Public Interest Patent Law Institute

ACLU

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

Docket Number: PTO-P-2021-0033

The Public Interest Patent Law Institute ("PIPLI") and American Civil Liberties Union ("ACLU") are grateful for the opportunity to provide comments in response to the United States Patent and Trademark Office's ("USPTO") notice regarding the Deferred Subject Matter Eligibility Response ("DSMER") Pilot Program, Docket No. PTO-P-2021-0033, published at 87 Fed. Reg. 776 on January 6, 2022 ("Notice").

I. INTRODUCTION

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, open-source developers, students, medical patients, and Internet users. As a result, the interests of these constituencies are inadequately represented in the institutions that decide the course of patent law despite the concrete, substantial impact of these decisions on 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.

The ACLU is a national, nonprofit, nonpartisan organization dedicated to the principles of liberty found in the U.S. Constitution. The ACLU recognizes that patent regulation can significantly affect civil liberties, including rights guaranteed under the First Amendment. Section 101 of the Patent Act and the long-standing prohibitions on patenting natural phenomena, laws of nature, and abstract ideas have played a vital role in securing intellectual freedom and fostering scientific innovation. The ACLU represented over 20 pathology and genetics organizations, geneticists, breast and ovarian cancer patients, and patient advocacy groups to challenge the practice of granting patents on isolated DNA, resulting in a unanimous 2013 U.S. Supreme Court decision striking down such patents in *Association for Molecular Pathology v. Myriad Genetics*. The ACLU also has regularly filed amicus briefs with the Supreme Court and engaged in advocacy with the PTO and Congress to support Section 101's prohibitions on patenting laws of nature and abstract ideas. The ACLU therefore has a significant interest in PTO actions that govern how the agency deals with patent eligibility determinations.

Patent eligibility law concretely affects the lives and livelihoods of all Americans. As such, PIPLI and the ACLU respectfully urge the USPTO to give the public's interest the full and fair

consideration it deserves when considering changes that may disrupt the patent system's balance between incentivizing investment and expanding public access to knowledge. If the USPTO wishes to ensure the DSMER program appropriately balances the important interests at stake, it needs to make a full appraisal of the possible effects that modifying the prosecution process in this manner will have on all members of the public. It is vital that the USPTO proceed carefully and rely on evidence rather than assumptions in conducting this pilot program and when deciding permanent actions to take following its conclusion.

II. PATENT ELIGIBILITY JURISPRUDENCE

A. Patent Eligibility Requirements Are Foundational to the Patent System.

Section 101's requirements for patent eligibility are the cornerstone of the patent system. The requirement that patent-eligible subject matter qualify as a "new and useful process, machine, manufacture, or composition of matter, or . . . new and useful improvement thereof"[1] is almost as old as our country, dating back to the Patent Act of 1793.[2] For the better part of two centuries, the Supreme Court has held that this provision excludes subject matter that humans did not and could not have invented: laws of nature, natural phenomena, and abstract ideas.[3]

These prohibitions cannot be taken lightly. They are rooted in the Constitution's mandate that the patent system "promote the progress of science and useful arts."[4] 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."[5]

Current jurisprudence, as set forth in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) ("*Myriad*"), *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012) ("*Mayo*"), and *Alice Corporation Pty. v. CLS Bank International*, 573 U.S. 208 (2014) ("*Alice*"), stays 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.

Together, *Myriad, Mayo,* and *Alice* establish that laws of nature, natural phenomena, and abstract ideas cannot be patented without an inventor adding significantly more. While the tests applied have been refined over the years, the basic distinction is an old one that has been successfully applied to a broad range of technologies, from pharmaceuticals and genetically manipulated organisms to combinations of bacteria, computerized financial techniques,[6] the

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[1] 35 U.S.C. § 101.
[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 the 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) (citing *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853)).
[4] U.S. CONST. art. I, § 8, cl. 8.
[5] *Chakrabarty*, 447 U.S. at 307 (internal quotation marks and citation omitted).
[6] *See Alice*, 573 U.S. at 212.

telephone,[7] and pencils with rubber erasers.[8] Current jurisprudence ensures the patent system can serve its constitutional mandate of promoting more innovation than it deters.

