Senate Committee on the Judiciary
Hearing: "From Genes to Machines: The Patent Eligibility Debate"
July 14, 2026

QUESTIONS FOR THE RECORD

Responses of Andrei Iancu
Partner, Sullivan & Cromwell LLP[1]*;*
Co-Chair, Council for Innovation Promotion;
Former Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office

QUESTIONS FROM SENATOR GRASSLEY

1. We must balance two important aspects of technology. First, it's critical that our country stays in first place in the development of artificial intelligence and other cutting-edge technologies. Second, it's also important that consumers, everyday Americans, have affordable access to computers and other benefits of our inventions.

(a) If patent eligibility reform legislation is passed, particularly PERA as written, will everyday technology become more expensive or out-of-reach for consumers? What about new technologies? Would cutting edge technological advancements and possibly even current technology become out-of-reach for small businesses and public schools?

RESPONSE No—not on its own. PERA does not set prices, extend patent terms, or change patent remedies. It addresses the threshold question of which categories of invention may be considered for patent protection. The bill retains express exclusions—including for mental processes, mathematical formulas as such, and substantially business or social processes that merely say "do it on a computer"—and leaves Sections 102, 103, and 112 unchanged. Any patent must still be novel, nonobvious, clearly claimed, and adequately disclosed.

There is no reliable basis to predict that it would make everyday or cutting-edge technology more expensive for consumers, small businesses, or schools. The longer-term question is whether clear, predictable patent rights encourage investment and market entry—both of which could in fact increase competition by introducing new products of the same class into the market. Empirical research following the Supreme Court's eligibility decisions has found disproportionate harm to smaller patent-dependent firms, increased reliance on secrecy, and reduced development of some molecular tests.[2] By helping smaller innovators and others

[1] The views expressed herein are personal to me, and do not represent the views of Sullivan & Cromwell LLP or its clients.
[2] Utku U. Acikalin et al., *Intellectual Property Protection Lost and Competition: An Examination Using Large Language Models*, 182 J. Fin. Econ. 104306 (2026); John Liddicoat et al., *The Effects of Myriad and Mayo on*

finance and disclose new technologies, PERA could be expected to expand the products and suppliers available—not place technology out of reach. All else equal, PERA should *increase* dynamic competition in the long run.

(b) What impact would PERA have on the development of — as well as consumer and small business access to — artificial intelligence?

RESPONSE: PERA would make patent protection more predictable for qualifying AI inventions, but it would not itself determine AI prices or access. Again, all else equal, PERA would increases innovation and dynamic competition in the long run. Current patent law does not categorically exclude AI patents. It does, however, make claims vulnerable when courts characterize them as collecting and analyzing information or merely applying generic machine learning to a new field. The Federal Circuit, for example, has held that applying established machine-learning methods to a new data environment is ineligible[3] and recently applied similar reasoning to deep-learning analysis of dental images[4]—an outcome approaching a categorical bar on a field Congress has never voted to exclude.

The risk of leaving the law as it stands is that it will reduce AI innovation and, at the same time, force remaining AI innovation to go dark and consolidate. When patents become unreliable, rational firms substitute secrecy: training methods, model architectures, and data pipelines need never be published if the patent that would have covered them is unlikely to survive a motion to dismiss. The public then loses the disclosure entirely, because a trade secret teaches no one and can last forever. And secrecy is a game large incumbents win. They can bind more employees, build more security, and absorb the cost of guarding know-how indefinitely; a startup cannot, and unlike a patent, a secret is not an asset it can typically take to an investor. So the alternative to reliable patents in AI is not free technology — it is proprietary know-how held indefinitely by whoever is already largest. Small businesses, schools, and consumers are worse off in that world, not better.

PERA would replace the judicial exceptions with express statutory exclusions while leaving the novelty, nonobviousness, and disclosure requirements of Sections 102, 103, and 112 unchanged. More AI inventions could therefore be evaluated on whether they are actually new, nonobvious, and adequately disclosed rather than being screened out at the eligibility threshold. More predictable patent rights can be particularly valuable to startups seeking outside financing; empirical research has found that receiving a patent materially improves startups' ability to raise external capital.[5]

Molecular-Test Development in the United States and Europe: Interviews from the Frontline, Vand. J. Ent. & Tech. L. (2020).

[3] Recentive Analytics, Inc. v. Fox Corp., 134 F.4th 1205 (Fed. Cir. 2025).

[4] Dental Monitoring SAS v. Align Tech., Inc., No. 2024-2270 (Fed. Cir. July 7, 2026) (nonprecedential).

[5] Joan Farre-Mensa, Deepak Hegde & Alexander Ljungqvist, *What Is a Patent Worth? Evidence from the U.S. Patent "Lottery"*, 75 J. Fin. 639 (2020).

For small businesses, schools, and consumers, PERA would support greater investment, entry, and disclosure. Accordingly, PERA could be expected to broaden opportunities to develop and commercialize competing AI technologies.

2. **Under current law some subject matter is not patent eligible. Examples of this are abstract ideas, laws of nature, and natural phenomena. Do you agree that these and/or other subject matters should not be patent eligible? If an invention contains subject matter that is currently not patent eligible, what should the legal test be to transform it into a patent-eligible invention? Please describe your proposed test and its practical impact.**

RESPONSE: At a certain level of principle, yes. No one should be able to patent a mathematical truth, a natural law, or a naturally occurring thing as such. The problem is not the principle; it is that as the courts have administered it, the principle has swallowed the statute. Every invention applies a law of nature, and every invention can be described at some level of abstraction, so a doctrine that asks what a claim is "directed to" supplies no stopping point. That is how a two-lens digital camera became an "abstract idea" (*Yu v. Apple*)[6] and a method of manufacturing an automobile driveshaft became a "law of nature" (*American Axle*)[7] — in neither case because the invention was necessarily old, obvious, or poorly described.

