NOVARTIS

RESPONSES TO QUESTIONS FOR THE RECORD

Corey Salsberg,
Vice President and Global Head IP Affairs, Novartis

Before the United States Senate Committee on the Judiciary
Subcommittee on Intellectual Property

Subcommittee Hearing on "*The Patent Eligibility Restoration Act* – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System"

I. Introduction

My name is Corey Salsberg, and I am Vice President, Global Head of IP Affairs for Novartis. On October 8, 2025, I testified before this Subcommittee on the need for patent eligibility reform in America, and supported PERA as a sensible bill that would restore the clarity and predictability that innovators need to continue to discover and develop the next generation of gene-therapies, gene-based medicine, and other advanced life sciences technologies here in the United States.

Following the hearing, on October 15, 2025, I received questions for the record from Chairman Tillis and Senator Schmitt. My responses to these questions are set forth below.

II. Questions from Chairman Tillis

1. The first set of hearings on patent eligibility were held in 2019, with 45 witnesses over multiple days. In 2024, another hearing was held consisting of 8 witnesses. Since then, there has been guidance from the USPTO and additional court cases. Is there a continuing need for Congress to step in with patent eligibility legislation? Please explain.

While Congress has held three hearings on patent eligibility reform since 2019, the draft bills that emerged from those hearings did not become law. In the meantime, far from improving patent eligibility law, courts have continued to expand the scope of ineligible subject matter, and to further blur and confuse the legal standards governing it. As some examples, in addition to continuing to find all diagnostic methods ineligible since 2019,[1] Courts have interpreted and applied *Mayo,*[2] *Myriad*,[3] and *Alice*[4] expansively to foreclose patents on cloned organisms created by humans,[5] synthetic DNA primers,[6] cardiac monitoring devices,[7] garage door openers,[8] drive shaft manufacturing methods,[9] and TSA-approved luggage locks,[10] to name but a few. Most alarming for the life sciences field, a district court recently held for the first time that an indisputably non-naturally occurring genetically engineered composition of matter is not eligible for a patent because it was made from components of nature.[11] As I explained in my testimony,

---

[1] See *Athena Diagnostics, Inc. v. Mayo Collab. Servs.,* 927 F.3d 1333, 1352, 1354 (Fed. Cir. 2019) (Moore, J., dissenting) ("Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible," turning it into "a per se rule that diagnostic kits and techniques are ineligible.")

[2] *Mayo v. Prometheus*, 566 U.S. 66 (2012).

[3] *Association for Molecular Pathology v. Myriad Genetics,* 569 U.S. 576 (2013).

[4] *Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 134 S. Ct. 2347, 2354 (2014).

[5] *In re Roslin Inst.,* 750 F.3d 1333, 1337 (Fed. Cir. 2014).

[6] *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp.*, 774 F.3d 755, 758 (Fed. Cir. 2014).

[7] *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358 (Fed. Cir. 2020).

[8] *Chamberlain Group Inc. v Techtronic Industr. Co.,* 935 F.3d 1341 (Fed. Cir. 2019).

[9] *Am. Axle & Mfg., Inc. v. Neapco Holdings*, 966 F.3d 1347, 1348 (Fed. Cir. 2020).

[10] *Travel Sentry Inc. v. Tropp,* Nos. 2021-1908 and 2021-1909 (Fed. Cir. Feb. 14, 2022).

[11] *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.,* No. 20-1226 RGA (D. Del., Jan. 5, 2024) (Holding that genetically-engineered host cells comprised of "two sequences from two different organisms" that do not occur together in nature are patent-ineligible because the inventors did "not chang[e] any of the claimed invention's naturally occurring components.")

that case, *Regenxbio v. Sarepta*, will at minimum continue to sow deep uncertainty in the biotechnology field even if it is overturned in its now-pending appeal—and if it is upheld, countless biotechnological inventions will be at risk in the United States, potentially devastating the field.

