Statement of the U.S. Chamber of Commerce

ON: The State of Patent Eligibility in America: Part I

TO: Senate Committee on the Judiciary, Subcommittee on Intellectual Property

BY: U.S. Chamber of Commerce

DATE: June 4, 2019

The Chamber is the world's largest business federation representing the interests of more than 3 million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations. The Chamber is dedicated to promoting, protecting, and defending America's free enterprise system. The Chamber also is home to a significant international team providing global coverage to advance the many policy interests of our members.

More than 96% of Chamber member companies have fewer than 100 employees, and many of the nation's largest companies are also active members. We are therefore cognizant not only of the challenges facing smaller businesses, but also those facing the business community at large.

Besides representing a cross-section of the American business community with respect to the number of employees, major classifications of American business—e.g., manufacturing, retailing, services, construction, wholesalers, and finance—are represented. The Chamber has membership in all 50 states.

The Chamber's international reach is substantial as well. We believe that global interdependence provides opportunities, not threats. In addition to the American Chambers of Commerce abroad, an increasing number of our members engage in the export and import of both goods and services and have ongoing investment activities. The Chamber favors strengthened international competitiveness and opposes artificial U.S. and foreign barriers to international business.

Positions on issues are developed by Chamber members serving on committees, subcommittees, councils, and task forces. Nearly 1,900 businesspeople participate in this process.

Statement
to the
SENATE JUDICIARY SUBCOMMITTE ON INTELLECTUAL PROPERTY
on behalf of the
U.S. CHAMBER OF COMMERCE
Wednesday, February 27, 2019

Introduction

- Thank you, Mr. Chairman, Ranking Member, and the Members of the Subcommittee for convening today's hearing on a topic critical to U.S. innovation and economic leadership.

- I am Patrick Kilbride, Senior Vice President of the Global Innovation Policy Center at the U.S. Chamber of Commerce.

- The Global Innovation Policy Center is the dedicated voice of the Chamber on issues of intellectual property-driven innovation and creativity.

- The U.S. Department of Commerce has recognized numerous U.S. industries, from movies and music, to software and life sciences, to be IP-intensive. The Department has also noted their outsized importance to the U.S. economy, attributing to them 45 million U.S. jobs, 38% of gross domestic product, and more than half of all U.S. exports.

- Among these industries, the patent-intensive sectors carry a special significance for America's legacy of technological prowess and economic leadership. The term "American Ingenuity" is virtually synonymous with invention and progress.

- These inventive sectors carry the inherent risk of newness. Their innovative goods, services, and technologies are produced - often at great time and cost - with no guarantee of either practical or commercial success.

- These products have the added risk of successful "free-riding" by others, which can deny the innovator a return on investment sufficient to reflect the cost of innovation.

- The explicit rationale for intellectual property rights is to further the public interest in creativity and innovation. Patents provide the innovator with a limited period to regain sunk costs in exchange for the advancement and dissemination of knowledge, while allowing for open competition within a reasonable time frame.

- An environment where such property rights are not effectively provided or protected is one where investments in research and development, or innovative and creative work, are neither systemic nor sustainable. This scenario is the current reality in much of the world today.

The Democratization of Private (including Intellectual) Property

- The value of intellectual property as a stimulus to domestic innovation and creativity is recognized and enshrined in the Constitution.

- Consequently, the principle that authors and inventors should own property rights to their creative and innovative work, no less than in the production of tangible assets, has underpinned the dynamism of the American economy from its outset.

- From its very beginnings, respect for private property has enabled and encouraged the formation of productive capital in the United States, making our country an engine of growth for the entire world.

- President Abraham Lincoln captured the spirit of this economic governance philosophy thus: "I always thought the man that made the corn should eat the corn."

- This key premise of the U.S. economy, applied to the products of mental labor as well as physical labor, has likewise enabled an extraordinary degree of intellectual capital formation to take place in the United States.

- Our patent system requires three core elements in order to successfully promote private sector investment in innovation: First, a private property right that is well and transparently defined in law; Second, the ready availability of that right to any inventor who earns it, on a non-discretionary and non-discriminatory basis; and Third, a culture of respect for and enforceability of that right.

- With these elements in place, patents can serve their intended purpose as a reliable vehicle for investment in long-term, capital-intensive, high-risk research and development endeavors.

Principles of Patent Eligibility

- It is the second leg of this three-legged stool – the accessibility of patents to the inventor - that is the subject of today's hearing.

- Patents were not an invention of the Founders, but in an important sense they were perfected here: America uniquely democratized invention, making patents legally and economically accessible to – and a right of - every would-be inventor.

- Early European patents were granted by the monarch as a reward for achievement of technological progress that conferred a particular benefit or advantage on their country.

- With the enactment over time of laws defining associated rights, the grant of patents became more frequent, yet no less discretionary.

- In a discretionary system, there is no right, only a reward. The high degree of uncertainty associated with patents meant that invention, like all science, was largely an activity for the independently wealthy.

