COMMENTS OF PUBLIC INTEREST PATENT LAW INSTITUTE ON PATENT ELIGIBILITY JURISPRUDENCE STUDY

Docket Number: PTO-P-2021-0032


PIPLI is a nonprofit, nonpartisan public interest organization dedicated to ensuring the patent system promotes innovation and access for the benefit of the whole public. Most Americans depend on access to patented technology but do not participate directly in the patent system—among them, research scientists, software programmers, small businesses, patients, and doctors. As a result, the interests of these constituencies are inadequately represented in the institutions that decide the course of patent law even though these decisions concretely affect their lives and livelihoods. This lack of representation makes it more difficult for the patent system to appropriately balance incentivizing private investment and protecting public access to knowledge.

PIPLI works to improve the patent system’s ability to strike a fair and effective balance for all members of the public. To enhance public representation in the patent system, PIPLI conducts policy research; engages in educational outreach; advocates for greater transparency, ethics, and equity in the patent system; and represents the public’s interest before institutions that shape patent law and policy, including courts, agencies, and standard-setting organizations.

Patent eligibility law concretely affects the lives and livelihoods of all Americans. As such, PIPLI respectfully urges the USPTO to give the public’s interest the full and fair consideration it deserves.

I. OVERVIEW


This longstanding prohibition is of paramount importance to the public. As the Court has repeatedly recognized, protecting public access to products of nature, natural phenomena, and abstract ideas ensures the patent system promotes more innovation than it deters. That is so because
these categories of subject matter do not encompass products of human invention, but rather, the building blocks on which human inventive potential depends.

The COVID-19 pandemic has highlighted the importance of preserving public access to laws of nature, natural phenomena, and abstract ideas. The patent eligibility requirements set forth in *Myriad*, *Mayo*, and *Alice* have been and remain crucial to our country’s COVID-19 response and recovery efforts. Because of them, we have more advanced, accessible, and affordable technology for COVID-19 testing, virus tracking, and telehealth services, which have significantly improved public health outcomes.

Given the public benefits attributable to current patent eligibility jurisprudence, the USPTO’s approach to assessing patent eligibility should be as faithful to that jurisprudence as possible. We respectfully urge the USPTO to ensure its patent eligibility guidance is consistent with the Constitution, Supreme Court precedent, and public interest.

II. THE CURRENT STATE OF PATENT-ELIGIBILITY JURISPRUDENCE.

Section 101 of the Patent Act defines patent eligible subject matter as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” The Supreme Court has long held that this provision, which has remained virtually intact since the Patent Act of 1793, implicitly excludes subject matter that humans did not and could not have invented: laws of nature, natural phenomena, and abstract ideas.

These implicit prohibitions are rooted in the Constitution, which defines the purpose of the patent system: “promot[ing] the progress of science and useful arts.” As the Supreme Court has recognized, “[t]he patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.”

*Myriad*, *Mayo*, and *Alice* stay true to the Constitution and the Patent Act by protecting the public’s access to the building blocks of scientific progress that humans did not and could not have invented. These cases establish that patents claiming laws of nature, natural phenomena, or abstract ideas without adding significantly more are not eligible for patent protection. In so doing, they apply well-established legal principles to modern technologies—namely, genetic testing, biological diagnostics, and computer networking—and thus ensure the patent system can promote more innovation than it deters.

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2 See *Diamond v. Diehr*, 450 U.S. 175, 182 (1981) (“[A] process has historically enjoyed patent protection because it was considered a form of ‘art’ as that term was used in the 1793 Act.”).
3 See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (rejecting suggestion “that § 101 has no limits or that it embraces every discovery,” pointing out that “[t]he laws of nature, physical phenomena, and abstract ideas have been held not patentable, and collecting cases dating back to 1853).
4 U.S. CONST. art. I, § 8, cl. 8.
III. THE IMPORTANCE OF CURRENT PATENT ELIGIBILITY JURISPRUDENCE TO COVID-19 RESPONSE AND RECOVERY EFFORTS.

