Questions for Jeff Birchak

1. You represent a coalition of some of biggest companies in the intellectual property arena. From the perspective of your association, how has the current state of patent eligibility hindered their ability to bring new and innovative products to market? What areas of research, development and innovation are they no longer investing in or pursuing because of the current jurisprudence?

Answer:

As noted in my written testimony, we have specific examples of how the present jurisprudence has adversely affected our member companies and their subsidiaries. For example, FotoNation is a subsidiary of Innovation Alliance member Xperi, and has developed image tracking technology that can track facial movements. This has several potential applications in the safety and security fields, such as, for example, for determining if drivers are focusing on the road instead of sleeping or looking their phone. Current 101 jurisprudence has made it much more difficult to get such patents through the USPTO and to enforce in the U.S., proven by the fact that FotoNation had to work through several actions to overcome 101 rejections, actions that cost more money to take, and could potentially have an adverse impact on enforcement activities in the future, where the same claims received no such objections in Europe, and therefore did not have the same cost issues or potential risks.

As Laurie Self provided in her written testimony for these hearings, the processing of signals and other digital processes for communications is essential for the development of future versions of communication standards. Ms. Self's testimony illustrated several examples of situations where her company has faced difficulty in prosecution of patents related to key aspects of communications technology.

However, our examples of how current 101 jurisprudence are adversely affecting our member companies is only part of the effect caused by this judicially created policy. In cases where a company faces such adversity, the company may choose not to apply for patents for inventions they feel may face similar uncertainty, instead choosing to keep it a trade secret. The misconception from many proponents is that the absence of patents is a positive as competitive products mean lower prices to consumers. However, when companies choose to elect trade secret protection instead of publicly disclosing their inventions, they and the public forego the patent bargain of public disclosure in exchange for a limited period of exclusivity in making the claimed invention. Therefore, there is no public benefit when a company elects trade secret because advances that are critical for improvements related to error correction, data correlation, or other forms of communications improvement.

These choices also impede collaboration and cross company collaborative innovation. When a company opts to forego patent protection because of the state of eligibility law choosing instead to rely on trade secret protection those innovations will not (for example) become the subject of an industry standard on which further innovations may have been built; they will not

be instantiated in open source software. In each case, these pro-collaborative options are not available because the innovator is forced to keep their innovation secret. There are other areas of technology where trade secret protection simply won't work. For example, user interface innovations that reveal their innovative content when implemented are not candidates for trade secret protection – and with the state of patent eligibility as it is now these and other such areas are and will continue to see less investment.

Proponents of the status quo for Section 101 judicially created policy ignore the positive effects of the exclusive patent rights for our society assuming competitors would know how to make competing products without the disclosure by the original inventor. This is simply naïve and radical considering the patent bargain is part of our constitutional underpinnings for economic prosperity. Their proposal would be a net negative for our country as invention disclosure allows research in new areas not considered by competitor companies, where knowing the boundaries of what is claimed by the inventor and knowing that in the future competitive products with the invention may be made by competitors allows companies to follow the research of its competitors. The absence of patents does not promote innovation as they claim, it promotes copying of today's inventions; innovation is the development of NEW inventions in the future to make our lives, safer, better and more fulfilling.

2. Can you talk about the national security implications of our failure to correct this area of the law? Do you get a sense from your member companies that innovation is going to be driven overseas unless we fix this mess?

Answer: We are at a critical juncture in the development of certain technologies right now, especially artificial intelligence, 5G communications technology, and quantum computing. The US patent system's careful balance between innovator incentives and public disclosure has been the engine powering U.S. leadership in many key technologies. Substantial disruptions to that balance could disadvantage U.S. companies discouraging investments in these critical fields leading to the development of those technologies in a foreign country.

In China, for example, companies have certain systemic advantages. For instance, image recognition applications of AI require review and feedback to ensure that things the AI identifies are accurately identified. In its story, "China's Big AI Advantage: Humans," Vice news recently reported on how Chinese companies are utilizing their advantage in gross human resources to address this problem¹. In China, companies are throwing tons of humans at this challenge utilizing large groups of college students to complete this necessary feedback function at a surprising and concerning rate. If a U.S. company were to try to automate this function through software, as shown by the examples above, it would face an uphill battle trying to secure patent protection for that automation. The chances of a company that was trying to develop such automation receiving the necessary funding to develop such technique is decreased. Therefore, that leaves only the largest companies with sufficient capital to address such needs. Our country should not rely only on the very largest companies to solve its

¹ https://news.vice.com/en_us/article/wjvpam/chinas-big-ai-advantage-humans

technological problems because of a judicially created policy based on backward looking analysis from the cases it was given, and this is especially true in such critical areas of discovery.

