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Before the United States Senate Committee on the Judiciary

Subcommittee on Intellectual Property

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

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Thank you, Chairman Tillis, Ranking Member Schiff, and Members of the Committee, for the opportunity to provide this testimony on the important issues raised by this hearing on *The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System (PERA).*

I currently serve as the Vice President and Chief Intellectual Property Counsel at the Dana-Farber Cancer Institute (Dana-Farber). I have studied, written, and published on patent eligibility extensively, and Dana-Farber recently joined as an amicus in *Regenxbio v. Sarepta* where subject matter eligibility is at issue. I have also co-authored amicus curiae submissions in *Sequenom, Inc. v. Ariosa Diagnostics*,[1] *In re Fisher*,[2] and provided written testimony to this subcommittee in June 2019.[3] Unfortunately, little progress has been made on the eligibility crisis since I last testified. Please make no mistake, this is a crisis. The fact that innovators and investors are adapting to the current legal framework and managing as best they can does not mean the crisis is solved. Today, perhaps even more than when I provided testimony in 2019, patent eligibility is a significant barrier to innovation reaching patients, particularly in medical diagnostics.

The current law of eligibility is often justified in the life science sector as an issue of patient access.[4] I wholeheartedly agree that patient access is critical. It is why Dana-Farber and other innovators and caregivers do what we do. Our mission is to help patients with innovative patient therapies and scientific discoveries.[5] The ultimate barrier to patient access, however, is a medicine or diagnostic never being discovered, developed, or commercialized. Patients who never receive the diagnostic testing that enables earlier detection or the treatment that could have saved their life are unquestionably denied access. Denying patient access to discoveries never developed and commercialized due to poor IP policy is the real travesty. Worse yet, the denial is the result of inaction for which they have little awareness. While patients are typically aware when insurance carriers deny claims for treatment, they remain unaware of treatments or diagnostics that are never developed due to the patent eligibility crisis. Nevertheless, lives are impacted and likely lost. This makes it all the more important to act urgently. As I noted in my 2019 testimony, patients are waiting. They are still waiting. It is time for Congress to advance *The Patent Eligibility Restoration Act* to remedy the eligibility crisis.

Dana-Farber is committed to providing patients with cancer the best treatment available today while developing tomorrow's cures. Dana-Farber places equal emphasis and commitment on the

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[1] *Sequenom, Inc. v. Ariosa Diagnostics, Inc.,* 579 U.S. 928 (2016).
[2] *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005)
[3] The State of Patent Eligibility in America: Part III: Hearing Before the Subcomm. on Intellectual Property of the S. Comm. on the Judiciary, 116th Cong. (2019) (written testimony of Steven P. Caltrider, Vice President & General Patent Counsel, Eli Lilly & Co.).
[4] See, e.g.,, Stakeholder Letter Opposing PERA, May 27, 2025, https://www.amp.org/AMP/assets/File/advocacy/Stakeholder_Letter_Opposing_PERA_Sept%202025.pdf
[5] DANA-FARBER CANCER INST., *Mission and Values*, https://www.dana-farber.org/about/our-mission-and-values (last visited Sept. 26, 2025).

provision of excellent patient care and cutting-edge research. The research is informed by patient care – and patient care relies on the research. The deep expertise in these two areas uniquely positions Dana-Farber to develop, test, and partner with industry to gain FDA approval for new cancer therapies in its laboratories and clinical settings. Dana-Farber researchers have contributed to the development of thirty-five (35) of seventy-five (75) cancer drugs recently approved by the FDA. As a principal teaching affiliate of Harvard Medical School, a federally designated Center for AIDS Research, and a founding member of the Dana-Farber/Harvard Cancer Center, Dana-Farber is a non-profit research institute that is supported by the National Cancer Institute, and the National Institute of Allergy and Infectious Diseases. The Institute has the generous support of numerous foundations and individuals who contribute to the Institute's individual research and clinical programs. Many also support the Jimmy Fund, the principal charitable fund of the Institute, named for one of its pediatric patients.