Given this continued deterioration of patent eligibility law in the courts, only Congress can restore the clarity and predictability needed to ensure the future of innovation and US leadership in fields like gene-based medicine and other advanced technologies. As I explained in my testimony, the Supreme Court has indicated that it will not resolve the issue, having now denied at least 64 *certiorari* petitions seeking further clarity since *Mayo*. Consistent with the Constitution's grant of authority to Congress to set the nation's innovation policy, the Court has further emphasized that "Congress, not the courts, must define the limits of patentability."[12] As for the USPTO, while it has provided useful guidance since 2019 that has helped to clarify some aspects of ineligibility law, it is bound by court decisions, its guidance does not bind courts, and its direction and rules are subject to change with each Administration. For all of these reasons, the state of patent eligibility law will not improve, and innovators will not have the clarity and predictability that they need to invest in tomorrow's technologies, unless Congress acts.

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

The current state of patent eligibility law disrupts the careful balance of the patent system, allowing immediate use and copying of valuable technologies by those who did not contribute to their creation or development, at the expense of those who did. Users and would-be infringers thus indeed benefit from the status quo, gaining immediate and "free" access to useful, novel, and non-obvious inventions that are nevertheless denied patents at the USPTO on the front end, or whose patents are set aside in court on the back-end, often after years or decades of investment, development and commercialization by someone else. While perhaps "free" to those users and copiers in the short term, those benefits ultimately come at a massive cost to society over the long term. Without the incentive of a limited term of exclusivity—the patent system's constitutional "means"—the public cannot sustainably realize the system's "end," the progress of science and useful arts. That is because innovators who cannot patent their inventions are forced to do one of three things: First, if the technology is amenable to trade secret protection, innovators may choose to protect it that way, but this keeps the technology secret potentially indefinitely, slowing or preventing improvements and scientific advancement. Second, if the technology is not amenable to trade secret protection, which is usually the case for any technology that is easily reverse-engineered, innovators may move their investments and innovative R&D overseas to countries that grant patents in the field, with negative impacts on US competitiveness and economic and national security. Third, innovators may simply stop investing in the field, depriving society of the technology altogether, once again undermining scientific and technological progress. None of

[12] *Diamond v. Chakrabarty,* 447 U.S. 303, 315 (1980); *see also United States v. Dubilier Condenser Corp.,* 289 U.S. 199 (1933) (Courts "should not read into the patent laws limitations and conditions which the legislature has not expressed.").

these outcomes is in the interest of the United States or the American public, which is why patent eligibility reform should be a national priority.

3. The technologies that the U.S. most needs to develop to compete with China's growth, including advanced computing, AI, and biotechnology, are often those that fall outside current patent eligibility standards. How will PERA help the U.S. maintain global leadership in these competitive sectors? What does a failure to enact such legislation mean to our global competitiveness in general?

In the biotechnology and broader life sciences fields, PERA will restore patent eligibility to medical diagnostic methods and provide innovators with the clarity, certainty and predictability they need to continue to invest in developing new genetic and other advanced technologies in the United States. Each of these fields is critical to U.S. global competitiveness, and to national security. Diagnostics, for instance, are not only critical tools for ensuring early disease detection, personalized treatments, and optimized health outcomes, but also encompass the types of technologies needed to quickly identify, test for, and rapidly respond to viral and bacterial pathogens that may be implicated in future pandemics, in the event of biological attacks, or in other national health crises. Cell and gene therapies and other gene-based medicines are, likewise, critical pillars of the future of medicine, with a host of health, economic, and security benefits. Countries who incentivize their local invention, development and manufacture will not only ensure fast and broad access to some of the most targeted and effective therapies and potential cures in medical history for their populations, but stand to set the global safety, efficacy, and ethical standards in the field, to benefit economically through the creation of cutting-edge jobs and revenue, and to position themselves as the venue of choice for future waves of medical progress. As I explained in my testimony, each of these fields and the benefits they promise for the United States are currently threatened by the current state of patent eligibility law here. In contrast, China continues to broadly allow patents on not only modifications and applications of genes, but even on isolated human genes and gene fragments.[13] This gives China a competitive edge in attracting investment and building an innovative industry in these fields. While PERA would not allow patents on isolated human genes as China does, it would go a long way to leveling the playing field, and enabling continued robust investment in US-based gene-related innovation.