PERA effectively codifies exceptions like "mathematical truths" that the Supreme Court has long recognized, but does so in an analytical manner that avoids reliance on the amorphous judicial exceptions that courts use now. Under PERA, the claimed invention would have to be considered as a whole, without discounting or disregarding any claim element; and excluded from further consideration for a patent only if it falls within an enumerated statutory category and claimed "as such," unless further conditions are present that add practical human intervention or technology to the categorical exclusion. Under PERA, the following is excluded:

- A mathematical formula or a substantially economic or social process, unless the claimed invention "cannot practically be performed without the use of a machine or manufacture";
- A mental process "performed solely in the human mind";
- A process that "occurs in nature wholly independent of, and prior to, any human activity";

[6] Yu v. Apple Inc., 1 F.4th 1040 (Fed. Cir. 2021).
[7] Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285 (Fed. Cir. 2020).

- A human gene, unless the gene has been modified by human intervention (including being purified or enriched—wording I understand is intended to codify the holding of *Myriad*);

- A natural material, unless the material has been modified by human intervention (including being isolated, purified, or enriched).

PERA provides a significantly clearer roadmap for what belongs in and out of the patent system than the current jurisprudence, and it provides more secure eligibility for critical categories of inventions such as medical diagnostics and innovation involving computers.

3. There's debate in the discussion surrounding PERA as to whether the bill overturns the four major Supreme Court cases that have narrowed patent eligibility over the last 16 years. Does PERA, as drafted for this Congress, overrule these Supreme Court decisions? If not, what's left of them? Please address each case.

RESPONSE: PERA displaces the reasoning of all four decisions — that is its purpose — while preserving the outcome in most of them. What it eliminates is the judge-made two-step framework and the "abstract idea," "law of nature," and "natural phenomena" exceptions those cases built on a statute that contains none of them, replacing those amorphous concepts with clearer rules. Under the improved analysis provided by PERA, however, many of the outcomes of the recent cases would remain the same. Taking each in turn:

***Bilski v. Kappos* (2010)** — result preserved, rationale replaced. The claimed method of hedging commodity price risk would remain ineligible,[8] but under a written statutory rule: proposed § 101(b)(1)(B) excludes a process that is "substantially economic, financial, business, social, cultural, or artistic." The claimed method is substantially financial because every step of it consists of identifying counterparties and initiating offsetting transactions to balance the risk of price movements—a sequence of commercial dealings, not the operation of any machine or the transformation of any article. What would not survive is the free-floating abstract-idea exception the Court used to get to the same result.

***Mayo v. Prometheus* (2012)** — effectively overruled. Under PERA, these claims would be patent eligible since they are more than simply a process that occurs in nature (which is excluded): the claimed invention involves giving a person a drug and then subsequently measuring the value of metabolites and assessing what the resultant range means for the patient. In other words, there are several claimed instances of practical human intervention.[9] Although the claims would be eligible, their validity would still be contestable under Sections 102, 103, and 112, as they were before 2012. Thus, if this case were continuing on today (which it is not), the defendant could still argue that the claims are not new, are

[8] Bilski v. Kappos, 561 U.S. 593 (2010).
[9] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).

obvious, or are too broadly drafted in light of the patent's disclosure, and it is theoretically possible that the patent would have been invalidated on one of these other bases.

***AMP v. Myriad Genetics* (2013)** — codified, not overruled. Proposed § 101(b)(1)(D) excludes an unmodified human gene as it exists in the human body, and this Congress's version deliberately dropped "isolated" from the activities that render a gene "modified" (§ 101(b)(2)(B)), so a merely isolated human gene remains ineligible — which aims to codify *Myriad*'s holding.[10] cDNA, which *Myriad* held eligible, remains eligible because it is altered by practical human activity. Section 2(5)(D)(iv) states the point expressly in the findings. At the hearing, other witnesses argued that the relevant language did not codify *Myriad* clearly enough and agreed to provide alternative language to the Committee; I would be happy to review such alternative language as well.

***Alice Corp. v. CLS Bank* (2014)** — result preserved, framework eliminated. The escrow-settlement claims at issue would remain ineligible as a substantially financial process,[11] reinforced by the bill's express rule that adding a computer as window dressing does not change this result (Sec. 2(5)(E)(i); Sec. 4(b)). What does not survive is the *Alice* two-step and its subsequent application by the lower courts to invalidate genuine technological advancements.

4. In your opinion, what subject matter, if any, should be ineligible for patent protection in the United States? Why?

RESPONSE: Broadly, the categories PERA enumerates, and for the reason the Constitution supplies: patents exist "to promote the Progress of Science and useful Arts," so the system should cover applied technology and stop short of inventions that are not technology at all. That means excluding mathematical formulas as such; processes that are substantially economic, financial, business, social, cultural, or artistic; processes performed solely in the human mind; unmodified human genes as they exist in the body or as merely isolated from it; and unmodified natural materials as they exist in nature.

5. Would enactment of PERA change the cost of doing business for Iowa main street businesses? How would it impact the cost to operate our Des Moines Home Depot or locally-owned, single storefront craft store? How would it impact the price competition between large, national and international online stores and local small businesses?

RESPONSE: PERA should not change the cost of operating a hardware store or a craft store. Section 101 does not set prices or govern retail operations; it decides only whether an invention may be considered for a patent at all, and PERA leaves every substantive requirement for actually obtaining one in place.

[10] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013) [hereinafter AMP v. Myriad].
[11] Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014).

