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The Patent Eligibility Restoration Act

Written Testimony of  
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## I. INTRODUCTION

Thank you for inviting me to provide testimony on patent eligibility and the draft Patent Eligibility Restoration Act (“PERA”), particularly as it pertains to life sciences technologies. I am a registered patent attorney and have been representing chemical, biotech, and pharmaceutical clients before the USPTO for over 30 years. My client base has included individual inventors, very small companies, universities and university technology transfer arms, government agencies and their technology transfer arms, companies in the food and nutritional products space, and medium and large pharmaceutical companies. I am a partner at Foley & Lardner LLP and a Vice Chair of Foley’s Intellectual Property Department, but my testimony is based on my personal opinions, and should not be understood to reflect the views of Foley & Lardner LLP, its partners, or its clients.

I started my career in the patent field as a registered patent agent at Foley, and then attended law school at what is now the Antonin Scalia Law School. I graduated with highest honors as valedictorian of the class of 1999, and then left Foley to clerk for The Honorable Alvin A. Schall on the U.S. Court of Appeals for the Federal Circuit for two years. After my clerkship ended, I returned to Foley where I have worked ever since.

Early in my career I took an interest in policies behind specific patent laws and their impact on stakeholders. I have developed a reputation as a thought leader through writing, speaking, and serving in leadership roles in various patent-related organizations, including the Intellectual Property Owners Association<sup>1</sup> and the PTAB Bar Association.<sup>2</sup> Much of my writing—including writing on patent eligibility issues—can be found at [pharmapatentsblog.com](http://pharmapatentsblog.com).

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<sup>1</sup> The Intellectual Property Owners Association (“IPO”) is an international trade association representing diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property (IP) rights.

<sup>2</sup> The PTAB Bar Association was formed after the passage of the America Invents Act (“AIA”), and seeks to preserve and promote the highest professional and ethical standards among lawyers and stakeholders who appear before the USPTO’s Patent Trial and Appeal Board (the “PTAB”).

I have reviewed the written testimony provided for the June 4, 2019, U.S. Senate Subcommittee on Intellectual Property hearing on The State of Patent Eligibility in America. I agree with many of the views expressed in the testimony of The Honorable Paul R. Michel, The Honorable Q. Todd Dickinson, The Honorable David J. Kappos, and Ms. Sherry M. Knowles, Esq., and share many of the concerns expressed by others, including Professor Jeffrey A. Lefstin, Professor David O. Taylor, and Professor Adam Mossoff. Indeed, going on five years later, many of the concerns they expressed persist and have been exacerbated by inconsistent and unpredictable applications of the judicial exceptions to Section 101 of the Patent Act (“§ 101”) since then. Rather than repeat information that already has been well-stated, in my written testimony below I try to provide additional insight based on my perspective as a patent practitioner in the trenches of helping clients obtain, enforce, and evaluate patents in the life sciences space.

I appreciate your ongoing concern for the confusion surrounding the current state of U.S. patent-eligibility, and your continued efforts to address the inconsistent manner in which recent court decisions are being applied on a case-by-case basis. I think PERA would go a long way towards restoring not only patent-eligibility, but also predictability and confidence in patent rights that can better foster investment in innovations in life sciences technologies.

## II. BACKGROUND

When I first started practicing in the early 1990s, 35 U.S.C. § 101 was an issue clients rarely faced, but might encounter if they were trying to patent methods of treating cancer. USPTO Examiners would question the “utility” of such methods, because in those days the ability to treat cancer was considered to be nearly incredible. As a person and a practitioner, I am grateful the ability to treat cancer has come so far that utility-type § 101 issues now are rare. Many types of cancers *are* treatable, and researchers continue to develop and patent new ways of treating cancer that promise to help even more patients. As a practitioner, though, it has been frustrating to see the rise in “patent eligibility” type § 101 issues, and the expansion of judicial exceptions to ensnare increasingly more types of inventions in surprising and unpredictable ways.