Dana-Farber scientists are attacking cancer at every level: unraveling the most basic mechanisms in cells and tissues, discovering molecular targets for new "smart" drug therapies, harnessing the immune forces to combat cancer, and seeking to identify disparities in cancer incidence and treatment in diverse populations. All of us – patients, clinicians, and researchers – hope for tests that diagnose cancer more accurately and earlier, including the need to detect recurrence sooner.

The research at Dana-Farber is often characterized as "basic" research. Dana-Farber does not undertake the development necessary to commercialize its research. For Dana-Farber innovation to reach patients broadly, we work with commercial partners who make substantial investment to secure the necessary regulatory approvals. Dana-Farber will continue the research to detect and diagnose cancer earlier and more accurately, without regard to return on investment. However, the uncertainty of strong patent protection puts investment and these critical partnerships with the private sector at risk.

As now Chief Judge Moore noted in *Athena Diagnostics* in 2019, "Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible. [Citations omitted.] Despite the significance of these diagnostic inventions and the high costs of developing them, we have held, because of *Mayo*, every one of these life-changing inventions and discoveries ineligible*."*[6]

The compelling point remains true today – the uncertainty of securing strong patent protection undermines investment in life-saving, innovative medical diagnostics. I see this nearly every day at Dana-Farber.

Unfortunately, the crisis now threatens innovative treatment options. As I noted, Dana-Farber joined as an amicus in *Regenxbio v. Sarepta*. The claims at issue in *Sarepta* are directed to a composition of matter and more specifically to a man-made cultured host cell. The host cell is engineered to include a non-natural nucleic acid or DNA sequence. The claim was found at the

[6] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1352–53 (Fed. Cir. 2019)*(Moore, J., dissenting from denial of reh'g en banc).

district court to include ineligible subject matter because one part of the nucleic acid sequence, the part that is akin to the delivery truck, is naturally occurring. Such an engineered host cell is useful in gene therapy. Gene therapy treats or prevents disease by adding a new gene to a cell to "restore the missing function of a faulty or missing gene."[7]

The *Sarepta* case was heard by the Federal Circuit on October 7, just yesterday. This is not the forum to litigate the merits of the case under current law, but this is the forum to step back and ask the policy question. Should there be any doubt that the subject matter – an engineered cell combining known portions of nucleic acid useful to deliver a gene to patients to provide hope for a cure – is not patent eligible? Without question it should be. Eligibility should not be an issue.[8]

The discoveries associated with gene therapy and cell therapy are part of transformative breakthroughs that are redefining medicine. Coupled with advances in research methods and artificial intelligence, we are in an unprecedented era in medical research. Innovation is occurring. Dana-Farber is at the heart of this innovation in cancer.

These innovative treatments – which have not yet reached their full potential – are leading to treatments for conditions once thought incurable. These gene-based treatment modalities are also not the only treatments at risk. I have seen allegations of invalidity or rejections based on subject matter eligibility for other innovative new treatment options. Man-made peptides called degrons that serve to signal targeted degradation have been rejected for subject matter eligibility because they share amino acids in common with natural peptides. Examiners demand applicants to show the variances in amino acid results in "marked differences" or "significantly more" over the natural peptide.[9] Another promising treatment modality, antisense oligonucleotides (ASO) are threatened. Claims to formulations of ASOs that overcome aggregation and stability issues, which make the ASO commercially viable as a drug, were rejected under § 101 because the nucleic acid sequence was a "product of nature" and the excipients and concentration limitations were not significantly more.[10] Similarly, RNA-based therapies are threatened. A claim to a composition that serves as a carrier for RNA was found to be ineligible because the unnatural elements of the claim were found to not be "significantly more."[11] This case illustrates how amiss patent eligibility is evolving. There is no debate that the natural claim elements, an enzyme and ADP, occur in nature, but they clearly do not exist in nature in the specific concentration, claimed conditions, or as a combination that results in a stable solution useful to

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[7] *NAT'L HEART, LUNG & BLOOD INST., What Are Genetic Therapies?,* https://www.nhlbi.nih.gov/health/genetic-therapies (Mar. 2022).

[8] If there are defects in drafting under Section 112 or issues of novelty or obviousness under Sections 102 and 103, those questions can and should be litigated on the merits.

[9] *See, e.g.*, U.S. Patent Application No. 17/413,859.