To the extent main-street businesses have a stake here, PERA helps them. The demand letters that historically landed on small retailers, restaurants, and hotels were built on business-method and "do it on a computer" patents — scanning a document to email, offering guest Wi-Fi, running an online shopping cart. PERA excludes that category by statute rather than by case law: processes that are substantially economic, financial, or business in nature are ineligible, and Section 4(b) confirms that pre- or post-solution computer activity cannot rescue such a claim. That is clearer and more durable protection than today's case-by-case abstract-idea litigation, which is expensive for a small defendant precisely because no one can predict how it will come out.

6. There is uncertainty and debate around the impact PERA would have if enacted. Please help us understand the practical applicability of several sections of S. 1546.

(a) Section 2(5)(A) eliminates all judicial exceptions to patent eligibility. Does this apply prospectively? What role would the courts have going forward in the application of section 101?

RESPONSE: I understand this provision to eliminate existing and future judicial exceptions, returning patent law to the normal rules of statutory interpretation where it is disfavored for courts to depart from statutory language with judicially created rules. But this would not eliminate the substantial role of future courts in continuing to decide eligibility in individual cases, construe statutory terms such as "substantially economic" and "unmodified," and build precedent applying the statute to facts Congress could not anticipate. Proposed § 101(c)(2) expressly preserves the court's authority to resolve eligibility at any time in an infringement action, including on motion where there is no genuine dispute of material fact, with limited discovery available. What courts would no longer do is create whole categories of ineligible subject matter that Congress never enacted. That is the same relationship the courts have to Sections 102, 103, and 112 — and it works.

(b) There is disagreement about precisely what Section 2(5)(D) excludes from patent protection. Please help us understand the breadth and limits of the following subsections:

(i) "(ii) A mental process performed solely in the mind of a human being." Please clarify the parameters of this exclusion with concrete examples. Also, would a mental process performed solely in the mind of a human include a process whereby a human might use paper to take notes, perform manual calculations, draw specifications, or something similar that aids in the process being performed in the human mind?

RESPONSE: The exclusion is narrow by its own terms: it reaches a process performed solely in the mind. It would apply to claims such as those the Supreme Court held ineligible in *Gottschalk v. Benson*. The applicants there claimed a method of converting numbers

written in binary-coded decimal form into pure binary form. The Court described the claims as "not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end use," and observed that the conversion itself "can be done mentally through use of the [conversion] table."[12] A claim of that kind falls squarely within proposed § 101(b)(1)(C)(i), the mental-process exclusion to which this question refers. (It would likely also fall within § 101(b)(1)(A) as a mathematical formula claimed as such.) Such a claim is excluded regardless of whether anyone had thought of the method before, because thinking is not technology.

On paper and pencil: by the plain terms of the statute, a process that requires writing notes, performing calculations on paper, or drawing a specification is not performed solely in the mind, and so falls outside this exclusion. That does not mean such a claim gets a patent. It must still not be a substantially economic, financial, business, social, cultural, or artistic process under § 101(b)(1)(B); and it must still be novel, non-obvious, and adequately disclosed. A claim that adds a trivial physical step to an otherwise mental exercise may have difficulty surviving Sections 102, 103, and 112.

(ii) "(iii) An unmodified human gene, as that gene exists in the human body." Please clarify the parameters of this exclusion with concrete examples. Also, what about a gene, which remains in the human body, that has been altered by a genetic treatment? Does that gene, as modified by a treatment, become patent eligible though it continues to exist in the human body? What if this modified gene continues to perform a function due to the treatment? What if this modified gene exerts a unique process inside the human [that] would not happen except for the treatment?

RESPONSE: The exclusion covers the gene as it naturally occurs in a person. A naturally occurring BRCA1 sequence in a patient's cells is not patentable subject matter, and neither is a naturally occurring variant of it — whether described as it sits in the body or after it has been isolated. That is *Myriad*'s result, and PERA codifies it in § 101(b)(1)(D) and reinforces it in the findings at Section 2(5)(D)(iii)–(iv).

It is worth being precise about what *Myriad* did and did not decide, because the decision is sometimes read more broadly than it was written. The Court held two things: that a naturally occurring DNA segment is a product of nature and does not become eligible merely by being isolated, and that cDNA — DNA synthesized in a laboratory based on a natural sequence but with segments removed ("introns") — *is* eligible precisely "because it is not naturally occurring."[13] *Myriad* accordingly establishes the principle that human-made genetic material stands on different footing from what nature produced — the same line PERA draws.

[12] Gottschalk v. Benson, 409 U.S. 63, 64, 67 (1972).
[13] AMP v. Myriad, 569 U.S. at 580.

PERA answers all three of your variations the same way. Under proposed § 101(b)(2)(B), a human gene is not "unmodified" if it has been "purified, enriched, or otherwise altered by human activity," or is "otherwise employed in a useful invention or discovery." A gene edited in vivo by a genetic treatment has been altered by human activity and therefore falls outside the exclusion. So has a gene that continues to perform a function only because of that treatment, and so has one that exerts a process in the body that would not occur but for it. In each case what is claimed is what human ingenuity produced, and it is not dependent on where the altered gene resides—in a human body, in a petri dish, or in a medicine used to deliver the altered gene to a patient. Eligibility remains only the threshold: any such claim must still be new under Section 102, non-obvious under Section 103, and adequately described under Section 112.

Finally, on the concern implicit in the question — whether a person who receives a genetic treatment could be sued because the altered gene remains in his or her body — the answer is that this is unlikely. Patents in this field operate as they do throughout the biopharmaceutical industry: patentees assert and license against commercial actors who make and sell, not against the patients treated. In many cases, doctrine forecloses it as well. A patient who obtains an authorized therapy takes it free of the patent — the authorized sale exhausts the patentee's rights in that article, and the patient holds at minimum an implied license to retain what the treatment produced.

