

WRITTEN STATEMENT OF

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BEFORE THE

UNITED STATES SENATE COMMITTEE ON THE JUDICIARY

Hearing on

“FROM GENES TO MACHINES: THE PATENT ELIGIBILITY DEBATE”

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SUBMITTED IN ADVANCE OF THE HEARING

Chairman Grassley, Ranking Member Durbin, Senator Tillis, and Members of the Committee:

I respectfully submit this written statement concerning patent eligibility under 35 U.S.C. § 101. This statement consolidates, expands, and updates two statements that I submitted in connection with the Senate Judiciary Subcommittee on Intellectual Property’s October 8, 2025 hearing on the Patent Eligibility Restoration Act of 2025 (PERA).¹ It also addresses developments since that hearing, including the Federal Circuit’s unanimous decision in *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*²

My October 2025 submissions also raised a question that remains unresolved: whether expanded eligibility would apply only to future-filed applications or would also benefit existing patents and pending claims. That distinction goes directly to the legislation’s stated rationale. If the objective is to induce future innovation, the Committee should ask why any new rule should benefit inventions and patent portfolios that already exist. I return to that issue below.

My Background

I served at the United States Patent and Trademark Office (USPTO) for 23 years, including five years as Solicitor, the foremost career position for a patent lawyer in the U.S. Government. I played a leading role in the USPTO’s participation in every Supreme Court patent-eligibility case during the 21 years from 2002 through 2023, as well as numerous eligibility cases before the Federal Circuit. I

¹ See Written Statement of Thomas W. Krause, Former Solicitor, U.S. Patent & Trademark Office, Before the Senate Judiciary Committee, Subcommittee on Intellectual Property, Hearing on the Patent Eligibility Restoration Act of 2025 (Oct. 8, 2025); Supplemental Written Statement of Thomas W. Krause, Former Solicitor, U.S. Patent & Trademark Office, Before the Senate Judiciary Committee, Subcommittee on Intellectual Property, Hearing on the Patent Eligibility Restoration Act of 2025 (Oct. 15, 2025). Both statements are available at [If you liked State Street, you’ll love PERA!](#) (Substack Oct. 17, 2025).

² 167 F.4th 1206 (Fed. Cir. 2026).

served on several USPTO committees concerning § 101, and taught patent eligibility in my classes at Georgetown University Law Center over a 17-year period. Those experiences allowed me to examine § 101 across a wide spectrum of subject matter over more than two decades, always from the standpoint of the public interest rather than that of a particular industry or client.³

I submit this statement in my personal capacity. I have no clients and no financial stake in the outcome. My interest is in preserving a patent system that rewards genuine technological invention while protecting competition, scientific inquiry, patient access, and the public from patent policies that impede more progress than they promote.

Executive Summary

Congress has held numerous hearings and received extensive testimony concerning patent eligibility, yet no clear consensus has emerged that § 101 requires broad revision, much less agreement on the proper direction of change. That continuing disagreement reflects a deeper problem: eligibility is being considered largely in isolation, without a comprehensive assessment of how the patent system as a whole serves the public, where its costs exceed its benefits, and how eligibility interacts with examination, remedies, post-issuance review, litigation incentives, foreign participation, and other features of the system. Such an assessment should also account for the growing use of acquired, late-term patents as vehicles for monetization. The approaching surge in AI-assisted invention and patent drafting makes that broader inquiry more urgent.

Congress should not enact new eligibility legislation without that understanding. A comprehensive, independent assessment by the Government Accountability Office, the Congressional Research Service, or another neutral body could provide a common framework for future reform. Because the Committee is presently considering PERA and related proposals, however, this statement addresses those proposals on their own terms.

Section 101 serves an essential gatekeeping function. Properly understood, it should help confine patents to the kinds of human-made contributions that advance the useful arts and thereby further the Constitution's purpose of promoting progress. The Supreme Court's modern cases seek to serve that function by making it more difficult to obtain patents on the use of computers to implement non-technological ideas and patents whose contribution lies principally in discoveries about nature. Although those cases still permit some non-technological patents and patents whose asserted contribution lies principally in a discovery about nature, current law is far closer to a sound patent-eligibility regime than the alternatives now before Congress.

PERA and similar proposals would seriously diminish § 101's gatekeeping function. They would broaden eligibility across several categories of claims that current law sensibly restricts, while replacing a substantial body of developed case law with new statutory terms and exceptions whose scope would have to be worked out through years of examination, litigation, and appellate review.

³ Since leaving the USPTO, I have continued to publish commentary on patent law and policy through [Krause on Patents on Substack](#). Many of those commentaries collect and link to the underlying primary materials.

Principal Conclusions

- Current law permits patents on genuine technological advances. The Federal Circuit's cases have converged on a workable line between improvements in technology and claims that use technology to implement an economic or informational idea.
- PERA's machine-based exceptions would restore § 101 eligibility to computer-implemented business methods, financial products, tax strategies, and other non-technological claims of the kind that produced widespread litigation and settlement pressure after *State Street Bank* and that Congress later singled out for special treatment in the America Invents Act.
- Broader eligibility would disproportionately benefit patent monetizers and armchair inventors by supplying more non-technological patents that can be asserted against productive companies, including companies that developed the accused practices independently.
- The Supreme Court's decisions in *Mayo* and *Myriad* did not make new diagnostic technologies unpatentable. New testing platforms and other technological improvements remain eligible, while naturally occurring correlations and genetic information remain available for clinicians, researchers, and patients to use.
- The evidence does not show that *Mayo* and *Myriad* caused diagnostic innovation to collapse; to the contrary, innovation and patient access have both increased.
- The Federal Circuit's unanimous 2026 decision in *REGENXBIO v. Sarepta* demonstrates that present law remains hospitable to engineered biotechnology. Although I believe the decision, like *Myriad's* treatment of cDNA, permits claims broader than sound policy warrants, it refutes the claim that biotechnology faces an eligibility crisis.
- Sections 102, 103, and 112 cannot substitute for § 101. A claim may be novel, nonobvious, enabled, and definite and still impose an unjustified monopoly on a business practice, mathematical relationship, natural correlation, or natural information.
- Any legislation expanding eligibility must include a clear prospective effective date. PERA's failure to do so is itself troubling. At a minimum, the omission would invite patent owners to argue that claims rendered unenforceable under *Mayo*, *Myriad*, or *Alice* have been revived, forcing businesses and the public to relitigate rights they were entitled to regard as settled. Any such revival would confer an enormous windfall on holders of patents that are invalid under the Supreme Court's current interpretation of § 101.

Congress should therefore preserve § 101’s essential gatekeeping role. If it acts, it should consider clearer statutory lines that further limit or eliminate patents on non-technological subject matter and on claims whose asserted inventive contribution lies principally in a discovery about nature. That approach would better confine patent eligibility to subject matter likely to promote progress in the useful arts.

I. Patent Reform Must Begin With the Constitutional Purpose and the Existing Costs of Patents

A. The Benefits of Patents Should Outweigh the Burdens They Place on the Free Market

The Constitution authorizes Congress to grant patents to promote progress in the useful arts. That language reflects the utilitarian purpose of the patent system. A temporary exclusive right is justified when the public benefits expected from the inducement outweigh the restrictions the patent places on competition and the use of disclosed ideas.

