



**Computer & Communications
Industry Association**

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Responses to Questions for the Record from Chairman Grassley

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“From Genes to Machines: the Patent Eligibility Debate”

Committee on the Judiciary, U.S. Senate

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Responses to Questions of Chairman Charles 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?

Any major change to patent law, including changes to patent eligibility law, could affect the affordability of a broad swath of technologies, both those available today and those under development. When a business's costs increase, some or all of that increase will be passed on to customers in the form of higher prices for products and services, including vital technology. Although cost increases can come about due to higher prices for raw materials, for example, they can also result from increased legal and related expenses, such as from defending more lawsuits and paying higher insurance costs.

Patent eligibility requirements provide an important protective function for businesses by serving as an important defense against unmeritorious litigation brought by patent assertion entities (PAEs).¹ Thus, any patent eligibility reform that weakens that protection would be expected to lead to more litigation and higher legal costs for businesses. By the time of the Supreme Court's decision in *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014), PAE litigation was estimated as costing businesses nearly \$30 billion per year.² To the extent that reform measures, like the proposed Patent Eligibility Restoration Act (PERA), seek to abrogate that decision, such high costs due to litigation seem likely to return. That is especially true because a patent eligibility defense is different from most other patent litigation

¹ *From Genes to Machines: the Patent Eligibility Debate, Hearing Before the S. Comm. on the Judiciary*, 119th Cong. 9-10 (2026) (statement of J. John Lee) ("Lee Hrg Testimony").

² James Bessen, *The Evidence Is In: Patent Trolls Do Hurt Innovation*, HARV. BUS. REV. (Nov. 2014), <https://tinyurl.com/4szjw6xw>.

defenses in that it typically allows cases to be adjudicated earlier, thereby avoiding much of the direct costs of litigation if the defense is successful.³

Reforms that introduce greater uncertainty may also affect costs for businesses; for example, by raising the costs of insurance simply due to the potential for higher litigation risks. Current patent eligibility law has been shown to be predictable, consistent, and well-understood.⁴ Replacing that body of law with new and untested rules, particularly based on ambiguous legal standards, would increase uncertainty. For example, the new legal standards proposed in PERA include determinations of whether a claimed invention is “substantially economic, financial, business, social, cultural, or artistic,” or whether a “computer (or other machine or manufacture)” is “necessary to practically perform the invention,” among others.⁵ Determining the bounds of what these terms mean will likely require many years of litigation.

Further, to the extent that reform measures, such as PERA, seek to widen the scope of what is eligible and, thus, allow patents on things that are currently ineligible, costs for businesses may increase because there are simply more patents that they must license and pay fees for. Proposals to abrogate the Supreme Court’s longstanding interpretation of 35 U.S.C. § 101 and undo the strict prohibition on patenting natural phenomena, laws of nature, and abstract ideas, are particularly concerning because such basic principles are more likely to be used broadly due to their fundamental nature.

Importantly, higher costs for businesses are especially problematic for small businesses. Large businesses generally have greater resources that allow them to better absorb higher costs and deal with greater uncertainty, whereas small businesses lack those resources. As such, reform measures that would increase costs are more likely to entrench large, established businesses at the expense of newer, smaller businesses.

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

Considering that PERA has the potential to increase costs for businesses generally—and, thus, the cost of products and services—those issues

³ This is because patent eligibility in many cases is considered a question of law, not a question of fact, allowing courts to adjudicate the cases early at the motion to dismiss stage. *See, e.g., SAP America, Inc. v. InvestPic, LLC*, 890 F.3d 1016 (Fed. Cir. 2018).

⁴ Lee Hrg Testimony, *supra* note 1, at 6-7.

⁵ Patent Eligibility Restoration Act of 2025, S. 1546, 119th Cong. § 4(b) (2025).

certainly would apply to artificial intelligence (AI) products and services. As such, PERA could have a significant impact on the cost and accessibility of AI technology, particularly to individual consumers and small businesses given their higher sensitivity to cost changes.

This effect may be particularly pronounced for AI because of the complexity of the technology and the broad array of components, systems, software, processes, etc., necessary to develop, deploy, and use AI technology. Simply put, there are more things to potentially patent in an AI system and its applications than in most other technology areas.