(iii) "(iv) An unmodified human gene that is isolated from the human body, but otherwise the same as the gene exists in the human body." Is a similar process as isolation of a gene, through a legal if not a scientific lens, used in medical or scientific research or treatment that we should be aware of when legislating in this area?

RESPONSE: Yes, dating back to the Judge Learned Hand decision of *Parke-Davis v. H.K. Mulford* (1911),[14] isolation and/or purification has been understood to confer patentability on such extracted natural materials, such as the purified adrenaline in that case. The rationale has been that the human act of extracting a chemically active compound is technological and confers benefits beyond what the material can offer in its non-isolated, natural form such as increased potency or fewer side effects from other substances.

PERA treats unmodified human genes differently from these other materials as a matter of policy, not science. For a human gene, mere isolation is not enough; that is the *Myriad* line, and this Congress's bill reinforces it by removing "isolated" from § 101(b)(2)(B). For other natural materials, § 101(b)(2)(C) provides that isolation or purification by human activity can

[14] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911) (Hand, J.), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912) (The inventor "was the first to make [adrenaline] available for any use by removing it from the gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, *it became for every practical purpose a new thing commercially and therapeutically*. That was a good ground for a patent.") (emphasis added).

render the material eligible — restoring the rule that governed American pharmaceutical and biotechnology innovation for the better part of a century before *Myriad*.

(iv) "(v) An unmodified natural material, as that material exists in nature." Please give several concrete examples of application of this section. What would be impacted?

RESPONSE: The exclusion reaches the material as nature made it and as it is found: an ore or mineral as mined, a wild plant, seawater, a naturally occurring bacterium in soil, a protein circulating in an organism, a mold growing on bread. Discovering such a thing — however valuable the discovery — does not entitle the discoverer to a patent on the thing itself. That principle is unchanged.

What would be affected is the step after discovery. Under proposed § 101(b)(2)(C), a natural material is no longer "unmodified" once it has been "isolated, purified, enriched, or otherwise altered by human activity" or "otherwise employed in a useful invention or discovery" — so a purified antibiotic compound, an enriched plant extract, a genetically modified organism, or a naturally occurring enzyme put to work in a new industrial process may be eligible, while the mold on the bread, the plant in the field, and the microbe in the soil remain outside the system.

Senate Committee on the Judiciary
Hearing: "From Genes to Machines: The Patent Eligibility Debate"
July 14, 2026

QUESTIONS FOR THE RECORD

Responses of Andrei Iancu
Partner, Sullivan & Cromwell LLP[1]*;*
Co-Chair, Council for Innovation Promotion;
Former Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office

QUESTIONS FROM SENATOR COONS

During the hearing, several members of the Committee noted their concern with the high costs of prescription drugs.

- **Please elaborate on your comments during the hearing about how the Patent Eligibility Restoration Act (PERA) would not increase drug pricing or materially impact pharmaceutical patent eligibility. Why is that the case?**

RESPONSE: Section 101, even after the four most recent Supreme Court cases, has largely not been a barrier to small molecule and biologic drug patents; these patents are rarely contested on eligibility grounds. They are classic compositions of matter and methods of treatment — the paradigm cases of eligible subject matter — and they were eligible before *Bilski* and remain eligible today. Thus, PERA will not meaningfully alter the status quo for this class of patents, even though it will have important impacts elsewhere in the patent system to provide concrete eligibility for other classes of inventions, such as mechanical inventions incorporating software and medical diagnostics.

In general, patents encourage innovation and enable more drugs and treatments, not less. At scale and in the long run, more innovation decreases costs. Drug prices are driven by other factors beyond the patent system: the structure of the rebate and pharmacy-benefit system, insurance design, and the fact that other wealthy nations impose price controls. As I said at the hearing, the cost of a drug that is never invented and brought to market is effectively infinite. Medical conditions that have no effective treatment are far more extensive for the United States. The pricing debate is a serious one and deserves a serious forum, but the patent eligibility debate is, practically speaking, a very separate issue.

[1] The views expressed herein are personal to me, and do not represent the views of Sullivan & Cromwell LLP or its clients.

- **In your view, how would enacting PERA benefit patients and their families?**

RESPONSE: Most directly, through more innovative diagnostics. As Chief Judge Moore has observed, since *Mayo* the Federal Circuit has held "every single diagnostic claim in every case before [it] ineligible" — a categorical exclusion no Congress ever debated or enacted.[2] That is why a laboratory test for myasthenia gravis was invalidated even though, before it existed, roughly 20 percent of patients with that disease could not be diagnosed at all[3], and why several judges wrote that they regretted the outcome but felt bound by precedent. Independent analysis estimates that U.S. investment in diagnostic technologies fell roughly $9 billion below trend in the years following *Mayo*, and interview-based research at Cambridge documented molecular tests abandoned outright, with university technology-transfer offices and small companies hit hardest.[4]

Restoring a clear threshold restores the incentive to do the expensive, unglamorous work that turns a laboratory correlation into a validated, FDA-cleared test a physician can actually order — and to disclose how it works publicly, rather than hold it as a trade secret inside a single laboratory. For the more than 30 million Americans living with rare diseases, most of which have no approved treatment, and for families waiting on an earlier or more accurate diagnosis, that is the difference between a technology that exists and one that does not.

A new study released this month by Dr. Amy Semet found that AI-related patents are substantially more likely to be invalidated than non-AI patents, with AI patents invalidated almost 30% more often than non-AI patents. Dr. Semet found that the main driver of this discrepancy is the current judicial test for patent eligibility. Meanwhile, China has changed its own patent eligibility rules to make it easier to obtain AI patents.

