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

1. **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?**

Answer: Simply put, yes, especially in the industries you cite. It is not only unpredictability in the strict sense, but

also an inability to clearly understand what the Supreme Court meant in its most recent §101 jurisprudence. For an another, singular example of the confusion and ambiguity of that jurisdiction, I would direct you to the recent opinions of the CAFC, denying *en banc* review to the important life sciences/diagnostics case, *Athena Medical, et al. v. Mayo, et al.* (CAFC 2017-2508 (July 3, 2019). http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/17-2508.Order.7-3-2019.1.pdf

The CAFC took no less than 86 pages and 8 separate opinions to try and parse what the Supreme Court meant in its recent §101 cases and how to apply it. Indeed, all 12 active judges expressed the view that the Supreme Court's jurisprudence, especially its *Mayo* opinion, was unworkable and denied patent protection to very worthy inventions or

discoveries. The court split 7-5 denying *en banc* review, the majority holding the view that even though the Supreme Court precedent was denying appropriate patent protection for important medical diagnostic technology, they felt that they were unfortunately bound by *Mayo*. The 5 in the minority simply felt either that they could distinguish *Mayo* or that the Court got it wrong.

What is even more amazing about these 8 opinions, however, is the realization that the most important and knowledgeable court for patent appeals, those who see these cases routinely, had to go to such extreme pedagogical lengths to try and explicate the Supreme Court's texts. If they can't figure it out, how is the general public, or the relevant researchers and investors, and their counsel, supposed to?

To answer more specifically, it is well-known to both the life sciences research community and their investors that this confusion and ambiguity has introduced a significant uncertainty into their work, with a resultant negative impact.

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?

Absolutely. The one, and maybe only, thing that the leadership of America's innovation infrastructure knows now about the patent system is how unpredictable it is, and industry hates nothing more than uncertainty. It both

reduces R&D in the U.S., and drives it overseas. It also drives it underground in the form of trade secrets, keeping valuable technologies from being improved on by others. We can also see it in the reduced rate of patents issuing to U.S.-based innovaters, in particular.

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?

As I suggested in my answer above, I very much agree with this concern. While there are anecdotal indications

that this is actually occurring, it would be hard to believe it was not, given the on-going erosion of our patent system by this problem and the strengthening of the systems of our global competitors. While I have heard that there are more empirical studies underway, this might also be a good project for the Administration or the Congress to undertake or fund.

Questions for the Record for the Honorable Q. Todd Dickinson
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 not sure that the proposals being discussed necessarily "broaden" subject matter patent eligibility so much as reform and clarify the appropriate standards under 35 USC 101 from the Supreme Court's recent 101 jurisprudence. This clarifying, and any broadening that might result, will hopefully lead to greater certainty for American industry and innovation, and therefore likely result in increased investment in R&D in the U.S. Such increased investment cannot help but expand the innovation economy, resulting in more innovation and new jobs.

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

      Please see the above answer with regard to "broadening". Similar to the effect on industry also noted above, greater investment in innovation will likely result in more new inventions, leading to greater competition and both greater choice for American consumers as well as additional jobs.

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

      For similar reasons to "b" above, it is not certain that any wide-spread increase consumer prices would necessarily result from the proposed reforms. To the contrary, greater investment in innovation should result in greater competition, which in turn, should actually lower consumer prices and provide more choices. It is somewhat hard to predict industry-specifically, but it would not be surprising if the positive effects of the proposed reforms were not felt broadly across many industries and products. Two that has been predicted to make a positive impact is in the area of life sciences and medical devices.

Questions for the Record for Q. Todd Dickinson
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 very much agree with Judges Lourie and Newman. I would also point to the CAFC's recent opinion denying *en banc* review in an in the important life sciences/diagnostics case, *Athena Medical, et al. v. Mayo, et al*. (CAFC 2017-2508 (July 3, 2019). http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/17-2508.Order.7-3-2019.1.pdf.

   As I replied to Chairman Tillis's additional questions, in this case the CAFC took no less than 86 pages, and 8 separate opinions to try and parse what the Supreme Court meant in its recent §101 cases. Indeed, all 12 active judges expressed the view that the Supreme Court's jurisprudence, especially its Mayo opinion, was unworkable and denied patent protection to very worthy inventions or discoveries.

   What is even more amazing about these 8 opinions, however, is the realization that the most important and knowledgeable court for patent appeals, those who see these cases routinely, had to go to such extreme pedagogical and jurisprudential lengths to try and explicate the Supreme Court's texts. If they can't figure it out, how is the general public, or the relevant researchers and investors, and their counsel, supposed to?

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 ever-changing." 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 I also noted in my written testimony that if this phrase is eventually used in the enacted legislation, I would strongly support the very broadest interpretation of it. History has always shown that it is extremely difficult to know where the next innovation breakthroughs will arise. Whether certain of those innovations meet this definition if is it interpreted too strictly could easily lead to greater uncertainty, limited reward for developing new innovation and reduced investment them. Moreover, to create a list of things that are either in or out of that definition would likely lead to the introduction of personal biases of what "should" be patent eligible, which is one thing we hope that we are getting away from in this legislation. If it does survive in the enacted legislation,

when there is a close call on eligibility, the default position should be that the invention should fall on the side of eligibility, rather than today, where it tends to tip in favor of ineligibility in many industries.