The Supreme Court has long stressed the foundational importance of the public’s interest to the patent system. Congress was given the authority to grant patents “in the hope that the productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.” In other words, the patent system was designed to benefit the public.

The patent system has met its goal of benefiting the public throughout the COVID-19 pandemic because of the protections patent eligibility law currently provides. The Supreme Court’s decisions in *Myriad*, *Mayo*, and *Alice* have saved countless lives through their impact on domestic COVID-19 recovery efforts, including crucial developments in testing, tracking, and treatment. Together, these precedents have ensured public access to essential technologies while enabling the government to focus its attention and resources on public health instead of defensive patenting efforts and inflated health care costs.

The contrast to the 2003 SARS outbreak is striking. That outbreak occurred before the Supreme Court made clear in *Myriad* that genetic sequences are ineligible for patent protection. As a result, private companies raced to obtain patents on key viral sequences. In response, the U.S. Centers for Disease Control and Prevention defensively filed its own patent applications to protect patients’ and researchers’ access to essential research and treatment tools. Thanks to *Myriad*’s prohibition on patenting gene sequences, patent races and waste of government resources have not again endangered public health as they did during the 2003 SARS outbreak.

As described further below, *Myriad*, *Mayo*, and *Alice* have all played key roles in protecting the public during the COVID-19 pandemic. Without them, public health outcomes would be significantly worse, and a full recovery from the pandemic even more difficult to achieve. The public has a compelling interest in preserving these precedents and ensuring their application so that we can fully recover from COVID-19 and effectively respond to similar threats in the future.

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7 See, e.g., *Graham*, 383 U.S. at 9 (“The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.”).
A. Accurate and Reliable COVID-19 Testing

Current patent eligibility jurisprudence—especially *Myriad’s* rule against the patenting of naturally occurring genetic sequences—enabled the rapid development, commercialization, and increased accuracy of COVID-19 diagnostic tests. Reliable access to the genetic sequence of the SARS-CoV-2 virus (which causes COVID-19 infections) allowed both public and private entities to produce diagnostic tests quickly without fear of oppressive licensing agreements or lawsuits.\(^9\) The fact that numerous entities could develop and distribute their own tests produced robust competition in molecular diagnostics, leading to advances in test accuracy due to protocol standardization and validation of results.\(^10\)

Current patent eligibility jurisprudence not only facilitated the development of more accurate COVID-19 diagnostic tests, but also ensured the continued availability of diagnostic tests despite problems affecting the supply chain. For example, test developers were free to create kits that relied on saline to overcome the shortage of viral transport media. Similarly, they were able to create kits that could detect the virus in saliva to alleviate the swab shortage.\(^11\)

The sheer quantity of COVID tests performed as well as the speed at which they must be processed to ensure public safety necessitated multiple variations of biological sample collection and processing. Freedom from patent monopolies allowed professional molecular scientists to build redundancy into their protocols by deploying multiple testing methodologies from different entities in order to maintain high testing capacity and overcome supply shortages.\(^12\) Were it not for current patent eligibility jurisprudence, a single entity could have held exclusive rights to create and deploy any, or all, of these alternate testing approaches. The risk of a single entity restricting access to different testing approaches would have constantly threatened to interrupt or thwart activities necessary for the development and deployment of effective COVID-19 tests.

In addition to promoting advancements in the accuracy of COVID-19 testing and enabling the circumvention of supply chain challenges, the freedom to innovate also enhanced the accessibility of COVID-19 diagnostic tests. New, innovative COVID-19 tests have reached an unprecedented number of patients, especially those in low-income, rural, and historically underserved communities.\(^13\) For example, earlier this year, the Food and Drug Administration authorized a COVID-19 test that served as the first ever molecular at-home test that did not require a prescription.\(^14\) Allowing patients to collect their own specimens overcame potential labor shortages at testing sites and made COVID-19 testing accessible to those who could not travel to get tested. Patent protection for naturally occurring genetic sequences and methods of using them

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\(^{10}\) *See* Letter from the Association for Molecular Pathology on Request for Comment on Current Pat. Eligibility Juris. (AMP Letter) (Sept. 8, 2021), https://www.regulations.gov/comment/PTO-P-2021-0032-0066.