- **How are U.S. inventors supposed to win the AI innovation race if they are playing on an uneven field?**

RESPONSE: They cannot, and we should not ask them to. Professor Semet's data confirm empirically that patent eligibility has become the dominant invalidity ground for AI patents in U.S. courts — and that this holds even when AI software patents are compared directly against other software patents, indicating that courts are treating AI inventions as a distinct and particularly vulnerable category within the broader software space.[5] Her findings also show what that substitution costs: AI patents are *less* likely than others to be invalidated for obviousness, so the prior-art doctrine best suited to police routine recombination is doing

[2] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 927 F.3d 1333, 1352 (Fed. Cir. 2019) (Moore, J., dissenting from denial of rehearing en banc).
[3] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 915 F.3d 743, 757 (Fed. Cir. 2019) (Newman, J., dissenting).
[4] A. Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, Wash. & Lee L. Rev. (2022); Liddicoat, *supra* note 2.
[5] Amy Semet, *An Empirical Study of Artificial Intelligence Patent Litigation* (July 2026).

comparatively little of the work, while a threshold characterization — is this an abstract idea? — does it instead.[6] The practical implication is to push inventors in this field toward trade secrecy where they can rely on it, which benefits incumbents and reduces public understanding of how AI technology actually works and advances.

Meanwhile, our competitors have moved in the opposite direction. China's revised Patent Examination Guidelines, issued in November 2025 and effective January 1, 2026, add detailed provisions on examining AI-related inventions and direct examiners to credit algorithmic features in assessing inventive step where those features functionally interact with the technical features of the claim — a change plainly designed to encourage AI filings.[7] The EU, Japan, and South Korea likewise protect categories of computing innovation that our own courts increasingly turn away.[8] Capital follows certainty. If we want the next generation of AI built here at scale, the answer is not to ask our inventors to work harder against our own law; it is to modernize the law.

- **How would enacting PERA promote U.S. innovation in AI and other critical and emerging technologies?**

RESPONSE: By restoring a threshold that turns on what an invention is rather than on how a court characterizes it. Under PERA, an AI architecture, a quantum computing system, or an advanced manufacturing process would be assessed as a claimed invention as a whole, without discounting elements as "conventional" or "routine," and a process that cannot practically be performed without a machine is expressly eligible. That description should allow more AI inventions to fit within the "eligibility" threshold, allowing the patentability analysis to proceed on to assess novelty, non-obviousness, written description, and enablement.

- **Please explain how the current state of patent eligibility law makes it harder for inventors and investors to decide when to invest in researching and commercializing new technologies.**

RESPONSE: Investment in these fields is a bet placed years before any return. A diagnostic must be developed, clinically validated, and often cleared by FDA; an AI or advanced-computing platform must be built, trained, and scaled. Investors commit capital at the beginning of that journey and need to know the rules that will apply at the end of it. Today they cannot. The same claim may survive examination under one framework and be invalidated in court under another; outcomes can turn on how a patent lawyer drafted the

[6] *Id.*
[7] *See* Amanda Zhang, *China | Patent rules changed for AI and bitstream*, Spruson & Ferguson (Nov. 21, 2025), https://www.spruson.com/china-patent-rules-changed-for-ai-and-bitstream/.
[8] Kevin Madigan & Adam Mossoff, *Five Years Later, the U.S. Patent System is Still Turning Gold to Lead*, IPWATCHDOG (Dec. 15, 2019), https://www.ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/id=116984/; Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 Geo. Mason L. Rev. 939 (2017).

claim or which panel hears the appeal. When counsel's honest answer to "is this protectable?" is "it depends on the judge," that is not a risk an investor can price — it is a risk an investor avoids.

The practical consequence is not that investors take the risk and lose; it is that they decline to take it. One study found that venture investors familiar with the eligibility case law invest less in the affected technologies.[9] Another study found organizations abandoning molecular tests, with small, patent-dependent entities — startups and university technology-transfer offices — and U.S.-headquartered organizations most affected.[10] Those are investments that appear in no statistic, because they were never made.

- **During the hearing, we heard testimony discussing a study published in the Iowa Law Review that found a high affirmance rate of district court Section 101 decisions by the Federal Circuit. There was a contention that this affirmance rate suggested current Section 101 law is predictable and does not need congressional reform. How do you respond to this contention?**

RESPONSE: The study does not eliminate the need for congressional action. At most, it suggests that judges often agree on the (incorrect) application of Section 101 after a dispute has been litigated and appealed.[11] That is a measure of stability — whether a ruling, once made, tends to stick — not of predictability, which is whether anyone could have known the answer in advance. The authors expressly acknowledge that their study does not measure whether practitioners, patent examiners, or business leaders can predict eligibility in advance — or how uncertainty affects investment and innovation.[12] They therefore conclude only that their findings do not support reform on the particular ground that judges cannot predictably apply the law. They do not conclude that the law draws the right substantive boundaries or should remain unchanged.

Moreover, there is a notable skew to the predictability that the study finds. When a district court held a patent ineligible, the Federal Circuit affirmed 87.8% of the time; when a district court held a patent eligible, it affirmed only 59.1%. In a decade, district courts found patents eligible in just 22 cases against 270 findings of ineligibility.[13] This discrepancy is not reassuring to inventors who need to rely on patent protection, especially once they are successful and others are interested in copying their work.

