Statement of Philip S. Johnson, Esq.

Before the

Intellectual Property Subcommittee of the
Judiciary Committee of the
United States Senate

on

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

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Executive Summary of the Statement of Philip S. Johnson

Chairman Coons, Ranking Member Tillis, and distinguished members of the Subcommittee:

Thank you for providing me with this opportunity to testify on S. 2140, "The Patent Eligibility Restoration Act of 2023," which I'll call "PERA."

I appear here today in my capacity as Chair of the Steering Committee of the Coalition for 21st Century Patent Reform, commonly referred to as "21C." 21C is a diverse coalition of American manufacturers who rely on patents to protect their inventions, who develop and manufacture products protected by those patents, who license patents to and from others in furtherance of their business activities, and who, when necessary, assert their patents against infringers and/or defend against patents asserted against them. 21C represents companies from many different industry sectors and is led by a Steering Committee that includes 3M, Bristol Myers Squibb, Boeing, Caterpillar, Eli Lilly, General Electric Aerospace, Johnson & Johnson, and RTX Corporation (the company formed by the merger of United Technologies and Raytheon).

As many others have stated, the law of patent eligibility in this country is now a mess. No one involved in the field of patent law, including the Federal Circuit Judges themselves, knows or can reasonably predict which inventions will be found to be patent eligible. This is because starting about a decade ago the Supreme Court concluded that inventions "directed to" "laws of nature," "natural phenomena," and/or "abstract ideas" should not be eligible for patenting even while at the same time recognizing that one or more of these characteristics is inherent in every invention. As a result, the lower courts now feel compelled to deny patent eligibility to some of our best inventions, including groundbreaking inventions in the fields of artificial intelligence, communications, software, diagnostics, and biotechnology. Above all else, Congress should pass PERA to restore patent eligibility to its traditional scope by closing these judicially-created loopholes.

Passing PERA will also ensure that inventors and others understand which kinds of inventions are eligible for patenting and which kinds are not. PERA accomplishes this by prohibiting the injection of *patentability* considerations into *patent eligibility* determinations, by clarifying the utility requirement of Section 101, by requiring that in determining patent eligibility the claimed invention must be considered as a whole, and by codifying certain exceptions to patent eligibility. Included in these eligibility exceptions are prohibitions against patenting human genes as they exist in the human body and naturally occurring materials as they exist in nature. These are all steps forward that 21C strongly supports.

21C believes that PERA's patent eligibility reforms are essential if we are to protect our national security and maintain our role as the world's technological leader. The passage of PERA will restore a critical incentive for the private sector to invest in innovation, economic development, and job growth. Consumers will be the ultimate beneficiaries of these reforms, as they will benefit not only from the additional innovation that these changes will spawn, but also from better prices on previously available goods or services that will be lowered in order to compete against these innovative alternatives.

I look forward to answering any questions you may have concerning these issues, which are discussed in more detail in my written testimony.

Statement of Philip S. Johnson

Introduction

I appear here today in my capacity as Chair of the Steering Committee of the Coalition for 21st Century Patent Reform (commonly called "21C").[1] 21C is a diverse coalition of American manufacturers who invest heavily in research and development, who rely on patents to protect their resulting inventions, who develop and manufacture products protected by those patents, who license patents to and from others in furtherance of their business activities, and who, when necessary, assert their patents against infringers and/or defend against patents asserted against them. 21C represents companies from many different industries. It is led by a Steering Committee that includes 3M, Bristol Myers Squibb, Boeing, Caterpillar, Eli Lilly, General Electric Aerospace, Johnson & Johnson, and RTX Corporation (the company formed in 2020 by the merger of United Technologies and Raytheon).

21C believes that a strong U.S. patent system is essential to American innovation. Our Founding Fathers recognized that for our country to prosper Congress needs "[t]o promote the Progress of . . . [the] useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[2] They recognized that our Government's promise to grant time-limited exclusive rights for inventions and discoveries in the "useful Arts" would encourage inventors not only to invest their time and money in researching and developing such inventions, but also to publicly disclose how to make and use them.