The Supreme Court described that principle in *Graham v. John Deere*.⁴ Although *Graham* addressed obviousness, its account of the constitutional design applies more broadly. The patent right was not created to reward inventors simply because they had made an invention. It was intended as a social inducement, granted only where the resulting addition to human knowledge justified the restrictive effect of the patent monopoly. The task, as the Court explained through Jefferson, is to identify the things “worth to the public the embarrassment of an exclusive patent.”⁵

In my May 29, 2025 submission to this Committee, I identified sixteen basic truths about the patent system and twenty-nine recurring “quarter-truths” that often distort debates over patent policy.⁶ I will not repeat that full analysis here. Its central lesson, however, should guide consideration of any proposal to change § 101: patents are government-created restraints on competition, justified only to the extent that they induce advances whose public benefits outweigh the resulting restrictions on others.

The existing patent system already imposes substantial costs. Patents are too easy to obtain,⁷ last too long,⁸ and are expensive to challenge. Many cover incremental advances that others developed, or would have developed, independently. More than half of U.S. patents are now awarded to foreign

⁴ 383 U.S. 1 (1966).

⁵ *Id.* at 5-6, 9-11.

⁶ Thomas W. Krause, Letter to the Senate Judiciary Committee Regarding the Nomination of John Squires for Director of the U.S. Patent and Trademark Office (May 29, 2025), available at <https://krauseonpatents.substack.com/p/opposition-to-squires-nomination>.

⁷ *See id.*, Truth No. 6.

⁸ *See id.*, Truth No. 5.

applicants.⁹ During their long terms, patents can block better products, burden follow-on innovation, and require productive businesses to pay for practices or technologies they developed without assistance from the patentee. The system also creates valuable assets for entities whose principal activity is acquiring and monetizing patents rather than developing technology.¹⁰

Those realities should determine the direction of reform. Congress should approach skeptically claims that more and stronger patents necessarily produce more innovation, that attracting investment establishes a public benefit, or that international competition requires stronger patent rights. Although this submission refutes many of the claims advanced for PERA, legislation revising eligibility remains premature. Before advancing such legislation, Congress should commission a comprehensive, independent assessment through the Government Accountability Office, the Congressional Research Service, or another neutral body to examine how the patent system as a whole serves the public, where its costs exceed its benefits, and how its principal features interact.

The assessment should establish a common factual foundation for patent policymaking. Among other things, it should examine the effective duration and scope of patent rights; the prevalence and significance of independent invention; patterns of domestic and foreign patenting, ownership, acquisition, licensing, and monetization; the role and effects of third-party litigation funding; the extent to which patents induce inventions that would not otherwise occur; the effects of artificial intelligence on invention, patent drafting, application volume, and examination; and the consequences of the U.S. patent system for competition, access, and global health. Against that foundation, Congress could better evaluate how eligibility, examination quality, injunctions, damages, post-issuance review, and other legal rules operate together and whether changing one part of the system would improve the overall bargain or merely increase the leverage conferred by patents. Without that foundation, Congress risks changing one component without understanding the consequences elsewhere.¹¹

B. Section 101 Helps Enforce the Patent Bargain

Section 101 is one of the principal means by which the patent system screens out claims that do not warrant a 20-year right to exclude. That right should generally be reserved for a genuine human-made advance in a technological art. Commercial usefulness, novelty, or ingenuity in the abstract should not be enough. A new method of structuring a transaction may be clever and profitable without advancing technology. A newly discovered natural correlation may be scientifically

⁹ See USPTO, FY 2024 Workload Tables, tbls. 7-10 (2024) (reporting patent origin by the residence of the first-named inventor), available at <https://www.uspto.gov/sites/default/files/documents/USPTOFY24WorkloadTables.xlsx>.

¹⁰ See [Opposition to Squires Nomination](#), Truth Nos. 7-8.

¹¹ Such an assessment would also allow future hearings to proceed from a common factual record, rather than another series of presentations by witnesses with settled positions and limited opportunity to engage one another's claims. The questions catalogued in my [Opposition to Squires Nomination](#) could provide one starting point for defining the scope of that review.

important without representing a human-made invention. Patents in either category can impede later work, restrict access, and raise prices even where the prospect of patent protection was not needed to induce the underlying contribution.

The Supreme Court's modern § 101 cases seek to perform that screening function through the judicial exceptions for abstract ideas, laws of nature, and natural phenomena. In application, those decisions place meaningful limits on claims that use conventional technology to implement non-technological ideas and on claims whose asserted contribution lies principally in a discovery about nature.

The resulting doctrine is imperfect. It still permits some patents whose contribution is principally economic or informational, as well as some claims that use formally human-made elements to obtain broad control over natural information. The judicial exceptions nevertheless preserve an important boundary between technological invention and claims that would give private control over economic practices, natural relationships, or natural information.

C. Artificial Intelligence Makes Broader Eligibility Especially Risky

Artificial intelligence will intensify the existing pressures on the patent system. AI systems increasingly assist in research, product design, software development, prior-art searching, and the drafting of patent specifications and claims. They will make it cheaper to generate and evaluate additional variations on existing products, processes, and designs and to prepare patent applications claiming them.¹² The likely result is a substantial increase in applications, including many covering incremental variations that previously would not have justified the cost of seeking a patent.

The USPTO should be preparing for that increase by strengthening examination quality and retaining an experienced, well-supported examiner corps. Instead, recent policies have weakened collective-bargaining protections, restricted telework for new examiners, and made it harder for the Office to recruit and retain technically trained personnel.¹³ Expanding eligibility would compound those problems by requiring examiners to process still more applications, including claims in non-technological fields where relevant prior art is often diffuse and difficult to locate. That would increase the risk of examination error at the moment when artificial intelligence is already likely to drive application volume sharply upward.

D. If Congress Revisits Section 101, It Should Draw a Sharper Line Between Patents That Promote Progress and Those That Do Not

Patent reform should address the documented weaknesses of the existing system rather than lower eligibility thresholds on the unsupported assumption that more patents necessarily produce more

¹² See [Opposition to Squires Nomination](#), Truth No. 16 (“One truth to rule them all: Advances in AI will result in explosive technological growth without the aid of the patent system.”).

¹³ See [Squires Oversight Hearing Takeaways](#) (Substack Mar. 29, 2026) (No. 10: “The morale explanation was detached from reality”).

innovation. If Congress nevertheless revisits § 101, it should preserve the provision’s essential gatekeeping role and consider clearer statutory lines that further limit or eliminate patents on non-technological subject matter and on claims whose asserted inventive contribution lies principally in a discovery about nature. That approach would align eligibility more closely with the Constitution’s purpose of promoting progress in the useful arts.

II. “Machines”: Current Law Places Meaningful Limits on Non-Technological Computer-Implemented Claims

A. The Federal Circuit Has Developed a Reasonably Workable Technological-Improvement Inquiry

For computer-implemented claims, Federal Circuit doctrine has increasingly focused on whether the claim improves the functioning of a computer or another technology. Claims directed to improved data structures, computer functionality, image processing, or network operation can be eligible. Claims that use computers to carry out longstanding commercial or informational practices generally are not.¹⁴

The line is not perfectly clear, but empirical research indicates that § 101 outcomes are broadly comparable in predictability and appellate consistency to those under other patent-law doctrines.¹⁵ That evidence undermines claims that eligibility is uniquely unadministrable. A desire for greater clarity therefore does not justify PERA or similar proposals, which would weaken § 101’s substantive limits rather than merely clarify them.

B. Alice Has Not Harmed Software Startups

The available evidence does not show that *Alice* impaired investment or entrepreneurship in the software industry. A recent study by Christian Helmers and Brian Love¹⁶ examined software startups whose patents were especially exposed to the decision and compared them with software startups whose patents were less affected. The study found no measurable adverse effect on financing or the likelihood of a successful exit.