---

[9] David O. Taylor, *Patent Eligibility and Investment*, Cardozo L. Rev. (2020).
[10] John Liddicoat et al., *The Effects of Myriad and Mayo on Molecular-Test Development in the United States and Europe: Interviews from the Frontline*, Vand. J. Ent. & Tech. L. (2020).
[11] Nikola L. Datzov & Jason Rantanen, *Predictable Unpredictability: The Surprising Administrability of Patent Subject Matter Eligibility*, Iowa L. Rev. (2025).
[12] *Id.* at 737; *see also id.* at 749 ("[W]e do not believe our Federal Circuit data provides an answer on whether the PTO examiners are predictably applying the law.").
[13] *Id.* at 722 & fig. 20.

The study is also dominated by abstract-idea cases, which accounted for 92.5% of the decisions examined. It included only twelve law-of-nature cases — the category most relevant to diagnostics and biotechnology. In that smaller group the affirmance rate fell to 58.3%, and the authors described those cases as showing the lowest level of predictability and cautioned against drawing broad conclusions.[14] The authors also concede that panel composition can matter, finding a 12.8% spread in eligibility rates between the Federal Circuit judges most and least likely to uphold a patent.[15]

More fundamentally, judicial consistency and sound patent policy are different questions. The authors say so themselves: "we do not examine where the line should be drawn for determining what is eligible for a patent. We examine whether judges can tell where the line has been drawn."[16] A rule can be applied consistently and still exclude inventions that Congress believes the patent system should protect. The Constitution gives Congress authority over the patent system, and PERA asks Congress to exercise that authority by defining eligibility expressly rather than leaving its boundaries to judicial exceptions. At best, the study may inform one narrow aspect of the debate, but it cannot answer that policy question. Congressional action is needed to do so.

[14] *Id.* at 745–46 & figs. 28–29.
[15] *Id.* at 705–06.
[16] *Id.* at 675 (emphasis omitted).

Senate Committee on the Judiciary
Hearing: "From Genes to Machines: The Patent Eligibility Debate"
July 14, 2026

QUESTIONS FOR THE RECORD

Responses of Andrei Iancu
Partner, Sullivan & Cromwell LLP[1]*;*
Co-Chair, Council for Innovation Promotion;
Former Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office

QUESTIONS FROM SENATOR TILLIS

1. Do you agree that the courts, specifically the Supreme Court, have turned Section 101 from a historically coarse filter into a fine filter?

RESPONSE: Yes. For most of our history Section 101 asked one broad question — is this the kind of invention the patent system covers? — and virtually everything technological passed through it, to be tested by the requirements that follow: novelty, obviousness, and disclosure. Congress designed it that way in 1793 and preserved that architecture in 1952, when it separated the requirements for a patent into distinct provisions, each with its own job.

Today, Section 101 is instead used to make fine-grained merits judgments: whether claimed steps are routine or conventional, whether a claim recites enough structural detail, what the "focus" of the claim is. Those are Sections 102, 103, and 112 questions. The consequences are visible in the cases — a two-lens digital camera held to be an abstract idea, a method of manufacturing a driveshaft held to be a law of nature. In neither case did the court find the invention old, obvious, or inadequately described; it never reached those questions. That is a fine filter doing work a coarse filter was designed to leave to others.

2. Do you agree that just because an invention is eligible under Section 101, it does not mean that the invention is automatically patentable?

RESPONSE: Yes, and this is a particularly consequential misunderstanding. Eligibility asks only whether an invention is the kind of subject matter the patent system may protect. Clearing that threshold entitles no one to anything. The applicant must still show that the invention is new (Section 102), that it would not have been obvious (Section 103), and that it is described clearly and fully enough to teach others how to make and use it (Section 112). Most of what critics mean by "bad patents" is addressed by these provisions.

[1] The views expressed herein are personal to me, and do not represent the views of Sullivan & Cromwell LLP or its clients.

3. Do you agree that there is a need for patent eligibility [reform]?

RESPONSE: Yes. The statutory provision that decides whether artificial intelligence systems, gene therapies, quantum computers, and life-saving diagnostic tests may be patented has remained effectively unchanged since 1793 — when the cutting edge of technology was the cotton gin — overlaid with exceptions the courts developed and, after 2010, dramatically expanded, that appear nowhere in the text.

The people closest to the problem have said so plainly. By 2019, all twelve then-sitting judges of the Federal Circuit had publicly criticized the state of eligibility law.[2] The USPTO has developed guidance that has helped promote consistency at the agency, but this guidance cannot bind the courts. That leaves one institution with both the authority and the capacity to fix this, and it is Congress.

4. The latest version of PERA incorporated several changes based on stakeholder feedback. Do you believe that these were good changes to the bill? Why or why not?

RESPONSE: The most significant is the treatment of human genes. By removing "isolated" from the activities that render a gene "modified" under § 101(b)(2)(B), the 2025 bill makes clear that a merely isolated but otherwise unmodified human gene stays outside the patent system. That codifies *Myriad* rather than disturbing it, and it answers the objection that has dominated opposition to this legislation for three Congresses. The expanded findings in Section 2 also give courts and the USPTO a clear statement of what the amendment is meant to accomplish. The new Section 4(a) removes any doubt that the bill might affect the judicial doctrine of obviousness-type double patenting, and the new Section 4(b) confirms that pre- or post-solution computer activity cannot confer eligibility where the computer is not necessary to practically perform the invention — which directly addresses the concern that PERA would revive "do it on a computer" patents. These are all policy choices that are reasonable for Congress to make.

5. During your time at the USPTO, you issued guidance to clarify the state of Section 101. This guidance did a lot of good and was well received by stakeholders and patent examiners. But you have said that this guidance is not enough.

Why was this guidance and quite frankly why is any guidance at the agency level not enough?

