Mr. Johnson's Answers to
Questions for the Record from Senator Alex Padilla
Senate Judiciary Committee
"The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System"
Tuesday, January 23, 2024

Questions for Philip S. Johnson

1. ***What would be a concrete expected outcome for consumers should the Patent Eligibility Restoration Act (PERA) become law?***

Mr. Johnson's Answer to Question #1:

Consumers will be the ultimate beneficiaries of this reform, as they will benefit from the additional innovation that these changes spawn. Enhanced innovation will also benefit consumers through the creation of value-added products and/or existing products being made available at lower prices.

For an innovation to be accepted by the market it must deliver a comparable benefit at a lower cost, an increased benefit at an incremental cost that is commensurate with or less than the increased value conferred, or a combination of the two. Simply stated, consumers won't pay for a new product or service unless its value is better than the value of other alternatives available to them.

When an innovation is one that lowers the cost of previously available goods or services, the commercialization of the innovation will tend to drive down the cost of preexisting alternatives. When the innovation provides greater benefit at prices that are attractive relative to preexisting alternatives, competitors may be prompted to lower their prices for a time while they are spurred into making further improvements to their own products to maintain or increase their market shares. Accordingly, the relative cost of a product or service cannot be fairly assessed without also assessing its benefit to the consumer. Advanced synthetic motor oils, for example, may be priced at twice the price of conventional motor oil, but last four times longer. Despite an initial higher cost, the benefits they confer may make them cheaper to consumers. The same is true across all industries.

Consumers will also benefit from the U.S. jobs that will be created in R&D and manufacturing, and in the other activities that will be needed to meet worldwide demand.

Recognizing these economic principles, the most important issue is whether the applicable policies affecting innovations encourage or discourage them. An innovation that never occurs can neither improve the benefit conferred to the consumer nor force the lowering of prices for existing products. Jurisdictions whose policies fail to encourage and reward innovation tend to perpetuate stagnant industries that become vulnerable to disruption from foreign competition.

The passage of PERA will be an important step towards ensuring that the U.S. does not become such a jurisdiction.

2. What specific types of inventions would become newly eligible for a patent under PERA, that are currently not patentable?

Mr. Johnson's Answer to Question #2:

PERA does not expand the types of inventions that are eligible for patenting, but rather restores patent eligibility to the scope that existed from at least 1952 until the Supreme Court began restricting that scope in the series of its cases beginning about a decade ago, as discussed in my written testimony.[1]

Section 101 of the Patent Act of 1952, which continues to be the controlling patent eligibility statute, defines patent eligibility as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

As referenced in *Diamond v. Chakrabarty*, "[t]his . . . language was employed by P. J. Federico, a principal draftsman of the 1952 Act, in his testimony regarding that legislation: '[U]nder section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man . . . .'"[2]

Section 101 defines the scope of patentable subject matter in two important respects. First, it limits what could be patented to inventions and discoveries that are the result of human intervention. It accomplishes this aim by specifying that only an "invention or discovery" which is a "process, machine, manufacture or composition of matter" or "improvement thereof" may be "eligible for patenting." Section 101 also currently requires that the invention or discovery be "new," but as PERA's sponsors appropriately recognize, this novelty requirement is redundant of the Patent Act's Section 102 novelty requirement and has caused problems because courts have misconstrued it to inject *patentability* issues into *patent eligibility* determinations.

Section 101's second important function is to limit patent eligible subject matter only to inventions and discoveries that are "useful." Contrary to the suggestions of some, Section 101 has been very effective in this respect, and a robust body of administrative and judicial precedent has developed that has been the source of very little controversy. As interpreted and applied by

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[1] *See* "The Origin of the Current Patentability Problem," at pages 4-5 of Mr. Johnson's written testimony, citing *Bilski v. Kappos*, 561 U.S. 593 (2010); *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014); *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

[2] *Diamond v. Chakrabarty*, 447 U.S. 303, 309 n.6 (1980) (citing Hearings on H. R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951)).

the USPTO during patent examination, the "useful" eligibility requirement means that the patent application must include a credible assertion that the claimed invention or discovery has a "specific and substantial utility." The intention of this requirement is to ensure that to be patent eligible, the claimed invention or discovery must have an identified, practical utility. As the Court of Customs and Patent Appeals stated:

> Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.[3]

Enactment of PERA would eliminate the judicially-created exceptions that are now denying patentability to inventions and discoveries that have specific and practical utilities that are the products of human intervention.

3. Can you provide an example of a patent denied under the Alice/Mayo framework that best illustrates the concerns you've raised about the existing patent system?

Mr. Johnson's Answer to Question #3:

Unfortunately, there are now many examples where the confusion created by the Supreme Court has resulted in meritorious discoveries and inventions being held patent ineligible. Two prominent ones are addressed in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) ("[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry") and *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, 915 F.3d 743, 757 (Fed. Cir. 2019) (methods for diagnosing neurological disorders by detecting antibodies to a protein called muscle specific tyrosine kinase found ineligible for patenting).

The Federal Circuit continues to find patents covering medical diagnostics to be ineligible, as for example in *CareDx, Inc. v. Natera, Inc.*, 40 F.4th 1371, 1381 (Fed. Cir. 2022) (methods for predicting organ transplant rejection using cell-free DNA found ineligible for patenting). This worrying trend prompted one Circuit Judge to remark: "The majority's broad pronouncement of ineligibility of medical treatment that relates to human physiology not only contravenes precedent, but contravenes the national interest in achieving new methods of medical treatment with the assistance of the patent incentive."[4]

Expansion of the judicial exceptions to patentable subject matter more recently reached a new zenith when patents on car parts and cameras—technologies traditionally expected to benefit from patent protection—were deemed invalid.[5] In *American Axle*, the Federal Circuit concluded that a method making an automotive driveshaft was patent ineligible because some of its

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[3] *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980).
[4] *INO Therapeutics v. Praxair Distrib. Inc.*, 782 F. App'x 1001, 1017 (Fed. Cir. 2019) (Newman, J., dissenting).
[5] *Am. Axle*, 967 F.3d at 1306 (Moore, J., dissenting) ("The majority's holding that these claims to manufacturing an automotive drive shaft are ineligible has sent shock waves through the patent community."); *Yu v. Apple Inc.*, 1 F.4th 1040, 1046 (Fed. Cir. 2021) (Newman, J., dissenting) ("This camera is a mechanical and electronic device of defined structure and mechanism; it is not an 'abstract idea.'").

components were tuned using Hook's law, even though the claim at issue made no mention thereof.[6] As Chief Judge Moore wrote in her dissent:[7]

> I cannot fathom the confusion that will be caused by declaring that claims are ineligible as directed to a natural law, when it is clear to all involved that this patent does not recite any particular natural law. Every mechanical invention must apply the laws of physics—that does not render them all ineligible, or maybe it does now.