Those findings undercut claims that *Alice* materially impaired software innovation or that uncertainty following the decision dampened investment. They also caution against predictions of economic harm unsupported by observed outcomes.

¹⁴ See, e.g., *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335-36 (Fed. Cir. 2016); *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299, 1313-16 (Fed. Cir. 2016); *Data Engine Technologies LLC v. Google LLC*, 906 F.3d 999, 1007-11 (Fed. Cir. 2018); *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350, 1353-56 (Fed. Cir. 2016).

¹⁵ Nikola L. Datzov & Jason Rantanen, *Predictable Unpredictability: The Surprising Administrability of Patent Subject Matter Eligibility*, 110 Iowa L. Rev. 667, 708-22 (2025), available at <https://ilr.law.uiowa.edu/sites/ilr.law.uiowa.edu/files/2025-01/ILR-110-Datzov-Rantanen.pdf>.

¹⁶ Christian Helmers & Brian J. Love, *Patent Protection and Software Firm Financing* (Oct. 13, 2025; last revised Jul. 6, 2026), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5600070.

C. Current Doctrine Permits Limited Prior-Art-Like Considerations Under Section 101

One recurring objection to the current eligibility framework is that it allows considerations associated with novelty and obviousness to enter the § 101 inquiry.¹⁷ That objection has a legitimate doctrinal basis. In *Diamond v. Diehr*, the Supreme Court stated that the novelty of claim elements was “wholly apart” from whether the claim recited eligible subject matter.¹⁸ Sections 101, 102, and 103 were generally understood to perform separate functions.

Mayo and *Alice* altered that understanding. Under their two-step framework, courts ask whether additional claim elements are “well-understood, routine, and conventional.”¹⁹ That inquiry resembles a prior-art analysis, even though it does not require the full anticipation or obviousness showing necessary under §§ 102 and 103. Judge Newman’s dissent in *Yu* reflects the traditional objection: once a claim recites a concrete machine, questions about whether its components or configuration are conventional should be left to the other patentability provisions. Whatever the merits of that objection, *Mayo* and *Alice* are now the governing law.

That limited overlap between eligibility and conventionality is often cited as evidence that the doctrine is incoherent. The comparison between *Yu v. Apple* and *Contour v. GoPro*,²⁰ however, provides a useful test of that claim.

D. *Yu* and *Contour* Do Not Show That Federal Circuit Doctrine Is Incoherent

PERA supporters frequently invoke *Yu* and *Contour* as evidence that current eligibility doctrine is incoherent, emphasizing that both cases involved digital cameras assembled from familiar components.²¹ The claims, however, presented materially different asserted contributions. Rather than demonstrating inconsistency, the decisions help show both how limited the role of prior-art-like considerations remains under § 101 and where the Federal Circuit has drawn the line.

In *Yu*, the representative claim recited a camera having two lenses, two image sensors, conversion circuitry, memory, and a processor that produced a resultant image by enhancing one image with another. Multi-lens and multi-sensor digital cameras were already known, and the individual components performed their ordinary functions. The Federal Circuit characterized the

¹⁷ See, e.g., Andrei Iancu, Statement Before the Senate Judiciary Subcommittee on Intellectual Property, at 4-5 (Oct. 8, 2025), available at <https://www.judiciary.senate.gov/imo/media/doc/4539f98c-f893-95c0-3976-2519d3d06087/2025-10-08%20-%20Testimony%20-%20Iancu1.pdf>

¹⁸ *Diamond v. Diehr*, 450 U.S. 175, 188-89 (1981).

¹⁹ *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 73, 79-80 (2012); *Alice Corp. Pty. Ltd. v. CLS Bank International*, 573 U.S. 208, 217-18, 225 (2014).

²⁰ *Yu v. Apple Inc.*, 1 F.4th 1040 (Fed. Cir. 2021); *Contour IP Holding LLC v. GoPro, Inc.*, 113 F.4th 1373 (Fed. Cir. 2024).

²¹ See, e.g., David Kappos, Statement Before the Senate Judiciary Subcommittee on Intellectual Property (Oct. 8, 2025), at 5-7, available at <https://www.judiciary.senate.gov/imo/media/doc/4539f98c-f893-95c0-3976-2519d3d06087/2025-10-08%20-%20Testimony%20-%20Kappos.pdf>.

claim as directed to the abstract idea of taking two pictures, possibly at different exposures, and using one to enhance the other in some way.

The claim did not identify any particular enhancement technique. Although the specification discussed a more specific four-sensor arrangement and described how a black-and-white intensity image could improve images from color-specific sensors, representative claim 1 did not require that arrangement or any specified processing method. The court also emphasized that photographers had used multiple pictures to enhance one another for more than a century. That longstanding practice supported the court's characterization of the claimed contribution as an abstract idea implemented through familiar camera components.²²

Judge Newman dissented. Because the claim recited a concrete mechanical and electronic camera with defined components performing specified functions, she believed it fell within the statutory category of a “machine” and should not be recharacterized as an abstract idea under § 101. Her position did not depend on a finding that the claimed camera architecture was novel. She viewed novelty and nonobviousness as matters for §§ 102 and 103.

Contour also involved familiar camera and processing components, but the claim required the camera to operate in a particular way. Point-of-view cameras are often mounted where the user cannot readily see what the camera is recording. Sending a high-quality video stream to a phone for real-time monitoring and adjustment can exceed available wireless bandwidth. The *Contour* claims addressed that limitation by requiring the camera to generate two video streams of different quality in parallel, transmit the lower-quality stream for real-time viewing and control, and retain the higher-quality stream for the final recording.

The unanimous *Contour* panel – which included Judge Prost, author of the majority opinion in *Yu* – expressly considered and rejected GoPro's reliance on *Yu*. It explained that *Yu* involved a longstanding and fundamental photographic practice. In *Contour*, by contrast, GoPro did not argue that recording two video streams in parallel and wirelessly transmitting the lower-quality stream for real-time viewing and adjustment was a long-known or fundamental practice. The court distinguished the cases based on the character of the asserted practice, without undertaking an anticipation or obviousness analysis under §§ 102 and 103.²³

Consideration of whether a claimed practice is “longstanding” and whether additional claim elements are “routine and conventional” departs from the cleaner separation suggested by *Diehr* and is open to criticism. But that limited overlap has not converted § 101 into a general prior-art inquiry. *Yu* and *Contour* draw a reasonably discernible distinction between using familiar machinery to carry out a longstanding abstract practice and requiring a specific mode of technological operation to address a technological problem. They do not support the claim that the Federal Circuit's eligibility decisions are inexplicably contradictory.

²² *Yu*, 1 F.4th at 1043-45.

²³ *Contour*, 113 F.4th at 1377-82.

E. Congress Should Not Revive Business-Method Patents It Previously Singled Out as Problematic

As explained below, PERA would restore § 101 eligibility to many computer-implemented business-method claims, including claims directed to financial products, tax strategies, and other commercial practices. That would be a serious policy mistake. Business-method patents present an especially weak case for a 20-year right to exclude. Competition already supplies strong incentives to improve business practices. Such practices are frequently developed independently, often by many firms at roughly the same time, and usually cannot be kept secret once implemented. Granting an exclusionary right to the first applicant does not ordinarily induce dissemination of a technological teaching that would otherwise remain unavailable. It instead gives one patent owner the power to control use of the practice, even where others developed it independently and may be better able to implement or improve it. The result can be higher prices, reduced quality, and fewer competitive alternatives.