- What distinguished the American system of patents from its beginnings was the accessibility of rights to every inventor, not just those with the political connections or economic resources to secure a discretionary grant.

- This represented a fundamental shift in the innovation equation.

- Where patent rights are viewed as a discretionary reward, they come after innovation, and are rightly reflected as a cost to society.

- In the American system, patents come first, conferring a right available to anyone who meets the eligibility requirements; investment follows, and innovation is the result.

- In the democratized American system the inventive capacity of every citizen was liberated and could be put to work.

U.S. Chamber International IP Index

- Throughout a period of intense globalization of international markets, the absolute and relative strength of its intellectual property laws lent the United States a tremendous competitive advantage, making it the world's economic engine.

- Now, following decades of globalization, the productivity edge of the United States in the creative and innovative sectors is being diluted by the failure of trading partners to respect intellectual property rights at a similar level, creating an unfair playing field for U.S. innovators and creators.

- GIPC seeks a global commitment to enact and enforce intellectual property at a high standard, one that empowers the creative capacity of all the world's citizens and provides them access to U.S. innovation at fair value.

- That is why, for the past seven years, the GIPC has published its International IP Index. The Index is a comparative law analysis, providing an objective metric by which the intellectual property protections of various countries are measured.

- The data accumulated in the Index provides clear evidence of a strong correlation between the strength of a country's intellectual property laws and its innovative and creative output, its access to innovation and creativity, and numerous other benefits of the knowledge economy.

- However, on the global stage we continue to see misguided efforts to reduce intellectual property rights to the lowest common denominator.

- Among them, patentability principles are frequently abused in order to deny U.S. innovators the property rights they deserve. Such efforts are inconsistent with either appropriate competition policy or the rule of law.

- Unfortunately, those who would pursue such disingenuous means often point to U.S. policies, which when taken out of context can be counterproductive.

- What happens at home matters abroad. The U.S. is watched very closely by its counterparts around the world. Within the U.S. system of checks and balances, rule of law, and a strong independent judiciary, a policy advocacy "nudge" should be effective in an appropriately limited way.

- Sometimes, those nudges add up to an overcorrection, and such may have been the case in the United States with respect to patent eligibility. In that case, a series of broad court decisions and consequent interpretive administrative guidance to examiners created a high degree of uncertainty regarding U.S. patent eligibility in key sectors.

- For a time, the result seemed to be a virtual prohibition on patent grants in key technological areas, violating a fundamental principle of non-discrimination by industry sector.

- The U.S. Chamber has consistently held that patents should be available in every industry sector without discrimination for any invention that meets the legal three-step test of novelty, non-obviousness, and utility.

- The U.S. scores on the patent eligibility indicators of the Chamber Index reflect this and are attached to this statement.

INDICATOR	2019	2018	2017	2016	2015	2014
Category 1: Patents, Related Rights, and Limitations						
2. Patentability requirements	0.75	0.75	0.75	0.75	0.75	1.00

- In relevant part, beginning with the 2014 edition, the Index notes the following:

- **(2014) 2. Patentability requirements:** The Leahy-Smith America Invents Act (AIA), signed into law in 2011 with its central provisions taking effect in March 2013, altered the American patent system from a "first to invent" to a "first inventor to file" system. This requirement is

in line with the approach followed by the rest of the world; however, a grace period on public disclosure remains in the act, effectively making it a "first to disclose" system instead. In general, the United States takes a broad approach to patentability standards. However, the Supreme Court's April 2013 decision in Association for Molecular Pathology v. Myriad Genetics limited the patentability of human genes.

- **(2015) 2. Patentability requirements:** In April 2014, the USPTO issued new guidelines on the patentability of biotechnology inventions aimed at providing further clarification and interpretation of recent judicial decisions (namely, Association for Molecular Pathology v. Myriad Genetics, Inc., 2013, and Mayo Collaborative Services v. Prometheus Laboratories, Inc., 2012). In particular, the guidelines extend the holdings from these decisions by introducing restrictions on patenting of naturally occurring substances (including genomic DNA, proteins, and stem cells), even if isolated and purified, if there is not sufficient distinction shown between a claim and the substance as found in nature. In a break from its typical approach of providing guidance on certain gray areas and leaving it to the courts to determine specific limits on wider issues, the new guidelines place broad restrictions on key areas of biotechnology. As such, they have considerable implications for many fields of biotechnology research, such as antibiotic, antiviral, and stem-cell research. The guidelines have generated significant uncertainty as to the scope of patentable subject matter for biotechnology inventions, and the biotech and biopharmaceutical industries have noted an increase in rejections of claims related to the guidelines since their introduction. The guidelines and their subsequent application widen the gap between current U.S. practice and that in other jurisdictions, such as the European Union, Australia, and Japan where, for instance, purified genomic DNA and proteins are patentable. In a positive, however, the USPTO opened the guidelines to public consultation following their release, and is expected to issue an updated version shortly; depending on the outcome of this revision, the United States' score for this indicator may change.