4. PERA 2025 has several changes this year compared to PERA from the prior Congress. Do you believe that these were good changes to the bill? Why or why not?

In the life sciences, the main change to PERA 2025 from the previous version of the bill was the new expansion of the human gene exclusion to now encompass isolated human genes, as well as genes as they occur in the human body, which were previously excluded. This change effectively codifies the Supreme Court's *Myriad* decision, which carefully distinguished ineligible natural and

[13] *See, e.g.,* China National Intellectual Property Administration (CNIPA), *Patent Examination Guidelines (2023)* Part II, Chapter 10, § 9.1.2.2 ("[I]f a gene or DNA fragment is first isolated or extracted from nature, its nucleotide sequence is not recorded in the prior art, can be precisely characterized, and has industrial utility, then both the gene or DNA fragment itself and the methods used to obtain it are subject matter eligible for patent protection.");

isolated human genes from eligible applications and modifications of genes, such as cDNA. While we support this change as a reasonable compromise if it helps to enact PERA, we do not view it as practically necessary or as particularly good policy. It is not necessary because isolated human genes are largely unpatentable today, regardless of their patent *eligibility*, since the full human genome, sequenced and published by 2003, now serves as prior art to human genes. It is also unnecessary because there is simply no evidence or logical reason to believe that allowing patents on isolated human genes would impede or have other negative impacts on innovation, scientific research, or access to technologies in genomics and other gene-related fields. To the contrary, as I explained in my testimony, China, Europe, Japan, and Korea, to name a few, all continue to grant patents on useful isolated human genes, and they do so without any of the ill effects that critics of patent-eligibility reform claim would occur if the same were done here. For this reason, we believe that the new *Myriad*-based exclusion for isolated human genes is also not the best policy, since, as described in my response to the previous question, it puts the United States at a competitive disadvantage to these other innovative economies. That said, if codifying *Myriad* in this way helps to advance and ultimately enact PERA, we believe it is a compromise worth making in order to restore the level of clarity and predictability around patent eligibility for other gene-based technologies that innovators like us need to invest in, invent and develop the next generation of cell and gene therapies and other gene-based medicines here in the United States.

5. We are all concerned about the cost of prescription medication. Some have argued that the enactment of this bill would lead to higher drug prices for consumers. What do you say to that?

We do not see a connection between PERA and drug prices. As a starting point, drug pricing is a complex issue that has nothing to do with patent eligibility. While patents provide limited terms of exclusivity for the inventions that comprise a novel drug, they do not dictate what the price of the drug is during those terms. Regardless, the types of inventions covered by drug-related patents today—e.g. compounds, compositions of matter, chemical forms, formulations and methods of treatment—are all firmly patent-eligible under *current* Section 101 and its associated case law. Indeed, in *Myriad*, the Supreme Court reaffirmed two centuries of statutory and judicial precedent upholding eligibility for non-naturally occurring compositions of matter, and in *Mayo*, the Court squarely deemed patents on new drugs and on new methods of using them to be patent-eligible, distinguishing them from the diagnostic methods at issue in that case.[14] Appropriately, PERA would not change that. As such, we do not believe or see how PERA's enactment would have any effect on drug prices. On the other hand, this codification of current law restores much-needed clarity and predictability to Section 101, ensuring that lower courts do not continue to expand the judicial exclusions in ways the Supreme Court never intended. As I explained in my testimony, that is a serious concern following cases like *Regenxbio v. Sarepta*, and one of the main reasons why PERA is needed to support the future of biotechnology and of U.S. leadership in the field.

[14] See *Myriad,* 569 U.S. at 595-96; *Mayo*, 566 U.S. at 87 ("Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the [diagnostic] patent claims do not confine their reach to particular applications of those laws [of nature].").