\(^{11}\) *Id.*

\(^{12}\) *Id.*


to test for diseases would have restricted the space for innovation and prevented the competition that enabled these transformative advancements in diagnostic testing during the pandemic.

**B. Affordable and Effective COVID-19 Tracking**

The current prohibition on patenting laws of nature has allowed researchers to share information and insights related to COVID-19, which has in turn facilitated the identification, tracking, and treatment of emerging coronavirus strains.¹⁵ Detecting and understanding the risks associated with a new virus variant requires global sharing of genetic sequencing data, information about the geographic spread of the virus, and inferential insights about the severity of associated disease variants.¹⁶ The accessibility of this information has facilitated the development of new testing and treatment approaches for novel COVID-19 strains, such as the Delta variant.¹⁷

*Mayo* has been particularly significant in supporting coordinated public health responses to the pandemic by guaranteeing access to natural correlations tied to COVID-19 infection trends. Captain Kimberly J. Elenberg, Director for Force Modeling and Analytics for the Department of Defense Coronavirus 2019 Task Force, credits current patent eligibility jurisprudence for playing a large role in allowing her team to coordinate the military’s response to the pandemic.¹⁸ For example, researchers discovered that a significant proportion of individuals infected with SARS-CoV-2 shed virus RNA in their stool, and therefore the level of virus RNA in wastewater can be measured to track community infection trends.¹⁹ Due to the ruling in *Mayo*, the correlation between the amount of SARS-CoV-2 virus RNA in stool samples and community COVID-19 infection levels was not eligible for patent protection, even with the addition of a conventional wastewater test. Therefore, as Captain Elenberg noted, both the CDC and military could freely conduct wastewater tests and use the results to determine where to allocate testing and clinical resources.²⁰

Current patent eligibility jurisprudence has not only protected public health during the COVID-19 pandemic but also plays a key role in protecting the public from future pandemics. Just like tracking new variants, detecting the emergence of new viruses requires unrestricted access to gene sequences, natural correlations, and conventional analytic methods implemented on generic computers. For example, Dr. Christopher Mason of Weill Medical College has led a coordinated effort among researchers to sequence and characterize microbiota (bacteria, fungi, viruses, and other microbes) in cities across the world.²¹ Thus far, their work has identified 10,928 viruses and...

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¹⁵ Id.
²⁰ Telephone interview with Kimberly Elenberg, supra note 18.
748 kinds of bacteria that had never before been documented.\textsuperscript{22} Thanks to the ability to freely match genes associated with pathogenic viruses as well as antimicrobial resistance to newly identified strains, Dr. Mason’s program is already helping us prepare for (and potentially mitigate) future health crises.\textsuperscript{23} As this example illustrates, current patent eligibility jurisprudence protects the public’s health from present and future dangers.

\textbf{C. Accessible Telehealth Services}

In addition to facilitating enhanced COVID-19 testing and tracking, current patent eligibility jurisprudence has also facilitated enhanced treatment by ensuring telehealth can be leveraged as a key public health tool. Alice in particular has allowed private and public entities to develop, improve, and provide access to telehealth products and services. One example is MyVitalz, a small telehealth business owned and operated by Justus Decher, a U.S. army veteran. Shortly after starting his business, Justus received exorbitant licensing demands from the owner of a patent that broadly claimed methods of using generic computers to monitor medical patients. Alice saved Justus from having to choose between paying for a license he did not need and risking his livelihood on expensive and protracted court litigation. Before he had to make that choice, a district court held that the patent asserted against him was ineligible under Alice.\textsuperscript{24}