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?

What's interesting about both the EU (via the EPO) and China is that they have generally relaxed their formerly stricter definitions of what they mean by the term. This has resulted in the phenomenon that broader and clearer patents on critical innovation areas, such as biotechnology and certain software inventions, are available in both of those regions than in the U.S. One likely result of that is shift in R&D investment from the U.S., a highly undesirable outcome for both U.S. innovation and jobs.

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?

I tend to agree with the lodestar of patent law and policy, the late judge Giles Southerland Rich, one of the co-drafter of 35 U.S.C. § 101, who in his opinion in *State Street Bank v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), addressed this question, when he stated that any invention, in particular process or method patents, that produces a "useful, tangible, and concrete result" is patent eligible. He also specifically said that he did not find a limitation excluding so-called "business method patents" in § 101.

Claims which merely take known inventions or concepts and try to claim them as being performed or implemented on a computer are unpatentable as obvious under 35 U.S.C. §103.

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

I would codify the presumption of eligibility that I mentioned above, and clarify in any legislative history or floor debate, that "field of technology" was to be interpreted broadly.

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?

I believe that Chairman Tillis and RM Coons's views in this matter are correct. Also, as they pointed out, since the entire human genome has been expressed and disclosed, any patents on human gene sequences are almost certainly unpatentable as anticipated or obvious in view of 35 U.S.C. §§102 and 103, with no need to invoke §101. The other limitations you mention

are, generally speaking, more the result of the political clout of certain trade groups or political interest groups without a direct stake in the patent system. That said, the limitation on eligibility of human beings has been a long-standing policy of U.S.P.T.O. dating back to the Reagan Administration, including my time at the PTO, and the limitation on tax strategies technically uses §103 obviousness, not an amended §101. Any attempt to develop a list of specific categories generally risks unproductive debates among stakeholders, likely ambiguous statutory language and a result that is the product of lobbying influence rather than reasoned analysis.

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?

See below "b".

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

Generally speaking, focusing on §112, in all of its subsections, and how it is used and interpreted by the PTO and the courts would have been a much better way to deal with patent quality, rather than the fruitless exercise of the Supreme Court's jurisprudence on §101. That said, the current proposed changes to §112(f) run a significant risk of overly restricting the ability of innovators to obtain valuable protection for their inventions. Specifically, it is possible that courts might use it later to basically reimpose an ambiguous or broadened interpretation of patentablity, which problem is what is attempted to be solved by the clarification and reform of §101 in the current proposal.

Additionally, the current language would likely very severely and unfairly limit the breadth of coverage of patent claims. This hinders certain technologies which rely on using the current language of §112(f) to more appropriately frame the claims of their invention. There is also the risk that these changes would result in "everything but the kitchen sink" disclosures, clogging up specifications and increasing the filing of continuation applications. This would also have a negative impact of the USPTO's ability to process patent application, increasing workloads and cost. The current language needs significantly more careful discussion.

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

Yes. As I indicated above, the current language risks overly narrow claims and, therefore, protection, resulting in greater ability of competitors to inappropriately design around those claims. Additionally, many technologies can only best be expressed by using functional language, particularly in the life sciences. Those concerned with over-breadth or ambiguousness in patent drafting should rather support the use of more consistent nomenclature and renewed consideration of the PTO's former pilot program

requiring a glossary of terms in patent applications as a more attractive solution to this concern.

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?

   I believe the phrase you cited came from Judge Dyk's opinion in *AbbVie v. Kennedy Institute,* 764 F.3d 1366 (CAFC, 2014), referencing *In re Longi,* 759 F.2d 887 (Fed. Cir. 1985). In both cases, this reference to §101addresses the prohibition against regular double patenting and not obviousness-type double patenting, specifically that §101 states that only one patent may issue on one invention:

   > "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, . . . may obtain ***a*** patent therefor." 35 U.S.C. § 101 (emphasis added). Thus, § 101 forbids an individual from obtaining more than one patent on the same invention, i.e., double patenting."

   The proposed language of the current bill contains the exactly same language regarding "***a*** *patent therefor***"**, resulting in no change in ordinary double patenting rule.

   As this case makes clear, the obviousness-type double patenting doctrine is grounded in §103 non-obviousness, not §101, so this line of cases will not be abrogated by the proposed legislation.

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 principal issue before the Court was primarily whether the America Invents Act's post-grant scheme was Constitutional. In their opinon, they stated in cases patents were to be considered public rights and that the granting and re-examination of patents falls within those public rights managed by the Executive Branch, but that this did not contradict established

case law that patents are private property, such as found in *United States v. American Bell Telephone Co*., 167 U.S. 224 (1897).

Since the proposed statute seeks primarily to clarify the language and scope of §101, it does not seem to implicate the possible retroactive application of the Due Process and potentially in the