Additionally, current patent eligibility law has helped foster extraordinary advancement and innovation in AI technology in the United States in recent years. Data on patenting, research and development (R&D) expenditures, and venture capital funding in AI all reflect strong U.S. technological leadership in this critical area.⁶ Major changes to patent eligibility law risk upsetting the balance that has led to recent success in AI development and innovation. Moreover, introducing a host of new patents on things not previously eligible, as PERA would do, could hamper fast-paced, broad-based, cost-effective innovation in AI by placing more obstacles in the path of researchers and innovators and diverting resources away from R&D to legal expenses and licensing fees.

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.

I agree with the Supreme Court's longstanding interpretation of § 101 as excluding abstract ideas, laws of nature, and natural phenomena from patent eligible subject matter. As the Court has explained, "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). "[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it, thereby thwarting the primary object of the patent laws." *Alice*, 573 U.S. at 216 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71, 132 S.Ct. 1289, 1293 (2012)).

⁶ Lee Hrg Testimony, *supra* note 1, at 8-9.

The current test, as clarified in the *Alice* and *Mayo* decisions, has two prongs: first, determining whether the claimed invention is “directed to” one of the above exceptions; and second, if so, determining whether additional elements are recited to “transform” the claimed invention such that, as a whole, it amounts to “significantly more” than the exception itself. *Alice*, 573 U.S. at 217-18. Empirical evidence has shown that this test is well-understood and consistently applied by courts and the U.S. Patent & Trademark Office (USPTO).⁷ Consistency (which provides predictability and certainty) is a virtue of the current system because it allows businesses to make long-term decisions about R&D, product development, capital investments, etc., thereby promoting innovation. I am unaware of any proposal for an alternative test that I believe would yield the same or similar levels of consistency and predictability while still preventing innovation-killing monopolization of fundamental building blocks of scientific research and advancement, and delivering effective protections to U.S. businesses against low quality patents, as the current system does.

Although there are those who contend that the current system, while consistent and predictable, is consistently “bad,” I respectfully urge the Committee to rely on objective evidence to determine whether the practical impact of the *Alice/Mayo* framework has produced positive or negative policy outcomes. For example, notwithstanding allegations that the current system prevents patenting of innovations in key technology areas like AI, empirical studies have shown that patenting of AI inventions has grown significantly faster after the *Alice/Mayo* framework was established, with approximately 50,000 such patents being granted in 2023 alone.⁸ Empirical studies have also shown that R&D expenditures increased following the *Alice/Mayo* framework.⁹ Recent objective data from just last year has also shown that global investors believe that U.S. firms lead the world in innovative AI technology, with 75% of global venture capital funding for AI flowing to U.S. companies—roughly 12 times as much as was invested in the European Union and approximately 15 times as much as was invested in the People’s Republic of China (PRC).¹⁰

⁷ *Id.* at 6-7 (citing Nikola L. Datzov & Jason Rantanen, *Predictable Unpredictability: The Surprising Administrability of Patent Subject Matter Eligibility*, 110 IOWA L. REV. 667, 716-17 (2025), <https://tinyurl.com/2sn5hj7d>)).

⁸ Hanming Fang et al., *China Leads the World in AI Patents, But Still Learns More from America*, STANFORD UNIV. CTR. ON CHINA’S ECON. & INSTS. (May 15, 2026), <https://tinyurl.com/3vdwzppa>.

⁹ Christian Helmers & Brian J. Love, *Patent Law Reform and Innovation An Empirical Assessment of the Last 20 Years*, INT’L REV. L. & ECON. (Mar. 24, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4580645.

¹⁰ Org. for Econ. Coop. & Dev., *Venture capital investments in artificial intelligence through 2025*, OECD POL’Y BRIEFS (Feb. 17, 2026), <https://tinyurl.com/y5k829fp>.

This empirical evidence indicates that the current system, including the *Alice/Mayo* framework, is producing positive results for U.S. innovation, competitiveness, and technological leadership, including in critical emerging technologies like AI.