B. The Public Has a Powerful Interest in Ensuring the USPTO Diligently Enforces Patent Eligibility Law.

Public access to abstract ideas, laws of nature, and natural phenomena is more important now than ever because we depend on digital and genomic technology in our daily lives more than ever. The COVID-19 pandemic has brought our day-to-day dependence on these technologies into sharper relief by making access to them essential to people's ability to work, learn, communicate, and receive medical care remotely.

The pandemic has also demonstrated why protecting public access to building blocks of scientific research is so important. For example, the prohibition on patenting naturally occurring gene sequences has facilitated 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 numerous entities to develop COVID-19 tests. This robust competition sparked technological advances in accuracy and improved public health outcomes by making tests more affordable and accessible to all Americans.[9]

The contrast between COVID-19 and the 2003 SARS outbreak is striking. The SARS outbreak occurred before the Supreme Court clarified in *Myriad* that naturally occurring DNA molecules, even when isolated from the chromosome, are ineligible for patent protection.[10] Private companies raced to obtain patents on key viral genetic sequences. To protect patients' and researchers' access to essential research, testing, and treatment tools, the U.S. Centers for Disease Control and Prevention had to file its own patent applications defensively.[11] Thanks to *Myriad*, the government did not need to waste time or money to prevent patents from imperiling scientific research and public access to COVID-19 testing.

The *Myriad* case powerfully illustrates the harm patents on ineligible subject matter can do. Before the Supreme Court's decision, one company, Myriad Genetics, held patents on the isolated *BRCA1* and *BRCA2* genes, which gave it the sole right to conduct tests to identify genetic mutations and inform patients about their risk of developing hereditary breast and ovarian cancer. Myriad's exclusive rights prevented other private and public entities from developing or administering tests for *BRCA* mutations, including tests that were more comprehensive than Myriad's, needlessly increasing the cost of testing and potentially misinforming individuals about the health risks they faced.[12]

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[7] *See The Telephone Cases*, 8 S. Ct. 778, 781–82 (1888).
[8] *See Rubber-Tip Pencil Co. v. Howard*, 87 U.S. 498, 499–500 (1874).
[9] *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.
[10] *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).
[11] *See* Paul Elias, *Race to Patent SARS Virus Renews Debate,* ASSOCIATED PRESS, May 5, 2003, https://apnews.com/article/145b4e8d156cddc93e996ae52dc24ec0.
[12] *See Myriad*, 569 U.S. at 585–86.

After the Supreme Court made clear that isolated DNA molecules are ineligible for patent protection, several companies immediately announced they would offer their own tests and screen for additional *BRCA* mutations, decreasing testing costs as well as the time between clinical research and commercialization.[13] Following the decision, a competitive genetic testing industry flourished, and investment in the pharma and biotech sector increased dramatically from $6.21 billion in 2013 to $17.72 billion in 2018.[14]

Public access to the building blocks of scientific research is critical to promoting the development of innovative technologies that are increasingly essential to public health. These technologies include precision medicine, which holds promise for the development of treatments for COVID-19, cancer, and opioid addiction; telehealth, which rural communities have long needed, but has become a public health necessity for all communities in the wake of COVID-19; and genomic data collection and analysis, which are tools researchers need to protect the public from new COVID-19 variants and future pandemics.

Because the public's access to these critically important technologies depends on the USPTO's vigorous enforcement of patent eligibility requirements, the public's interest should be carefully considered when evaluating or modifying their enforcement.

III. COMMENTS ON DSMER PILOT PROGRAM

There are compelling reasons to expect that deferring patent eligibility responses will negatively impact patent quality, patent clarity, and the efficiency of patent examination. Even if patent applicants benefit, countless Americans who do not own, assert, or acquire patents will bear the brunt of these negative effects. We urge the USPTO to pause the DSMER pilot program upon completion and scrutinize the evidence of its effects before extending it.