Jeffrey Ding, in his testimony titled, "China's Current Capabilities, Policies, and Industrial Ecosystem in AI," before the U.S.-China Economic and Security Review Commission characterized several advantages Chinese companies developing technology have, including government funding, patenting advantages resulting from current 101 jurisprudence, and incentives for academic publications.² In that same hearing, Elsa B. Kania discussed the Chinese government's initiatives supporting its drive for military supremacy in AI, in her testimony, "Chinese Military Innovation in Artificial Intelligence."

With the advantaged availability of injunctive relief in China over the U.S., advantages in government funding and initiatives, and now the improved state of patent eligibility vis-à-vis the U.S., China is a more attractive venue then in the past and presents a real threat in the development of AI for sensitive applications. Confusion around patent eligibility, therefore creates another factor that must be considered in the competition for the development of AI and the pursuit AI funding. When considering the balance of factors that has led to U.S. supremacy in research in such areas in the past, and the concerns regarding military application of AI, it is essential that patent eligibility does not adversely affect incentives to performing such critical research in the U.S. Section 101 is lauded by those opposing the proposed legislation due to its procedural advantages in court proceedings. However, we cannot risk the future of critical technologies just so that certain patents can be disposed of in the most cost-efficient way. Congress can propose other procedural tools if indeed they are needed.

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 $https://www.uscc.gov/sites/default/files/June\%207\%20 Hearing_Panel\%201_Jeffrey\%20 Ding_China\%27s\%20 Current\%20 Capabilities\%2C\%20 Policies\%2C\%20 and \%20 Industrial\%20 Ecosystem\%20 in \%20 AI.pdf$

3. Regarding our draft proposal, do you believe it would restore the predictability and stability to the system that your member companies need to continue innovating?

Are there any changes to our draft proposal you'd suggest we make?

Answer: We believe the proposed amendment to Section 101 as proposed moves us well down the path in regaining the predictability and stability we used to have in the patent system relating to patent eligibility. We understand the intent of the definition of the word "useful" and believe the proposed change is a very workable start, provided we can address the potential ambiguity created by the use of the word "technology." The ambiguity created by the word "technology" must be addressed, or the Supreme Court and the Federal Circuit will not have the guidance required to ensure that their decisions follow the intent of this statutory reform. Similarly, the change proposed to 112(f) we believe is well intended, but in practice would be wholly antithetical to the intent of this whole effort to reform 101 jurisprudence. We believe the proposed change to 112(f) while intended to narrow the scope of some claims would instead substantially undermine the 101 reform efforts and set back patent rights an indeterminable amount. The problems intended to be addressed by this change need to be properly defined so that a solution can be identified that is narrowly tailored to address the problem without adversely affecting all other patents having any functional language. To that end we believe it would be productive if the 112(f) proposal be subjected to the same 'round table' process as were the proposed changes to 101.

4. The Innovation Alliance consists of some well-known large companies, like Qualcomm, Dolby Labs, and TiVo, and some smaller companies, like Cummins Allison and your company, Fallbrook Technologies. Can you speak to the importance of reforming section 101 for both smaller companies and larger ones? Is this an issue that affects all kinds of inventors?

Answer: For large companies, current 101 jurisprudence will lead companies to keep certain technologies as trade secrets rather than disclose them publicly in a patent application and risk not being able to get a patent on them. For other technologies, the lack of predictable 101 jurisprudence is leading to a shift of investment away from such technical areas. A shift to trade secrecy means less collaboration through open standards and open source. Large companies that rely on licensing their patents to generate income to fund further technological development have seen an unprecedented loss in their ability to reliably license their patented technologies.

For small companies, the lack of predictability presents a different challenge. If such a company were to try to develop innovative solutions in software, signal processing, or medical diagnostics, it is highly likely today that they may have trouble getting a patent to their solutions or may not even get patents at all, given the state of patent eligibility caselaw under the Court's judicially created policy. For small companies like mine, attracting venture capital is the life blood of the company and is essential to survival as the company spends years or decades (in our case) trying to commercialize its technology in a way that

provides meaningful return on investment. Patents are essential assets to provide angel, venture, and late stage investors comfort in potential returns on investment necessary to make their investments in startups. Any instability or unpredictability either prevents the ability to attract venture capital or severely changes the terms under which a company like ours can get that capital. Section 101's unpredictability has significant adverse ramifications for companies small and large alike.