In *Yu v. Apple Inc.*, 1 F.4th 1040 (Fed. Cir. 2021) the Federal Circuit declared the involved patent on a dual image digital camera to be unpatentable, notwithstanding the fact that no "law of nature," "natural phenomenon" or "abstract idea," was claimed. The case demonstrates how current Supreme Court precedent invites confusing patent eligibility (a section 101 issue) with novelty (a section 102 patentability requirement). As Judge Newman wrote in dissent,[8]

> In the current state of Section 101 jurisprudence, inconsistency and unpredictability of adjudication have destabilized technologic development in important fields of commerce. Although today's Section 101 uncertainties have arisen primarily in the biological and computer-implemented technologies, all fields are affected. The case before us enlarges this instability in all fields, for the court holds that the question of whether the components of a new device are well-known and conventional affects Section 101 eligibility, without reaching the patentability criteria of novelty and nonobviousness.
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> The digital camera described and claimed in the '289 patent is a mechanical/electronic device that easily fits the standard subject matter eligibility criteria. Neither the panel majority nor the district court decided patentability under Section 102 or Section 103, having eliminated the claims under Section 101. The '289 claims warrant review under the substantive criteria of patentability—a review that they have never received.

Judicially-created exceptions to statutorily-defined patent eligible subject matter such as those represented by the above-cited cases are inappropriate because our Constitution vests the responsibility for defining the scope of what subject matter may be patented in Congress alone.[9] Congress fulfilled this responsibility when it enacted 35 U.S.C. § 101, and has not ceded authority to the Supreme Court to re-write this definition or create whatever exceptions to it the Court might wish. Not only has the Supreme Court created such exceptions, but experience has

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[6] Claim 22 of the patent held patent ineligible in *American Axle* read:

> 22. A method for manufacturing a shaft assembly of a driveline system, the driveline system further including a first driveline component and a second driveline component, the shaft assembly being adapted to transmit torque between the first driveline component and the second driveline component, the method comprising: providing a hollow shaft member; tuning a mass and a stiffness of at least one liner, and inserting the at least one liner into the shaft member; wherein the at least one liner is a tuned resistive absorber for attenuating shell mode vibrations and wherein the at least one liner is a tuned reactive absorber for attenuating bending mode vibrations.

[7] *Am. Axle & Mfg. v. Neapco Holdings*, 967 F.3d 1285, 1318 (Fed. Cir. 2020)

[8] *Yu v. Apple Inc.*, 1 F.4th 1040 at 1046 (Fed. Cir. 2021)

[9] U.S. Constitution Article I, Section 8, Clause 8 provides that "The Congress shall have the Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."

shown that it was ill-suited to the task. As the Supreme Court itself recognized in its *Alice* decision:

> At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. At some level, "all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept.[10]

Yet the courts have not "tread carefully." And while the Supreme Court's exclusionary principles have not yet "swallow[ed] all of patent law," they have expanded them to the point that no one in the IP profession can now predict with certainty whether any given invention that relies in any way upon a law of nature, natural phenomenon, or abstract idea, or utilizes a naturally derived material, will be ultimately held patent eligible.[11] Such amorphous and undefinable criteria have no place in our patent system.

4. How does the current state of the law impact smaller innovators and academic research?

Mr. Johnson's Answer to Question #4:

The current state of patent eligibility law has injected enormous uncertainty and unpredictability into whether inventions in many important fields will ultimately be held to be patent eligible. While there is a degree of risk in all R&D, that risk is much greater when the research is transformational rather than incremental. Because transformational research is more basic, under the current law it is much more likely to be found patent ineligible as being "abstract," directed to a "law of nature," or claiming a "natural phenomenon."

As an emeritus board member with nearly 50 years of experience with the Monell Chemical Senses Center, a non-profit basic research institute that conducts research relating to the senses of taste and smell, I have witnessed a dramatic increase in the difficulty of translating basic research insights into commercial products. As prior Subcommittee witnesses who are also involved in early-stage research have explained, the availability of reliable patent protection is essential to the invention and development of fundamental breakthroughs. Patents are needed to justify the formation of startups, to attract venture capital, and/or to license development partners to do the work needed to commercialize the invention. As Peter O'Neill, Executive Director of Cleveland Clinic Innovations, testified to this Subcommittee:

> At Cleveland Clinic Innovations, we have an established process to assess inventions, based on their likelihood to be able to be developed into commercial products. Ability to get protectable intellectual property (usually in the form of a patent) is the first, and most

[10] *Alice*, 573 U.S. at 217 (citing *Mayo*, 566 U.S. at 71.

[11] *The State of Patent Eligibility in America: Part I Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. (June 4, 2019) (live testimony of Paul R. Michel, Former Chief Judge, United States Court of Appeals for the Federal Circuit) (stating, at 00:21:40 to 00:22:13: "The most fundamental problem . . . is unpredictability. I spent 22 years on the Federal Circuit and 9 years since dealing with patent cases, and I cannot predict in a given case whether eligibility will be found or not found. If I can't do it, how can bankers, venture capitalists, business executives, and all the other players in the system make reliable predictions and sensible decisions?").

> influential factor in our assessment. If an invention can't get intellectual property protection, usually that is a fatal flaw and the invention is abandoned at the point."[12]

As I have seen and we also have heard, if patent protection is not reliably available, further R&D won't happen and nothing will be commercialized to the detriment of those who could have benefited from it. Patents are needed to justify the formation of startups, to attract venture capital, and/or to license development partners to do the work needed to commercialize the invention.

5. The Courts and the U.S. Patent Office have had 10 years to develop the Alice/Mayo caselaw and guidance for the innovation ecosystem. PERA introduces new terms and standards that would have to be newly interpreted by the Courts. How long do you think it would take the Courts and the Patent Office to bring certainty to the application of the new Section 101, should PERA become law? Can you explain why a potential new period of uncertainty would be more attractive than the current status quo?