6. Some argue that medical diagnostics will continue to be invented and developed notwithstanding the change in subject matter eligibility from the Supreme Court, because of other factors promoting or protecting innovation – such as the incentives to "publish or perish" in academic, or the ability to protect innovation through other means like trade secrets. Do you agree? Why or why not?

We disagree that academic incentives or trade secrets alone can adequately substitute for patent protection in any field, including diagnostics. The patent system was designed to not only encourage invention, but to further incentivize inventors to both publish and commercialize the fruits of their efforts, converting mere inventions into innovations that promote scientific and technological progress, and disseminating knowledge and ideas that others can expand upon and put to further use. For over 230 years, the patent system has done just that in the United States, across all fields of technology. Neither academic credit nor trade secret protection can achieve all three of these goals—invention, publication and commercialization—all of which are necessary to fulfill the constitutional and societal imperative of promoting progress.

With respect to academic credit and goodwill, while these may encourage some academics to publish scientific knowledge, and to develop certain diagnostics for their own, likely small-scale use, such "incentives" do not and would not motivate private or non-academic public sector innovators to do the same. With such a limited pool of inventors contributing to creative and industrial output in the United States, the country would quickly fall behind its competitors. Likewise, such incentives do not and would not incentivize the creation of any diagnostics that require significant capital investments to develop, scale-up, manufacture or improve, such as at-home diagnostic test kits, companion diagnostics for biopharmaceuticals, or complex diagnostics used by clinical, commercial or other private sector laboratories.

Trade secrets present the inverse set of problems. While trade secrets are powerful incentives that encourage invention, because they depend on secrecy, they only work in fields and for specific inventions that cannot be easily reverse-engineered, such as lab-based diagnostic tests that rely on algorithms and proprietary methods. If patents remain unavailable for diagnostics, exclusive reliance on trade secrets would, thus, continue to limit the type and scope of diagnostics innovation in the United States. Additionally, the technology and knowledge behind those limited diagnostics that are incentivized by trade secrets remain secret, potentially indefinitely, which ultimately impedes scientific and technological progress, in contrast to patents.

7. One of the witnesses testified that PERA would allow for the privatization of biomarkers. Do you agree, and if not, why?

We do not agree that PERA would allow for the "privatization" of biomarkers. With respect to any biomarker that is naturally-occurring—be it a gene, a protein, or any other natural material that exists in the human body—PERA makes clear that such materials are not patent-eligible. As explained in my testimony and in my answer to Question 4, PERA 2025 now also excludes even isolated human genes, so these too could not be patented or "privatized." With respect to genes or other natural materials that are *modified* or *applied* in ways that do not occur in nature in order to

make them useful as biomarkers, those inventions are currently patent-eligible under existing law. PERA would merely codify *Myriad*, which expressly distinguished eligible modifications and applications of genes, including cDNA, from the naturally occurring and isolated human genes the Court found ineligible.[15] Last, as I further explained in my answer to Question 4, concerns that continuing to allow patents on useful modifications and applications of genes will stifle research, innovation and access are not based on evidence or logic, as China, Europe and Japan all continue to grant patents on a much broader array of gene-related subject matter than PERA would, including isolated and even naturally occurring genes, all without any of the ill effects that critics of patent-eligibility reform claim would occur if PERA were enacted.