Although some argue that foreign competitors, such as from the PRC, are catching up to, or have eclipsed, the United States in the AI race, many believe that they are doing so by using or acquiring (or, perhaps, “stealing”) U.S. innovation in AI rather than truly surpassing it with industry-leading innovations of their own,¹¹ in which case the response should not be to replace or weaken our current system and the innovation it promotes, whether it be patent eligibility law or other key aspects of our patent system (e.g., the Patent Trial and Appeal Board).

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.**

Overall, PERA would overturn the Supreme Court’s decisions not only in *Alice*, *Mayo*, and *Bilski*, but also other patent eligibility precedents from the Court. PERA explicitly abrogates all exceptions that have been outlined by the Court in interpreting 35 U.S.C. § 101 (and its predecessors) in the context of the Constitution, a line of precedents that began in the 1850s and has been refined and clarified in numerous cases over more than 170 years. PERA replaces this 170 years of precedents with new statutory language, the scope and meaning of which is unclear and will be subject to years of litigation, but which appears to significantly widen the types of things that can be patented.

For example, current Supreme Court case law prohibits patents on any law of nature, regardless of whether they are claimed as a process, machine, manufacture, or composition of matter.¹² Thus, if “ $E=mc^2$ ” were newly discovered today, it could not be patented, whether as a process (e.g., a method of calculating energy based on mass) or a manufacture (e.g., a computer-readable medium containing or storing the formula) or a machine (e.g., a general purpose computer chip programmed to calculate energy based on mass).

Some or all of these claims, however, appear to be eligible under PERA. For instance, PERA prohibits patents on mathematical formulas only if they are “claimed as such” and are “not part of a claimed invention in” a statutory category (i.e., a “process, machine, manufacture, or composition of matter). All of the above

¹¹ Michael Froman, *The Latest in U.S.-China AI Competition*, COUNCIL ON FOREIGN RELS. (Jul. 31, 2026), <https://www.cfr.org/articles/the-latest-in-u-s-china-ai-competition>.

¹² See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Mayo Collaborative Servs. v. Prometheus Labs.*, 566 U.S. 66, 75-77 (2012).

hypothetical claims recite “ $E=mc^2$ ” as part of a claimed invention in one of those categories. And all of the remaining exclusions in PERA apply only to processes, human genes, or “natural material,” so at minimum they would not apply to the above manufacture or machine claims.

PERA also requires that eligibility determinations only consider a claimed invention “as a whole and without discounting or disregarding any claim element.” PERA then affirmatively provides that a claimed invention IS eligible—even if it is a pure mathematical formula or an “economic, financial, business, social, cultural, or artistic” process—if it “cannot practically be performed without the use of a machine or manufacture.”

But by considering a claimed invention only as a whole without considering any individual claim elements, the claimed invention by definition cannot be performed—practically or otherwise—without the recited machine or manufacture. Thus, it appears that PERA may allow any mathematical formula or even any “social” or “cultural” process to be patent eligible so long as the claim recites a generic computer or any other machine or manufacture.

PERA does include a “rule of construction” in a section of the bill that is not intended to be codified, which states that “pre- or post-solution activity by a computer (or other machine or manufacture)” cannot confer eligibility if the computer is “not necessary to practically perform the invention.” But it is unclear why this language is not included as part of the provisions intended to be codified in Title 35, and whether and how courts will interpret and apply the language. And in any event, again, if claimed inventions can only be evaluated as a whole, any recited computer will, by definition, be necessary to perform the invention.

One of the central holdings of *Alice* was that generic computer implementation (i.e., “do it on a computer”) cannot transform a claim directed to a law of nature, natural phenomenon, or abstract idea into a patent eligible invention, regardless of how it is claimed. PERA appears to effectively abrogate or at least substantially undermine that holding, thereby opening the doors to numerous additional patents that may evade eligibility restrictions simply by reciting a generic computer.

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

This is a policy question that rests with Congress, but certainly the history of the patent system has shown that avoiding unnecessary intervention in the area of eligibility is good for innovation by allowing innovators the freedom to pursue a

wide and diverse universe of new technologies and advances, and the certainty of an established and well-understood system they can rely on.