RESPONSE: For three reasons. First, guidance binds USPTO examiners, not courts. A patent that issues under a clear USPTO framework can still be invalidated in litigation under

[2] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 927 F.3d 1333, 1352 (Fed. Cir. 2019) (denying rehearing en banc) (all twelve then-active judges of the Federal Circuit agreed — across eight separate opinions accompanying the denial of rehearing en banc — that the diagnostic claims before them should be patent eligible. A majority nonetheless concluded that *Mayo* compelled the opposite result, and the court called on the Supreme Court or Congress to act.).

binding case law, which means the certainty an applicant gets at the Office is not the certainty an investor needs. Second, guidance can only synthesize existing case law; it cannot change it. Our 2019 guidance made the doctrine more usable, not more correct — the substantive exclusions the courts created remained exactly where they were. Third, guidance is revocable. It can be rewritten or withdrawn with any change of administration, and no one plans a decade of research and capital investment around a rule with that shelf life.

The guidance did prove the underlying premise, though. According to the USPTO's Chief Economist, uncertainty in first-action eligibility determinations fell by 44 percent within a year of its issuance.[3] Clearer rules do produce more consistent results. Only a statute can make the rule clear for the agency and the courts alike — and durable enough that industry can rely on it.

6. Despite how broken the current situation is, is it in the interest of some parties to maintain the broken status quo? Why is this?

RESPONSE: Uncertain eligibility is an asset to firms that are already large. It supplies an inexpensive, early-stage defense — frequently resolvable on a motion to dismiss, before claim construction, discovery, or any examination of prior art — against infringement claims brought by smaller competitors. A defendant who can characterize a claim as "directed to" an abstract idea never has to litigate whether the invention was actually new or non-obvious. And to the extent weak eligibility pushes innovation from patents toward trade secrecy, the advantage runs to whoever already holds the largest store of proprietary know-how and has the resources to guard it.

That is not an accusation of bad faith — these are rational business positions for the firms that hold them. This does not mean that it is good for the United States and our innovation economy at large. The Committee should weigh the argument that "the system is working" against who is making it, and against the fact that the parties most consistently asking for reform are startups, universities, independent inventors, and research-intensive smaller companies — the entities least able to absorb the cost of an unpredictable rule.

7. You've said that when patent protection becomes unreliable, companies stop disclosing.

(a) How is today's uncertainty pushing entire fields, like diagnostics and AI, away from patents and toward trade secrecy?

RESPONSE: The patent bargain trades public disclosure for a limited term of exclusivity. When the exclusivity becomes unreliable, rational firms stop disclosing wherever secrecy is a workable substitute. Diagnostics is a clear case: the same innovation that would be sold as a

[3] Andrew A. Toole & Nicholas A. Pairolero, *Adjusting to Alice: USPTO Patent Examination Outcomes After Alice Corp. v. CLS Bank International*, USPTO (Apr. 2020), https://www.uspto.gov/sites/default/files/documents/OCE-DH_AdjustingtoAlice.pdf.

patented test kit — published, teachable, and eventually free for all to use — can instead be offered as a laboratory-developed service, with the underlying method held confidential indefinitely. There is evidence that eligibility uncertainty has pushed parts of the U.S. diagnostics industry in exactly that direction. In AI, the same logic applies to training methods, model architectures, and data pipelines, none of which need ever be published if the patent that would have covered them is unlikely to survive a motion to dismiss.

The empirical work supports this. The comprehensive study of firm behavior before and after *Alice* found that small firms that lost patent protection responded as one would predict — increasing their use of nondisclosure agreements by roughly a third, substituting secrecy for the patent they could no longer rely on.[4]

(b) What does this cost the public, and why does it especially hurt smaller competitors trying to break in?

RESPONSE: The public loses the advantages of a patent's disclosure. A patent teaches the world how an invention works and places that knowledge in the public domain for use when the term ends. A trade secret teaches no one and can last forever. Every method that goes dark is a method other researchers cannot read, build on, design around, or improve — which slows the cumulative process that drives technological progress. That is the opposite of what the patent clause was written to accomplish.

Smaller competitors lose twice. First, they cannot keep secrets as effectively as large firms: less security infrastructure, often high turnover, and a constant need to disclose to partners, customers, and investors simply to survive. Second, a patent is a portable, defensible, financeable asset — often the very thing that persuades an investor to fund years of development — and a trade secret cannot always readily operate as a substitute, especially given that sharing the trade secret, even under an NDA, always risks destroying the asset if the secret is leaked. A shift from patents to secrecy therefore transfers advantage systematically to incumbents. The patent system was designed to democratize innovation; today's Section 101 does the opposite.

8. Our principal economic competitors — such as the EU, China, Japan, and South Korea — all protect categories of invention that our own courts now turn away.

What does it mean for U.S. competitiveness and for our national security, when an inventor can protect these technologies abroad but not here — and how would PERA change that?

RESPONSE: It means we have handed our competitors an advantage they did not have to earn. Each of those jurisdictions takes a more permissive and more coherent approach to eligibility than the United States now does, protecting categories of computing, diagnostic,

[4] Utku U. Acikalin et al., *Intellectual Property Protection Lost and Competition: An Examination Using Large Language Models*, 182 J. Fin. Econ. 104306 (2026).

and biotechnology innovation that our courts increasingly refuse. On the threshold question of what may be protected at all, they today offer American inventors more certainty than their own country does — a competitive advantage they gained largely because we surrendered it.

The national security dimension follows from where the research goes. Advanced computing, AI, biotechnology, and next-generation manufacturing are the technologies on which defense and economic security now depend, and China leads in 66 of 74 critical emerging technologies tracked in one recent assessment.[5] Firms locate research — and investors place capital — where returns can be secured. PERA would end this self-inflicted disadvantage and realign the United States with the rest of the developed world, so that an inventor has at least as much reason to build here as anywhere abroad.