A. Deferring Eligibility Responses Will Diminish Patent Quality, Clarity, and Examination Efficiency.

As the Supreme Court reiterated in *Alice*, § 101 performs a distinct task that §§ 102, 103, and 112 "are not equipped to do."[15] Unlike other patentability requirements, patent eligibility questions can be and often are resolved by comparing patent claims to those addressed in judicial opinions. Neither § 103 nor § 112 allow for such comparisons. As a result, analyzing claims under those sections first does not allow for the resolution of many, if not all, patent eligibility issues.

Importantly, the legal questions at the heart of patent eligibility reviews often do not require extensive factual research or technical analysis. That makes them less research-intensive and time-

[13] Andrew Pollack, *After Patent Ruling, Availability of Gene Tests Could Broaden*, N.Y. TIMES (June 13, 2013), https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html.

[14] *The State of Patent Eligibility in America: Part III: Hearing Before the Subcomm. on Intellectual Property of the S. Comm. on the Judiciary*, 116th Cong. (2019) (statement of Sean George, CEO, Invitae Corp.), https://www.judiciary.senate.gov/imo/media/doc/George%20Testimony.pdf.

[15] *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90 (2012) ("[T]o shift the patent-eligibility inquiry entirely to [§§ 102, 103, and 112] risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.").

consuming for examiners. Given the resource constraints examiners currently face,[16] they should be encouraged to resolve patent eligibility questions first, not last. There is no reason to encourage examiners to conduct a more time-consuming task, like evaluating obviousness based on multiple technical references, *before* conducting the less time-consuming task of evaluating patent-eligibility.

Early patent eligibility determinations improve the quality and clarity of granted patents, as well as the efficiency and efficacy of the patent examination process. Applicants seeking to traverse a patent-eligibility rejection must explain why their claimed invention is patent-eligible, including by identifying an "inventive concept." In so doing, the applicant provides crucial information for the prosecution history file that will help the public understand the scope of the patent, if granted, enhancing its clarity. In some cases, applicants may go further by amending their claims to limit them to patent-eligible subject matter even more clearly. Rejections that lead applicants to submit remarks or amendments not only enhances the clarity of granted patents, but also enhances the quality and efficiency of examination for compliance with §§ 103 and 112. Applicant remarks and amendments provide examiners with greater clarity about the scope of the applicant's claimed invention, helping them conduct more targeted and time-efficient prior art searches while potentially resolving written description and indefiniteness issues.

To illustrate these benefits, consider the following hypothetical patent claim:

> A method of generating an image comprising:
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> providing a query;
> receiving a response to said query;
> generating an image based on said response;
> displaying said image on a display.

Under standard patent examination procedures, an examiner could readily reject this claim under § 101 for, among other reasons, describing a method of organizing human activity that requires no specific technical intervention. For example, the same description could apply to a caricaturist who performs these steps by asking someone what activities they enjoy, receiving a response (e.g., baseball) drawing a picture of them based on their chosen activity (e.g., with a baseball mitt in hand), and then showing them the picture.

In response to the examiner's rejection, the applicant could provide remarks or amendments to clarify that the "query" must be a request for computer input, the "response" must indicate a particular file format, the "display" must be an electronic visual display, and "generating" requires running a specific algorithm to convert the image into the appropriate format. These clarifications would make the scope of the claim narrower and clearer, both to members of the public and the patent examiner, which, in turn, would facilitate a more targeted and efficient prior art search. Deferring the applicant's patent-eligibility response would

[16] *See* Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents? Evidence from Microlevel Application Data*, 99 REV. ECON. & STAT. 550, 551 (2017), https://doi.org/10.1162/REST_a_00605 ("[E]xaminers appear to be operating at the point where time constraints indeed bind.").

necessitate a much broader prior art search and provide no guarantee of prompting the same clarifications as to claim scope from the applicant.