The “patent eligibility” requirement of § 101 was *not* an issue life sciences clients typically faced before the Supreme Court 2012 and 2013 decisions in *Mayo*<sup>3</sup> and *Myriad*.<sup>4</sup> For example, until the *Myriad* decision, inventors who had discovered, isolated, identified, characterized, and determined the usefulness of a product “found in nature” could obtain a patent on an isolated or purified form of the product. The Supreme Court’s *Myriad* decision invalidated thousands of granted patents, and has made it difficult to obtain patents on products that are derived from nature, even if considerable ingenuity and effort is required to identify and characterize the product and its usefulness. Judges applying *Myriad* expansively often cite the Supreme Court’s unfortunate statement that “Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry.”<sup>5</sup> Restoring the patent eligibility of such discoveries as long as they have a specific and practical utility (as I understand PERA would) would restore U.S. patent eligibility to a more predictable state, which would permit innovators to answer the question “can I patent this?” with more certainty, and thus invest in their innovations with more confidence.

The Supreme Court took care in *Myriad* to state that its decision did not implicate the ability to patent “new applications of knowledge” about naturally-occurring products,<sup>6</sup> but any comfort innovators took in that guidance was eviscerated when the Court refused to review the Federal Circuit decision in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*<sup>7</sup> The method at issue in *Sequenom* permitted diagnosis of certain fetal characteristics via maternal blood tests instead of invasive and dangerous amniocentesis procedures, but the court held that because the method “begins and ends with a natural phenomenon” (the presence of paternal DNA in maternal serum), it was not eligible for patenting.<sup>8</sup> That decision has come to stand for the principle that many

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<sup>3</sup> *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012).

<sup>4</sup> *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

<sup>5</sup> 569 U.S. at 591.

<sup>6</sup> *Id.* at 596.

<sup>7</sup> 788 F.3d 1371 (Fed. Cir. 2015).

<sup>8</sup> *Id.* at 1376.

diagnostic methods cannot be patented because they pertain to so-called “natural phenomenon.”<sup>9</sup> Thus, even when a diagnostic method reflects a “new application of knowledge,” it may be found ineligible for a U.S. patent. In the wake of *Mayo* and *Sequenom*, many clients no longer pursue U.S. patents on their diagnostic discoveries, and some have decided to focus their research and development resources in other countries where such technologies still can be patented.

Judge Lourie of the U.S. Court of Appeals for the Federal Circuit has written several concurring opinions expressing his frustration with the state of the law pertaining to diagnostic methods under *Mayo* that I commend to your attention.<sup>10</sup> Judge Lourie stated that if he “could write on a clean slate,” the only exception to patent eligibility pertaining to “natural laws” would be “claims directed to the natural law itself, e.g. ,  $E=mc^2$ ,  $F=ma$ , Boyle's Law, Maxwell's Equations, etc.”<sup>11</sup> He “would not exclude uses or detection of natural laws.”<sup>12</sup> As I understand it, PERA would be consistent with Judge Lourie’s proposal, and would restore patent eligibility of most diagnostic methods. I think that would encourage U.S. investment in this space, and ultimately promote development of new groundbreaking and innovative diagnostic methods.

As Judge Lourie noted, even when subject matter is *eligible* for patenting under § 101, “[t]he laws of anticipation, obviousness, indefiniteness, and written description provide other filters to determine what is *patentable*.”<sup>13</sup> Thus, for example, concerns about broad claims that

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<sup>9</sup> See, e.g., *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333 (Fed. Cir. 2019) (Lourie, J., concurring).

<sup>10</sup> *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1335-36 (Fed. Cir. 2019) (Lourie, J., concurring); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1284-87 (Fed. Cir. 2015) (Lourie, J., concurring).

<sup>11</sup> *Athena Diagnostics*, 927 F.3d at 1335.

<sup>12</sup> *Id.*

<sup>13</sup> *Athena Diagnostics*, 927 F.3d at 1335 (emphasis added).

courts have been addressing under the “abstract idea” exception,<sup>14</sup> could be addressed by the requirements for novelty, non-obviousness, written description, enablement, and definiteness.