The experience following *State Street Bank*²⁴ confirmed the danger. Non-technological financial and commercial patents became tools for extracting settlements from productive companies, including companies that had independently developed the accused practices. Such patents are particularly attractive to monetizers because their value can lie primarily in litigation leverage rather than in any technology the patent owner developed or brought to market.

Congress responded in the America Invents Act in two relevant ways. Section 14 provides that any strategy for reducing, avoiding, or deferring tax liability is insufficient to distinguish a claimed invention from the prior art under §§ 102 or 103, while preserving patent protection for genuinely new tax-preparation or financial-management technology. Section 18 created a transitional post-grant review proceeding for patents claiming methods or corresponding apparatuses used in the practice, administration, or management of financial products or services, while excluding technological inventions. The proceeding was available only to parties that had been sued or charged with infringement. Although those provisions stopped short of a categorical prohibition on business-method patents, they plainly identified tax strategies and non-technological financial patents as categories warranting special treatment.²⁵

The covered-business-method program expired on September 16, 2020, by operation of the AIA's original eight-year sunset provision.²⁶ PERA would now restore § 101 eligibility to many machine-dependent commercial claims after the special review mechanism Congress created has disappeared. It would restart the cycle Congress sought to contain.

PERA excludes mathematical formulas and substantially economic, financial, business, social, cultural, or artistic processes, but restores eligibility when the process cannot practically be

²⁴ *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).

²⁵ Leahy-Smith America Invents Act, Pub. L. No. 112-29, §§ 14, 18, 125 Stat. 284, 327, 329-31 (2011), available at <https://www.govinfo.gov/content/pkg/PLAW-112publ29/pdf/PLAW-112publ29.pdf>.

²⁶ Leahy-Smith America Invents Act § 18(a)(3), 125 Stat. at 330, available at <https://www.govinfo.gov/content/pkg/PLAW-112publ29/pdf/PLAW-112publ29.pdf>.

performed without a machine or manufacture.²⁷ That exception would reach many of the types of claims restricted by *Alice* and subsequent decisions and previously singled out by Congress for special treatment in the America Invents Act. *State Street Bank* involved a programmed data-processing system for administering a hub-and-spoke investment structure with tax-accounting consequences, and *Alice* involved computerized intermediated settlement. Complex tax strategies may likewise depend on computer implementation; U.S. Patent No. 6,766,303,²⁸ for example, describes a computer-assisted method for designing and implementing a tax-related wealth-transfer strategy. A statute that treats practical dependence on a machine as sufficient would make claims of this kind eligible under § 101. The exception could even reach a marriage proposal deliberately structured so that it can be carried out only through a particular computer system.

This result is intended by at least some of PERA's leading supporters. In his October 2025 statement for the record, USPTO Director John Squires expressly rejected a technological-arts limitation, praised decisions recognizing eligibility for pure business processes, and argued that advances in applied economics can promote the useful arts. He relied in part on financial-monitoring patents filed for a company he helped found and represented. His statement confirms that restoration of business-method eligibility is a feature of the proposal, rather than an unintended consequence.²⁹

Revival would also impose substantial costs on the USPTO. Technically trained examiners already face unprecedented application volumes and backlogs.³⁰ As already discussed, artificial intelligence is likely to accelerate that pressure by reducing the cost of generating inventions, drafting specifications and claims, and filing applications covering large numbers of incremental variations. Expanding eligibility to computer-implemented financial products, tax strategies, business practices, and other machine-dependent non-technological processes would add applications in fields where the most relevant prior art often lies outside patents and technical publications. Examiners would be required to search diffuse and poorly indexed evidence of commercial practice while examination resources are diverted from technological inventions.

²⁷ Patent Eligibility Restoration Act of 2025, proposed 35 U.S.C. § 101(b)(1)(A)-(B), (b)(2)(A), available at <https://www.tillis.senate.gov/services/files/66582271-634A-4102-9658-5E4A98E4D206>.

²⁸ See *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1370-73 (Fed. Cir. 1998) (U.S. Patent No. 5,193,056, available at <https://patents.google.com/patent/US5193056A/en>); *Alice Corp. Pty. Ltd. v. CLS Bank International*, 573 U.S. 208, 213-14 (2014) (U.S. Patent No. 5,970,479, available at <https://patents.google.com/patent/US5970479A/en>); U.S. Patent No. 6,766,303, available at <https://patents.google.com/patent/US6766303B2/en>.

²⁹ John A. Squires, Statement for the Record Before the Senate Judiciary Subcommittee on Intellectual Property (Oct. 10, 2025), available at <https://www.uspto.gov/about-us/news-updates/statement-director-squires-united-states-senate-subcommittee-intellectual>.

³⁰ See USPTO, Patents Dashboard (data through May 2026), available at <https://www.uspto.gov/dashboard/patents/>.

F. The Administration Is Moving Eligibility Policy in the Wrong Direction

The USPTO's shift toward broader eligibility should be understood as an Administration policy, rather than an initiative attributable solely to Director Squires. Director Squires made clear at his March 25, 2026 oversight hearing that Commerce Secretary Howard Lutnick sets the Administration's policy direction for the USPTO.³¹ Consistent with that direction, the Office has instructed examiners to avoid eligibility rejections in close cases, designated *Ex parte Desjardins* precedential to encourage broader recognition of asserted technological improvements, revised the MPEP accordingly, and created a mechanism for applicants to submit declarations aimed at overcoming § 101 rejections.³²

That approach risks repeating an earlier institutional failure. Before the Supreme Court clarified the law in *Mayo* and *Alice*, the Office issued large numbers of patents that later proved unenforceable, after businesses and the public had already incurred substantial examination, litigation, licensing, and settlement costs. As I explained in my Opposition to the Squires nomination, where the governing law is genuinely uncertain, the USPTO should generally preserve the issue through rejection and permit applicants to seek judicial review.³³ A permissive administrative policy can insulate questionable claims from judicial scrutiny because competitors often cannot challenge them until years after issuance. Issuing patents first and awaiting eventual correction externalizes the cost of uncertainty onto the public.

Secretary Lutnick is frequently described as someone who understands the patent system because he is named as an inventor on more than 400 United States patents and over two hundred pending patent applications.³⁴ His experience is principally commercial. Secretary Lutnick holds a

³¹ See [Squires Oversight Hearing Takeaways](#) (Substack Mar. 29, 2026) (No. 1: "Lutnick, not Squires, is in charge").

³² See USPTO, Reminders on Evaluating Subject Matter Eligibility of Claims Under 35 U.S.C. § 101, at 5 (Aug. 4, 2025), <https://www.uspto.gov/sites/default/files/documents/memo-101-20250804.pdf> (instructing examiners that, in a close case, they should reject only when it is more likely than not that the claim is ineligible); USPTO, Advance Notice of Change to the MPEP in Light of *Ex parte Desjardins* (Dec. 5, 2025), available at <https://www.uspto.gov/sites/default/files/documents/memo-desjardins.pdf>; USPTO, Patent Related Notices - 2025 (listing Best Practices for Submission of Rule 132 Subject Matter Eligibility Declarations), available at <https://www.uspto.gov/patents/laws/patent-related-notices/patent-related-notices-2025>.

³³ [Opposition to Squires Nomination](#), at 42-43.