[10] Ex parte Hayes, Appeal No. 2015-000614, Application No. 13/748,964 (Patent Trial and Appeal Board 2015)

[11] Ex parte Eshoo, Appeal No. 2017-003234, Application No. 13/340,962 (Patent Trial and Appeal Board 2017) (where a composition containing polynucleotide phosphorylase (an enzyme that naturally occurs in cell), specific concentrations of unlabeled adenosine diphosphate (ADP), which is also found in the cell, a buffering agent to maintain the composition at a specific pH range and a divalent metal cation were found to be ineligible subject matter.

serve as a carrier for RNA. Even traditional small molecule method of treatment patents are not beyond such allegations. The method of treating small cell lung cancer with pemetrexed in combination with certain vitamins was alleged to be invalid under § 101 for lack of subject matter eligibility.[12]

While the legal landscape for treatment-related patents is not yet as dire as for medical diagnostics, defending against patent eligibility challenges creates a strong headwind against innovation and remains only one adverse court decision away from being catastrophic for patients awaiting cures.[13]

The question for the Subcommittee today is whether the country should have sound IP policy, which includes PERA as a solution to the eligibility crisis, that supports these breakthroughs? In my opinion, the answer is clearly "yes." Again, patients are waiting.

But, what about patient access? Patient access to genetic testing and serving cancer patients through genetic testing is obviously a priority. However, I'm certain that IP – and PERA in particular – is not a problem in this regard.[14]

The current standard of care and testing of genes linked to hereditary cancers will not change or be impacted by PERA. Stated plainly, you cannot patent what is already known and standard of care. A patent does not and cannot validly block known technology but rather provides the foundation for further innovation and improvement – new, better and more accurate diagnostic tests. Such future innovation is good for patients.

As I understand, the opponents of PERA argue that the current law prevents patents of "unprecedented scope," ensures that the "fundamental building blocks cannot be monopolized," and preserves the foundations of knowledge available to all.[15] Respectfully, I'm confident this argument is flawed in the life science sector.

A single patent holder could no more control all pre-clinical and clinical research on a human gene after this bill passes than they could today. For human genes, PERA actually preserves the status quo because it codifies the Supreme Court's decision in *Myriad*. While the bill provided a narrower form of this exemption last year for human genes in the human body, the bill, as it was

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[12] See, for example, Eli Lilly and Company, Plaintiff/Counter-Defendant, v. Accord Healthcare, Inc., USA, Defendant/Counterclaimant., 2012 WL 2601785 (S.D.Ind.) and Eli Lilly and Company, Plaintiff, v. Apotex, INC., Defendant., 2017 WL 7037972 (S.D.Ind.)

[13] Claims directed to obtaining siRNA sequence for a target gene were found ineligible by the Patent Trial and Appeal Board. Ex Parte Khvorova, No. APPEAL 2012-010359, 2015 WL 4267897, at *3 (P.T.A.B. July 10, 2015). This leaves uncertainty whether a composition or method of treatment siRNA claim would suffer a similar fate.

[14] Issues relating to price, reimbursement, and access are far more consequential to patient access to genetic testing than patents with or without PERA.

[15] *See, e.g.*, Stakeholder Letter Opposing PERA, May 27, 2025, https://www.amp.org/AMP/assets/File/advocacy/Stakeholder_Letter_Opposing_PERA_Sept%202025.pdf, and *Coalition Letter in Opposition to S. 2140 – Patent Eligibility Restoration Act of 2023 (PERA)*, R STREET INST., https://www.rstreet.org/outreach/coalition-letter-in-opposition-to-s-2140-patent-eligibility-restoration-act-of-2023-pera/ (Jan. 30, 2024).

reintroduced in this Congress, was expanded to exclude from eligibility "isolated" human genes—effectively following the contours of the *Myriad* decision.

For human genes especially, it is notable that the full sequencing of the human genome as well as the extensive work that has already been done on mapping genetic variants means that, even if there were no restrictions on eligibility (which is not what PERA proposes), other provisions of the Patent Act would preclude patentability because the gene or sequence would not be "new" and therefore would not meet the test for novelty.