### III. INTERNATIONAL DISHARMONY AND QUID PRO QUO IMBALANCES

Although the U.S. is considered a leader on the global stage, it is noteworthy that other countries have not followed the U.S. very far down this road of patent ineligibility. Isolated and purified forms of naturally-occurring products remain eligible for patenting everywhere else in the world, although some countries have specific exceptions for isolated genes.<sup>15</sup> For example, the European Patent Office permits patenting of isolated genes and gene fragments as long as the patent’s description “indicate[s] the way in which the invention is capable of exploitation in industry.”<sup>16</sup> Likewise, Australia, China, Japan, and Korea (for example) continue to grant patents on isolated natural products. Most countries permit patenting of diagnostic methods unless they are excepted on public policy grounds. For example, the European Patent Office permits patenting of diagnostic methods as long as they are not “practised on the human or animal body,”<sup>17</sup> and so permits patenting of diagnostic methods conducted using saliva or blood samples (for example). Australia permits patenting of diagnostic methods without restriction (similar to the U.S. prior to *Mayo*), and methods of detecting specific markers of a disease or condition in a biological sample

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<sup>14</sup> See, e.g., *Am. Axle & Mfg. v. Neapco Holdings*, 967 F.3d 1285 (Fed. Cir. 2020); *PureCircle U.S. v. SweeGen, Inc.*, No. 2022-1946 (Fed. Cir. Jan. 2, 2024).

<sup>15</sup> See, e.g., IP Australia, “What biological inventions can be patented?,” <https://www.ipaustralia.gov.au/patents/what-are-patents/what-biological-inventions-can-be-patented> (noting that isolated microorganisms and isolated proteins can be patented in Australia, but “[p]atents aren't available for gene sequences.”) (accessed Jan. 13, 2024).

<sup>16</sup> European Patent Office, “Guidelines for Examination in the European Patent Office,” Part G (Patentability), Section III (Industrial application), part 4 (Sequences and partial sequences of genes), [https://www.epo.org/en/legal/guidelines-epc/2023/g\\_iii\\_4.html](https://www.epo.org/en/legal/guidelines-epc/2023/g_iii_4.html) (accessed Jan. 13, 2024).

<sup>17</sup> European Patent Office, “Guidelines for Examination in the European Patent Office,” Part G (Patentability), Section II (Inventions), part 4 (Exceptions to patentability), [https://www.epo.org/en/legal/guidelines-epc/2023/g\\_ii\\_4\\_2.html](https://www.epo.org/en/legal/guidelines-epc/2023/g_ii_4_2.html) (accessed Jan. 13, 2024).

may be patented in China, Japan, and Korea (although methods of “diagnosing” a patient are excepted on public policy grounds).

This means that, since the changes in U.S. patent eligibility law flowing from *Mayo*, *Myriad*, and *Alice*,<sup>18</sup> there are inventions that cannot be patented in the U.S. that can be patented in other countries. For example, as outlined above, isolated natural products that may be useful as medications, diagnostic agents, vaccines, antibiotics, or in industrial applications, can be patented around the world, except in the U.S. This leads to an imbalance in intellectual property rights that can be obtained in the U.S. versus elsewhere.

Regardless of where you seek to obtain a patent, you have to describe your invention in your patent application in a level of detail sufficient for others to practice the invention. This means that inventors who pursue patent protection have to disclose their inventions to the whole world, but cannot protect them to the same extent in the U.S. if they are caught in the § 101 snares of *Mayo*, *Myriad*, and *Alice*. This imbalance may cause innovators to think twice before pursuing a patent. If they do not expect to be able to adequately protect their investments, they may decide to maintain the technology as a trade secret, or shelve it altogether.

The imbalance in the “*quid pro quo*” of disclosure in return for patent rights<sup>19</sup> is particularly acute for technologies related to isolated microorganisms, such as bacteria determined to have specific properties that make them particularly useful in commercial and industrial processes. (A few examples include bacteria used in brewing, baking, cheese- and yogurt-making, oil- and plastic-degrading bacteria used for environmental remediation, and carbon-fixing microbes used to address CO<sub>2</sub> emissions.) In order to satisfy the 35 U.S.C. § 112 “written description” requirement for obtaining a patent relating to a newly discovered microorganism that is not readily available to the public, the patent applicant must “deposit” a sample of the bacteria with a qualified

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<sup>18</sup> *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014).