8. How does PERA compare to the current eligibility laws in China, Europe, and Japan?

As I explained in my answer to Question 4, unlike PERA, which would codify *Myriad* and exclude patents on both naturally-occurring and isolated human genes, China, Europe and Japan all currently allow patents on those types of inventions where they are useful or form part of a useful invention. More specifically, in China, both a "gene or DNA fragment itself and the methods used to obtain it are subject matter eligible for patent protection" if the "gene or DNA fragment is first isolated or extracted from nature, its nucleotide sequence is not recorded in the prior art, can be precisely characterized, and has industrial utility."[16] In Europe, a "[b]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention *even if it previously occurred in nature*." This includes "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene . . . *even if the structure of that element is identical to that of a natural element*." [17] In Japan, "if things in nature such as chemical substances [including genes] or microorganisms have been isolated artificially from their surroundings, those are creations and considered as a statutory 'invention.'"[18] As these laws demonstrate, even reversing *Myriad* and restoring patent eligibility to isolated human genes would not impede science, innovation or access, all of which flourish in these other innovative economies. PERA, however, would not go so far, and would merely codify the status quo, prohibiting patents on isolated human genes, but ensuring that *modifications* and *applications* of genes remain patent-eligible.

---

[15] *See Myriad,* 569 U.S. at 596 ("We merely hold that genes and the information they encode are not patent eligible under §101 . . . ."); *id.* at 595 (A "lab technician unquestionably creates something new when cDNA is made . . . . cDNA is not a 'product of nature' and is patent eligible under § 101."); *id.* at 595-96 ("It is important to note what is *not* implicated by this decision. First, . . . [h]ad Myriad created an innovative *method of manipulating genes* while searching for [a] . . . gene it could possibly have sought a method patent . . . Similarly, this case does not involve patents on *new applications of knowledge* about … genes . . . . Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a *different inquiry* . . . .") (emphases added).

[16] China National Intellectual Property Administration (CNIPA), Patent Examination Guidelines (2023) Part II, Chapter 10, § 9.1.2.2.

[17] EU Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, Article 3(1); 5(2) (emphases added).

[18] JPO, Examination Guidelines for Patent and Utility Model in Japan, Part III Ch. 1, Section 2.1.2.

9. There is a lot of misinformation out there about PERA. Top among these is the assumption that it would enable patenting of human genes.

a. For those who are unaware of the intricacies of patent law and how it works, can you explain how it is not possible to seek patents for discovering a naturally occurring phenomenon?

Mere discoveries of naturally occurring phenomena without modification or other human intervention have never been patent-eligible, because they are not considered to be inventions. Even if such discoveries were treated as eligible for patenting—which they have never been—such natural phenomena standing alone would almost certainly be unpatentable, because they would fail the utility test of Section 101, the novelty test of Section 102 of the Patent Act (since natural phenomena are publicly available), or perhaps the obviousness test of Section 103. Regardless, as I explained in my previous answers, PERA would maintain and codify the longstanding principle that such natural phenomena are not patent-eligible. The bill is explicit that "a person may not obtain a patent for . . . . an unmodified natural material, as that material exists in nature," which includes "an unmodified human gene, as that gene exists in the human body."

b. Can you explain what type of discoveries related to genes can be patented? How would PERA change these principles?

As I explained in my previous answers, with respect to human genes, PERA would codify *Myriad*, expressly foreclosing patents on naturally occurring and isolated human genes, while continuing to allow patents on useful modifications and applications of genes, including cDNA. The latter types of inventions form the basis of modern biotechnology, and must remain patent-eligible if the United States wishes to continue to be a leader in cell and gene therapy, gene-based medicine, and other areas of biotechnology.

III. Questions from Senator Eric Schmitt

1. On balance, would PERA make it easier or harder for patent trolls to extort U.S. businesses and companies?

We do not believe that PERA would have any effect on patent assertion entities, or so-called "patent trolls," in the life sciences sector. That said, given the critical role that Section 101 plays in enabling innovation in all fields of technology, including the life sciences, we believe that, to the extent the activities of these entities raise concerns over patent enforcement abuse, such concerns should be addressed through means other than patent eligibility law. In addition to other more appropriate sections of US patent law that can be used effectively for this purpose (e.g. Sections 102, 103 and 112), the Supreme Court has taken many steps in recent years to make it more difficult for bad actors to inappropriately enforce patents. These include *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), *Ashcroft v. Iqbal*, 556 US 662 (2009), and the abrogation of Rule 84 from the Federal Rules of Civil Procedure in 2015, which together heightened the pleading standards needed to bring a patent infringement suit. They also include *TC Heartland v. Kraft Foods*, 581 US 258 (2017), which greatly restricted the venues in which patent infringement suits