In order for these incentives to be effective, it was and is imperative that would-be inventors be able to discern in advance what is and is not eligible for patent protection. Inventors need to be confident that if their invention is of a kind eligible for patenting and has met several additional patentability criteria, their resulting patent will be respected throughout its full term. While this was the case for most of my first forty years of practicing patent law, it is no longer the case today.

In a series of Supreme Court cases beginning with its *Bilski* decision in 2010 and culminating with its *Alice* decision in 2014, the Court confused the difference between which types of discoveries and inventions are *eligible* for patenting and which of those eligible inventions are actually *patentable*.[3] Just because an invention or discovery is of a kind that is patent eligible doesn't mean that it will meet the other conditions required for it to be patentable. To be patentable, a patent eligible invention or discovery must further meet the statutory requirements of being (1) novel, (2) non-obvious, and (3) disclosed in sufficient detail to enable one of ordinary skill in the art to which it pertains to make and use it.[4]

In this series of cases, the Supreme Court decided that inventions "directed to" "laws of nature," "natural phenomena," and/or "abstract ideas" should not be eligible for patenting. The Court reached this conclusion even though it recognized that one or more of these characteristics is inherent to some degree in every invention, and that these exceptions could "swallow all of patent law."[5] Because of the ambiguity of this Supreme Court precedent, no one involved in the field of patent law, including our

[1] I am pleased to serve in this capacity *pro bono.* A summary biography of my qualifications and experience is attached as Exhibit A.
[2] U.S. CONST., art. 1, cl. 8.
[3] *Bilski v. Kappos*, 561 U.S. 593 (2010); *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014). *See also Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).
[4] *See* 35 U.S.C. §§ 102, 103, 112.
[5] *Alice*, 573 U.S. at 217.

Federal Circuit Judges,[6] now knows or can reasonably predict which inventions will be found to be patent eligible. And although hundreds of patents have now been invalidated or never came into being under this new Section 101 jurisprudence, the Supreme Court has declined numerous opportunities to clarify the law of patent eligibility since creating this confusion a decade ago.[7]

In this Subcommittee's June 2019 hearings on the State of Patent Eligibility in America most, if not all, of the 45 witnesses agreed that the U.S. law of patent eligibility was already a "mess."[8] Since then it has gotten worse, with traditionally patentable inventions like garage door openers, automotive driveshafts, and diamond drill bits being held to be ineligible for patenting.[9]

21C believes that the enactment of PERA is an important step towards fixing the U.S. law of patent eligibility. It eliminates all judicially-created eligibility exceptions and recognizes that the touchstones of patent eligibility require (1) that the subject matter must involve an "invention or discovery" (i.e. some form of human intervention), (2) that it be a "useful process, machine, manufacture or composition of matter, or any useful improvement thereof," and (3) that to be "useful" the invention or discovery must have a "specific and practical utility."

PERA also sets out five eligibility exceptions to reassure critics that certain things that would not have been considered patent eligible prior to the aforementioned Supreme Court rulings are still patent ineligible. PERA also requires that the claimed invention be considered as a whole, and specifies that the courts may consider eligibility issues and limited discovery relating thereto "at any time."

Our Constitution places on Congress the responsibility for legislating which inventions qualify for patenting. Given the emergence of China as a technological rival, unless legislation like PERA is passed, our future will be that substantial private sector investments in important new technologies will simply not be made unless they will be otherwise protected by a party's market dominance, by an applicable regulatory exclusivity, by copyright, or by trade secret. But these other incentives are simply not enough to assure that we will maintain our technological leadership.

The Traditional Role of Section 101 in Defining Patent Eligibility

Section 101 currently defines patent eligibility as follows:

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[6] *See, e.g., Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1306 (Fed. Cir. 2020) (Moore, J., dissenting) ("Our job, our mandate from Congress is to create a clear, uniform body of law. Our inability to do so in the § 101 space has not been a mess of our making. But, the unfairness, confusion and uncertainty that will be caused by this opinion is all us."), *reh'g denied* 966 F.3d 1347 (Fed. Cir. 2020) (mem.); *Am. Axle*, 966 F.3d at 1357 (Chen, J., concurring in denial of rehearing) ("Assessing claim validity under section 101 is difficult work . . . . Differences of opinion within our court on how to apply those principles to a particular case inevitably arise from time to time, given the inherently imprecise nature of the legal framework."); *Am. Axle*, 966 F.3d at 1357 (Newman, J., dissenting) ("The court's rulings on patent eligibility have become so diverse and unpredictable as to have a serious effect on the innovation incentive in all fields of technology."); *Am. Axle*, 966 F.3d at 1365 (Stoll, J., dissenting) ("Without clear direction from this court, the Patent Office and district courts will likely reach inconsistent results when assessing the patent eligibility of mechanical inventions.").