Furthermore, even if PERA reversed the *Myriad* decision, the patent claims in *Myriad* were invalid under other sections of the Patent Act. Eligibility is a threshold question. Eligibility does not answer the question whether the subject matter is *patentable*. Other Sections of the Patent Act directed to overbreadth and novelty would have invalidated the *Myriad* claims.

The law against overbreadth dates back to the 1800s and Samual Morse, when the Supreme Court rejected a claim to all methods of communication using electronic signals.[16] Numerous decisions of the Supreme Court and the Federal Circuit have rejected overly broad claims that threaten to block fields of research under Sections 112. In addition to *Morse*, notable other cases struck down as being overly broad include the *Incandescent Lamp*[17] and cases in the life sciences, including claims to nucleic acids. PERA returns the issue of overbreadth to the well-developed section of the statute intended to address the issue.

In my opinion, what PERA's opponents are really against is the loss of an opportunity for a "quick kill" in litigation.[18] That is, it is argued that "weakening" subject matter eligibility necessarily will result in more costly district court litigation. This is because subject matter eligibility is determined as a threshold issue. Of course, if the invention is meritorious – that is, it is patentable under the rigorous standards of novelty, non-obviousness, and the invention is described, enabled, and claimed commensurately with the scope of what was invented – then invalidating the patent on the basis of subject matter eligibility is precisely what is wrong with the current state of the law. As Judge Moore noted, life-changing inventions and discoveries are

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[16] *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112 (1854)) (rejecting claims to all means for telegraphic communication*)*.

[17] *Consol. Elec. Light Co v. McKeesport Light Co*, 159 U.S. 465, 472 (1895) (Rejecting claims to all fibrous and textile material that could serve as an incandescing conductor).

[18] Coalition Letter, *supra* note 15 ("Section 101 is unique because district courts can decide patent eligibility as a question of law without resort to expert testimony or evidence beyond the patent. As a result, meritless cases can be resolved at an early stage before huge sums of money are wasted on attorney's fees and other litigation costs."); *See also* the U.S. PAT. & TRADEMARK OFF., *Patent Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States*, https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf (June 2022). USPTO Report to Congress Patent eligible subject matter: Public views on the current jurisprudence in the United States, June 2022 ("Those in support of the current state of the law on eligibility tended to be companies faced with abusive and costly litigation involving "overbroad," mostly software, patents. Those companies noted that the current law allows them to avoid or more efficiently resolve abusive, costly litigation.")

being found ineligible. This undermines the very purpose of a strong IP system. If the invention lacks merit – lacks novelty, is obvious, or not properly described, enabled and claimed – then any alleged challenger and patentee may have their day in court to consider the merits, and the court decides if the rigorous standards of patentability have been met.

The cost and time required to litigate a patent is a real issue, but furthering the eligibility crisis because it may be faster to kill certain patents that lack merit is throwing the baby out with the bath water. It is obviously not good IP policy to undermine life-changing innovation so that so-called "low quality" patents are more easily invalidated.[19] In other words, using subject matter eligibility as the tool to invalidate "low quality patents" is, at best, a blunt instrument that does more harm than good to the IP system.[20]

A related point by opponents of PERA, particularly outside of life sciences, is that PERA would enable the return of low-quality patents.[21] The argument is that by weakening the subject-matter eligibility standard under § 101, PERA would permit more abstract ideas, natural laws, and natural phenomena to be patented—categories the Supreme Court previously excluded through its judicial exceptions. Furthermore, because Inter Partes Review ("IPR") only permits challenges based on §§ 102 and 103 (novelty and obviousness) and not § 101 eligibility, these patents would be insulated from Patent Trial and Appeal Board ("PTAB') review, leaving accused infringers with only costly district-court litigation to contest them.

