Questions for Henry Hadad
President, Intellectual Property Owners Association

1. You know firsthand the impact the current state of patent eligibility has on them. Just from an economic perspective, can you briefly discuss how much the current law is costing us in terms of lost economic output, jobs, and productivity?

Confusion about what is patent-eligible discourages innovators from pursuing work in certain R&D intensive technological areas, including discovering new genetic biomarkers and developing diagnostic and artificial intelligence technologies. For businesses, this uncertainty discourages the enormous investment in research and development that is necessary to fuel the innovation cycle in these areas. This is detrimental to America's competitiveness in the global economy as other large economic markets such as China and the European Union take a more expansive view of what is patent-eligible. The current state of play increases the risk that investment dollars will be spent overseas rather than in the U.S., for which there is evidence to suggest is already happening,[1] particularly in small companies or start-ups that rely on a predictable patent system to justify investment. Perhaps most importantly, discouraging innovation is bad for the American public, which will suffer from the lack of valuable new products, services and jobs.

2. What have your member companies said about the current state of Section 101? Can you share personal stories about

[1] *See* Lance Ng, *China Could Dominate Venture Capital in 2019*, MEDIUM (Jan. 11, 2019) https://medium.com/behind-the-great-wall/chinas-venture-capital-market-could-dominate-the-world-in-2019-5bc56e7d4edd.

how the current law has impacted them, their business operations, and their future investments in cutting edge research and technologies?

IPO's membership is large and diverse, and there are a range of views among our members on this issue. Despite the wide variety of technologies and business models among our members, in 2017, our Board of Directors supported legislation to amend section 101 by a large majority.

Several of our member companies appeared before the Subcommittee on June 11 to testify about how the current state of Section 101 has affected their businesses. Their written statements contain numerous examples of how the current law has affected their businesses and investment in innovation. For example, Robert DeBerardine discussed how Johnson & Johnson relies on the patent system "to provide the predictability needed to allow us to invest in new technologies and develop the next generation of medical breakthroughs." He went on to say, "Patent protections allow innovative drug companies to take on this level of uncertainty and financial risk. Without a predictable patent system, new discoveries would be immediately copied, and investors would pursue far less risky endeavors. Ultimately new research would be limited, and many new medicines would go undiscovered."

Similarly, Corey Salsberg of Novartis testified that the "true story of biopharmaceutical innovation is the story of risk-taking, investment, a willingness to fail, and a practical means to keep it all going at a scope and scale that can keep yielding results. The patent system has successfully provided that means since the earliest days of modern medicine, and continues to do so today." He noted that "under Section 101 [Novartis has] lost several cancer-related 'method of treatment' claims that involve first checking to ensure that the patient has a specific genetic mutation before administering the novel drug that targets that mutation" and that these "are the very types of inventions that the current law threatens, and will continue to disincentivize without reforms." He expressed the

company's concern "that eligibility law is on a collision course with the future of medicine."

Laurie Hill of Genentech noted that "the life-changing work of our scientists depends on a stable and predictable patent system that rewards innovation" and "on amendments to Section 101 of the patent law along the lines of the legislation drafted by Senators Tillis and Coons." She described "[a] stable patent system" as "critical to developing breakthrough medicines," arguing that the current state of the law "will inevitably steer investment away from ground-breaking and novel medicines and therapies as well as potentially slow the progress of science as companies will start to keep more and more of their work a trade secret." She said "[t]he type of investment like the kind Genentech is making depends on a stable U.S. patent system that rewards innovation and risk-taking. Biotechnology companies pursuing innovative medicines are willing to make the significant dedication of resources necessary to develop new products, but given the considerable investments of time, resources, and human power to develop a potential therapy, they need to be assured that the patent system will offer protections for their innovations. Ambiguous or shifting rules on patent protection can be nearly as damaging as providing no protection at all."

Kimberly Chotkowski testified that "InterDigital's incentive to invest in promising new technology in the form of research and development, patents, and jobs has been reduced. Further, it has driven InterDigital to consider other jurisdictions and means of protection and enforcement for valuable technologies that are at risk under the current 35 USC § 101 analysis. This is not by choice but by necessity as other nations' goals of technical supremacy in software and 5G, for example, continue marching ahead." She said that "certainty regarding patent protection for valuable software inventions is critical to the continued investment and development of technologies by InterDigital and the U.S. economy. A robust and properly functioning patent system with clear guidance as to what is and is not patent eligible is a key component to promoting investment and development of technology thereby fostering a strong overall economy."