[7] *See* Kirk Hartung, *Recapping Eight Years of the Patent Eligibility Mess: Clearly It's Past Time for the Supreme Court or Congress to Provide Clarity*, IP Watchdog (May 12, 2023), available at https://ipwatchdog.com/2023/05/12/recapping-eight-years-patent-eligibility-mess-clearly-past-time-supreme-court-congress-provide-clarity/id=160805/.

[8] *See, e.g., 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. 1 (June 4, 2019) (statement of Mark A. Lemley, William H. Neukom Professor of Law, Director, Program in Law, Science & Technology, Stanford University School of Law) ("Lemley Testimony") ("The law of patentable subject matter is a mess."). *See also id.*, 116th Cong. 1 (June 4, 2019) (statement of David J. Kappos, Former Director, United States Patent and Trademark Office) ("Kappos Testimony") ("Our current patent eligibility law truly is a mess.").

[9] *See Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341 (Fed. Cir. 2019); *Am. Axle*, 967 F.3d 1285 (Fed. Cir. 2020); *Certain Polycrystalline Diamond Compacts and Articles Containing Same*, Inv. No. 337-TA-1236, USITC (Oct. 26, 2022) (Comm'n Op.).

> 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 recodification, 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 . . . .'"[10]

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 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.[11]

The Origin of the Current Patent Eligibility Problem

Patent cases seeking invalidation based upon Section 101 were virtually unheard of until about 2010 when the Supreme Court began changing patent eligibility policy in a series of decisions culminating in *Alice Corp. Pty. Ltd. v. CLS Bank International*, 573 U.S. 208 (2014). Together with the decisions in *Bilski v. Kappos*, 561 U.S. 593 (2010), *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), the *Alice* decision sparked a firestorm of invalidity challenges based solely on patent eligibility grounds that soon engulfed not only software patents, but also medical diagnostics, biologics, and many other types of invention that are critical to American innovation and global competitiveness.

[10] *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)).
[11] *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980).

Such judicially-created exceptions to statutorily-defined patent eligible subject matter are inappropriate because our Constitution vests the responsibility for defining the scope of what subject matter may be patented in Congress alone.[12] 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. But not only has the Supreme Court created such exceptions, experience has 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.[13]

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.[14] Such amorphous and undefinable criteria have no place in our patent system.

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."[15] Expansion of the judicial exceptions to patentable subject matter reached a new zenith when patents on

[12] 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."
[13] *Alice*, 573 U.S. at 217 (citing *Mayo*, 566 U.S. at 71).
[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. (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?").
[15] *INO Therapeutics v. Praxair Distrib. Inc.*, 782 F. App'x 1001, 1017 (Fed. Cir. 2019) (Newman, J., dissenting).

car parts and cameras—technologies traditionally expected to benefit from patent protection—were deemed invalid.[16]

Current Patent Eligibility Law is Hindering Development of Innovative Technologies

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 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 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.

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,[17] 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 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

[16] *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.'").

[17] *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").

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.

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 jurisdictions such as the U.S. where patent eligibility is uncertain, research and development are discouraged.

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, projected sales volumes, and the availability of patent protection in the jurisdiction of manufacture.

For all of the above-stated reasons, the current state of patent eligibility law in the United States (1) discourages inventors and their investors from pursuing transformational breakthroughs in favor of incremental product improvements; (2) discourages research that depends on patent protection as opposed to trade secrets; (3) discourages research and development by inventors who are required to publicly disclose their research; (4) discourages research and development by independent inventors, small businesses, and new entrants; (5) discourages investment in activities in need of patent protection as opposed to investment in activities that are protectable by copyrights or other forms of competitive protection; and (6) discourages research and development into products that are likely to be protected by relatively few (basic) patents as opposed to many (incremental) patents.