The availability of telehealth from businesses like MyVitalz has enabled millions of patients to access medical care without the risk of exposing others or being exposed to COVID-19. Were it not for Alice, fewer health care providers would be able to offer telehealth services and overall costs would be higher due to licensing fees. Patients who could not afford to pay more would have lost access and had to decide whether to risk infecting themselves and others by seeing providers in person. Even after the pandemic, telehealth will continue to play a critical role in expanding access to care, especially in rural and underserved communities.\textsuperscript{25}

Telehealth is part of an overall trend in point-of-care (POC) diagnostics and treatment that could revolutionize healthcare. According to healthcare analytics expert Dr. Martin Kohn, sophisticated data analytics drive personalized care through a telemedicine discipline known as remote patient monitoring.\textsuperscript{26} Alice’s prohibition on patents that use generic computers to transmit, store, and process data is critical to the nascent POC industry. Weakening that prohibition would create uncertainty and restrict space for innovation, stifling development and investment in the entire POC industry, thereby impeding downstream innovation in precision medicine. One benefit of current patent eligibility jurisprudence is the protection and encouragement it provides to

\textsuperscript{22} Id.
\textsuperscript{23} Id.
\textsuperscript{25} See Dep’t of Health and Human Servs., Biden-Harris Administration Invests over $19 Million to Expand Telehealth Nationwide and Improve Health in Rural, Other Underserved Communities (Aug. 18, 2021), https://www.hhs.gov/about/news/2021/08/18/biden-harris-administration-invests-over-19-million-expand-telehealth-nationwide-improve-health-rural.html.
downstream innovation in scientific and technological fields, especially those that are still in their infancy such as precision medicine.

The success of the telehealth market and increasing investment within that space demonstrates that software-based industries do not need ineligible patents to be successful or innovative. In the first quarter of 2021, telehealth investment hit an all-time high of $4.2 billion, almost doubling the $2.2 billion raised in the same quarter in the prior year.\(^{27}\) It is clear that Alice has not stifled the industry’s expansion; if anything, Alice has facilitated greater investment in the field by providing freedom and space for innovation and reducing litigation associated risks for startups.

**IV. THE USPTO’S CURRENT PATENT ELIGIBILITY GUIDANCE**

Patent eligibility case law has been remarkably clear and consistent since the Supreme Court decided Alice in 2014. That decision made clear that (1) abstract ideas are identified by way of comparison to abstract ideas courts have previously identified, (2) methods of organizing human activity qualify as abstract ideas even if they are not purely mental processes, and (3) conventional computer implementation cannot make an abstract idea eligible for patent protection.\(^{28}\) Concerningly, the USPTO has in recent years revised its patent eligibility guidance in ways that contravene these important aspects of Alice’s holding.

In 2014, the year Alice was decided, the USPTO issued interim guidance on patent eligibility, which it updated in response to public comments the following year.\(^{29}\) This guidance was largely consistent with Alice. Of particular relevance, the guidance instructed examiners to

1. “refer to the body of case law precedent in order to identify abstract ideas by way of comparison to concepts already found to be abstract”;
2. identify ideas that “can be performed in the human mind, or by a human using pen and paper” as abstract; and
3. reject claims directed to abstract ideas combined with elements which “courts have recognized, or those in the art would recognize, as . . . well-understood, routine and conventional,” e.g., “performing repetitive calculations,” “receiving, processing, and storing data,” and “receiving or transmitting data over a network.”\(^{30}\)


\(^{28}\) *Alice*, 573 U.S. at 221, 220, and 225–26.


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.\(^{31}\) When the USPTO issued its new guidance, public commenters objected that the changes were inconsistent with Alice and thus contrary to governing law.\(^{32}\) Nevertheless, the changes came into and remain in effect.

The USPTO’s revised guidance instructs examiners to:

1. identify as abstract only ideas within three “enumerated groupings” consisting of mathematical concepts, certain methods of organizing human activity, and mental processes;

2. even if a claim is directed to an abstract idea within the three enumerated categories, treat it as non-abstract if the idea “is integrated into a practical application”; and

3. allow claims directed to abstract ideas combined with elements which are “well-understood, routine, conventional” because a “claim that includes conventional elements may still integrate an exception into a practical application, thereby satisfying the subject matter eligibility requirement of Section 101.”\(^{33}\)

These instructions diverge from the USPTO’s original guidance in ways that contradict the Supreme Court’s holding in Alice in at least three critical respects.