<sup>19</sup> This *quid pro quo* was recently discussed by the Supreme Court in *Amgen Inc. v. Sanofi*, 143 S. Ct. 1243 (2023).

depository—such as the American Type Culture Collection (ATCC) in Gaithersburg, Maryland.<sup>20</sup> The patent applicant also must assure that “all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.”<sup>21</sup>

Prior to *Myriad*, isolated bacteria were included in patent-eligible subject matter. Thus, even though members of the public could obtain a sample of the bacteria once a patent granted, the public’s freedom to use the bacteria often was limited by patent rights that covered any and all uses of the isolated bacteria. Under *Myriad*, however, it is no longer possible to obtain a patent on isolated bacteria *per se*. That means that a U.S. patent granted today might only cover a specific method of using the bacteria. Nevertheless, the patent owner still must irrevocably remove “all restrictions ... on the availability to the public of the deposited material” once the patent grants.<sup>22</sup> This is another imbalance that has arisen in the wake of *Mayo*, *Myriad*, and *Alice* that may cause innovators to hesitate before pursuing a U.S. patent or developing technology for the U.S. market.

#### IV. EVOLVING AND INCONSISTENT COURT DECISIONS CREATE UNTENABLE UNPREDICTABILITY AND UNCERTAINTY

The “Findings” section of the current draft of PERA notes “extensive confusion and a lack of consistency” in how courts are applying the judicial exceptions to § 101. I agree. This confusion and inconsistency makes it difficult to counsel clients on whether or how a given innovation can be patented in the U.S. It also makes it difficult to assess the value of patent portfolios for corporate valuations or transactions, since that depends on the validity of the constituent patents.

Perhaps because courts are applying *judicial* exceptions, judges seem more willing to extrapolate a prior decision to the case at hand, and recent years have seen expansion of the scope

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<sup>20</sup> 37 C.F.R. § 1.801, *et seq.*

<sup>21</sup> 37 C.F.R. § 1.808.

<sup>22</sup> *See, e.g.*, World Intellectual Property Organization, “Guide to the Deposit of Microorganisms under the Budapest Treaty,” 2015, <https://cil.nus.edu.sg/wp-content/uploads/2015/12/Ses5-14.-Guide-to-the-Deposit-of-Microorganisms-under-the-Budapest-Treaty-2015.pdf> (accessed Jan. 13, 2024).

of the judicial exceptions to an extent that does not occur with the statutory requirements for patentability (e.g., §§ 102, 103, and 112). Practitioners aware of the latest district court decisions still face uncertainty surrounding whether and when the decision will be appealed, whether it will be upheld by the Federal Circuit, and if the Supreme Court will take it up for review. This uncertainty can extend for years, during which it is difficult to predict whether or how the reasoning of the original decision may be applied to other claims.

The USPTO provides guidance to patent examiners based on precedential court decisions,<sup>23</sup> but there is an inevitable lag between a new court decision and the USPTO's implementation of updated guidance. (The most recent court decisions cited in current USPTO guidance for examiners are from 2019).<sup>24</sup> This means that patents may be examined and granted under a standard that is inconsistent with the latest judicial pronouncement on patent eligibility.

For example, in May 2016 the USPTO issued patent eligibility guidance under *Mayo* with specific examples for life sciences technologies. Example 29 pertained to the diagnosis and treatment of the fictional condition “Julitis.” The following claim was said to be *eligible* for patenting under *Mayo*, because the claimed steps “do not recite or describe any recognized [judicial] exception.”<sup>25</sup>

1. A method of detecting JUL-1 in a patient, said method comprising:
  - a. obtaining a plasma sample from a human patient; and
  - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

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<sup>23</sup> See, e.g., USPTO, “Subject Matter Eligibility,” <https://www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility> (accessed Jan. 15, 2024).

<sup>24</sup> USPTO, Manual of Patent Examining Procedure § 2106, <https://www.uspto.gov/web/offices/pac/mpep/s2106.html> (accessed Jan. 15, 2024).

<sup>25</sup> USPTO, “2014 USPTO Subject Matter Eligibility Examples: Life Sciences,” at 9, 11, available at <https://www.bitlaw.com/source/pto/examples/May-2016-Examples.pdf> (accessed Jan, 15, 2024).

This guidance effectively instructed USPTO examiners to *not* reject such claims under § 101, which means claims directed to methods of detecting newly identified disease markers continued to be granted after *Mayo*.