Areas of Research Most Negatively Affected By Our Current Eligibility Jurisprudence

Investors, startups, and established companies are no longer investing 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 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,[18] including those denying patent eligibility for isolated

[18] *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

natural products,[19] diagnostics,[20] pharmaceuticals,[21] methods of treatment,[22] vaccines and antibiotics,[23] personalized medicine,[24] biotechnology products,[25] genetic innovations,[26] medical devices,[27] computer implemented inventions,[28] quantum computing,[29] data compression algorithms,[30] 5G,[31] blockchain,[32] the internet of things,[33] polar coding,[34] electronic games,[35] artificial intelligence,[36] and many others are negatively affected and/or not being undertaken because of the effects of current patent eligibility law.

National Security Is Being Negatively Affected by Our Current Eligibility Jurisprudence

As I warned in my prior pre-Covid testimony to this Subcommittee, new diseases that originate elsewhere in the world pose a threat to our nation's security unless they can be effectively combatted by cutting-edge life sciences inventions.[37] As our populations grow and infectious diseases continue to evolve we can't afford to let our guard down thinking that our current armamentarium of therapeutics will be sufficient to counter future pandemics.

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"); *Id.*, 116th Cong. 3 (June 11, 2019) (statement of Peter O'Neill, Executive Director, Cleveland Clinic Innovations).

[19] *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").

[20] Knowles Testimony at 28; Brandon Testimony at 2.

[21] *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").

[22] Salsberg Testimony at 4.

[23] 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").

[24] 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).

[25] Taylor Testimony at 6; Sauer Testimony at 1-3.

[26] *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).

[27] 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) ("Birchak Testimony"); Salsberg Testimony at 4.

[28] Schecter Testimony at 2-4.

[29] Kappos Testimony at 2-3; Schecter Testimony at 3-4.

[30] *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.).

[31] 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.

[32] Schecter Testimony at 5.

[33] *Id.*

[34] Self Testimony at 6.

[35] *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).

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

[37] *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. (June 5, 2019) (live testimony of Phil Johnson, Chair, Steering Committee, Coalition for 21st Century Patent Reform) at 02:28:02 through 02:29:28.

Other witnesses who have testified agree that denials of patent eligibility in the U.S. are negatively affecting other security-critical fields. As former USPTO Director David Kappos previously testified, artificial intelligence, quantum computing, and 5G are all fields bearing directly on our national security yet are being disproportionately denied patent protection as a result of current patent eligibility law.[38]

As Jeffrey Birchak of Fallbrook Technologies explained in his prior written testimony to this Subcommittee:

> Foreign dominance of any critical technology presents significant national security concerns, as competitors, many with ties to hostile governments, control wireless networks, computer hardware, medical devices, and other technologies used by individuals, businesses, and governments in the United States. The World Intellectual Property Organization (WIPO) recently reported that China is now rivaling the U.S. in the patenting of Artificial Intelligence technologies, potentially providing China with a competitive advantage in the further development and control of AI technology.[39]

As explained by Laurie Self of Qualcomm in her prior testimony to this Subcommittee:

> The importance of maintaining U.S. leadership in global technology innovation cannot be overstated. [. . .] 5G in particular carries an elevated risk of foreign control because U.S. companies are not competitive in all areas of the 5G ecosystem. Today's mobile 5G ecosystem is built upon a foundation of 5G R&D and standards setting that enables the entire wireless environment. The other elements—mobile phones and other devices, 5G infrastructure, and mobile semiconductors—each present their own challenges and opportunities for U.S. leadership in the broader 5G environment, and key implications for U.S. national security.[40]

These are valid concerns that deserve our attention, particularly in the current environment where cyber and ransomware attacks on governments and private enterprises are becoming more common, and where our national defense is increasingly dependent on digital superiority. The same can be said of the other areas of innovation that are currently being discouraged because in a broader sense our national security depends on technological superiority and encompasses other areas including, for example, biosecurity.

