of the *Alice* decision on patent prosecution, discussed above, reports that "*Alice* increases transaction costs associated with patent prosecution and creating uncertain outcomes in patent allowance."[15] In the face of increased rejections based on *Alice*, applicants are using a number of different strategies including filing

[13] Jay P. Kesan and Runhua Wang, Eligible Subject Matter at the Patent Office: An Empirical Study of the Influence of Alice on Patent Examiners and Patent Applicants (March 17, 2020). Minnesota Law Review, Vol. 105, Issue 2, 2020 (Forthcoming), available at SSRN: https://ssrn.com/abstract=3556216. ("Patent applicants in all three technology areas decreased their reliance on the patent system and filed fewer patent applications, compared to the time period before Alice, with the greatest reduction occurring in bioinformatics. Patentees in some technology areas were successful in overcoming Sec. 101 rejections after Alice, but patentees in other areas were not as successful in overcoming Alice-based rejections. Applications in bio-informatics received many more Sec. 101 rejections based on Alice, but these applicants also faced difficulties in overcoming those rejections. Meanwhile, patent applications based on business methods also received more Sec. 101 rejections based on Alice. But patent applicants in business methods learned from Alice and received fewer Sec. 101 rejections when they filed patent applications after Alice. Alice also imposed various degrees of patenting costs for different types of software innovation.")

[14] *Id.*

[15] Kesan and Wang, at 78.

amended claims, filing new patent applications, abandoning patent prosecution entirely, or choosing not to pursue patent protection for at least certain innovations.[16]

This is consistent with our members' experiences. As noted above, AIPLA member surveys going back to 2012 identified Section 101 as the most important issue facing our members as they try to advise their clients on how to spend their limited resources. Our members have been unable to advise their clients with enough certainty about what inventions would be deemed patent eligible by patent examiners and later by the courts.

Fewer patent applications and the higher cost of patent prosecution with uncertainty about the availability of patent protection will adversely impact transactions involving patents and patent applications, including the licensing and sales of patent assets. The chilling of transactions will, in turn, limit economic growth, including investment on research and development activity as well as the creation of jobs to support that activity.

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.

Response:

Patent eligibility jurisprudence impacts patent enforcement. Section 101 may be raised as a defense at the outset of litigation through a motion to dismiss or an early motion for summary judgment.[17] Such motions are filed frequently, especially in cases involving computer-implemented technology. The Federal Circuit has recognized the problems with such pre-trial determinations of ineligibility. *See, e.g.*,*Berkheimer v. HP Inc*., 881 F.3d 1360 (Fed. Cir. 2018), *en banc review denied*, 890 F. 3d 1369 (Fed. Cir. 2018) (fact issues on whether a technology was well-understood and routine precluded summary judgment); *AAtrix Software, Inc. v. Green Shades Software, Inc.*, 882 F. 3d 1121 (Fed. Cir. 2018) (patent owner's allegations as to the presence of an inventive concept raise fact issues that precluded dismissal under Rule 12(b)(6)). Nevertheless, these decisions fall short of providing sufficient guidance to bring pre-trial determinations of ineligibility under control, fact issues underlying *Alice-Mayo* test are glossed over and there is no detailed examination of the merits of an invention informed by claim construction, fact discovery, and expert discovery.

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 U.S. economy as a whole.

[16] *Id.*
[17] See discussion above in response to Question 2.

Response:

As explained above in response to questions 3 and 7, the 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) and limited access to funding to small companies. In the short term, economic growth and jobs are limited. In the long term, innovation is limited by the decrease the disclosure of inventions through the patenting process.

Indeed, scholars have noted that the United States patent system has been at the forefront of conveying intellectual property rights in technological innovation.[18] The Madigan-Mossoff study notes that in the last two centuries "the spread of patent laws across the world ... were explicitly modeled on the U.S. system."[19] In particular, "the [U.S.] patent system has generally secured stable and effective property rights in the new innovation that drove the Industrial Revolution, the Biotech Revolution, and the Digital Revolution."[20] The 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. AIPLA is deeply concerned that this loss of leadership by our country's patent system will have serious negative implications for our economy in the future.

11. Please identify how the current state of subject matter eligibility jurisprudence in the United States impacts the global strength of U.S. intellectual property and the U.S. economy in any of the following areas:

a. quantum computing;
b. artificial intelligence;
c. precision medicine;
d. diagnostic methods;
e. pharmaceutical treatments; and
f. other computer-related inventions (e.g., software, business methods, computer security, databases and data structures, computer networking, and graphical user interfaces).

Response:

As noted above in response to Questions 1, 3, and 5, the current state of patent eligibility jurisprudence has adversely impacted the ability to obtain patent protection in a number of technologies, including the technological fields of precision medicine, diagnostic methods, pharmaceutical treatments, as well as software and computer-implemented inventions. The Taylor Survey results discussed above confirm that investors knowledgeable about subject matter eligibility jurisprudence shifted investments out of the pharmaceutical, biotechnology, medical device, and software and Internet industries, thereby weakening some of this country's largest industries.

[18] Madigan & Mossoff at 942.
[19] *Id.* at 942.
[20] *Id.* at 946.

12. 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?

Response:

For the reasons explained above, the current eroding state of patent eligibility jurisprudence (and its uncertain boundaries) adversely affects the public by decreasing incentives to invest in the development of products that will improve our well-being, including medical diagnostics and treatments as well as computer-implemented inventions.

AIPLA further notes that the uncertainty around Section 101 law and its application to innovations of artificial intelligence also threatens to undermine our national security. The 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. This is especially important considering China's efforts to leverage and exploit IP policies. 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." Final Report at 12 (emphasis added).

AIPLA appreciates the opportunity to provide these comments and would be happy to answer questions they may raise.

Sincerely,

Joseph R. Re
President
American Intellectual Property Law Association