³⁴ Annelise Levy & Michael Shapiro, *Lutnick's Inventor Past Offers Glimpse Into Commerce Patent Role*, Bloomberg Law (Jan. 28, 2025), available at <https://news.bloomberglaw.com/ip-law/lutnicks-inventor-past-offers-glimpse-into-commerce-patent-role> (reporting that Lutnick is named as sole or co-inventor on more than 400 active or expired U.S. patents and quoting former USPTO Director Andrei Iancu as stating that Lutnick "obviously knows patents and the patent system"); Howard W. Lutnick, iDiyas Inventor Profile (reporting more than 500 USPTO-granted patents and more than 200 pending U.S. applications), available at <https://idiyas.com/inventor/howard-w-lutnick>; Justia Patents, *Patents by Inventor Howard W. Lutnick* (listing

degree in economics and spent his career as a bond broker and financial-services executive.³⁵ His patent portfolio is concentrated heavily in electronic trading, financial systems, online gaming, and related computer-implemented business processes.³⁶

That portfolio illustrates the central issue presented by expansive eligibility. The asserted novelty in such claims ordinarily lies in a new way of conducting a trade, structuring a wager, organizing a market, or presenting financial information. Defenders describe sophisticated uses of computers to accomplish transactions that earlier systems could not practically perform. But a commercially valuable use of a computer does not necessarily improve computer technology. When the inventive concept lies in the transaction, the claim remains a software-implemented business method, even if it was novel and nonobvious when filed. It is difficult to believe that the constitutional reference to progress in the “useful Arts” was intended to encompass new methods of trading, gaming, or gambling whose only technological feature is the use of existing machinery to carry them out.³⁷

issued patents and pending U.S. patent applications naming Lutnick as an inventor, including 31 patents that issued after he became Commerce Secretary on February 18, 2025), available at <https://patents.justia.com/inventor/howard-w-lutnick>.

³⁵ See *Nomination of Howard Lutnick, Nominee to Be Secretary, U.S. Department of Commerce: Hearing Before the S. Comm. on Commerce, Science, and Transportation*, 119th Cong., S. Hrg. 119-207, Biographical Information, Questions 7, 8 and 22 (2025), available at <https://www.congress.gov/event/119th-congress/senate-event/LC74854/text> (describing Lutnick’s career as a broker, trader, and executive in financial-services and real-estate businesses).

³⁶ See Levy & Shapiro, [*Lutnick’s Inventor Past Offers Glimpse Into Commerce Patent Role*](#) (reporting that most of Cantor Fitzgerald’s patents involved sophisticated computer implementations of trading transactions and discussing the company’s online-gaming portfolio); Justia Patents, *Patents by Inventor Howard W. Lutnick* (listing patents and applications concerning electronic trading, financial products, payment processing, gaming, and related computer-implemented systems), available at <https://patents.justia.com/inventor/howard-w-lutnick>.

³⁷ Secretary Lutnick’s relationship to interests affected by patent policy also creates an appearance concern. His former firm, now led by his sons, is affiliated with a company that sued DraftKings and FanDuel in April 2026 on five mobile-gaming patents, two of which name him as an inventor. The Commerce Department has stated that he complied with applicable divestiture and recusal requirements, but at the March 25, 2026 USPTO oversight hearing, Chairman Issa openly questioned whether he had eliminated all holdings capable of benefiting from the Administration’s patent policies. Oversight Hearing on the U.S. Patent and Trademark Office, House Judiciary Committee, Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet (Mar. 25, 2026), [Tr. 2:08:46-2:10:46](#). The litigation illustrates the unusual proximity between the business-method patent interests affected by USPTO policy and the official directing the Department that oversees the agency. See Blake Brittain, *Cantor Fitzgerald Affiliate Sues DraftKings, FanDuel over Patents Invented by Commerce Secretary*, Reuters (Apr. 2, 2026), available at <https://www.reuters.com/legal/litigation/cantor-fitzgerald-affiliate-sues-draftkings-fanduel-over-patents-invented-by-2026-04-02/>; Blake Brittain, *U.S. Patent Office Head Faces Bipartisan Grilling in Congress*, Reuters (Mar. 25, 2026), available at <https://www.reuters.com/legal/government/us-patent-office-head-faces-bipartisan-grilling-congress-2026-03-25/>.

The issuance of such patents after *Alice* does not establish that they would survive judicial review under the Federal Circuit’s eligibility cases. The USPTO’s permissive implementation of *Alice* may allow claims of this kind to issue, but their eligibility ordinarily will not be meaningfully tested unless and until they are asserted. By then, the accused company may face years of district-court litigation before an appellate court finally determines whether the claims should have issued. The more direct path to certainty would have been for the USPTO to reject claims when their eligibility was doubtful, allowing the applicant to seek judicial review before an issued patent imposed litigation and settlement costs on the public.

PERA would change the analysis. Its machine-based exception would make an economic, financial, or business process eligible whenever it cannot practically be performed without a machine or manufacture. Many computer-implemented trading, financial, and gaming claims would therefore have a substantially stronger eligibility argument under PERA even where the asserted contribution lies in the transaction rather than in computer technology.

Secretary Lutnick’s portfolio also illustrates why PERA must specify an effective date. If PERA applies to existing patents and pending applications, owners of already-issued patents could invoke the new standard before their claims are ever tested under current law, and applicants with claims already on file could obtain the same benefit. Existing portfolios could thus be strengthened without inducing any future innovation. If Congress instead limits PERA to original applications filed after a future effective date, existing patents and pending applications would remain subject to the eligibility law governing them before PERA’s enactment. Congress should not leave that question for years of litigation.

Secretary Lutnick’s experience provides substantial familiarity with obtaining and monetizing patents in financial and gaming businesses. It does not necessarily provide the perspective of companies that develop technology or of competitors required to defend against business-method patents. His portfolio therefore illustrates, rather than resolves, the central policy question: whether a commercially novel transaction becomes the kind of advance warranting a patent merely because software or existing machinery is used to carry it out.

III. “Genes”: Current Law Protects Technological Biotechnology While Preserving Important Limits on Patents Over Natural Information

A. *Mayo* and *Myriad* Did Not Make New Diagnostic Technologies Unpatentable

Supporters of eligibility reform often state or imply that patents on diagnostic methods or techniques became unavailable after *Mayo* and *Myriad*. That is incorrect. *Mayo* held that a claim reciting a natural relationship, combined only with routine and conventional administration and testing steps, was not eligible. *Myriad* held that naturally occurring DNA is not made patentable merely because it has been isolated. Neither decision bars patents on new testing platforms, new laboratory techniques, engineered reagents, improved instruments, or other technological advances used to detect biomarkers.³⁸

³⁸ *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 72-80 (2012); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580-96 (2013).

The distinction is important. Discovering that a naturally occurring biomarker correlates with a disease or treatment response is valuable scientific work, but allowing one party to control every conventional use of that information can restrict confirmatory testing, second opinions, research, and clinical care. Inventing a new technological means of detecting that biomarker is different. The inventor has added a human-made tool, and current law permits protection directed to that contribution.

Recent experience confirms that this approach is administrable. Diagnostic technologies were rapidly developed and deployed during the COVID-19 pandemic, and genetic testing expanded dramatically after *Mayo* and *Myriad*. One published estimate concluded that the number of genetic tests developed increased at least sevenfold between 2013 and 2022.³⁹ Those developments are difficult to reconcile with the claim that current law has broadly disabled diagnostic innovation.