There are also compelling reasons to expect delaying patent eligibility determinations will skew examiners' results in favor of allowance. Conducting a prior art search and comparison requires examiners to conceptualize a claimed invention, and in most cases, compare it to one or more issued patents. By taking these steps, an examiner effectively assumes there is a patent-eligible invention that can be used as the basis of such comparisons. If non-obviousness over the prior art is established, that means a patentable advance has been identified. It is extremely unlikely that an examiner who has identified such an advance on the assumption of patent-eligibility will be able to consider the question of patent-eligibility as fairly and open-mindedly as an examiner facing that question first. These assumptions will likely result in less accurate determinations of eligibility and less refinement of claim scope, leading to broader, vaguer, and lower quality patents.

Indeed, well-settled insights from clinical and social psychology and behavioral economics indicate that initial assumptions have a strong influence on subsequent decision making. Even the most highly qualified experts are not immune to the effects of belief perseverance, and the influence of a previous judgement, even implicit, can be observed even when new information is provided that directly contradicts the previous assumption.[17]

A letter from Senators Thom Tillis and Tom Cotton (the "Tillis/Cotton Letter") to the USPTO asserts that relegating eligibility determinations to the end of the patent application process "in no way shortcuts or truncates" § 101 analysis.[18] This assertion is wrong. In fact, it directly contradicts another assertion in the same letter: that deferring eligibility responses would "avoid unnecessary and inefficient rejections on grounds of patent eligibility." If the DSMER program avoids eligibility-based determinations that would otherwise have been performed, it not only truncates, but also distorts patent examination. Instead of a meaningful eligibility analysis, applications will receive an evaluation that is skewed in the applicant's favor. Deferring eligibility responses will thus increase the likelihood that patents on ineligible subject matter are granted. As the likelihood of ineligible patents increase, so does the risk of depriving the public of access to essential research tools that § 101 protects.

The risks associated with ineligible patents are exacerbated by the lack of opportunities for post-grant review on eligibility grounds. Because § 101 is not a permissible basis for instituting *inter partes* or post-grant review proceedings before the Patent and Trial Appeal Board, there is no opportunity to challenge granted patents on eligibility grounds outside of district court litigation. But granted patents are harder to challenge in district court where they receive a

[17] Eva Jonas et al, C*onfirmation Bias in Sequential Information Search After Preliminary Decisions: An Expansion of Dissonance Theoretical Research on Selective Exposure to Information,* 80 J. PERSONALITY. SOC. PSYCH. 557, 558 (2001); Christoph Engel et al., *Coherence-based Reasoning and Order Effects in Legal Judgments,* 26 PSYCH., PUB. POL'Y. & L. 333, 333 (2020); *see also* Itiel E. Dror, *Cognitive and Human Factors in Expert Decision Making: Six Fallacies and the Eight Sources of Bias*, 92 Analytical Chem. 7998, 7999 (2020) (finding experts are just as vulnerable—and perhaps more so—to cognitive bias); Bernd Schünemann & Wolfgang Bandilla, *Perseverance in Courtroom Decisions*, *in* CRIMINAL BEHAVIOR AND THE JUSTICE SYSTEM: PSYCHOLOGICAL PERSPECTIVES 181, 181–92 (Hermann Wegener et al. eds., 1989) (finding that judges are susceptible to sequencing effects in criminal cases).
[18] Letter from Sens. Thom Tillis & Tom Cotton to Drew Hirshfeld, Comm'r for Patents, USPTO (Mar. 22, 2021) (https://www.uspto.gov/sites/default/files/documents/sens-sequencedexam-20210322.pdf).

presumption of validity that requires clear and convincing evidence to overcome. Once a patent issues, it can never receive the same degree of scrutiny on patent eligibility issues that it could have received during examination. As a result, the public suffers irreparable harm when patent eligibility issues receive insufficient, incomplete, or distorted consideration during examination.

B. The Apparent Rationale for the DSMER Pilot Program is Flawed.

There have been no recent changes to the Constitution or the Patent Act that suggest changing the role of § 101 during patent examination is necessary or appropriate. It appears that the DSMER pilot program was implemented in response to the Tillis/Cotton Letter. The Tillis/Cotton Letter states that questions of eligibility are "abstract, vague, and subjective," and based on that statement, asserts that deferring eligibility determinations until after complete examination of other areas of patentability would lead to "stronger, more reliable, and higher quality patents[.]"