Byron Holz testified that "Nokia believes that recent changes in U.S. patent law—including in the

area of subject matter eligibility—have tipped the scales too much against the interests of patent owners." He reported Nokia's rate of Section 101 rejections for AI-related applications increased by about 50% from before *Alice* to the 3-year period after *Alice* and that the trend had continued. He noted that the USPTO's examination guidance could lead to some improvement, however, "agency-issued guidelines will not provide the same level of certainty as a change in the controlling law." He said that uncertainty with regard to "which rights may be secured in important technologies like artificial intelligence and other software-based technologies" can "discourage investment and increase the cost of prosecuting patents."

Laurie Self said that "consistency and predictability in patent eligibility standards are important features of a strong patent system that facilitates 5G R&D" but that "whether [Qualcomm] will be able to obtain adequate patent protection for this incredibly important technology is murky and uncertain." She detailed how numerous Qualcomm patents on 5G network technology "have been abandoned, rejected, or delayed due to the difficulty of applying section 101" and said the company has "great concerns about the scope of the abstract idea exception and how it will impact our ability to protect our innovations in this field." She also discussed the "comparative disadvantage that section 101 confusion creates for U.S. innovators," explaining how "three patents [Qualcomm] abandoned, denied, or delayed in the United States [were] granted by European and Chinese examiners reviewing them under the Patent Cooperation Treaty (PCT). In none of these cases did the PCT examiner raise any concerns regarding subject matter eligibility." She also discussed the essentiality of patents to national security and U.S. competitiveness in the global economy.

Finally, Manny Schecter of IBM testified that the "inherent ambiguity of these standards has made it more difficult to obtain and enforce patents, especially with respect to a key driver of our economy -- computer implemented inventions." He said that the Supreme Court's case law has resulted in a reduced ability to protect inventions and to disseminate knowledge via work with research partners and a diminishment of patent protection for "cutting-edge computer related inventions" such as "quantum computing, artificial intelligence, blockchain, and the internet of things." He also

indicated that “the current patent eligibility standards do not provide the certainty needed to enable modern business to operate effectively” and discussed the threat of a “ripple effect throughout the broader economy, as artificial intelligence and other advanced software innovations are increasingly infused across all industries, such as automotive, healthcare, and manufacturing.”

Questions for the Record for Mr. Henry Hadad
Senate Committee on the Judiciary
Subcommittee on Intellectual Property
Hearing on "The State of Patent Eligibility in America: Part II"
June 5, 2019

QUESTIONS FROM SENATOR BLUMENTHAL

1. Striking the appropriate balance between encouraging innovation and protecting consumers is a key goal of our patent system.
    a. **What impact will broadening the subject matter that can be patented have on industry?**

Rather than broadening the scope of patent-eligible subject matter, overturning the Supreme Court's narrowing interpretations of section 101 will restore the scope of subject matter eligibility to that intended by Congress in the passage of the Patent Act of 1952. The Framers in 1790 and Congress in 1952 intended that "anything under the sun that is made by man" should be eligible.[1] Thus, human activity to "make" something should be the touchstone of eligibility.

As many witnesses testified to the Subcommittee, the lack of clarity surrounding patent eligibility has undermined research and development and threatens the ability of businesses to develop 5G, AI, quantum computing, new medicines and diagnostic tests, and genetic biomarkers. It has become easier to obtain a patent on certain technologies in the EU and China than in the U.S. Restoring the scope of patent-eligible subject matter is necessary for the U.S. to maintain its global competitiveness in these important areas.