Consumers Will Benefit from Patent Eligibility Reform

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

[38] Kappos Testimony at 2-3.
[39] Birchak Testimony at 8 (citing World Intellectual Property Org., *Technology Trends 2019: Artificial Intelligence* (2019), at 15-16, https://www.wipo.int/edocs/pubdocs/en/wipopub1055.pdf).
[40] Self Testimony at 7.

conferred, or a combination of the two. Stated simply, 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.

Provision-by-Provision Comments on the Text of PERA

Subsection 100(b)

The amendment to Subsection 100(b) appropriately clarifies the definition of the term "process," the change to which is shown in redline below:

> (b) The term "process" means process, art or method, and ~~includes a new use of a known process~~ includes a use, application, or method of manufacture or a known or naturally-occurring process.

Subsection 100(k)

The addition of Subsection 100(k) adopts 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:

> "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.[41]

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 guidance on utility that has long been applied for examining patent applications under Section 101.[42]

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.[43]

Subsection 101(a)

The proposed amendment of Subsection 101(a) (shown in redline) drops the word "new" from the current text and references new subsection (b) 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.

21C supports these proposed changes. As mentioned above, the term "new" as previously used in this subsection 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).

Subsection 101(b) ELIGIBILITY EXCLUSIONS

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

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[41] *Nelson*, 626 F.2d at 856.
[42] *See* Manual of Patent Examining Procedure § 2107, pt. II.
[43] 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 . . . ."

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 that economic, financial, and business ideas and 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."

Clause (b)(1)(B)(ii), in 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," limits the exclusion of clause (i) if 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." For the reasons discussed above, 21C agrees with these patent eligibility exclusions.

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) CONDITIONS

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.[44] 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.

Subsection 101(c) ELIGIBILITY

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.

Paragraph 101(c)(2) INFRINGEMENT ACTION

Subparagraph 101(c)(2)(A) specifies that "[i]n an action brought for infringement under this title, the court, at any time, may determine whether an invention or discovery that is a subject of the action is eligible for a patent under this section, including on motion of a party when there are no genuine issues of material fact." This provision appears to be included in PERA in response to the fears expressed on behalf of accused infringers that courts may not be able to consider patent eligibility issues early in a

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

patent infringement action to potentially obtain dismissal of that action to avoid lengthy and costly merits and damages discovery and trial. 21C agrees that courts should have the flexibility to consider such a motion at any time "when there are no genuine issues of material fact" and 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~~.

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."[45] 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.

Subparagraph 101(c)(2)(B) provides for "LIMITED DISCOVERY" by specifying that "[w]ith respect to a determination described in subparagraph (A), the court may consider limited discovery relevant only to the eligibility described in that subparagraph before ruling on a motion described in that subparagraph." 21C supports this provision while noting that if its proposal to reference FRCP Rule 56 were adopted, this provision would not be necessary as Rule 56 routinely involves the use of limited discovery.

Proposed Addition of Subparagraph 101(c)(2)(C)

PERA's Finding (5)(A) states:

> (5) Under this Act, and the amendments made by this Act, the state of the law shall be as follows:
>
> (A) All judicial exceptions to patent eligibility are eliminated.

While 21C agrees with Finding (5)(A), it nonetheless proposes that Subparagraph 101(c)(2)(C) be added to PERA, as follows:

> "(C) NO EXCEPTIONS. – Exceptions to patent eligibility other than those expressly set forth in this title are prohibited."

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

This addition is desirable in view of public commentary suggesting that the recitation in Finding (5)(A) is insufficient to ensure that courts won't somehow conclude that previous judicially-created eligibility exceptions have not been overruled and/or that in the absence of express codification, the findings are not binding on the courts. To eliminate any ambiguity, 21C therefore suggests that PERA expressly codify the elimination of all judicial exceptions to patent eligibility.

Conclusion

21C strongly supports the passage of PERA and looks forward to continuing to work with the Subcommittee to achieve enactment of effective patent eligibility legislation that will stimulate the private sector to invest in innovation, economic development, and job growth.