But that USTPO guidance was inconsistent with the Federal Circuit’s 2015 decision in *Sequenom* (discussed above),<sup>26</sup> where the court held the following claim ineligible under the “natural phenomenon” judicial exception:

1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

Like the claim at issue in the USPTO example, the claim at issue in *Sequenom* recited a physical method that included detecting the presence of a substance in a sample. In both cases, both the discovery of the potential existence of the substance in the sample and the clinical significance of its presence were contributions of the invention that were not known in the prior art. Yet, the court held the *Sequenom* claim ineligible for a patent because the claim encompassed the use of conventional laboratory techniques to detect the “natural phenomenon.”

The fact that even the USPTO did not predict how *Mayo* would be applied to methods of detecting newly identified disease markers underscores the high level of uncertainty in the application of judicial exceptions to § 101. This uncertainty is exacerbated by jurisprudence that supports parsing claims into individual elements that are each evaluated on a stand-alone-basis and/or determining the “gist” of a claim and assessing eligibility on that basis. I think it is important that PERA expressly prohibits such an approach, by requiring in PERA § 101(c) that eligibility be determined “by considering the claimed invention as a whole” and “without regard to ... whether a claim element is known, conventional, routine, or naturally occurring.”

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<sup>26</sup> The Supreme Court denied *certiorari* in *Sequenom* in June 21016, after the USPTO’s May 2016 guidance was promulgated.

The Federal Circuit’s 2021 decision in *Yu v. Apple Inc.*<sup>27</sup> is emblematic of the ongoing problem of the unexpected manner in which courts continue to apply and expand the judicial exceptions. The claims at issue in *Yu* were directed to a digital camera that included a number of structural elements, including sensors, lenses, and circuitry:

1. An improved digital camera comprising:

a first and second image sensor closely positioned with respect to a common plane, said second image sensor sensitive to a full region of visible color spectrum;

two lenses, each being mounted in front of one of said two image sensors;

said first image sensor producing a first image and said second image sensor producing a second image;

an analog-to-digital converting circuitry coupled to said first and said second image sensor and digitizing said first and said second intensity images to produce correspondingly a first digital image and a second digital image;

an image memory, coupled to said analog-to-digital converting circuitry, for storing said first digital image and said second digital image; and

a digital image processor, coupled to said image memory and receiving said first digital image and said second digital image, producing a resultant digital image from said first digital image enhanced with said second digital image.

Nevertheless, the court held the claims invalid as being directed to “*the abstract idea* of taking two pictures ... and using one picture to enhance the other in some way.”<sup>28</sup> Although the court cited *Alice* for the proposition that claiming a “tangible system” is “not dispositive” under § 101,<sup>29</sup> practitioners, commentators and scholars alike saw *Yu* as expanding the judicial exception.<sup>30</sup>

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<sup>27</sup> 1 F.4th 1040 (Fed. Cir. 2021).

<sup>28</sup> *Id.* at 1043 (emphasis added).

<sup>29</sup> *Id.* at 1044, n.2.

<sup>30</sup> See, e.g., Pool, Seven Words You Can Never Say to the USPTO, 102 J. PAT. & TRADEMARK OFF. SOC'y 266 (2022); Kumaresan, *Yu v. Apple – The Abstract Idea Conundrum: It’s Time to Either Adopt the Dictionary Definitions or Abandon the Unworkable Abstract Idea Doctrine*, 56 UIC L. Rev. 301 (2023); Borella, “*Yu v. Apple* (Fed. Cir. 2021),” Patent Docs, June 13, 2021, <https://www.patentdocs.org/2021/06/you-v-apple-fed-cir-2021.html> (accessed Jan. 15, 2024); Quinn, “*Yu v. Apple* Settles It: The CAFC is Suffering from a Prolonged Version of *Alice* in Wonderland Syndrome,” IPWatchdog, June

*Yu* was not the first time the Federal Circuit had been asked to consider patent-eligibility of a device. A year earlier in *Cardionet, LLC v. Infobionic, Inc.*<sup>31</sup> the Federal Circuit **upheld** claims directed to “a device for detecting and reporting the presence of atrial fibrillation or atrial flutter in a patient,” which was claimed as follows:

1. A device, comprising:

a beat detector to identify a beat-to-beat timing of cardiac activity;

a ventricular beat detector to identify ventricular beats in the cardiac activity;

variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats;

relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to at least one of atrial fibrillation and atrial flutter ; and

an event generator to generate an event when the variability in the beat-to-beat timing is identified as relevant to the at least one of atrial fibrillation and atrial flutter in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector.