Mr. Johnson's Answer to Question #5:

21C does not view PERA as introducing new terms and standards that would need to be interpreted by the courts. It instead would take us back to the eligibility standards with which practitioners were familiar during the first 60 years after the advent of the 1952 Patent Act. Take for example Section 100(k), which sets forth an explicit definition of the term "useful" as it is used in Section 101:

> (k) The term "useful" means, with respect to an invention or discovery, that the invention or discovery has a specific and practical utility from the perspective of a person of ordinary skill in the art to which the invention or discovery pertains.

It has long been recognized that to meet Section 101's requirement, patent eligible subject matter must be "useful." This utility requirement derives from the Constitution, which authorizes Congress to provide exclusive rights to inventors for their inventions and discoveries which advance the progress of the "useful arts." In determining whether a claimed invention is "useful" within the meaning of Section 101 the USPTO and the courts have long required patent applications to disclose "specific and substantial" utilities for the inventions claimed. As the Court of Customs and Patent Appeals stated forty-two years ago:

> Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.[13]

By requiring that for an invention or discovery to be "useful" it must provide "a specific and practical utility" this definition conforms both with existing judicial precedent and the USPTO's

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[12] Written Testimony of Peter O'Neill, Executive Director of Cleveland Clinic Innovations, to the Subcommittee on Intellectual Property of the Senate Judiciary Committee, June 11, 2019, at pg. 3, accessible at

[13] *Nelson v. Bowler*, 626 F.2d 853 (C.C.P.A. 1980).

guidance on utility that has long been applied for examining patent applications under Section 101.[14]

By further specifying that the specific and practical utility is one that is to be viewed "from the perspective of a person of ordinary skill in the art to which the invention or discovery pertains" the definition makes explicit what was previously implicit in Section 101, as 35 U.S.C. § 112 already requires that the disclosures of patents are to be understood and construed according to this standard.[15]

As explained in my written testimony, the change to Subsection 101(a) does not expand the traditional eligibility standard. The proposed amendment of Subsection 101(a) (shown in redline) removes the word "new" from the current text to avoid overlap with Section 102's novelty standard for patentability and references new subsection (b) to codify the traditional limits of eligibility, as follows:

> (a) Whoever invents or discovers any ~~new and~~ useful process, machine, manufacture, or composition of matter, or any ~~new and~~ useful improvement thereof, may obtain a patent therefor, subject only to the exclusions in subsection (b) and to the further conditions and requirements of this title.

As exemplified by the digital camera case discussed above, the term "new" as previously used in this subsection has caused considerable confusion, inappropriately injecting the patentability criterion of novelty, which is extensively defined in Section 102, into patent eligibility determinations which should have nothing to do with novelty. It is also appropriate to reference that this subsection is subject only to the exclusions in subsection (b).

As explained in my written testimony, the Eligibility Exclusions of Subsection 101(b) have been added to PERA to reassure its critics that items that never would have been eligible for patenting under prior to the recent Supreme Court's activity will still be ineligible for patenting. Subsection 101(b) codifies five eligibility exclusions.

Subparagraph (b)(1)(A) appropriately excludes a "mathematical formula that is not part of a claimed invention in a category described in subsection (a)." This exclusion is appropriate, as a standalone formula is merely an idea, not a useful process, machine, manufacture, or composition of matter.

Clause (b)(1)(B)(i) excludes, subject to the limitations of clause (b)(1)(B)(ii), "a process that is substantially economic, financial, business, social, cultural, or artistic, even though not less than 1 step in the process refers to a machine or manufacture." This exclusion appears intended to respond to critics' claims that certain ideas or forms of human expression are not proper subjects for patenting. By specifying that such activities are excluded "even though not less than 1 step in the process refers to a machine or manufacture" this exclusion responds to critics' contentions

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[14] *See* Manual of Patent Examining Procedure § 2107, pt. II.

[15] 35 U.S.C. § 112(a) provides that a patent "specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . ."

that economic, financial, and business ideas and that purely social, cultural, or artistic expressions, such as marriage proposals, athletic or dance moves, and the like, shouldn't become patentable eligible simply by directing to "do it on a computer."

21C agrees that standalone economic, financial, and business ideas, without more, should not be patent eligible, as they are not inventions. 21C is unaware of any successful efforts to patent marriage proposals, athletic performances (such as football plays), or dance moves *per se*, but agrees that social, cultural, or artistic forms of human expression (whether or not otherwise protectable by copyright) should not be patent eligible.

21C suggests that there is an opportunity to improve the language of clause (b)(1)(B)(i). This clause might better be worded to exclude "a process that is nothing more than an economic, financial or business idea, or a social, cultural or artistic form of human expression, even if that process as claimed refers to a non-essential use of a machine or manufacture." By adding Clause (b)(1)(B)(ii), stating that "[t]he process described in clause (i) shall not be excluded from eligibility for a patent if the process cannot practically be performed without the use of a machine or manufacture," the exclusion of clause (i) is limited to exclude situations where the referenced machine or manufacture is essential to the practical performance of the claimed process. 21C agrees with this proviso.

Subparagraph (b)(1)(C) excludes from patent eligibility "a mental process performed solely in the human mind" and a process that "occurs in nature wholly independent of, and prior to, any human activity." These categories of subject never were and still won't be patent eligible under PERA.

Subparagraphs (b)(1)(D) and (b)(1)(E) respectively exclude from patent eligibility "[a]n unmodified human gene, as that gene exists in the human body," and "[a]n unmodified natural material, as that material exists in nature." Recitation of these exclusions has been made necessary by repeated but unjustified criticisms that "someone could patent your genes," even though that was never the case. The practical effects of these subparagraphs will be to codify that naturally occurring materials and compositions as they exist in nature, including human genes, will remain patent ineligible. In particular, and in contrast to the assertions of the ACLU and others, the Proposal would not "authorize patenting products and laws of nature, abstract ideas, and other general fields of knowledge," nor would it "permit patenting of human genes and naturally-occurring associations between genes and diseases." These would remain patent ineligible because they are not "inventions or discoveries," are not the result of any "human activity," and do not provide any "specific and practical utility" to a claimed invention or discovery. Genes as they exist in the human body and unmodified natural materials as they exist in nature are not inventions and never were eligible for patenting. Nonetheless, to allay any lingering public concerns, 21C supports inclusion of these subparagraphs.