The distortion of the patent statute in this argument is palpable. Section 101 determines what subject matter is eligible for a patent application. In its first introduction in the Patent Act of 1793, Congress was purposeful to cast eligibility broadly. This language was recodified in the 1952 Act, for which the legislative history famously notes that Congress intended statutory subject matter to "include anything under the sun that is made by man."[22] This was for good reason – today's inventions were unimaginable in 1793 or 1952, and more restrictive eligibility criteria risks the very problem that we confront today through judicial fiat – entire promising fields of research are threatened by misguided eligibility standards. Congress was correct in 1793 and 1952 that eligibility should be broadly cast as a threshold question. Notably, in the splintered opinions of concurrences and dissents, the judges of the Federal Circuit in *Athena*

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[19] To the extent the objective is to enable more efficient patent litigation (i.e., achieve answer to allegations of invalidity more cheaply), other reforms could be considered. For example, compliance with written description could be framed as a question of law -- a question of construction of the specification – rather than a question of fact. This would allow most issues of overbreadth due to abstract claiming to be decided early in litigation.

[20] It is beyond the scope of this testimony but there are a number of steps the USPTO and Congress could take to improve the quality of patents.

[21] BPI Staff, *BPI and Coalition of Trades Oppose PREVAIL Act and Patent Eligibility Restoration Act*, BANK POL'Y INST., https://bpi.com/bpi-and-coalition-of-trades-oppose-prevail-act-and-patent-eligibility-restoration-act/ (Sept. 17, 2024) (expressing strong opposition to PERA on behalf of the Quality Patents Coalition and claiming it would open the 'flood gates of low-quality patents').

[22] *Diamond v. Diehr,* 450 U.S. 175, 182 (1981) citing the legislative history found at S.Rep.No.1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep.No.1923, 82d Cong., 2d Sess., 6 (1952), U.S.Code Cong. & Admin.News 1952, pp. 2394, 2399.

acknowledged that Congress intended the patent law be given wide scope, nevertheless felt bound by Supreme Court precedent to hold the claims at issue ineligible, and looked to Congress to fix the issue.[23] And four judges remarkably noted that the Supreme Court "ignored" or "disregarded Congress's wishes."[24] PERA corrects this disregard by defining eligibility broadly and letting the substantive sections of the patent statute that set out the conditions of patentability, §§ 102, 103 and 112, do the heavy work of sorting meritorious inventions from unpatentable subject matter.

The opponents of PERA also raise COVID-19 to support their opposition.[25] It is a false premise for the opponents to suggest that "[t]his awe-inspiring innovation could not have occurred in the United States if an entity had been allowed to patent the COVID-19 genome(s), as was possible before the *Myriad* decision." To the contrary, a strong patent system *positioned* the US to respond rapidly. Companies had made a massive investment – based on patents – in vaccine and antibody technology. This investment enabled the companies to pivot quickly. A patent application filed on the COVID-19 genome would have had *no impact* on the awe-inspiring innovation that led to treatment options. I know this because I was working in industry at the time. Furthermore, a patent application directed to the COVID-19 genome would have been properly rejected by the USPTO for lacking a substantial and practical utility under Section 101 properly applied[26] and, if claimed so broadly to block the wide variety of treatments and vaccines developed during the pandemic, the claims would have been invalid under Section 112. In other words, even if the COVID genome were eligible subject matter, the patent statute would have prevented any patent from issuing that would have had any impact on the remarkable innovation that led to treatment options.

In closing, the current Supreme Court test for eligibility is ambiguous and flawed. An unclear test does not support a stable IP landscape necessary for tomorrow's diagnostics and cures. PERA would provide this clarity.

I commend you and your staff for your continued efforts on this legislation. The Patent Eligibility Restoration Act will eliminate judiciary exceptions and provide clearer guidance on patent eligibility. This is especially true in areas of medical diagnostics, biotechnology, and personalized medicine. I urge the Committee to report this important legislation to the full Senate for a vote this congressional session and welcome the opportunity to assist you in any way.

Thank you

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[23] *Athena Diagnostics* at 1333.

[24] *Athena Diagnostics* at 1359, 1373 (O'Malley dissenting from denial of reh'g en banc) "Had the Supreme Court not disregarded Congress's wishes for a second time, perhaps the outcome in this case would be different." See also Moore, J., dissenting from denial of reh'g en banc).

[25] Stakeholder letter, *supra* note 4.

[26] See, *e.g.,*, In re Fisher, 421 F.3d 1365, 1375 (Fed. Cir. 2005) rejecting a claim to DNA fragments for a variety of non-specific uses in research, including as a research intermediate to discover useful inventions.