can be brought, and *Octane Fitness v. ICON Health*, 572 U.S. 545 (2014) and *Highmark Inc. v. Allcare Health,* 572 U.S. 559 (2014), which made it substantially easier for accused infringers to prove litigation abuse and secure awards of attorneys' fees. The purpose of Section 101 is to broadly direct investment and enable innovative R&D in fields that promote societal, scientific and technological progress. As such, we encourage Congress to approach patent eligibility reform through that innovation policy lens, and, to the extent still necessary after the aforementioned Supreme Court cases, to address any remaining enforcement concerns through other mechanisms.

2. **How would expanding patent eligibility for AI processes under PERA impact the ability of businesses to implement those technologies?**

As a leader in the adoption and use of AI technologies in the life sciences, we believe that AI tools have a strong potential to help accelerate and optimize biopharmaceutical innovation, to make our R&D more efficient, and to streamline our operations in order to bring novel drugs to patients faster. As with any other field of technology, we believe that AI-based technologies and processes should be broadly patent-eligible, because the patent system provides an effective balance between encouraging invention on the one hand, and facilitating publication and commercialization on the other. If AI-based processes were excluded from the patent system, innovators in the field would either rely on trade secret protection, which undermines transparency and slows improvements in the field, or would invest in other areas. Those outcomes would ultimately hinder development and broad adoption of AI-enabled processes, to the detriment of potential users like us. In contrast, based on our experience to date using and developing a variety of AI-based technologies and inventions, patents and other IP rights in these technologies have helped to drive new partnerships, and to clarify the sharing of rights in our collaborations with third-party AI developers.

3. **What are examples of the types of medical innovations that are ineligible under current law but would be eligible under PERA?**

Under current law, all medical diagnostic methods are effectively patent-ineligible in the United States,[19] though it is not clear that the Supreme Court intended this result when it narrowly found the particular claims in *Mayo* to be ineligible.[20] PERA, in any event, would restore eligibility to inventions in this important field. Most significantly for innovative medicines companies like us, PERA would also restore clarity and predictability to patent eligibility law for compositions of matter useful in gene-based medicine like cell and gene therapy, and for methods of treatment. While these inventions are generally patent-eligible today, they are threatened by the expansion of the "judicial exceptions" under the current legal framework. As detailed in my testimony, gene-based medical technologies are particularly vulnerable after a district court, in a recent case called *Regenxbio v. Sarepta*, held for the first time that a non-naturally occurring genetically engineered composition of matter used to create important components of gene therapy is not patent-eligible because it was made from components of nature. That ruling flouts nearly half-a-century of

[19] See *Athena Diagnostics,* 927 F.3d at 1352, 1354 (Moore, J., dissenting) ("Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible," turning it into "a per se rule that diagnostic kits and techniques are ineligible.")

[20] *Mayo,* 566 U.S. at 72 ("Our conclusion rests upon an examination of the particular claims before us . . . .").

Supreme Court precedent, and if it stands on appeal, it will threaten the foundations of not just gene therapy, but all of biotechnology.[21] PERA would provide much needed clarity in this area, codifying the Supreme Court's distinction in *Myriad* between ineligible natural and isolated human genes, and eligible *modifications* and *applications* of genes and other natural materials, such as the ones at issue in the *Regenxbio* case. With regard to methods of treatment, while the Supreme Court has indicated that they are firmly patent-eligible and distinguishable from diagnostic methods,[22] lower courts continue to blur the lines between the two, adding unpredictability for innovators in the field. PERA would cure this unpredictability by restoring eligibility to diagnostics and most other types of applied biotechnological methods.