Paragraph 101(b)(2) appropriately conditions that the human gene or natural material referenced in subparagraphs (b)(1)(D) and (b)(1)(E) "shall not be considered to be unmodified if the gene or material, as applicable, is . . . (A) isolated, purified, enriched, or otherwise altered by human activity; or (B) otherwise employed in a useful invention or discovery."

These conditions are entirely appropriate and strongly supported by 21C. These conditions do not alter patent eligibility as it was traditionally applied to isolated, purified, enriched, or otherwise altered natural materials and/or those that were used in a useful invention or discovery. The touchstone of patent eligibility in these situations is that human activity was required to achieve the claimed inventions or discoveries and the referenced materials are facilitating a specific and practical utility that is different from those that these materials play in nature.

Life sciences inventions in the diagnostics area should qualify as patent eligible because they are the result of human activity and do have a specific and practical utility in the field of medicine. Isolated, purified, or modified compositions *per se* may not be patent eligible if they have no known utilities, but may be incorporated as claimed elements in methods or compositions that constitute discoveries or inventions which, when viewed as a whole, are the result of human activity and do facilitate the invention's specific and practical utility.[16] Inclusion of these conditions in PERA is thus critical to the protection of inventions in the field of personalized medicine, diagnostics, and therapeutics, as well as in many other fields whose inventions rely on uses of naturally occurring starting materials.

Subparagraph 101(c)(1)(A) expressly forbids the recent court practice of discounting or disregarding certain claim limitations when determining patent eligibility, restoring the time-honored rule that all claim limitations must be considered and credited when considering the claimed invention as a whole. This provision remains of critical importance in view of the Supreme Court's demonstrated propensity for discounting important claim elements.

Subparagraph 101(c)(1)(B) expressly forbids determining eligibility by reference to "(i) the manner in which the claimed invention was made; (ii) whether a claim element is known, conventional, routine, or naturally occurring; (iii) the state of the applicable art, as of the date on which the claimed invention is invented; or (iv) any other consideration in section 102, 103, or 112." While some of these considerations may be relevant to determinations of *patentability*, this subparagraph appropriately forbids them from being considered in connection with *patent eligibility*. This subparagraph should thus prevent the courts from repeating the mistakes they have made in the past by conflating these separate considerations.

21C agrees that courts should have the flexibility to consider patent eligibility motions at any time "when there are no genuine issues of material fact," as proposed in PERA's paragraph 101(c)(2), but suggests that the most effective way of doing so would be to reword this provision to read (with the additions and deletions being shown in redline):

> "(A) IN GENERAL.—In an action brought for infringement under this title, the court, at any time, may hear and decide a motion brought pursuant to Federal Rules of Civil Procedure Rule 56 to determine whether an invention or discovery that is a subject of the action is ineligible for a patent under this section, ~~including on motion of a party when there are no genuine issues of material fact~~.

[16] Other statutory limitations on patenting, such as those on patenting tax strategies and human organisms, will not be disturbed by PERA. *See* "AIA Oddities: Tax Strategy Patents and Human Organisms," IPWatchdog, September 12, 2013.

Motions under FRCP Rule 56 for summary judgment are expressly designed to facilitate the early disposition of cases, particularly in cases "when there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[17] Direct reference to Rule 56 is preferred over the original language in PERA because parties and the courts are familiar with the requirements and procedures relating to Rule 56 motions, and the law is well settled as to how such motions are to be handled and decided. Rule 56 practice itself would not be modified except to the extent that the courts are expressly authorized to hear such motion "at any time," which would allow motions seeking declarations of patent ineligibility to be brought very early in the case notwithstanding local rules or practice that might otherwise delay them. Adoption of this suggestion would also make the inclusion of Subparagraph 101(c)(2)(B) relating to "LIMITED DISCOVERY" unnecessary as Rule 56 practice routinely provides for such limited discovery.

In summary, with the enactment of PERA, certainty will immediately be reestablished as to what subject matter is and is not patent eligible.

6. ***How does the approach to subject matter eligibility in PERA compare with that taken by other countries? And is there research showing a difference in quality and access to innovation for consumers, and ability to compete for innovators here in the U.S., relative to those jurisdictions?***

Mr. Johnson's Answer to Question #6

As Subcommittee witness Courtney Brinckerhoff explains in her written testimony, there are "international disharmony" and quid pro quo "imbalances" that have developed because of our Supreme Court's recent restrictions on patent eligibility:[18]

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

21C agrees with Ms. Brinckerhoff that this means there are important, useful inventions that cannot be patented in the U.S. that can be and routinely are patented in other countries that include isolated natural products that may be useful as medications, diagnostic agents, vaccines, antibiotics, or in

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[17] FED. R. CIV. P. 56(a).

[18] Senate Judiciary IP Subcommittee written testimony of Courtney Brinckerhoff, January 23, 2024 at pp 6-7 (footnotes omitted), accessible at https://www.judiciary.senate.gov/download/2024-01-23-testimony-brinckerhoff

industrial applications. 21C also agrees that the resulting disclosure imbalances may indeed "cause innovators to hesitate before pursuing a U.S. patent or developing technology for the U.S. market."[19]

Former USPTO Director Kappos cites to several studies that confirm the firsthand evidence presented to this Subcommittee opining "that the Supreme Court's changes to subject matter eligibility have decreased confidence in the U.S. patent system, decreased private investment in key areas of technology that rely on patents, decreased commercialization of innovations in these areas, and created threats to America's economic, social and national security interests."[20] 21C members share this opinion.

7. I understand that Alice/Mayo and the changes proposed in PERA affect innovation differently depending on many factors, including, among other things, the economic sector, industry, and firm size in question. What economic research or studies should policymakers be aware of in assessing Alice/Mayo's impact on innovation and the expected impact of PERA?

Mr. Johnson's Answer to Question #7

Other than the research studies already cited to the Subcommittee, 21C is not aware of any further studies of which the Subcommittee should be made aware. This is because industry participants generally do not reveal the research proposals they have considered but declined to pursue, nor do they share the detailed strategic thinking that led to those decisions. Nonetheless, as it relates to PERA, the record of firsthand testimony before this Subcommittee from involved U.S. industry participants more than sufficiently establishes the fact that Alice/Mayo has had a deleterious impact on U.S. R&D, and needs to be fixed if we are to maintain our technological leadership relative to China, Europe and other jurisdictions with broader patent eligibility standards.