5. You testified that the uncertainty around what is and isn't patentable under section 101 harms innovation. As you know, USPTO Director Andrei Iancu has made a similar argument, before this Subcommittee and elsewhere, when explaining that his efforts at the USPTO aim to restore "predictability" to the patent system. Do you agree with Director Iancu? Can you elaborate on why certainty and predictability are important for incentivizing innovators to invest in R&D?

Answer: We agree with Director Iancu on this point. As I said in the answer to question 4 above, small companies need patents to provide comfort to investors at all stages that they will have a sustainable competitive advantage in bringing a new product to market. Large companies like Google, Intel, Dell, Microsoft, Apple, and others have several advantages such as prime market position, name recognition, established channels of commerce and distribution, and many other advantages that they leverage to hold dominant market positions with or without patent protection. Patents are necessary assets for new market entrants and small companies with disruptive technologies to break into the market and compete with such companies, providing the public with new products and technologies those market incumbents cannot provide. Without patents, investors would rarely if ever risk investing in such a risky endeavor, knowing that the large market incumbent could step in and copy the product without having to do the research. Current 101 jurisprudence created by the Supreme Court's misinterpretation of the existing 101 statute has led to a situation where those small companies in some very critical areas of technology cannot confidently tell their potential investors that they will receive patent protection for their work and investment.

6. How does section 101 affect Innovation Alliance companies? Can you speak to the impact the uncertainty from current patent eligibility caselaw affects your members?

Answer: As I described in response to Question 1 above, we have specific examples of how today's uncertainty created by the Supreme Court's policy it created in Mayo and Alice have adversely affected Innovation Alliance companies.

Questions for the Record for Mr. Jeffrey A. Birchak 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?

Answer: To the extent that returning Section 101 determinations back to a period of consistency and predictability prior to the Supreme Court's judicially created policy found in the Mayo/Alice line of cases is considered "broadening," we believe such a change provides substantial benefits to affected industries.

The founding fathers knew, as laid out in the Constitution, that the availability of patent rights provides a positive incentive for companies and individuals to disclose their technological discoveries to the public in exchange for a limited period of exclusivity. Industries are benefited when inventors disclose their inventions and how to make and use them to their competitors. Where patent rights are unclear companies are not incentivized to share their learnings, as there is no clear benefit to do so, and instead resort to trade secret protection to maintain a competitive advantage regarding their discoveries.

Without such disclosures, competitive companies are forced to try to reverse engineer those same products without the benefit of the teaching disclosures. The difficulty in reproducing the results of a successful product in order to create a competing or complimentary product depends on the nature of the discovery. For certain pharmaceutical innovations it can be very difficult or even potentially impossible to determine exactly what something is or how it works. In deciding whether to pursue such efforts, companies would have to dedicate enormous resources with only the hope of trying to replicate the effects of a drug or therapy to offset the cost. For computer implemented improvements, reverse engineering can range from simple to nearly impossible as well. Without confidence that research will lead to a competitive or complimentary product, we cannot expect that companies can afford to devote substantial resources to trying to advancing their scientific field, knowing they are going to be so far behind the inventing company. These industries would therefore suffer from less development of technology when there is a lack of disclosure. Therefore, the disclosure of inventions plays a critical role in advancing science and research in areas where strong patent rights are expected.

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

Answer: If the proposed change were indeed to be considered "broadening," we believe such a change provides substantial benefits to consumers as well. As noted above, the disclosure of inventions under the patent bargain allows competitive companies to take off from an advantaged position compared to if there were no such disclosure. In searching for how to make competing or complimentary products, competitors can read exactly how to make and use a product or process, and then determine competitive ways to achieve the same result differently, such that the patents of the inventor are not infringed. This rapidly advances science and the production of competitive products and technology, thereby providing consumers with competitive alternatives to choose from.

As Paul Morinville testified in these same hearings, patent rights provide a strong and natural check on monopolies and monopolistic behavior. Patents allow smaller competitive companies to piggy back off the research of others and develop new products that can compete with large market incumbents who have several competitive advantages, like brand recognition, channels of distribution, first mover position, etc., and bring competitive products to the public that provide competitive choices for consumers. Consumers are benefitted by choices. Therefore, any increased patentability, or clarity relating to patentability, would be a net positive for consumers.