As the Supreme Court has recognized, patent eligibility as well as other patentability requirements of the Patent Act were enacted by Congress to fulfill the remit outlined in the Constitution, namely “[t]o promote the Progress of Science and useful Arts.”¹³ The eligibility requirements of § 101 reflect Congress’s recognition that not all things, even if newly discovered or created, would promote the progress of science and useful arts if allowed to be patented and exclusively owned by the patent’s owner(s).

To that end, the Supreme Court has explained that § 101 excludes laws of nature, natural phenomena, and abstract ideas because “they are the basic tools of scientific and technological work.” *Gottschalk*, 409 U.S. at 67. “[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,’ thereby thwarting the primary object of the patent laws.” *Alice*, 573 U.S. at 216 (quoting *Mayo*, 132 S.Ct. at 1293). These exclusions, which have existed for well over a century, have served the country well, and they should be continued.

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?

PERA could have an impact on all businesses nationwide, including Iowan businesses of all sizes. Replacing longstanding legal standards with uncertain new standards, allowing patents on generic computer implementations of basic and fundamental business or financial practices, undermining the availability of a patent eligibility defense in many cases, and other effects of PERA could lead to significantly increased costs for Iowan businesses.

These increased costs could take the form of higher prices for products and services they need, more and higher cost licenses needed for vital technology, higher litigation costs to defend against an increasing number of lawsuits that are also more expensive to defend on average, and higher insurance costs due to increased litigation and legal risks. Both large store chains like Home Depot and locally-owned brick-and-mortar stores have been targeted by PAE litigation in the past, for example, and there is every reason to believe they will be targeted in the future if the protection from patent eligibility defenses is diminished. Further, for those

¹³ U.S. Const., art. 1, sec. 8, cl. 8.

businesses who typically indemnify their customers against litigation relating to their products and services, the problems presented by growing litigation costs and risks are compounded.

Small businesses are most at risk when costs increase because they have fewer resources to absorb higher costs and deal with potential litigation losses. Even if they are able to continue operating, they are more likely to need to pass on the costs to their customers such as through higher prices, placing them at a disadvantage when competing with larger businesses. Their competitiveness may also suffer due to being unable to afford the newest and best technology, or having to take longer to upgrade systems. Their customers may be more wary of choosing their products and services due to concerns about their ability to handle legal risks.

U.S. businesses also could face greater competitiveness challenges against foreign competitors. It is a common misconception that U.S. patents represent U.S. innovation. To the contrary, U.S. patents can be obtained to protect foreign innovations as well. In fact, the majority of U.S. patents every year are awarded to foreign recipients to help them protect their innovations, even if developed abroad.¹⁴ In fact, only 18 of the top 50 recipients of U.S. patents last year were U.S. companies.¹⁵ And each owner of a U.S. patent, whether a U.S. company or a foreign competitor, can assert and enforce their patent in the United States.

The effect of that enforcement, however, disproportionately targets U.S. companies because patents are territorial.¹⁶ In other words, the difference between a U.S. patent and a foreign patent is not that a U.S. patent protects U.S. innovation, but instead that a U.S. patent can only be enforced against activities within the United States, specifically anyone who “makes, uses, offers to sell, or sells . . . or imports” the patented invention within the United States.¹⁷ Thus, a U.S. company that manufactures a product in the United States is subject to enforcement, but a Chinese company producing the same product in Shenzhen is not. A U.S. importer or retailer or consumer of the product is subject to enforcement, but the Chinese manufacturer is not.

Also, if a manufacturer moves its manufacturing operations abroad, it is no longer subject to enforcement on U.S. patents except for the products they sell or import into the United States—its exports are, thus, exempt. But if the company manufactures in the United States, all of its products—whether sold domestically or exported abroad—are subject to enforcement.

¹⁴ See U.S. Pat. & Trademark Off., FY 2025 Workload Tables (2025).

¹⁵ Harrity LLP, *The 2026 Patent 300 List*, <https://harrityllp.com/patent300/>.

¹⁶ See *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 454–55 (2007).

¹⁷ 35 U.S.C. § 271(a).