8. Mr. Jones's testimony included proposed alternative approaches to addressing concerns with the state of Section 101. He proposed the two possible alternative approaches: (1) "[] a narrow solution that is targeted specifically and exclusively at any areas of technology for which the current jurisprudence has created significant and empirically demonstrable impediments to obtaining patent protection to the extent that such impediments can be shown to have resulted in clearly insufficient levels of R&D investment."; (2) "a broader legislative solution that tethers patentability to its underlying policy purpose by explicitly limiting the availability of patent protection to only those inventions that embody an advance in technology." What are your views on these proposals as compared to the approach of PERA?

[19] *Id.* at page 8.

[20] *See* the written testimony of David J Kappos regarding PERA at page 6 available at https://www.judiciary.senate.gov/download/2024-01-23-testimony-kappos

Mr. Johnson's Answer to Question #8

Mr. Jones' suggestion that legislation should be specifically and exclusively targeted at "any areas of technology for which the current jurisprudence has created significant and empirically demonstrable impediments to obtaining patent protection to the extent that such impediments can be shown to have resulted in clearly insufficient levels of R&D investment" does not merit serious consideration because it is premised on the idea that such legislation could not be written and passed until after it was proven that the existing eligibility law had already failed. Under the Jones proposal, the U.S. would never catch up because the law would never address the next emerging new technology, so the resulting U.S. track record would be to have belatedly conferred patent eligibility when it no longer would matter. Patent eligibility needs to be open ended, to encourage our innovation community to invest in developing emerging technologies that don't yet exist and/or are in their early stages of development, and to reward them with reliable patent protection without having to await new legislation for that to happen.

Mr. Jones' second suggestion, "to develop a broader legislative solution that tethers patentability to its underlying policy purpose by explicitly limiting the availability of patent protection to only those inventions that embody and advance in technology," is an invitation to intermingle *patent eligibility* determinations with *patentability* determinations. This is exactly the approach that led the Supreme Court astray and got us to where we are today. 21C agrees that patent protection should be made available only to those inventions that represent "an advance in technology," which is what Sections 102 and 103 of the Patent Act are designed to assure. 35 USC 102 currently sets forth specific patentability requirements that represent absolute bars to patentability for otherwise patent eligible inventions.[21] More significantly, 35 USC 103 sets

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[21] **§102. Conditions for patentability; novelty and loss of right to patent**

A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) The [1] invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

forth the significant requirement that the claimed invention embodies and represents an advance in that technology by requiring:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

This standard has served us well since its original enactment in 1952, and should not be disturbed now.

Respectfully submitted,

s/Philip S Johnson

Chair, Steering Committee
Coalition for 21st Century Patent Reform

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(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a); [2] or

(f) he did not himself invent the subject matter sought to be patented, or

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Answers to Questions from Senator Tillis
for Philip Johnson
Witness for the Senate Committee on the Judiciary Subcommittee on Intellectual Property
Hearing "The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System"

1. ***One of the key concerns from innovators is that, absent additional clarity in this space, we're going to start seeing American companies start developing their inventions overseas in jurisdictions which have broader standards of patent eligibility.***

   Do you agree with that concern and, if you do, what evidence have you seen to suggest that technological inversion is already occurring?

21C's Answer to Question #1:

Yes. Research and development-based companies, such as the members of 21C, favor designing and developing state-of-the-art products for sale in markets where the market success of those products will be protected by reliable patent protection. This helps to ensure that if their inventions are commercially successful they will not be knocked off by copyists, and will likely receive a fair return on their investments.

In many fields, the best way to ensure commercial success is to locate R&D locally within the target market, so that the products may be designed to meet local requirements and tailored to meet local needs and tastes. In then deciding where to manufacture the newly invented product, companies consider a great many factors, including the proximity of the point of manufacture to the R&D facility that originated the product, the proximity of the point of manufacture to the target market, the cost of manufacturing in the location, the expected tax burden on the product, and the availability of patent protection in the jurisdiction of manufacture.

In the last ten years there has been an increasing trend to expand foreign research, development, and manufacturing capabilities. In the pharmaceutical field, for instance, it is increasingly likely that new drugs will be developed based in significant part on foreign clinical trials. Large increases in foreign patent filings by manufacturers seeking patents on inventions not now eligible for patenting in the U.S. also suggest that an increasing proportion of the R&D that led to these inventions is being conducted outside the U.S.

2. ***a. In your opinion, how has the current state of unpredictability surrounding Section 101 hampered research, development and innovation, particularly in critical industries like life sciences, diagnostics, and artificial intelligence?***

21C's Answer to Question #2a:

The current state of patent eligibility law has injected enormous uncertainty and unpredictability into whether inventions in many important fields will ultimately be held to be patent eligible. While there is a degree of risk inherent in all R&D, that risk is much greater when the research is

transformational rather than incremental. Because transformational research is more basic, under the current law it is much more likely to be found patent ineligible as being "abstract," directed to a "law of nature," or claiming a "natural phenomenon."

As prior Subcommittee witnesses who are involved in early-stage research have explained, the availability of reliable patent protection is essential to the invention and development of fundamental breakthroughs. Patents are needed to justify the formation of startups, to attract venture capital, and/or to license development partners to do the work needed to commercialize the invention. As Peter O'Neill, Executive Director of Cleveland Clinic Innovations, testified to this Subcommittee:

> At Cleveland Clinic Innovations, we have an established process to assess inventions, based on their likelihood to be able to be developed into commercial products. Ability to get protectable intellectual property (usually in the form of a patent) is the first, and most influential factor in our assessment. If an invention can't get intellectual property protection, usually that is a fatal flaw and the invention is abandoned at the point."[1]

As we have also heard, if patent protection is not reliably available, further R&D won't happen and nothing will be commercialized to the detriment of those who could have benefited from it.

It is true that in some fields, it may be possible to keep the invention as a trade secret, yet still commercialize it. Examples are the formulas for Coca Cola® and Listerine®, Google's search algorithms, targeted personal advertising methods, and certain proprietary manufacturing methods. In other fields, trade secrets are not a realistic option because the invention is disclosed by its commercialization, because the risk of inadvertent disclosure or misappropriation is too high, or because the rules or regulations applying to the research activity and/or its commercialization demand public disclosure.