9. How has the uncertainty in eligibility law affected startups and small inventors in particular — and the patient, long-horizon investment, including in domestic manufacturing, that depends on reliable patent rights?

RESPONSE: A startup's patents are often its principal asset — the collateral for the years of development that stand between an idea and a product. Large incumbents have alternatives: scale, distribution, and litigation budgets. A startup has none of those, so when eligibility becomes unreliable in its field the effect is not a marginal loss of leverage but the loss of the thing that makes it fundable. The Cambridge study of the post-*Mayo* and post-*Myriad* period found exactly this pattern: small, patent-dependent organizations were most affected, and half of the U.S. university technology-transfer offices interviewed decided not to develop tests at all.[6] A recent comprehensive firm-level analysis also found that large firms came out ahead after *Alice* while smaller firms saw valuations fall.[7]

Manufacturing runs on the same logic over a longer horizon. Companies build plants when they can expect to protect the underlying technology long enough to earn a return on that capital, which is why IP-intensive industries account for so much of our manufacturing output and high-wage jobs.[8] The counterfactual is instructive: over the past two decades U.S. patent rights narrowed substantially — through limits on injunctions, the eligibility cases, and new administrative cancellation proceedings — and over the same period the United States lost roughly five million manufacturing jobs. Weakening patent rights did not bring factories home, and there is little reason to think weakening them further would.

---

[5] Jenny Wong-Leung et al., *ASPI's Critical Technology Tracker: 2025 Updates and 10 New Technologies*, Austl. Strategic Pol'y Inst. (Dec. 1, 2025), https://www.aspistrategist.org.au/aspis-critical-technology-tracker-2025-updates-and-10-new-technologies/.

[6] John Liddicoat et al., *The Effects of Myriad and Mayo on Molecular-Test Development in the United States and Europe: Interviews from the Frontline*, Vand. J. Ent. & Tech. L. (2020).

[7] Acikalin, *supra* note 4.

[8] Toole, *supra* note 3.

10. What has more than a decade of uncertainty over patent eligibility cost American innovation as a whole?

RESPONSE: The largest costs are in fact the ones no one can count — the diagnostic never developed, the startup never funded, the application never filed because counsel could not promise the claim would survive. Likewise, the measurable evidence all points the same direction: an estimated $9 billion shortfall in U.S. diagnostic investment relative to trend after that decision; a de facto judicial rule under which virtually no medical diagnostic is upheld as eligible in the Federal Circuit; AI patents now invalidated on eligibility grounds at rates well above other technologies; documented abandonment of molecular tests, concentrated among small and U.S.-based innovators; and a measurable shift toward trade secrecy that removes technical knowledge from the public record.

11. Some argue the courts can fix patent eligibility on their own, and that PERA would open the door to weak or overbroad patents.

(a) What is the difference between eligibility and patentability?

RESPONSE: Eligibility asks what kind of thing the claim is: a process, machine, manufacture, or composition of matter? It is a gate. Passing through it means only that the invention may be examined. Patentability, on the other hand, asks whether this particular invention has earned a patent: is it new (Section 102), would it have been obvious to a person of ordinary skill (Section 103), and has the inventor described it clearly and fully enough to teach others to make and use it (Section 112)? That is where the substantive judgment happens, and where most applications — and many asserted patents — fail.

Judge Giles Rich, a principal architect of the 1952 Patent Act, cautioned that these provisions should not be "commingled."[9] Modern eligibility doctrine commingles them constantly — asking under Section 101 whether claim elements are conventional, which is a Sections 102 and 103 question, or whether a claim recites enough detail, which is a Section 112 question. PERA analytically separates them again, as the modern statutes intended, which will help improve the consistency and reliability of the analysis.

(b) Why does restoring Section 101 to a simple threshold not lower the bar for receiving a patent?

RESPONSE: PERA only changes what is allowed into the patent system to be examined—it does not change the novelty, non-obviousness, written description, and enablement requirements, which assess an invention's newness and disclosure. An AI method, a diagnostic, or a purified compound, all of which are technological and become eligible under

[9] In re Bergy, 596 F.2d 952, 960–61 (C.C.P.A. 1979).

PERA, still have to be new, non-obvious, and fully disclosed — and the great majority of the claims critics have in mind may well fail one of those patentability tests.

What PERA eliminates is not the ability to challenge invalid patents but the tactical opportunity to avoid the merits. Today a defendant can prevail at the pleading stage by characterizing a claim as "directed to" an abstract idea, without prior art and often without claim construction. Removing that shortcut does not lower the standard — it requires the challenge to be made under the provisions Congress actually wrote for the purpose. Defendants should win when a patent fails the statute, not because an amorphous judicial doctrine offers an early exit.

12. We hear concerns that PERA would revive patents on human genes and create thickets that block patients from getting genetic tests.

Do you agree that the changes made this Congress — in particular, the revised "human gene" exclusion — address those concerns? And can you explain what the current bill does?

RESPONSE: I do think they address the central objection. Proposed § 101(b)(1)(D) excludes an unmodified human gene as it exists in the human body. Proposed § 101(b)(2)(B) — unlike the 2023 version — no longer treats mere isolation as a "modification." The result is that a human gene isolated from the body but otherwise unchanged remains ineligible. That is *Myriad*'s holding, codified, and Section 2(5)(D)(iv) states the point expressly in the findings. It is the opposite of reviving gene patents.

Independently of PERA, a second obstacle stands in the way of gene patents. The human genome was sequenced more than two decades ago, and the reference sequence and an enormous catalogue of population variants have been public ever since. That published record is prior art. A claim to a gene sequence or a common variant may well fail for anticipation under Section 102 or obviousness under Section 103 regardless of what Section 101 says.