B. The Claimed \$9.3 Billion Investment Loss Is Not an Observed Decline

Proponents repeatedly cite an asserted \$9.3 billion reduction in diagnostic investment following *Mayo* and *Myriad*.⁴⁰ That figure is often presented as though researchers measured an actual collapse in investment. They did not. It derives from a regression model in a student law-review note estimating how much faster diagnostic investment *might have grown* had it followed the growth rate of selected comparison sectors. The underlying work acknowledges that annual investment totals in diagnostic technologies generally increased after *Mayo*.⁴¹

Even if it could be shown that some capital shifted away from diagnostics, that would not establish a loss to the economy or to innovation. Investment that leaves one sector ordinarily flows elsewhere, potentially toward projects with greater unmet need or better expected social returns. Nor does the model establish that the hypothetical additional investment would have produced socially valuable tests rather than duplicative development, higher prices, exclusive licensing, or barriers to access.

The claim that patents are needed to attract investment can also become self-confirming. If the government offers monopoly returns in a field, investors will predictably pursue them. That does

³⁹ Charles Duan, *Patent Eligibility and Diagnostic Testing*, R Street Policy Study No. 269, at 2 (Nov. 2022), available at <https://www.rstreet.org/wp-content/uploads/2022/11/Patent-Eligibility-And-Diagnostic-Testing.pdf>.

⁴⁰ See, e.g., [Iancu October 2025 Statement](#), at 5; Sue Peschin, Statement Before the Senate Judiciary Subcommittee on Intellectual Property, at 2 (Oct. 8, 2025), available at <https://www.judiciary.senate.gov/imo/media/doc/4539f98c-f893-95c0-3976-2519d3d06087/2025-10-08%20-%20Testimony%20-%20Peschin.pdf>.

⁴¹ A. Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 Wash. & Lee L. Rev. 397, 445-46 (2022), available at <https://scholarlycommons.law.wlu.edu/wlulr/vol79/iss1/8/> (“[T]he yearly investment totals for disease diagnostic technologies have generally increased in the years following *Mayo*—but they have increased at a lower rate compared to all other industries.”).

not show that the underlying innovation would not occur without patents, or that granting broader patents produces the best allocation of capital.

The available evidence concerning simple genetic diagnostic methods weighs strongly against the claim that broad patent rights are necessary to induce their development. Such patents can also harm patients, health-care providers, clinical laboratories, and follow-on innovators by restricting access, preventing second opinions, increasing prices, and impeding improved testing.⁴²

C. Diagnostic Development Is Not Economically the Same as Drug Development

Arguments for broad diagnostic patents often borrow the economics of pharmaceutical development. Bringing a new drug to market can require large clinical trials, extensive regulatory review, and hundreds of millions of dollars.⁴³ The patent incentive may therefore play a substantial role in financing drug development.

Most diagnostic methods do not involve the same cost structure. Many laboratory-developed tests do not require premarket FDA approval. Even advanced diagnostics that do require substantial validation generally cost far less to develop than new drugs.⁴⁴ And the diagnostic claims most directly affected by *Mayo* frequently involve the application of newly discovered medical knowledge using existing collection and testing methods.

Researchers, universities, clinicians, nonprofit institutions, public agencies, and laboratories have powerful incentives to discover and publish medically significant correlations even without the power to exclude every other clinician from using them. To the extent a genuine gap exists, targeted public funding, prizes, reimbursement reform, or carefully drawn regulatory incentives would address it more directly than granting broad patents over natural information.

D. Patient Access Should Be Central to the Patent-Eligibility Inquiry

Diagnostic patents and drug patents share one economically important feature: demand can be highly inelastic. A patient who needs a genetic test or other diagnosis often cannot substitute a different product or wait for the patent to expire. Broad claims over natural correlations can

⁴² See Charles Duan, *Patent Eligibility and Diagnostic Testing*, at 2, 4-7; Robert Cook-Deegan et al., *Sorry You Asked? Mayo, Myriad, and the Battles over Patent Eligibility*, 11 J.L. & Biosciences 1, 13-16 (2024), available at <https://academic.oup.com/jlb/article/11/1/lsae010/7687768>; see also Brief for American Medical Association et al. as Amici Curiae in Support of Plaintiffs-Appellees at 1-8, *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), available at https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1003&context=pub_disc_briefs.

⁴³ See Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (Apr. 2021), <https://www.cbo.gov/publication/57126>.

⁴⁴ See Boston Consulting Group, *Bringing Advanced Diagnostics to Market* (Nov. 9, 2023), available at <https://www.bcg.com/publications/2023/bringing-advanced-diagnostics-testing-to-market>; Charles Duan, *Patent Eligibility and Diagnostic Testing* at 4-7.

therefore permit the owner to restrict confirmatory testing, dictate which laboratories may perform a test, and charge prices unrelated to the incremental cost of applying the discovered information.

The removal of exclusive rights over BRCA1 and BRCA2 sequences facilitated multi-gene panel testing, exome analysis, whole-genome analysis, and additional sources of testing.⁴⁵ That experience supports keeping natural genetic information available for later research and clinical care. The policy question is whether society benefits from allowing one private party to control all practical uses of information supplied by nature.

E. *REGENXBIO* Confirms That Existing Law Does Not Threaten Biotechnology

At the October 2025 hearing, several witnesses invoked the then-pending appeal in *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*⁴⁶ as evidence that existing eligibility doctrine placed biotechnology on the brink of catastrophe. The Federal Circuit has since unanimously rejected that premise. It held that claims to cultured host cells containing recombinant nucleic-acid molecules were patent-eligible because the claimed cells, considered as a whole, were human-engineered compositions with characteristics markedly different from anything occurring in nature.⁴⁷ The decision demonstrates that current law can distinguish engineered biological compositions from natural products without congressional intervention.

The decision still raises policy concerns. By claiming a naturally occurring DNA sequence in combination with unspecified additional DNA in a generic host cell, a patentee may obtain a broad composition-of-matter right untethered to any particular treatment or other concrete use. A later method may therefore infringe whenever it employs a molecule or host cell falling within that broad genus, even where later researchers supplied the particular combination, application, and much of the technology responsible for its practical value.

REGENXBIO follows the formal distinction drawn in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, which treated cDNA as eligible because the physical molecule ordinarily does not occur naturally⁴⁸ even though nature supplies its biologically significant informational content. In both settings, the discovery of a naturally occurring DNA sequence can support broad control over downstream uses of that sequence through claims framed in formally human-made terms. Those claims may reach research, testing, and therapeutic uses far removed from anything the patentee actually contemplated. That is already a poor bargain for the public.

PERA would move still farther in the wrong direction. To current law's already overly permissive treatment of cDNA and recombinant host cells, PERA would add eligibility for naturally

⁴⁵ Robert Cook-Deegan et al., [*Sorry You Asked? Mayo, Myriad, and the Battles over Patent Eligibility*](#), 11 J.L. & Biosciences at 13.

⁴⁶ 167 F.4th 1206 (Fed. Cir. 2026).

⁴⁷ *Id.* at 1210-16.

⁴⁸ *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 593-95 (2013).

occurring human genes once they have been purified, enriched, otherwise altered by human activity, or employed in a useful invention or discovery.⁴⁹ That expansion could restore broad control over diagnostic and research uses of natural genetic information, including later-developed tests based on relationships the original discoverer neither identified nor understood. PERA is therefore not merely an effort to preserve protection for engineered biotechnology. It seeks still greater private control over information and materials supplied by nature.

IV. Patented Innovation Is Not Necessarily Patent-Induced Innovation

Arguments for broader patent eligibility often treat the existence of patents as evidence that patent protection caused the underlying innovation. That inference is unsound. A patent may attach to an innovation without having induced it. Important advances in software, biotechnology, medicine, and other fields may occur because of public funding, urgent practical need, scientific collaboration, ordinary commercial competition, or incentives unrelated to patent exclusivity.

