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.