In summary, patent reforms that increase litigation and undermine patent defenses benefit owners of U.S. patents, whether they are U.S. or foreign companies, and the majority of patents every year are issued to foreign entities. In fact, a foreign owner of a U.S. patent need not have any U.S. presence or do anything with the patent in the United States—for example, Huawei Technologies, a PRC national champion with close ties to the Chinese Communist Party, received the fourth most U.S. patents in 2025 out of all patent recipients (nearly 3,500 U.S. patents) despite being sanctioned and effectively banned from the U.S. market by the U.S. government.¹⁸ With regard to enforcement of its thousands of U.S. patents, Huawei receives the same benefits as any other U.S. patent owner.

In contrast, patent reforms that increase litigation and undermine patent defenses disadvantage entities that make, use, or sell patented products in the United States, i.e., those who are subject to enforcement of U.S. patents. Logically, such entities are disproportionately American—i.e., most manufacturers, stores, and consumers in the United States are American. Thus, such reforms can discourage economic activity in the United States, especially onshoring and reshoring of manufacturing in the United States.

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?

As an initial matter, it is unclear what legal effect Section 2 of PERA would have. Although Section 2 represents the findings of Congress, it is only Section 3 that will be codified and alter the statutory language of § 101. Based on the canons of statutory construction, courts are likely to conclude that Section 2 has no legal effect of its own, and that Section 3 alone provides the statutory language that implements the findings in Section 2 in the manner Congress intends. Section 3, however, does amend § 101 to provide that inventions are subject “only” to the exceptions expressly set forth in PERA, thereby abrogating all exclusions outlined by the Supreme Court.

In general, new statutes are presumed to apply only prospectively absent an indication that Congress intended them to apply retroactively. With respect to PERA, however, even if the provisions of PERA apply only prospectively,

¹⁸ Harrity, *supra* note 15; see Jill C. Gallagher, *U.S. Restrictions on Huawei Technologies: National Security, Foreign Policy, and Economic Interests*, R47012, CONG. RESEARCH SERV. (2022).

they may have an arguably retroactive effect. Specifically, when a court adjudicates a patent case after PERA and considers the eligibility of existing patents that were issued before PERA, courts will likely apply PERA's provisions rather than the previous statutory language to determine whether the asserted patent claims are eligible. Thus, PERA would apply and affect not only new patents going forward, but also all patents that are currently in force.

Even under PERA, which abrogates all current exclusions to patentable subject matter, courts would continue to have a significant role. As an initial matter, courts would have to interpret all of the new language of PERA. Unlike current case law, PERA's various legal terms, tests, and standards are new and untested, so significant litigation over a number of years will be required to fully understand them. As is common in such situations, different courts across the country are likely to interpret the new statutory language differently at first, creating inconsistency and uncertainty until new precedents can be established on a national level by the Federal Circuit and, ultimately, the Supreme Court.

It is worth noting that these issues would not only affect patent eligibility because PERA also modifies other aspects of the Patent Act. Most notably, PERA also modifies the separate utility requirement of § 101, including a new definition of “useful.”¹⁹ It is unclear whether and how much the new language will represent a change to current law (which has largely been settled for at least 60 years), which will only be known once new case law is established over time in the courts.

Additionally, courts will also have significant other roles in adjudicating eligibility issues under PERA. For instance, PERA acknowledges that its new eligibility rules could require additional discovery, which courts will have to manage.²⁰ PERA also incorporates what will likely be applied as factual inquiries, which will require fact-finding by courts—for example, whether a claimed process “occurs in nature wholly independent of, and prior to, any human activity,” which will require a court to determine whether the process occurs in nature, whether it does so wholly independent of human activity, and whether the process occurred in nature prior to “any” human activity.²¹ This is in addition to the years of litigation required to establish the legal

¹⁹ Patent Eligibility Restoration Act of 2025, S. 1546, 119th Cong., sec. 3(a)(1) (2025) (“PERA”).

²⁰ PERA sec. 3(a)(2) (providing for new § 101(c)(2)(B)).

²¹ PERA sec. 3(a)(2) (providing for new § 101(b)(1)(C)(ii)).

meaning of “in nature,” “wholly independent,” and “human activity,” for example.