- **(2016) 2. Patentability requirements and 3. Patentability of computer-implemented inventions (CIIs):** New U.S. Patent and Trademark Office (USPTO) guidance issued in late 2014 and 2015 on patentability of biotechnology and computer-implemented inventions based on recent court decisions (namely, Association for Molecular

Pathology v. Myriad Genetics, Inc., 2013; Mayo Collaborative Services v. Prometheus Laboratories, Inc., 2012; and Alice Corporation Pty. Ltd. v. CLS Bank, 2014) confirm and extend the increasingly narrow approach taken by the USPTO to patentability. Under the new guidance, such an approach includes not only biotechnology and diagnostic-related subject matter but also business methods and computing. The guidelines present a two-step eligibility test in which subject matter dealing with these types of exceptions must demonstrate an inventive step—something "significantly more" than a generic process and/or a material change from a naturally occurring substance—and in such a way that it will not inhibit other uses of the general exception in order to qualify as patentable. The USPTO has attempted to clarify what this means using various examples from recent case law; however, further clarification is still needed. Court decisions in 2015 (for instance, Ariosa Diagnostics v. Sequenom, 2015) appear to further raise the threshold for patentability for subject matter involving a generic process to include lack of any knowledge of that process at the time the patent was filed. In relation to CIIs, while the new guidance provides further clarity on what types of CIIs are considered patentable, more is needed. Since the guidelines' release, a high number of claim invalidations related to computing processes have been issued (about 90% of claims proceedings, with roughly two-thirds of these relating to computing claims, or ideas implemented on a generic computer). This may suggest that while the guidelines themselves continue to permit patentability of software, there is need for further clarity in order to avoid an approach that is overly narrow or prohibitive for true software inventions. Future scores for these indicators will depend on how existing and forthcoming USPTO guidance is interpreted in practice.

- **(2017) 2. Patentability requirements:** In 2016, as part of its ongoing effort to develop guidance on recent key Supreme Court decisions in Myriad, Mayo, and Alice, the USPTO issued new guidelines on eligibility for patentable subject matter for naturally occurring substances. Although greater clarity is still needed, the guidance thus far appears to indicate that certain biologic claims and diagnostic methods are patentable, particularly where they involve something "significantly more" than an underlying "law of nature." A number of court cases in 2016 appear to mirror this approach. In Rapid Litigation Management Ltd. v. Cellzdirect Inc., a Federal Circuit decision reversed an earlier decision limiting patentability of diagnostic claims, finding that biologic processes and diagnostic claims applying laws of nature (beyond merely

observing or identifying such laws) and leading to a "new and useful" result are patentable. In Vanda Pharmaceuticals Inc. v. Roxane Labs, Inc., claims on a personalized medicine method were upheld on the basis that both diagnostic and treatment methods included an additional step that went beyond merely depending on the laws of nature. Nevertheless, the patenting environment in the U.S. continues to be affected by uncertainty as to how to interpret Myriad and other key decisions, and greater clarity, consistency, and closing of gaps with international best practices is crucial to upholding a supportive innovation environment.

- **(2018) 2. Patentability requirements:** In 2017, interpretation of the recent Supreme Court decisions in *Myriad*, *Mayo*, and *Alice* by lower courts and guidance from the USPTO remained inconsistent and difficult to apply. This has led to considerable uncertainty for innovators and the legal community, as well as an overly cautious and restrictive approach to determining eligibility for patentable subject matter for areas such as biotech, business methods, and computer-implemented inventions that is out of sync with international best practices. The environment seriously undermines the long-standing world-class innovation environment and global competitiveness of the United States. As a result, in 2017 a number of legal societies and industry groups called for legislative reform of Section 101 of the U.S. Patent Act, citing the need for providing clarity on patentability in a wider, legislative context rather than in highly specific guidelines and case law.

- While the U.S. maintains the highest-rated overall IP system in the world as measured by the Index, it is not perfect. Restrictive patentability standards, excessive litigation burdens, and legal uncertainty regarding the durability of rights, have dampened the economic incentive for long-term, capital-intensive, and high-risk research and development in cutting-edge sectors.

- Recent steps by the U.S. Patent and Trademark Office to improve the predictability, consistency, and confidence in the American patent system represent important steps toward addressing these concerns.

- The work of this Committee to foster an open and deliberative debate is another essential contribution.

- For its part, the Chamber is committed to preserving and promoting U.S. innovation leadership through a system that recognizes the economic incentives and impacts for innovators, technology adopters, and the American public alike.

- A nuanced and sophisticated approach to law and regulation is not exclusive of a clear and unequivocal political commitment to property rights. A fair and competitive marketplace demands no less.

- I thank the Committee for its leadership, and I would be happy to answer any questions you may have.