The impact of clarifying the law on patent subject matter eligibility will be to restore confidence in a system that requires certainty, consistency, and predictability necessary for businesses to innovate and invest in research and development with the knowledge that the patent system will protect that investment from infringement. Reform to the current state of patent eligibility will not change the criteria of patentability—that is, an invention must be novel, non-obvious, and adequately described. These patentability requirements would continue to regulate patent quality and ensure that only meritorious inventions receive patent protection.

    b. **What impact will broadening the subject matter that can be patented have on consumers?**

For businesses, excluding important technological areas from patent eligibility, or at the very least making such patent protection less certain, discourages the investment in research and development necessary to fuel the innovation cycle. When important technologies are not developed and never come to market, consumers are the ultimate losers. Clarifying the law of patent-eligible subject matter will improve U.S. consumers' lives by assuring that key technologies are developed to prevent and cure diseases, facilitate and increase human connectivity and productivity, and otherwise improve our quality of life. Moreover, restoring the patent eligibility standard to the role intended by Congress in 1952 and in the Constitution will make us more competitive with other global economies, increasing domestic R&D, investment and job creation.

[1] S. Rep. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952).

c. Could these reforms increase consumer prices? If so, in what industries or on what products?

Broad access to technology for consumers requires a restoration of the fundamental incentives that allow that technology to be brought to market in the first place. By rectifying current exclusions in patent eligibility, and their uncertainty and predictability, with legislation, Congress will ensure that U.S. consumers have access to valuable new products, services, and jobs. Additionally, allowing innovation into cutting-edge technologies should result in more new products and accompanying competition and feed the cycle of innovation, which also leads to lower prices. For example, improvements in personalized medicine will result in more targeted and efficacious treatments that improve patient outcomes and reduce overall healthcare costs while improving our overall economy through a healthier work force.

6/25/2019

Questions for the Record for Henry Hadad
From Senator Mazie K. Hirono

1. Last year, Judge Alan Lourie and Judge Pauline Newman of the Federal Circuit issued a concurring opinion to the court's denial of *en banc* rehearing in *Berkheimer v. HP Inc.*, in which they stated that "the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are § 101 problems."

   Do you agree with Judges Lourie and Newman? Does § 101 require a Congressional fix or should we let the courts continue to work things out?

Yes. The current patent eligibility jurisprudence is unjustified as a matter of legal principle and sound domestic policy. Moreover, confusion about what is patent-eligible discourages inventors from pursuing work in certain technology areas, including discovering new genetic biomarkers and developing diagnostic and artificial intelligence technologies. For businesses, excluding key technologies from patent protection and creating uncertainty about what is protectable discourages the enormous investment in research and development that is necessary to fuel the innovation cycle. This is detrimental to America's competitiveness in the global economy.

In 2017, IPO adopted the first proposed statutory amendment of section 101. Our goal was to clarify the scope of subject matter eligibility in a technology-neutral manner, require evaluation of the invention as a whole rather than parsing a patent's claims into individual elements, and clearly state that no consideration of an "inventive concept," nor the requirements of sections 102, 103, and 112, should factor into determining whether an invention is patent-eligible. Shortly thereafter, we joined forces with the American Intellectual Property Law Association (AIPLA) and synthesized our work into a joint legislative proposal that both associations adopted in 2018. That the two largest IP organizations have adopted this proposal is indicative that the profession as a whole believes legislative reform is necessary.

   a. **The European Union, China, and many other countries include some sort of "technology" requirement in their patent eligibility statutes. What can we learn from their experiences?**

IPO is still studying the proposed definition of useful as requiring "human intervention" in a "field of technology." We note, however, that the proposed use of the term "technology" in the Tillis/Coons draft language from May 22, 2019 seems distinct from the technology requirements of other countries.

For example, the European patent eligibility standard differs from the U.S. standard—both current and proposed—in a key aspect. Rather than stating a positive standard for what is regarded as patent-eligible, the European Patent Convention states the eligibility requirement in the negative as a non-exhaustive list of subject matter that is not eligible. Because these types of lists are necessarily backward-looking and are not broad enough to encompass future technologies, we believe a more forward-looking approach that is predicated on the four categories of patent eligibility, as well as the utility requirement and need for human intervention, provides appropriate guidance as to whether new subject matter has a technical character and thus constitutes an invention eligible for a patent.

The IPO-AIPLA proposal supports a technology-neutral approach to stating the test for subject matter eligibility, and language that is flexible enough to apply to as-yet-unknown technological advances.

b. Is a claim that describes a method for hedging against the financial risk of price fluctuations—like the one at issue in the *Bilski* case—in a "field of technology"? What if the claim requires performing the method on a computer?