First, the revised guidance limits the categories of abstract ideas to three potential groupings while the original guidance directed examiners to identify abstract ideas by comparing them to concepts classified as abstract in case law. That direction reflects the approach the Court used and approved in Alice, where it did “not labor to delimit the precise contours of the ‘abstract ideas’ category,” because “[i]t is enough to recognize that there is no meaningful distinction between the concept of risk hedging in [prior precedent] and the concept of intermediated settlement at issue here.”\(^{34}\) Alice makes clear that abstract ideas should be identified by comparison to concepts classified as abstract in judicial precedents, not by reference to precisely defined categories, as the USPTO’s revised guidance requires.

Second, the USPTO’s revised guidance introduces a “practical application” exemption for abstract ideas that is absent from both its original guidance and judicial precedent. The term “practical application” does not appear in Alice. Nor is an exemption for claims integrating abstract ideas into practical applications consistent with the Court’s holding in that case. The parties in Alice stipulated that the “claimed method requires the use of a computer to create electronic

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34 Alice, 573 U.S. at 221.
records, track multiple transactions, and issue simultaneous instructions.” But the Court still classified it as an abstract idea. As it explained, “[t]here is no dispute that a computer is a tangible system (in § 101 terms, a “machine”), . . . [b]ut if that were the end of the § 101 inquiry, an applicant could claim any principle of the physical or social sciences by reciting a computer system configured to implement the relevant concept[,] . . . thereby eviscerating the rule that laws of nature, natural phenomena, and abstract ideas are not patentable.” The “practical application” exemption in the USPTO’s revised guidance similarly eviscerates that rule.

Third, the revised guidance permits patents on abstract ideas combined with well-understood, routine, and conventional elements as long as they qualify as practical applications. That contradicts its original guidance, which directed examiners to reject such claims, as well as longstanding patent eligibility jurisprudence. Alice re-affirmed the Court’s prior holding that combining an abstract idea with purely conventional implementation does not establish patent eligibility. The Court was crystal clear that “the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment.” The revised guidance’s exemption for patents claiming abstract ideas performed by conventional elements is flatly inconsistent with governing law.

The impact of the revised patent eligibility guidance has been swift and striking. According to the USPTO’s own report, the likelihood of a first rejection on patent eligibility grounds fell by 25% in the year after the 2019 guidance—a stark contrast to the 31% increase in such rejections during the year after the 2014 guidance went into effect.

There is also evidence that the revised guidance is leading to the allowance of patent claims that are ineligible under Alice. For example, the USPTO has allowed patents on conventional, well-understood, and routine aspects of essential telehealth technology, such as a network of camera-equipped computers that can start and stop communicating with each other.

To the extent that there has been any lack of clarity or consistency affecting patent eligibility in recent years, the USPTO’s shifting patent eligibility guidance may be at least partly responsible. We strongly urge the USPTO to review and, as necessary, revise its guidance to ensure consistency with Supreme Court precedent.

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35 Id. at 224.
36 Id. (quotation marks, alterations, and citations in original omitted).
37 Id. at 222 (discussing Parker v. Flook, 437 U.S. 584 (1978), where “the formula itself was an abstract idea, . . . the computer implementation was purely conventional,” and the “process was patent ineligible”).
38 Id. (citations omitted).
V. CONCLUSION

Current patent eligibility jurisprudence, as expounded in *Myriad*, *Mayo*, and *Alice*, is clear, consistent, and faithful to the Constitution as well as the public’s interest in promoting technological innovation and access to knowledge. The Public Interest Patent Law Institute is grateful to the USPTO for requesting comments from the public on this important issue. We hope the breadth and depth of public support for current patent eligibility jurisprudence are reflected in the USPTO’s next steps.

Respectfully submitted,

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