The experience with genetic testing illustrates the point. As discussed above, the number of genetic tests developed increased at least sevenfold between 2013 and 2022, despite the eligibility limits imposed by *Mayo* and *Myriad*. Patents may contribute to certain forms of diagnostic development, including new testing platforms and other technological improvements that remain eligible under current law. But the dramatic growth in testing undercuts the assumption that broader patent rights over natural correlations or genetic information are necessary to sustain diagnostic innovation.

Wartime radar provides another example. Director Squires has invoked Alfred Loomis and radar as an illustration of innovation driven by patent rights.⁵⁰ But the decisive development of microwave radar occurred through an extraordinary government-organized research program responding to the immediate demands of World War II, including the National Defense Research Committee and the MIT Radiation Laboratory. Patents may have existed in the background, but the principal drivers were direct public funding, mission-oriented research, scientific collaboration, and urgent military necessity.⁵¹

These examples expose a recurring weakness in maximalist patent arguments. The fact that an invention was patented does not establish that the patent induced it, that broader eligibility would have produced it sooner, or that the innovation would have been lost without private exclusionary

⁴⁹ [Patent Eligibility Restoration Act of 2025](#), proposed 35 U.S.C. § 101(b)(1)(D)-(E), (b)(2)(B)-(C).

⁵⁰ See John A. Squires, Statement for the Record Before the Senate Judiciary Subcommittee on Intellectual Property (Oct. 10, 2025), available at <https://www.uspto.gov/about-us/news-updates/statement-director-squires-united-states-senate-subcommittee-intellectual>.

⁵¹ See Wikipedia, *National Defense Research Committee*, available at https://en.wikipedia.org/wiki/National_Defense_Research_Committee; The Rad Lab, PBS American Experience, available at <https://www.pbs.org/wgbh/americanexperience/features/secret-tuxedo-park-rad-lab/>.

rights. Congress should not expand § 101 on the unsupported assumption that more patentable subject matter necessarily produces more innovation.

V. Sections 102, 103, and 112 Cannot Do Section 101's Work

Supporters of expansive eligibility frequently contend that § 101 should be only a coarse filter and that §§ 102, 103, and 112 can eliminate undeserving claims.⁵² That argument mistakes the nature of the exclusions.

Claims directed to tax strategies, financial arrangements, isolated natural substances, or natural-correlation-based diagnostics may be drafted to satisfy PERA's eligibility rules. Once framed that way, they may also be novel, nonobvious, fully enabled, and clearly claimed, and therefore satisfy §§ 102, 103, and 112. Those provisions do not answer the antecedent question whether the claimed subject matter represents the kind of human-made technological contribution for which the patent system should grant an exclusive right. Without a meaningful § 101 inquiry, the resulting patents may leave one party with long-lasting control over an economic practice, natural material, or natural relationship despite the absence of a commensurate technological advance.

Section 101 also serves an institutional function. It permits early resolution when a claim's defect is apparent from its character. Requiring exhaustive prior-art discovery and full claim-by-claim analysis under §§ 102, 103, and 112 would increase examination and litigation costs, divert USPTO resources from examining technological inventions, and allow weak patents to exert settlement pressure for years.

Section 101 should not be a coarse filter. It performs a distinct threshold function by excluding claims whose defect lies neither in novelty nor in the adequacy of their disclosure, but in the kind of subject matter over which the patent system should confer exclusive rights. Sections 102, 103, and 112 provide no adequate substitute for screening out non-technological claims and claims whose asserted inventive contribution lies principally in a discovery about nature.

VI. Artificial Intelligence Provides No Basis for Lowering the Eligibility Threshold

Artificial intelligence is frequently invoked as a reason to broaden eligibility, yet the field is already advancing rapidly under current law, supported by enormous private investment,⁵³ public research,⁵⁴ and ordinary commercial competition. That experience provides no basis for assuming that a lower eligibility threshold would produce more or better AI innovation.

Broader eligibility could instead create additional patent barriers around techniques and applications that researchers, startups, and downstream users now develop and improve competitively. Before changing § 101 in the name of artificial intelligence, Congress should hear

⁵² See, e.g., [Kappos October 2025 Statement](#), at 3-4, 6-7; [Iancu October 2025 Statement](#), at 7-8.

⁵³ See Stanford Institute for Human-Centered Artificial Intelligence, *The 2026 AI Index Report* (2026), <https://hai.stanford.edu/ai-index/2026-ai-index-report> ("U.S. private AI investment reached \$285.9 billion in 2025.).

⁵⁴ National Science Foundation, *Artificial Intelligence*, <https://www.nsf.gov/focus-areas/ai>

from researchers, open-source developers, startups, and users as well as patent owners. It should determine whether broader eligibility would encourage advances that otherwise would not occur or would instead increase litigation, overlapping patent rights, and barriers to follow-on development. Congress may well conclude that the threshold should be raised, not lowered.

VII. International Comparisons Do Not Support PERA's Unrestricted Approach

Eligibility reform is also defended as necessary to compete with China. Those comparisons are often incomplete. China's approach to computer-implemented inventions generally asks whether a claim uses technical means to solve a technical problem and achieve a technical effect.⁵⁵ That requirement resembles the Federal Circuit's technological-improvement inquiry far more than PERA's machine-dependent exception for economic and business processes.

If Congress believes international harmonization is essential, it should study and define a technological-contribution requirement. PERA instead confers eligibility on economic, financial, social, cultural, or artistic processes whenever they cannot practically be performed without a machine. There is no national-security race to issue patents on tax strategies or routine commercial arrangements.

Nor should the United States copy foreign diagnostic-patent rules without considering differences in health-care pricing and access. Broad medical patents are less likely to produce unaffordable testing in systems that regulate prices directly. In the United States, where diagnostic pricing can be far less constrained, patent exclusivity can translate directly into restricted testing and higher patient costs.

VIII. Any Change Must Be Expressly Prospective

PERA's supporters justify broader eligibility principally as a means of inducing future innovation. As already explained, that rationale does not justify extending eligibility to business methods, natural correlations, and the like. But if Congress accepts it, then Congress should specify that PERA only applies to applications filed after a future date,⁵⁶ since those applications represent the "innovation" that PERA supposedly incentivizes.

At a minimum, before any vote, PERA should specify whether it applies to existing patents and pending applications or only to applications filed after a future effective date. Applying the new rule to existing portfolios could revive patents already held invalid or strengthen patents that would be invalid under current Supreme Court precedent, creating a windfall for their holders at the expense of competitors and the public. Members of Congress should know whether the bill preserves settled expectations or reopens them.

Of course, for the reasons already given, a prospective-only PERA is still a bad idea.

⁵⁵ Mark A. Cohen, Testimony Before the Senate Judiciary Subcommittee on Intellectual Property 5 (Oct. 8, 2025), available at <https://www.judiciary.senate.gov/imo/media/doc/4539f98c-f893-95c0-3976-2519d3d06087/2025-10-08%20-%20Testimony%20-%20Cohen.pdf>.

⁵⁶ See [Patent Eligibility Restoration Act of 2025](#) (containing no express effective-date provision).

IX. A Better Path Forward

If Congress concludes that particular technologies face genuine eligibility problems, it should identify those problems precisely and evaluate their real-world costs and benefits. A targeted inquiry could examine a narrowly defined class of medical inventions or ask whether reimbursement policy and public funding would work better than patent expansion.⁵⁷ It could also determine whether a particular line of cases has inadvertently excluded a concrete technological contribution.