That statement contradicts objective evidence showing that examiners and courts apply patent eligibility requirements as—or more—competently and consistently than other patentability requirements.

For example, in 2020, the Patent Trial and Appeal Board ("PTAB") affirmed patent application rejections based on § 101 at a rate of 82% compared to an overall rate of ~71% for all rejections.[19] Between 2014 and 2018, rejections based on subject matter eligibility had the highest affirmance rate of all rejection types.[20] This strongly indicates that the PTAB and the patent examiners share a common understanding of subject matter eligibility jurisprudence and that examiners' determinations of subject matter eligibility are reliable.

Objective measurements of the Federal Circuit's affirmance rates of patent eligibility decisions indicate similarly high levels of consistent agreement and reliability. While the rate of patent invalidation on grounds of subject matter eligibility increased after *Alice*, the Federal Circuit affirmed 89% of ineligibility decisions in the five years following *Alice*.[21] From 2013 through 2020, decisions applying § 101 had an affirmance rate of 65% when appealed to the Federal Circuit and decided in precedential opinions—higher than the circuit's overall affirmance rate of 56%.[22]

Comparing the affirmance rates of § 101 decisions with those made on other grounds suggests that districts courts and agencies have a clear understanding of § 101 that is more consistent with the Federal Circuit's understanding than other patentability issues. From 2014

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[19] James R. Love, *Section 101 at the Patent Trials and Appeals Board – A Surprising Result*, OBLON (Jul. 13, 2020), https://www.oblon.com/section-101-at-the-patent-trial-and-appeals-board-a-surprising-result.

[20] Samuel Hayim and Kate Gaudry, *Nearly All Post-Alice Eligibility Rejections are Affirmed in Whole by the PTAB*, JDSUPRA (February 28, 2018), https://www.jdsupra.com/legalnews/nearly-all-post-alice-eligibility-74926/.

[21] 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-tyrantanalyzing-five-years-of-case-law-since-alice-v-cls-bank-part-i/id=112722/.

[22] Am. Civ. Liberties Union, Comments on Patent Eligibility Jurisprudence Study, Docket Number: PTO-P-2021-0032, Attach. 1, 3 (Sept. 7, 2021), https://www.regulations.gov/comment/PTO-P-2021-0032-0052.

through 2020, the affirmance rate for district court and agency decisions on § 101 was higher than the rate for decisions on §§ 102, 103 or 112.[23]

When the analysis includes non-precedential affirmances under Federal Circuit Rule 36, the § 101 affirmance rate rises further. In 2018, Paul Gugliuzza and Mark Lemley conducted an analysis of all Federal Circuit patent-eligibility decisions since *Alice*, including precedential opinions and non-precedential Rule 36 affirmances.[24] Their analysis showed that the Federal Circuit affirmed patent eligibility decisions in 90% of all cases that came before it. The relatively high affirmance rate shows that district courts', administrative law judges', and the Federal Circuit's share a clear and consistent understanding of § 101.

The best available evidence indicates strong consensus among patent examiners, the PTAB, district courts, and the Federal Circuit on how to apply current eligibility criteria to patent claims. Any lasting changes to the role of patent eligibility determinations in patent examination should be made with caution and on the basis of reliable evidence demonstrating their benefits will outweigh harms to the public and patent system.

C. The Design of the DSMER Pilot Program Conflicts with its Stated Goals.

The structure of the pilot program raises serious experimental design issues which undermine its ability to serve its stated purpose: evaluating how DSMER affects "examination efficiency and patent quality." Flaws affecting the program's design will impede its ability to provide reliable information that can be used to evaluate the program's effect on examination efficiency or patent quality.

For example, the pilot program, as implemented, is a non-randomized trial without a control group. This design is at odds with well-established standards for research studies.[25] Of particular concern is the potential for selection biases inherent to the voluntary structure of the pilot program to obscure the negative effects of deferring eligibility responses.

