Questions for Q. Todd Dickinson and David Kappos Former Directors of USPTO

- This set of questions is for both Mr. Dickinson and Mr. Kappos. As former USPTO
 Directors I think both of you are uniquely positioned to talk about how the current law is impacting America's economic strength and vitality.
 - a. In your opinion(s), how has the current state of unpredictability surrounding Section 101 hampered research, development and innovation, particularly in critical industries like life sciences, diagnostics, and artificial intelligence?
 - i. The current state of unpredictability surrounding Section 101 has hampered American innovation in these critical industries that rely on expensive research and development, by suppressing the amount of capital available to innovators. Companies do not invest in research and development that does not lead to a protectable product. If a company cannot obtain patent protection for a product, it will not provide the funding necessary to create that product. Instead, rational companies will look to reallocate funding to products that are more likely to receive patent protection, and away from innovation in the life sciences, diagnostics, and artificial intelligence areas.
 - b. Absent legislative reforms—or some type of clarity from the Supreme Court—do you anticipate America falling behind in not only those key industries but other emerging technologies?
 - i. Unfortunately, yes. Business abhors uncertainty. Currently, there is too much uncertainty in the United States about whether life altering innovations will receive patent protection and, even once obtained, whether patents covering life altering innovations will be enforceable, to enable American innovation in the life sciences, diagnostics, and artificial intelligence industries.
 - ii. As David Taylor's forthcoming Cardozo Law Review article titled *Patent Eligibility and Investment* shows, the funding needed to fuel American innovation in these key industries is already being reduced due to uncertainty regarding what constitutes patentable subject matter. As a result of reduced investment, American innovation is already falling behind, and will continue to fall behind, foreign innovation in these critical industries.

- c. One of the key concerns I've heard from companies big and small is that absent additional clarity in this space, we're going to start seeing American companies start developing their inventions overseas in jurisdictions which have broader standards of patent eligibility. Do you agree with that concern and, if you do, what evidence have you seen to suggest that technological inversion is already occurring?
 - i. I agree with this concern. While it is still early days and I am unaware of hard data that is directly on point, it is not hard to believe that technological inversion is already occurring when foreign countries such as China are actively seeking to use their considerable monetary resources and strong patent laws to bring technological innovation to market. To better understand the effects of technological inversion, I urge Congress to commission research on this pressing concern.

Questions for the Record for the Honorable David J. Kappos Senate Committee on the Judiciary Subcommittee on Intellectual Property Hearing on "The State of Patent Eligibility in America: Part I" June 4, 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?
 - i. Broadening the subject matter that can be patented will have a positive impact on industry because it will encourage investment in innovation by removing the current uncertainty surrounding what constitutes patentable subject matter. Further, I do not anticipate that broadening the subject matter that can be patented will have any material negative impact on industry because the changes the America Invents Act made to Title 35 of the United States Code already solve for the patent abuse that previously negatively impacted industry. Said differently, there is very little downside, and almost all upside, to this change.
 - b. What impact will broadening the subject matter that can be patented have on consumers?
 - i. Broadening the subject matter that can be patented will have a positive impact on consumers because it will bring more innovative products to market. By properly incentivizing and protecting innovators, consumers will have increased access to new health solutions, diagnostic methods and information technology.
 - c. Could the proposed reforms increase consumer prices? If so, in what industries or on what products?
 - i. I do not believe the proposed reforms will increase consumer prices. Instead, I believe the proposed reforms will increase the rate of investment in innovative technologies, which will increase the rate of innovation. Increased innovation leads to more products in the market, and more products in the market place leads to cost-lowering competition.
 - ii. Further, patent rights expire, which means any potential short-term increase in consumer prices is necessarily limited to the length of the patent rights protecting the consumer products. After the patent expires, the innovation inures to the public benefit forever. The alternative to this limited-term patent protection is trade secrecy, which can lead to indefinitely higher consumer prices.

Questions for the Record for David J. Kappos 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?

I agree with Judges Lourie and Newman. Section 101 requires a Congressional fix for two reasons. First, courts have struggled to create a workable and sustainable patent eligibility framework that promotes innovation. Second, national innovation policy is within the purview of Congress. Congress must use its authority to commission studies, hold hearings and legislate to fix the current problems introduced by case law that are plaguing Section 101.

- 2. The Federal Circuit rejected a "technological arts test" in its *en banc Bilski* opinion. It explained that "the terms 'technological arts' and 'technology' are both ambiguous and everchanging." The draft legislation includes the requirement that an invention be in a "field of technology."
 - a. Do you consider this a clear, understood term? If so, what does it mean for an invention to be in a "field of technology"?

I think the phrase "field of technology" will require further refinement to become a clear, understood term. Fortunately, this further refinement can be achieved over time through the creation of case law interpreting the phrase.

As shown by the success of the Covered Business Method review program introduced in 2011 by the America Invents Act, where a "technological" test is already in use, and has been applied by the USPTO for about 7 years, the phrase "field of technology" can provide a workable construct for use in the patent system.

b. 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?

We can, and should, learn that including a technology requirement in a patent eligibility statute works. Introducing a technological contribution standard to the United States' patent eligibility statute would be a step in the right direction because such a standard is generally workable and avoids the chaos currently hampering American innovation.

Further, a technological contribution standard will be easily met by most innovation, and the edge cases should not be allowed to impede the reform the current patent eligibility statute requires. Do not let the perfect be the enemy of the good.

c. 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?

Whether such a claim is in a "field of technology" depends on the ultimate definition of "field of technology" and the particular limitations of the claim.

Whether a claim is in a "field of technology" should not depend on whether the claim requires performing a method on a computer.

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

I recommend consulting with the USPTO regarding the technology based test it uses during Covered Business Method reviews to learn how to make the "field of technology" requirement clear. Engaging with the USPTO will undoubtedly help clarify the "field of technology" requirement present in the current draft.

3. 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?

None that I am aware of.

4. 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?

Case law regarding Section 112 continues to improve, but more can be done to increase uniformity in Section 112 case law. This is indeed an area where more can be done to strengthen the text circulated by Senator's Tillis and Coons. Section 112 should be applied vigorously by the USPTO and the courts to ensure that patent claims do not exceed the scope of the disclosure supporting them.

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

The proposed changes to Section 112 are helpful, but more can be done by codifying the Supreme Court and Federal Circuit decisions that fortify the written description requirement 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?

No. Patent applicants have the ability to mitigate these concerns by including detailed descriptions of their inventions in their specifications and by including more structural language in their claims.

5. 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?

Obviousness-type, or non-statutory, double patenting is still rooted in Section 103, and Sections 102 and 103 substantially cover the concerns associated with obviousness-type double patenting. The proposed legislation does not do away with the doctrine of obviousness-type double patenting.

6. 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 point of the proposed changes to Section 101 is to broaden the definition of patentable subject matter, not to invalidate already-issued patents. Therefore, the Due Process Clause and the Takings Clause do not appear to be implicated by the proposed changes to Section 101.