4. Why should Congress—or why should Congress not—expand eligibility to such medical innovations?

We do not view PERA as expanding eligibility to the medical innovations referenced in my previous response, so much as clarifying and restoring the scope of eligibility that Congress intended. For over 230 years, Congress has made clear that useful "processes" and "compositions of matter" in all fields of technology are patent-eligible. As the Supreme Court has explained, "Congress intended statutory subject matter to 'include anything under the sun that is made by man,'" and "cast [the statute] in broad terms to fulfill the constitutional and statutory goal of promoting 'the Progress of Science and the useful Arts' with all that means for the social and economic benefits envisioned by Jefferson."[23] With respect to diagnostic methods, this subject matter was always patent-eligible, until the Supreme Court in *Mayo* took issue with "the particular claims before [it]"[24] and equated those claims to an ineligible "law of nature." Congress, which never endorsed this type of exclusion—let alone for the entire field of diagnostics—should restore eligibility for these important technologies, because they are critical aspects of personalized medicine, and help to ensure early and accurate diagnoses and treatment efficacy. Other types of diagnostic methods are also important for pandemic preparedness. Congress should also codify the Supreme Court's own clear guidance that methods of *treatment* are eligible, because these inventions enable chemical and biological compositions to be developed into effective therapies for particular diseases and patient populations, and eventually to be further developed to treat additional diseases and patient populations. Finally, Congress should codify the Supreme Court's careful distinction in *Myriad* between ineligible natural and isolated human genes, and eligible *modifications* and *applications* of genes, because this clarity and predictability are necessary to enable innovators like us to invest in the invention, development and manufacture of the next generation of cell and gene therapies, gene-based medicines, and other advanced technologies in the United States. As explained in my testimony and in my previous answers, in providing this clarity, PERA would also help narrow current gaps between US law and patent-eligibility laws in China, Europe and Japan, to ensure that the US remains globally competitive.

[21] See Testimony of Corey Salsberg (Oct. 8, 2025) ("PERA Testimony") at 2-4.
[22] See *Mayo*, 566 U.S. at 87 ("Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the [diagnostic] patent claims do not confine their reach to particular applications of those laws [of nature].").
[23] *Chakrabarty,* 447 U.S. at 309, 315.
[24] *Mayo,* 566 U.S. at 72.

5. Critics of PERA have advocated a more narrowly tailored approach to expanding eligibility for specific innovation areas like medical diagnostics, arguing PERA is too broad. Are those concerns founded or unfounded? Please explain why.

We believe these concerns are unfounded. PERA's approach is appropriately general, because the problems that the Supreme Court's eligibility framework created are general, and applicable to all fields of technology, as with all of patent law. The Court's eligibility framework incorporates technology-neutral judicial exceptions to technology-neutral statutory categories, and it was developed across cases that spanned diverse fields of technology: *Mayo* (diagnostic methods), *Myriad* (isolated human genes), and *Alice* (software). Lower courts have since applied it in a technology-neutral manner, to exclude an ever-expanding scope of subject matter, which is particularly concerning given the increasing technological convergence that characterizes today's computer and AI-driven innovation. Even if the problems in eligibility law were isolated to a particular technological area today, we do not believe it would be possible to adequately address them through a narrow technology-specific solution. To use the example in the question, a legislative proposal that simply declared medical diagnostics to once again be patent-eligible would leave the broader *Mayo/Alice* framework and the subsequent case law that led to those exclusions intact, as well as the underlying "laws of nature" and "abstract ideas" exceptions. Under such an approach, it would likely only be a matter of time before the vague framework and now-expansive judicial exceptions were once again applied to chip away at medical diagnostics, particularly since diagnostics encompass a broad and diverse array of technologies that are often described and claimed in different ways.[25] As the Supreme Court reminds us, "Congress employed broad general language in drafting § 101 precisely because [the most groundbreaking] inventions are often unforeseeable."[26] Because that truism will never change, Congress should not now attempt to pick technological winners and losers by confining patent eligibility reform to only certain fields.

[25] See PERA Testimony at 5.
[26] *Chakrabarty*, 447 U.S. at 316 (internal citations omitted).