In certain situations, the nature of the business may make the availability of patent protection more or less important. For example, dependable patents are more likely to be of critical importance to small competitors or new entrants in an industry,[2] whereas they may be less important to well entrenched and/or dominant competitors who benefit from other advantages, including, for example, established customer goodwill, supply chains, and other economies of scale.

In the software and entertainment fields, copyright protection often provides protection against copying, which perhaps explains the unprecedented recent influx of capital into the development of copyrightable content. While some forms of available clinical trial data protection may help to encourage the development of therapeutic biologics, these forms of protection are time limited

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[1] *The State of Patent Eligibility in America: Part I Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 3 (June 11, 2019) (statement of Peter O'Neill, Executive Director of Cleveland Clinic Innovations) ("O'Neill Testimony").

[2] *See The State of Patent Eligibility in America: Part II Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 2 (2019) (statement of Paul Morinville, President, U.S. Inventor) ("Morinville Testimony").

and not available against competitors who conduct their own clinical trials and apply for BLA approvals for biologics that compete in treating the same or similar indications.

Current patent eligibility law also discourages research into products or methods that are likely to gain patent coverage through the issuance of only one patent, or just a few patents, as opposed to a great many patents. A breakthrough new drug is an example of an important invention that is often covered by no more than a handful of patents, whereas today's mobile phones may be covered by hundreds of patents. In the event of product copying, the odds strongly favor the owner of hundreds of relevant patents over the one who has just a few, particularly in our current system in which there is a lower probability of success in defending the validity of any given patent.

Investors, startups, and established companies will not invest in research and development of inventions where the unpredictable nature of patent eligibility causes the projected return on the investment to drop below the levels that are required to justify the cumulative risk of the proposed undertaking. Current eligibility law is an important factor, but not the only factor, affecting the dependability of patent protection. Examples of other factors are the pro-challenger nature of USPTO IPR proceedings, the relative unavailability of preliminary and final injunctions to stop competitive infringement, and the availability of a number of other judge-made defenses that have evolved to make it difficult to successfully enforce valid patents.
As many of the witnesses appearing before this Subcommittee have confirmed, inventive efforts relating to the life sciences and software industries,[3] including those denying patent eligibility for isolated natural products,[4] diagnostics,[5] pharmaceuticals,[6] methods of treatment,[7] vaccines and antibiotics,[8] personalized medicine,[9] biotechnology products,[10] genetic innovations,[11] medical

[3] *The State of Patent Eligibility in America: Part II Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 8-9 (June 5, 2019) (statement of Barbara Fiacco, President-Elect, American Intellectual Property Law Association); *Id.*, 116th Cong. 4 (June 5, 2019) (statement of Scott Partridge, Immediate Past Chair, Intellectual Property Law Section, American Bar Association); *Id.*, 116th Cong. 8-9 (June 5, 2019) (statement of Henry Hadad, President, Intellectual Property Owners Association) ("Hadad Testimony"); *Id.*, 116th Cong. 1-2 (June 5, 2019) (statement of Rick Brandon, Associate General Counsel, The University of Michigan) ("Brandon Testimony"); Morinville Testimony at 12-13; *The State of Patent Eligibility in America: Part III Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 7 (June 11, 2019) (Manny Schecter, Chief Patent Counsel, IBM) ("Schecter Testimony"); *Id.*, 116th Cong. 5 (June 11, 2019) (statement of Kim Chotkowski, Vice President, Head of Licensing Strategy and Operations, InterDigital) ("Chotkowski Testimony"); O'Neill Testimony at 3.
[4] *The State of Patent Eligibility in America: Part I Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 28 (June 4, 2019) (Statement of Sherry M. Knowles, Principal, Knowles Intellectual Property Strategies) ("Knowles Testimony"); *The State of Patent Eligibility in America: Part II Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 4-6 (June 5. 2019) (statement of Hans Sauer, Deputy General Counsel for Intellectual Property, Biotechnology Innovation Organization) ("Sauer Testimony"); *The State of Patent Eligibility in America: Part III Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 10-12 (June 11, 2019) (statement of Laurie Hill, Vice President, Intellectual Property, Genentech) ("Hill Testimony").
[5] Knowles Testimony at 28; Brandon Testimony at 2.
[6] *The State of Patent Eligibility in America: Part I Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 6 (June 4, 2019) (statement of David O. Taylor, Co-Director of the Tsai Center for Law, Science and Innovation, Associate Professor of Law, Southern Methodist University Dedman School of Law) ("Taylor Testimony"); *The State of Patent Eligibility in America: Part III Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 4 (June 11, 2019) (statement of Corey Salsberg, Vice President, Global Head IP Affairs, Novartis) ("Salsberg Testimony").
[7] Salsberg Testimony at 4.
[8] Sauer Testimony at 6; *The State of Patent Eligibility in America: Part II Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 11 (June 5, 2019) (statement of Natalie M. Derzko, Of Counsel, Covington & Burling LLP) ("Derzko Testimony").
[9] Hadad Testimony at 7-8; Derzko Testimony at 3-4, 7-9; Hill Testimony at 9-10; *The State of Patent Eligibility in America: Part III Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 3-6 (June 11, 2019) (statement of David Spetzler, President and Chief Scientific Officer, Caris Life Sciences).
[10] Taylor Testimony at 6; Sauer Testimony at 1-3.
[11] *The State of Patent Eligibility in America: Part III Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 2 (June 11, 2019) (statement of Gonzalo Merino, Vice President and Chief Intellectual Property Counsel, Regeneron Pharmaceuticals).

devices,[12] computer implemented inventions,[13] quantum computing,[14] data compression algorithms,[15] 5G,[16] blockchain,[17] the internet of things,[18] polar coding,[19] electronic games,[20] artificial intelligence,[21] and many others are negatively affected and/or not being undertaken because of the effects of current patent eligibility law.

2. ***b. Absent legislative reforms – or some type of clarity from the Supreme Court – do you anticipate America falling behind in not only those key industries but other emerging technologies?***

21C's Answer to Question #2.b:

Unfortunately, yes.

The U.S. is rich in energy, minerals, and materials. Health, human life, and individual freedoms are highly valued in the United States, which is a free market economy governed by law. The American workforce is and promises to be highly educated. Our government, both directly and through grants made to our universities, supplies support for basic research. And American ingenuity, when properly supported, is still second to none. These attributes are important, but alone insufficient to maintain our industrial leadership.