Congress should resist generalized claims that innovation is collapsing or that other countries are winning because they issue more patents. Making almost everything eligible will not eliminate uncertainty. The system's costs are borne by competitors, patients, researchers, and future inventors, whose interests deserve the same attention as those of current patent owners.

A sensible eligibility regime should protect genuine human-made technological contributions. Natural products and natural information should remain available for research and practical use unless the claimant has added a specific engineered application. Dependence on a computer or machine should not transform a non-technological practice into a patentable invention.

As discussed in Part I, any future eligibility proposal should be evaluated against a comprehensive, independent assessment of the patent system as a whole. That broader inquiry would allow future hearings to proceed from a common factual record.

X. Congress Should Reassert Control Over Patent Policy

PERA should also be evaluated in institutional context. It is being advanced alongside other efforts to strengthen issued patents and weaken mechanisms for correcting error.

PERA is part of a broader campaign to increase the value and power of issued patents, promoted in substantial part by patent owners and other interests that would benefit from stronger exclusionary rights. The RESTORE Act would establish a presumption favoring permanent injunctions after a finding of infringement.⁵⁸ The PREVAIL Act would make inter partes review less available as a means of testing issued patents.⁵⁹ Under Secretary Lutnick, the USPTO has been pursuing the same overall objectives through administrative policy.

Those policies magnify one another. Broadening § 101 would allow more non-technological claims to enter the patent system. Weakening post-issuance review would make those patents harder

⁵⁷ See [Opposition to Squires Nomination](#), at 14-15 (Truth No. 14: There is no reason to think that the patent system as currently configured is the best way to promote medical innovation).

⁵⁸ See Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive Patent Rights Act of 2025 (RESTORE Act), summary available at <https://moran.house.gov/news/documentsingle.aspx?DocumentID=1009>.

⁵⁹ Promoting and Respecting Economically Vital American Innovation Leadership Act of 2025 (PREVAIL Act), summary available at <https://www.coons.senate.gov/news/press-releases/senators-coons-tillis-colleagues-introduce-bipartisan-bicameral-bill-to-foster-american-innovation-by-modernizing-the-patent-trial-and-appeal-board/>.

to challenge. Restoring a presumption of injunctive relief would then increase their power to block products and extract settlements. A computer-implemented business method that should never have qualified for a patent could become difficult to review and capable of supporting an injunction against a business that developed the accused practice independently.

The USPTO is already using administrative policy to bring about much of the shift that Congress is still considering. It has made eligibility examination more permissive; filed briefs urging broader injunctive relief, including in cases involving standard-essential patents;⁶⁰ greatly expanded discretionary denials at the Patent Trial and Appeal Board;⁶¹ and placed new obstacles in the path of ex parte reexamination.⁶² These actions are changing the practical balance among patent owners, competitors, and the public while Congress is actively considering legislation on the same subjects.

That is an inappropriate role for an agency whose principal statutory responsibilities are to examine patent applications and conduct the review proceedings Congress created. The USPTO should administer the patent system Congress enacted, rather than use shifting administrative policies to anticipate or preempt legislative choices about eligibility, remedies, and patent-validity review.

Congress should not respond to the USPTO's unilateral movement toward stronger patent rights by enacting legislation that would push the system still farther in the same direction. Before considering PERA, RESTORE, or PREVAIL, Congress should conduct sustained oversight of the agency's changes to eligibility examination, post-issuance review, ex parte reexamination, and remedies. Those administrative actions are already altering the balance Congress established through statutes such as the America Invents Act. The immediate task is to determine what the Office has changed, who directed those changes, what effects they are having, and which changes should be reversed. Otherwise, Congress risks ratifying and compounding a policy shift before it has understood either the shift or its consequences.

Congress can take a useful first step now. It should clarify that the USPTO may not deny inter partes review on open-ended, nonstatutory policy grounds when the petition satisfies the statutory prerequisites and demonstrates a reasonable likelihood that the petitioner will prevail on at least one

⁶⁰ See Thomas W. Krause, Comments for the Record: The Squires Oversight Hearing 1-4 (Apr. 13, 2026), available at <https://krauseonpatents.substack.com/p/comments-for-the-record-the-squires>.

⁶¹ See USPTO, Interim Director Discretionary Process (updated 2026), available at <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>; USPTO, Additional Discretionary Institution Factors (Mar. 11, 2026), available at <https://www.uspto.gov/subscription-center/2026/uspto-issues-additional-discretionary-institution-facts>.

⁶² USPTO, Pre-Order Procedure Regarding Substantial New Question Determination in Ex Parte Reexamination Proceedings (Apr. 1, 2026), available at <https://www.uspto.gov/sites/default/files/documents/og-preorder-snq-apr2026.pdf>; *Reexamination, Rewritten* (Substack April 4, 2026), available at <https://krauseonpatents.substack.com/p/reexamination-rewritten>.

challenged claim.⁶³ Congress should make clear that the agency cannot add a second, discretionary screen based on considerations Congress did not enact.

That clarification would restore the balance Congress established in the America Invents Act, provide a needed reset while Congress considers broader patent reform, and help stabilize the Patent Trial and Appeal Board before further institutional capacity is lost. It would also preserve meaningful review of issued patents at the very moment when artificial intelligence and the USPTO's eligibility policies threaten to produce far more applications and a greater risk of examination error.

Congress should consider the cumulative effect of the pending proposals and the USPTO's administrative actions before expanding patent rights further. A system that grants more patents, makes them harder to challenge, and gives their owners greater power to exclude imposes a larger system of private restraints on competition. The immediate need is for more selective patenting, reliable examination, and meaningful review of patents that should not have issued.

Conclusion

Current § 101 doctrine performs indispensable work despite its imperfections. Developments since the October 2025 hearing, including the Federal Circuit's unanimous eligibility ruling in *REGENXBIO*, confirm that the predicted biotechnology crisis has not occurred. *Alice*, *Mayo*, and *Myriad* continue to limit patents reaching too far into economic practices and natural information while leaving ample room for patents on genuine technological advances.

Congress should reject PERA and similar proposals that would restore eligibility to broad categories of computer-implemented business methods and weaken existing limits on claims derived principally from discoveries about nature. If Congress eventually revises § 101, the legislation should draw a sharper line between patents likely to promote progress in the useful arts and those likely to impede it. Any amendment – whether it broadens or narrows eligibility – should apply prospectively so that neither patent owners nor the public lose rights they reasonably understood to be settled under the law in effect at the relevant time.

Eligibility also should not be considered in isolation. The effects of § 101 depend on examination quality, patent scope and duration, remedies, damages, post-issuance review, ownership and monetization patterns, independent invention, litigation funding, and the growing role of artificial intelligence. Congress should develop a comprehensive, independent understanding of how those features interact and how the patent system as a whole serves the public before undertaking unexamined, system-wide expansions of patent rights. That inquiry need not delay targeted legislation addressing problems Congress has already studied and documented.

The immediate priority should be to restore congressional control over patent policy. Congress should conduct sustained oversight of the USPTO's unilateral restructuring, prevent further erosion of meaningful patent review, and clarify that the Office may not use open-ended policy grounds to defeat the review system Congress created in the America Invents Act. Enacting PERA, RESTORE,

⁶³ 35 U.S.C. § 314(a).

or PREVAIL before examining the agency's actions would compound the very problems that require congressional attention.

Respectfully submitted,

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