IPO has not taken a position on this issue.

c. What changes to the draft, if any, do you recommend to make the "field of technology" requirement more clear?

IPO has not taken a position on this requirement.

2. Sen. Tillis and Sen. Coons have made clear that genes as they exist in the human body would not be patent eligible under their proposal.

Are there other things that Congress should make clear are not patent eligible? There are already statutes that prevent patents on tax strategies and human organisms. Are there other categories that should be excluded?

IPO supports the use of restraint when it comes to creating exceptions to patent eligibility. Our joint proposal with AIPLA emphasizes the principle that human activity to "make" something should be the touchstone of eligibility, reflecting the Framers' intent in 1790 and Congressional intent when passing the 1952 Patent Act that "anything under the sun that is made by man" should be eligible. The four existing categories of inventions—process, machine, manufacture, and composition of matter—do most of this work. The two narrow, precisely defined exceptions in the IPO-AIPLA proposal were intended to further distinguish useful subject matter that is made by humans from that which is not and to preserve a broad scope of subject matter eligibility. Patentability criteria, such as novelty, non-obviousness, and adequate disclosure, will continue their important role as safeguards on patent quality.

3. I have heard complaints that courts do not consistently enforce Section 112 with respect to claims for inventions in the high tech space.

a. Are these valid complaints?

The section 112 doctrine has been able to develop more extensively in other fields of technology, e.g., the life sciences, possibly as a consequence of the courts' current focus on analyzing claims for computer-implemented inventions under section 101. Many claims that have been rejected by the courts under section 101 as "abstract ideas" actually have been explicitly described by the courts as overly broad, indefinite, not enabled, or lacking written description—which are all requirements of current section 112. Using section 101 as a proxy for these requirements creates inconsistency and uncertainty.

The existing requirements of section 112 already serve as an effective check on patent claim breadth. Rigorous application of section 112's current requirements of written description, enablement, and definiteness in claiming could address many concerns that courts are currently addressing improperly under section 101.

b. Do the proposed changes to Section 112 adequately address those complaints and limit the scope of claims to what was actually invented?

IPO has not taken a position on the suggested changes to section 112(f). These proposed changes may require further study to understand how they would interplay with the existing requirements of section 112.

c. Are you concerned that the proposed changes will make it too easy for competitors to design around patent claims that use functional language?

IPO is studying the proposed amendment's impact.

4. There is an intense debate going on right now about what to do about the high cost of prescription drugs. One concern is that pharmaceutical companies are gaming the patent system by extending their patent terms through additional patents on minor changes to their drugs. My understanding is that the doctrine of obviousness-type double patenting is designed to prevent this very thing.

   The Federal Circuit has explained that obviousness-type double patenting "is grounded in the text of the Patent Act" and specifically cited Section 101 for support.

   Would the proposed changes to Section 101 and the additional provision abrogating cases establishing judicial exceptions to Section 101 do away with the doctrine of obviousness-type double patenting? If so, should the doctrine of obvious-type double patenting be codified?

IPO has not taken a position on this question, but in general, the proposed changes to section 101 should have no impact on the doctrine of obviousness-type double patenting. Restoring patent eligibility through legislative action will not impact the criteria for patentability, including obviousness-type double patenting.

There are generally two types of "double patenting". The "same invention" double patenting rejection is grounded in section 101's statement that an inventor may obtain **a** patent. The draft legislative language retains this phrasing and thus this interpretation should continue to apply.

The second type of double patenting is "obviousness-type double patenting," which is judicially created and prevents prolonging patent term by prohibiting claims from issuing in a second patent that are patentably indistinct from the claims in a first patent. Applicants are permitted to submit terminal disclaimers to overcome this prohibition so that later patents claiming obvious variations of the invention can issue but with the same expiration date as the first patent. Obviousness-type double patenting analysis is akin to that undertaken to determine whether claims are nonobvious and should be unaffected by any abrogation of cases interpreting section 101.

5. In its *Oil States* decision, the Supreme Court explicitly avoided answering the question of whether a patent is property for purposes of the Due Process Clause or the Takings Clause.

   What are the Due Process and Takings implications of changing Section 101 and applying it retroactively to already-issued patents?

The question of retroactive or prospective effect is not addressed by the proposal. IPO has not taken a position on this question.