The district court had found the claims to be ineligible as directed to “the abstract idea that atrial fibrillation and atrial flutter can be distinguished by focusing on the variability of the irregular heartbeat.”<sup>32</sup> But the Federal Circuit determined that, “[w]hen read as a whole, and in light of the written description, we conclude that claim 1 ... is directed to an improved cardiac monitoring device and not to an abstract idea.”<sup>33</sup>

Considering *Yu* and *Cardionet* together highlights the difficulty of predicting how a given claim will be analyzed under § 101. Every useful invention has a purpose that could be described as an abstract idea by analogy to *Yu*, but most inventions can be claimed such that the subject

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20, 2021, <https://ipwatchdog.com/2021/06/20/yu-v-apple-settles-cafc-suffering-prolonged-version-alice-wonderland-syndrome/id=134765/> (accessed Jan. 15, 2024).

<sup>31</sup> 955 F.3d 1358 (Fed. Cir. 2020).

<sup>32</sup> *Id.* at 1366 (internal quotations omitted).

<sup>33</sup> *Id.* at 1368.

matter as a whole could be found eligible by analogy to *Cardionet*. How can patent owners and their competitors predict which approach will be taken? When the judicial exceptions are applied in an unpredictable manner, that means the validity of a patent—and the value of associated patent rights—also may be unpredictable. Such uncertainty undermines the ability of patents to encourage further investment in patented technologies.

I think PERA would go a long way towards addressing and resolving these problems with the current state of U.S. patent eligibility. By eliminating the judicial exceptions and requiring a statutory-based analysis limited to specific exceptions, PERA would provide a more predictable framework for evaluating patents under § 101. By requiring eligibility to be determined “by considering the claimed invention as a whole” and “without regard to ... whether a claim element is known, conventional, routine, or naturally occurring,” I would expect PERA to reduce uncertainty regarding the types of inventions that can be patented. This in turn could stimulate more confident U.S. investment in life sciences technologies related to naturally-occurring products, diagnostic methods, and other innovations caught in the § 101 snares of *Mayo*, *Myriad*, and *Alice*.

## V. COMMENTS ON SPECIFIC PERA LANGUAGE

I have considered the current draft PERA language and generally agree that it should address concerns outlined in the “Findings” section, including reducing confusion and restoring consistency and predictability in the application of § 101.

One important issue that is not expressly addressed by the draft I have seen is the effective date. I think it will be important to make clear whether the PERA version of § 101 will apply immediately and retroactively to all U.S. patents and pending U.S. patent applications upon its date of enactment, or if it will have a more limited, forward-looking effect.

Turning to specific language:

- In Section 2 (Findings), paragraph 5(B) refers to “invention or discovery” while paragraph 5(D) refers only to “invention.” I suggest using the same phrase throughout. Since (35 U.S.C. § 100 states that "invention" means “invention or discovery” it could be sufficient to use “invention” throughout.
- In Section 3 (Patent Eligibility), in the amendments to § 100(b) shown below, what is meant by a “method of manufacture of a known or naturally-occurring process”?

(1) in section 100—

(A) in subsection (b), by striking “includes a new use of a known process” and inserting “includes a use, application, or method of manufacture **of** a known or naturally-occurring process”; and

Would the intended meaning be captured by replacing “of” with “using”?

- In added § 100(c)(1)(B)(ii), could mention of “natural phenomenon” be added to signal that case law regarding diagnostic methods (e.g., *Mayo* and its progeny) is being addressed?

“(ii) whether a claim element is known, conventional, routine, or naturally occurring;

## VI. CONCLUSION

Thank you again for your efforts to address the inconsistent manner in which § 101 is being applied on a case-by-case basis to technologies that were unquestionably eligible for patenting before 2012, and largely remain so today outside the U.S. As I have explained above, by restoring patent-eligibility of important life sciences technologies, I believe PERA also would restore predictability and increase confidence in patent rights to better foster investment in and commercialization of a wide variety of life sciences innovations in the U.S.