Exhibit A

PHILIP S. JOHNSON

Phil is the principal of Johnson-IP Strategy and Policy Consulting, which he founded after his retirement in February 2017 as Senior Vice President - Intellectual Property Policy & Strategy of Johnson & Johnson – Law Department. At Johnson-IP, Phil has been active in strategic IP consulting and has served as a testimonial expert in various IP-related litigation and arbitration matters. He is currently Chair of the Steering Committee of the Coalition for 21st Century Patent Reform, and an Emeritus Board Member of the Monell Chemical Senses Center. Prior to April of 2014, he was Senior Vice President and Chief Intellectual Property Counsel of Johnson & Johnson where he managed a worldwide group of about 270 IP professionals, of whom over 100 were patent and trademark attorneys.

Before joining Johnson & Johnson in 2000, Phil was a senior partner and co-chair of IP litigation at Woodcock Washburn in Philadelphia. During his 27 years in private practice, Phil counseled independent inventors, startups, universities, and businesses of all sizes in all aspects of intellectual property law. His diverse practice pertained to advances in a wide variety of technologies, including pharmaceuticals, diagnostics, medical devices, consumer products, semi-conductor fabrication, automated manufacturing, materials, and waste management. During his time in private practice, Phil served as trial counsel in countless IP disputes, including cases resolved by arbitration, bench trials, jury trials, and appeals to the Federal Circuit Court of Appeals, many of which resulted in reported decisions.

During his tenure at Johnson & Johnson, Phil served terms on the Medical Device & Diagnostics and Pharmaceutical Group Operating Committees responsible for managing J&J's many businesses in these fields, while also serving on the senior management team responsible for J&J's legal organization, which then comprised over 450 attorneys located in 70+ locations in 35+ countries.

Phil previously served as the Chair of the Board of American Intellectual Property Law Education Foundation (now the Foundation for the Advancement of Diversity in IP Law), as President of the Intellectual Property Owners Association, as President of INTERPAT, as President of the Association of Corporate Patent Counsel, as President of the Intellectual Property Owners Education Foundation, as Chair of PhRMA's IP Focus Group, and as Board Member of the American Intellectual Property Law Association.

Phil has testified frequently before the House and Senate Judiciary Committees about patent law reform, abusive patent litigation practices, and, more recently, "Sovereign Immunity and the Intellectual

Property System." Phil served as a member of Chief Judge Michel's Advisory Council on Patent Reform and was recognized in the Congressional Record as a member of the Minority Whip Jon Kyle's "Kitchen Cabinet" for the America Invents Act ("AIA"). Thereafter, Phil served as IPO's representative on the ABA-AIPLA-IPO committee of six experts ("COSE") formed at the Director's request to propose regulations to the USPTO for implementing the PGR-IPR post-grant proceedings created by the AIA.

Phil co-authored "Compensatory Damages Issues In Patent Infringement Cases, A Pocket Guide for Federal District Court Judges," and its 2017 edition, "Compensatory Damages Issues in Patent Infringement Cases," both published by the Federal Judicial Center, and has served that Center as a faculty member on its IP-related judicial education programming. Phil served as Co-Chapter Editor of the Sedona Conference WG10 biopharmaceutical patent litigation project and was featured in Landslide's March/April 2013 issue. Phil also authored "The America Invents Act on Its Fifth Anniversary: A Promise Thus Far Only Partially Fulfilled," (9/15/2016), and "A Look Back at the Legislative Origin of IPRs" (9/19/2017), both published in IP Watchdog.

Phil's awards include the Woodcock Prize for Legal Excellence (1997); the New Jersey Intellectual Property Law Association's Jefferson Medal (2013); the Philadelphia Intellectual Property Association's Distinguished Intellectual Property Practitioner award (May 2017); induction into the international IP Hall of Fame by the IP Hall of Fame Academy (June 2017); the Intellectual Property Owners Association "Carl B. Horton President's Distinguished Service Award" (September 2017); an honorary "Doctor of Laws" degree conferred by the University of New Hampshire Franklin Pierce Law School "in recognition of his pathbreaking leadership in revolutionizing the practice of intellectual property law in the healthcare and consumer product sectors" (May 2021); and IP Watchdog Masters™ "Hall of Fame" "recognizing a lifetime of contributions to the field of intellectual property" (October 2022).

Phil received his Bachelor of Science degree, *cum laude* with distinction in biology from Bucknell University, and his J.D. degree from Harvard Law School.