In the past, we have been successful because a strong and reliable patent system has provided the incentive needed to attract the venture and investment capital needed to support the robust development of new technologies. These new technologies led to leaps in productivity and have enhanced our quality and enjoyment of life.

We have succeeded in the past by attracting massive amounts of private capital which have been invested on risky but potentially highly rewarding new technologies based on the promise that, if successful, their developers will enjoy a limited term of U.S. patent exclusivity within which to recover and make fair returns on their investments. However, as explained in my written testimony, over the past decade the confidence required by investors to make similar future investments has now eroded to the point where legislative reform is critical if we are not to slip behind to our foreign competitors. The passage of PERA is an important step towards restoring that confidence.

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[12] Taylor Testimony at 6; *The State of Patent Eligibility in America: Part II Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 7-8 (June 5, 2019) (statement of Jeffrey A. Birchak, General Counsel, Vice President of Intellectual Property, and Secretary, Fallbrook Technologies); Salsberg Testimony at 4.

[13] Schecter Testimony at 2-4.

[14] *The State of Patent Eligibility in America: Part I Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 2-3 (June 4, 2019) (statement of the Honorable David J. Kappos, Former Director, United States Patent and Trademark Office) ("Kappos Testimony"); Schecter Testimony at 3-4.

[15] *The State of Patent Eligibility in America: Part II Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 1-4 (June 5, 2019) (statement of Nicholas Dupont, CEO and Executive Chairman, Cyborg Inc.).

[16] Kappos Testimony at 2-3; *The State of Patent Eligibility in America: Part III Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 2-5 (June 11, 2019) (statement of Laurie Self, Senior Vice-President and Counsel, Government Affairs, Qualcomm) ("Self Testimony"); Chotkowski Testimony at 5.

[17] Schecter Testimony at 5.

[18] *Id.*

[19] Self Testimony at 6.

[20] *The State of Patent Eligibility in America: Part III Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. 1-3 (June 11, 2019) (statement of Michael Blankstein, Senior Vice President and Deputy General Counsel – Patents and Licensing, Scientific Games).

[21] Kappos Testimony at 2-3; Schecter Testimony at 3-4; Hill Testimony at 13-15.

3. ***As a critical figure in the legislative efforts that led to the enactment of the America Invents Act (AIA), can you walk us through how you and your organization, 21C, helped reconcile differences and forge a legislative consensus?***

21C's Answer to Question #3:

It took six years to develop consensus on the provisions of the AIA. From the standpoint of the Patent Fairness Coalition ("PFC," whose members included Google, Intel, Microsoft, Apple, and other information technology companies), the principal issues were patent quality and outsized infringement awards. Mainstream users of the patent system, including 21C's members, were concerned with modernizing and harmonizing our patent system to improve its reliability, as recommended by a 2004 study by the National Academies of Science.[22] Hallmarks of 21C's proposals were (a) to end diversion of USPTO user fees so they could be used to clear up the USPTO's backlog of applications to examine; (b) to allow the public to bring prior art to the attention of patent examiners during a patent's original examination; (c) to move to a first-inventor-to-file (rather than first-to-invent) system to eliminate third party secret prior-invention prior art while retaining a one year grace period for an inventor's own prior public invention disclosures (so that patent examiners would know of all of the relevant prior art at the time of patent examination); (d) to restrict the doctrine of inequitable conduct to instances where the specific intent to mislead or deceive the USPTO was proven by clear and convincing evidence; (e) to eliminate unnecessary "subjective intent" criteria relating to patentability; and (f) to provide a procedure allowing the USPTO to insulate a patent from future inequitable conduct assertions by considering newly submitted information and reexamining the affected patents when necessary.

In addition, there was general agreement that the then-current *inter partes* reexamination procedure (which was little used) was not working, but disagreement about whether any third party life-of-the-patent challenge procedure (beyond the existing *ex parte* reexamination process) should be allowed. There was little disagreement about the proposal to move to a first-inventor-to-file rather than a first-to-invent system, primarily because its effect was prospective (existing patents and patent applications were not affected), and it came with a "prior user rights" exemption to protect prior secret users of a later-patented invention against infringement liability.

Unlike now, before passage of the AIA, district court rulings were more a cause of concern than Federal Circuit and Supreme Court rulings. Over the six-year period of developing the AIA, the Supreme Court handed down its *eBay* ruling making it harder for non-practicing entities to gain injunctions against infringement, and the Federal Circuit issued precedential rulings requiring (a) that for inequitable conduct, intent to mislead or deceive must be specifically proven; and (b) that for damages purposes, the contribution of a patented component of an invention would be assessed based on the value that invention contributed to the infringing product or process.[23] As a result, these decisions substantially reduced the need for the legislative reforms then being

[22] *See* The National Academies Press, A Patent System for the 21st Century (Stephen A. Merrill et al. eds., 2004), *available at* https://nap.nationalacademies.org/read/10976/chapter/1.

[23] *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006); *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290-91 (Fed. Cir. 2011); *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1318 (Fed. Cir. 2011).

sought by certain stakeholders. In view of these developments, legislative reforms for inequitable conduct and damages/injunction reforms ended up being compromised out of the AIA legislation.

During the negotiation of the AIA, compromise on the issue of third party life-of-the-patent challenges was more difficult.[24] While PFC and its allies sought "all issues," life-of-the-patent third party patent challenges to be decided by the USPTO, 21C and others advocated that third party challenges should be limited to the first nine months after patent issuance, as it is in Europe, and that nothing more was needed. This would ensure that patent challenges would be brought early and that quiet title to newly issued patents would quickly be established, thus fostering more investment in them.

The USPTO's position was that the institution of third party patent challenges should be left to the discretion of the Director of the USPTO, and that that discretion would be used sparingly.