Section 101 rejection rates vary significantly across subject matter areas.[26] Allowing individual examiners to independently elect to participate creates a strong likelihood that only those whose practices would not be substantially or negatively impacted will participate in the initial pilot program. Moreover, the double selection bias in which both examiners and applicants agree to participate will almost certainly distort the results of the program beyond usefulness.

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[23] *Id.*

[24] Paul Gugliuzza & Mark Lemley, *Can a Court Change the Law By Saying Nothing?*, 71 VAND. L. REV. 765, 787 (2018).

[25] *See* Edwin G. Boring, *The Nature and History of Experimental Control*, 67 AM. J. PSYCH. 573, 581 (1954), https://www.jstor.org/stable/1418483 ("There can be no doubt that use of control observation, either implicit or explicit, is essential in sound experimental work…to give the datum significance."); *see also* D. R. Cox, *Randomization in the Design of Experiments*, 77 INT'L. STAT. REV. 415, 426 (2009), https://www.jstor.org/stable/27919766 ("[R]andomization plays a key role, sometimes indeed an absolutely essential role, in situations in which subjective biases may enter.").

[26] *See generally* Collen Chien & Jiun-Ying Wu, *Decoding Patentable Subject Matter*, 2018 PATENTLY-O PAT. L.J. 1, 10, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3267742.

Similarly concerning is the lack of publicly available information about how or when the USPTO plans to evaluate the pilot program. In the absence of transparent or objective assessment criteria, the pilot program is little more than a black box from the public's perspective. This opacity raises concerns that the program be used to justify the imposition of policies that the public has no meaningful opportunity to address.

Under these circumstances, the public has little reason to expect—and compelling reasons to doubt—that the DSMER pilot program will help the patent system fulfill its constitutional goal of promoting innovation and the dissemination of knowledge.

IV. RECOMMENDATIONS

Given the unclear benefits and distinct possible drawbacks of this program, it is vital that the USPTO adequately, accurately, and transparently evaluate its results before taking any permanent action. Pilot programs enable risk-managed evaluation of novel approaches,[27] but must be designed with enough rigor to enable meaningful assessment.[28] Given the limited information currently available to the public, it is difficult to determine whether the DSMER pilot program is sufficiently rigorous to justify the risks it entails. It is not clear how the results of the pilot program will be assessed, nor how or when the program will be scaled.

In order to adequately account for the risks inherent to DSMER, the USPTO should consider the following:

- Once the pilot program concludes, conduct a study of the program's results before extending it.
- Define objective metrics for how efficiency, patent quality, and any other issues will be evaluated before evaluation begins.
- Monitor post-issuance events, including district and appellate court rulings on patents granted while the program was in effect under §§ 101, 102, 103, and 112.
- Make the program's methodology, evaluation metrics, and resulting data available to the public.
- Give members of the public a meaningful opportunity to review and respond to the USPTO's study of the pilot program.
- Consider feedback from all stakeholders—including members of the public who seek to access or contribute to patented technology, but do not acquire patents—before making a decision on whether to extended or implement the program permanently.

V. CONCLUSION

The USPTO's evaluation of patent eligibility is of paramount importance to the public. Section 101 is the only part of the Patent Act designed to protect public access to the building

[27] Shane Zbrodoff, *Pilot Projects—Making Innovations and New Concepts Fly* (PMI Global Congress, 2012), https://www.pmi.org/learning/library/pilot-projects-innovations-new-concepts-6043.
[28] Ron Ashkenas & Nadim Matta, *How to Scale a Successful Pilot Project*, HARV. BUS. REV. (Jan. 8, 2021), https://hbr.org/2021/01/how-to-scale-a-successful-pilot-project.

blocks of scientific research. The best available evidence shows that examiners are more likely to be affirmed by the PTAB and Federal Circuit on patent eligibility determinations than other patentability issues. Based on that, the USPTO should be encouraging examiners to make patent eligibility determinations early and often. While the DSMER pilot program pursues the admirable purposes of improving efficiency and patent quality, it is not calibrated to achieve those goals. Given the importance of patent eligibility issues to the public, we urge the USPTO to consider its interest in these issues carefully and seriously when evaluating the DSMER pilot program and deciding its future.

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