- 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?

As an initial matter, Section 2(5)(D) itself is unlikely to exclude anything, but the same language is included in Section 3 in § 101(b)(1)(C) as amended. It is unclear how that provision will be interpreted by the courts.

The express language of this provision seems to exclude only claimed inventions that consist only of a purely mental process that occurs “solely” in the human mind. Take, for example, the following hypothetical patent claim:

A process comprising:

receiving a first audible signal via a sound reception mechanism, the first audible signal comprising a question;

determining an answer to the question; and

transmitting the answer in the form of a second audible signal via a sound projection mechanism.

As written, this claim would encompass hearing a question with ears (a “sound reception mechanism”), thinking of an answer (mental process), and speaking the answer verbally with a human voice (a “sound projection mechanism”). Current law would reject this claim as ineligible as it is directed to an abstract idea (i.e., the mental process), and the rest of the claim limitations do not transform it into eligible subject matter because they are just the natural, conventional

parts of how a human conducts and communicates the mental process through purely human activity without any technology.

PERA's amended version of § 101, however, would only exclude this claim if it is a mental process "performed solely in the mind of a human being." The claim clearly requires hearing through a sound reception mechanism (ears) and communicating aloud through a sound projection system (voice), neither of which is "solely" performed in the human mind. Thus, § 101 as amended by PERA could be applied to permit this claim as eligible for patenting.

Changing the above hypothetical patent claim to incorporate a step of writing the question and/or answer on paper—or, for that matter, a generic electronic device or computer—would only emphasize that the claimed invention is not performed "solely" in the human mind, even though writing the answer down before speaking it does not actually change or transform the process in a meaningful way.

To the extent that others may argue that a meaningless writing step would be "insignificant post-solution activity" that would be ignored by a court to conclude that the process falls within PERA's mental process exception, I note that PERA forbids such an analysis by explicitly codifying in new § 101(c)(1)(A) the requirement of courts to consider the claimed invention "as a whole and without discounting or disregarding any claim element."

- 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?

Similar to the "mental process" exception, it is unclear how courts would interpret PERA's "unmodified human gene" exception (in Section 3, which amends § 101 to add new § 101(b)(1)(D)). Human genes in the body generally exist as parts of DNA strands, each of which comprises numerous genes. DNA strands in the body are also generally attached to various other molecules and structures. Under

current law, a patent claiming a human gene that is “isolated” from the rest of the DNA strand and the attendant molecules and structures would be held ineligible under *Myriad*.²²

Under PERA, it is unclear whether an isolated human gene would be ineligible. An isolated human gene is not how that gene exists in the body (i.e., not part of a larger DNA strand) and so may not be considered “unmodified” in that sense. PERA specifies in new § 101(b)(2)(B)(i) that a gene is not unmodified if it is “purified, enriched, or otherwise altered by human activity.” It is possible, as Dr. Leonard testified, that an isolated gene can be considered “purified,” since the rest of the DNA strand and other molecules and structures are removed.²³ In that case, an isolated (i.e., “purified”) human gene could be patented under PERA, abrogating *Myriad*.

It is also unclear how PERA would address *in vivo* genes that have been altered by human activity, such as gene therapy. A patent claiming such an altered gene would be claiming a gene as it exists in the human body, but it is unclear whether it would be “unmodified.” Again, new § 101(b)(2)(B)(i) would provide that a gene that is “purified, enriched, or otherwise altered by human activity” is not considered “unmodified” and, thus, is patent eligible. Thus, if gene therapy (human activity) alters a gene within a person’s body, a third party patent owner may be able to “own” the gene in their body under PERA as currently written.

If the modified gene causes the body to perform a new biological process (e.g., producing a new protein, or a modified version of an enzyme), that biological process may also be eligible for patenting because the only relevant exclusion under PERA would be its exclusion of a process that “occurs in nature wholly independent of, and prior to, any human activity.”²⁴ A court could determine that the new process occurring in the person’s body is not “wholly independent of, and prior to” the gene therapy (i.e., human activity),

²² *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116-19 (2013).