The compromise that was eventually reached had several major parts. The first was to allow third party "all issues" challenges to patents within nine months of issuance, subject only to an "only-issues-raised" estoppel. The second part allowed life-of-the-patent challenges requesting to cancel claim(s) of a patent "only on a ground that could be raised under section 102 [anticipation] or 103 [obviousness] and only on the basis of prior art consisting of patents or prior printed publications,"[25] subject to a "raised or could have been raised" estoppel. The third part was to create a "covered business method" patent challenge proceeding that could be brought only by parties having at least declaratory judgment standing.[26] The fourth part was to authorize broad rule making authority to the USPTO as to how the proceedings were to be instituted and conducted, based in large part on the USPTO's view that the early availability of post-grant review without a broad estoppel would be used more, and that the USPTO would be circumspect in instituting *inter partes* review proceedings.[27]

The current situation relating to PERA is quite different. As explained in my written testimony, the current need for legislative action stems from a series of Supreme Court decisions that have created ambiguities and proven to be unworkable in practice. After lengthy deliberations involving several years of stakeholder roundtables, consideration of a number of third party proposals from various patent-focused professional associations, and hearings featuring over fifty witnesses representing the full spectrum of stakeholder views, PERA represents compromise legislation that includes explicit eligibility exclusions to address its critics' concerns while clarifying the law of patent eligibility to restore the clarity and reliability that our patent system needs.

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[24] *See* Phil Johnson, *A Look Back at the Legislative Origin of IPRs*, IPWATCHDOG (Sept. 20, 2017), https://ipwatchdog.com/2017/09/20/look-back-legislative-origin-iprs/id=88075/.
[25] 35 U.S.C. § 311.
[26] *See* Leahy–Smith America Invents Act, § 18, entitled "Transitional Program for Covered Business Method Patents." Standing to bring a so-called CBM challenge required that the petitioner already be in patent litigation on the patent, or already have standing to bring a declaratory judgment action on the patent (usually because the party had been charged with infringement by the patentee). Per the AIA, this proceeding was to be transitional, and would sunset after 10 years, which it since has.
[27] *See* Phil Johnson, *The AIA: A Promise Thus Far only Partially Fulfilled*, IPWATCHDOG (Sept. 15, 2016), https://ipwatchdog.com/2016/09/15/aia-promise-partially-fulfilled/id=72680/.

In my written testimony, 21C does propose one further compromise to reassure critics that accused infringers may have their patent eligibility challenges heard in court "at any time" during a patent infringement litigation. This proposal would authorize the courts to utilize FRCP Rule 56 summary judgment motions to seek early disposal of patent infringement actions when there are no genuine issues of material fact relating to the patent eligibility issue. As so written, PERA will restore patent eligibility to its original scope as envisaged by our Constitution and as enacted in the 1952 codification of our patent laws.[28]

4. ***PERA will continue to exclude patents on unmodified natural materials as they exist in nature, but it also ensures that natural materials that are isolated, purified, or similarly altered or enriched by human activity will remain patent-eligible.***

   Can you tell us why that's important for innovation in the field of medicine and related fields?

21C's Answer to Question #4:

Many of our most important diagnostics and medicines have been developed using natural materials that have been isolated, purified, or similarly altered or enriched by human activity. Prior to the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[29] such materials were routinely considered to be patent eligible. Sherry Knowles, a former Chief Patent Counsel of SmithKline, in her June 2019 testimony before this Subcommittee, has detailed the many life-saving or disease curative drugs that have been derived from natural sources. As Ms. Knowles explained, these include "penicillin, amoxil, tetracycline, cyclosporin, cephalosporin, streptomycin, chloramphenicol, insulin, Taxol, doxorubicin, vincristine, vinblastine, and many others" including a multi-page listing of such drugs attached as Exhibit 4 to her testimony.[30]

As the testimony presented in connection with PERA has confirmed, the need to continue to base drugs and diagnostic on isolated, purified, or similarly altered or enriched by human activity has not abated. For example, even PERA's detractors, such as Mr. Blaylock (testifying on behalf of Invitae), admit that there are important variations in the human genome (i.e. biomarkers), such as the collection of variants in the sequences of the BRCA1 and BRAC2 genes which indicate a lifetime risk of suffering from breast cancer, that remain to be discovered and that could be developed for diagnosing disease risks and for determining a patient's suitability for certain treatments.[31] But contrary to Mr. Blaylock's contentions, patenting of these diagnostics is what facilitates the substantial further investments that are needed to bring useful diagnostic tests to the market.[32] As Mr. Rick Brandon testified on behalf of the Association of American Universities, "patents are the lifeblood for many of our scientific discoveries and the key to

[28] In my written testimony, 21C also proposes several clarifying amendments to the wording of PERA.
[29] 569 U.S. 576 (2013).
[30] Knowles Testimony at 3.
[31] *The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 118th Cong. 1 (Jan. 23, 2024) (statement of Richard Blaylock, Partner, Pillsbury Winthrop Shaw Pittman LLP).
[32] *See* Knowles Testimony at 27-28 ("[R]esearch and investment on isolated natural products as new medicines precipitously declined after *Myriad* and will continue to stall until *Myriad* is abrogated. . . . I have first-hand knowledge that this is true. Companies adamantly will not pursue a lengthy and costly product development program without any assurance of a repayment and return on the investment. . . . The Supreme Court's unconstitutional decision have forced research funding away from isolated natural products and personal diagnostics.").

moving those discoveries from the lab to the marketplace. . . . In the case of products that require FDA approval, including diagnostics, this can take years and millions of dollars. . . . If we don't allow for U.S. patenting of medical diagnostics, we'll miss out on better patient outcomes, cost savings through screening methods that predict disease or the most appropriate course of treatment, as well as other foundations for precision medicine."[33]

The patent eligibility of natural materials that have been isolated, purified, or similarly altered or enriched by human activity is similarly important in many other fields of technology. As the former USPTO Director reminded us during this hearing, a natural material isolated from bamboo served as the original filament for Thomas Edison's light bulb. The development of isolated, purified, and/or human-modified materials remains important in many field of technology today.

5. ***With 21C representing companies ranging from high tech to pharmaceuticals, you sit at a fulcrum point where you can see many industry divides.***

   Based on that, how do you recommend we amend PERA to achieve consensus?

21C's Answer to Question 5:

Within 21C, which is a coalition of companies from diverse industries, there is a strong consensus in favor of passing PERA without making substantial modifications to it, except to improve its clarity in a few places, as mentioned in my written testimony. We sense a very wide consensus within the academic, start up, and manufacturing communities in support of PERA, and do not believe that the critics of PERA have made a credible case against its passage.

In 21C's view, the existing consensus on PERA is at least as great, if not greater, than that which existed at the time of the passage of the America Invents Act, and should be moved out of Committee and enacted into law as soon as possible.

Respectfully submitted,

s/Philip S. Johnson

Chair of the Steering Committee
Coalition for 21st Century Patent Reform

[33] Brandon Testimony at 1.