²³ See *From Genes to Machines: the Patent Eligibility Debate*, Hearing Before the S. Comm. on the Judiciary, 119th Cong. (2026) (oral testimony of Debra G.B. Leonard, M.D., Ph.D.). Under PERA, new § 101(b)(2)(C)(i), which relates to patent claims on “natural material,” does mention “isolated” in addition to “purified,” which could persuade a court that “isolated” and “purified” are not synonymous and interchangeable. That is not certain, however, and it remains unclear whether an isolated human gene could be both “isolated” and “purified,” even if those terms are not interchangeable, or whether those are mutually exclusive terms.

²⁴ PERA sec. 3(a)(2) (providing for new § 101(b)(1)(C)(ii)).

which would render that process eligible for patenting. Thus, a patient of gene therapy could find that a biological process in their own body is subject to a patent owned by a third party.

- 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?

As an initial matter, again, this language in Section 2 of PERA may not have any legal effect. Critically, the operative language in Section 3 of PERA that addresses unmodified genes differs from this language in Section 2. In fact, notwithstanding this language in Section 2, Section 3 of PERA may result in isolated genes being eligible for patenting, as I discussed above with respect to Question 6(b)(ii). I note that Section 3 of PERA also explicitly provides that a gene that is “purified, enriched, or otherwise altered by human activity” is patent eligible, so at least processes meeting those descriptions would be relevant as they are used in medical or scientific research or treatment.

- 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?

This language is operatively set forth in Section 3 of PERA, which amends § 101 to add new § 101(b)(1)(E). PERA also adds new § 101(b)(2)(C), which explicitly provides that a “natural material” is not considered “unmodified” if it is “isolated, purified, enriched, or otherwise altered by human activity.”

The impact of these provisions is unclear. “Natural material” is not defined in PERA, nor is it a term of art in patent law, and years of litigation may be required to ascertain its meaning. The same concern applies to discerning the scope of “as that material exists in nature” and “otherwise altered by human activity.”

These ambiguities raise a number of questions. For example, what about materials that exist in nature but are modified unintentionally by human-created conditions, such as wild salmon that have trace amounts of human pollutants incorporated into their bodies—can

such fish be patented because they are “altered by human activity”? Can wild plants in nature be considered “altered by human activity” because of general environmental contamination?

If human hunting were shown to have unintentionally caused a population of wild animals to evolve certain traits, are those animals “altered by human activity”? Does ranching of otherwise wild animals, such as bison, render them “altered by human activity”? What about human-managed wild populations of animals, such as Maine lobsters or Maryland blue crab?

Although some may argue that these examples are addressed through other statutory requirements for patents, that is not necessarily the case. One major reason is that the relevant burden of proof is on the examiner or litigant to show that something is not eligible, not the applicant or patent owner to demonstrate that it is eligible. If that burden is not met, the patent is allowed by default. For example, to argue that a patent on wild fish is invalid because the presence of certain pollutants is not novel under § 102 or obvious under § 103, one would have to find documentary evidence proving that those pollutants existed before the priority date of the patent. If the presence of the pollutants is newly discovered or was not the subject of scientific or other literature for any reason, such evidence would not be available or be difficult to find. This is similar to why patents on even longstanding business methods, for example, were difficult to invalidate prior to the Supreme Court’s clarification of § 101, because literature and other documentary proof of business methods did not exist or was difficult to find.

Another major reason is that § 101 operates differently in litigation than, for example, § 102 or § 103. Often, § 101 defenses are adjudicated in the early stages of a lawsuit in a motion to dismiss under Rule 12 of the Federal Rules of Civil Procedure. *See, e.g., SAP America, Inc. v. InvestPic, LLC*, 890 F.3d 1016 (Fed. Cir. 2018). This is because the majority of § 101 defenses depend solely on questions of law rather than fact. *See id.* Defenses under § 102 or § 103, for example, are virtually never decided at the Rule 12 stage because they involve contested issues of fact that require discovery and fact-finding. Thus, § 102 and § 103 defenses are not substitutes for § 101 defenses because that difference in timing can cost millions of dollars in

litigation costs, years of time spent litigating, and substantial business disruptions.