Arguments that claim patent eligibility for certain types of inventions or discoveries work some harm upon consumers are backward looking and make the erroneous assumption that research intensive products and other competitive products would just naturally be present without the disclosures and concomitant rights under the patent bargain. For instance, it is a leap to assume diagnostic tools and therapies that exist today and for which complaints of predatory pricing are lodged would even exist without the benefit of patent rights to support the investment in their discovery and disclosure associated with the acquisition of those rights. Such arguments only consider what exists today, and fail to consider the source of such products in the first place and all of the future products that increased patent certainty will lead to. The patent system exists to encourage investments in new products and has done so for centuries leading to our country's technological leadership in so many technological fields.

Congress should take immediate action to restore the balance of the patent bargain before the long term effects of today's uncertainty around patent eligibility cause real lasting disadvantages and harm to our society. To the extent that behavior of certain rights holders needs to be modified or adjusted, Congress should use its considerable power to create laws and regulations that manage such behavior appropriately. Using patent eligibility standards as the tool to adjust any such behavior is improper, has caused harm to American innovation, and will retard invention in key areas in the U.S. The proper tools to adjust such behavior should be created so that any unintended side-effects of this judicially created policy can be minimized.

2.

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

Answer: As stated above in 1.b., restoring certainty and predictability to 101 eligibility determinations benefits consumer choices, which in turn benefits consumer pricing. The Judiciary is poorly positioned to create policy that affects consumer prices and it is improper for the Court to insert itself into Congress' role in developing such policy. Congress must restore balance to the patent system by returning us to a time of predictability and certainty prior to the Mayo/Alice line of cases. Consumers and the public welfare require such action to ensure the maximum number of choices are available at the most economically appropriate pricing.

Questions for the Record for Jeffrey A. Birchak 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?

Answer: Yes, we agree with this statement. The founding fathers knew, as laid out in the Constitution, that the availability of patent rights provides a positive incentive for companies and individuals to disclose their technological discoveries to the public in exchange for a limited period of exclusivity. Industries are benefited when inventors disclose their inventions and how to make and use them to their competitors. Where patent rights are unclear and unpredictable, companies are not incentivized to share their learnings, as there is no clear benefit to do so, and instead resort to trade secret protection to maintain a competitive advantage regarding their discoveries.

Without such disclosures, competitive companies are forced to try to reverse engineer those same products without the benefit of the teaching disclosures. The difficulty in reproducing the results of a successful product in order to create a competing or complimentary product can be very significant and require substantial investment of resources. Uncertainty around patent eligibility thus has a doubly negative effect. First, primary innovators are less incentivized to disclose their inventions, as a result of the uncertainty in receiving patents. Secondly, follow on research and development is hindered as fewer innovations are disclosed upon which to build.

Furthermore, consumers are punished by this ill-advised judicially created policy as well. Patents allow smaller competitive companies to piggy back off the research of others and develop new products that can compete with large market incumbents who have several competitive advantages (like brand recognition, channels of distribution, first mover position, etc.) and bring competitive products to the public that provide competitive choices for consumers. Consumers are benefitted by choices. Therefore, increased clarity relating to patent eligibility is necessary to remedy all of these effects of this judicially created policy.

Finally, as Q. Todd Dickenson testified before this same panel, the Supreme Court has denied the grant of certiorari on patent eligibility cases 42 times after *Alice* – refusing to clarify the hopelessly ambiguous test it has created. It is Congress' duty to bring certainty required by the Constitution to this critical area of patent law.

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"?

The term "technology" lacks proper clarity and is subject to significant variations in interpretation. During the negotiations and drafting that led to the AIA, specifically relating to the determination of the bounds of the Covered Business Methods challenge, it was recognized and widely understood that this term lacked a coherent definition. Subsequently there was substantial discussion around what a "technological" invention should be. Determining a proper definition for this term relating only to financial business methods was hard enough to accomplish without unnecessarily affecting and therefore disincentivizing research in surrounding areas in that context. Trying to use this term in the current proposal that relates to all areas of research and invention is perilous. Nevertheless, if this term were to be used as it is in the definition of "useful" it would be best to properly define it as well.

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?

Answer: While both Europe and China include a "technological arts" requirement, China amended its patent laws to align closely with German laws, China is more permissive than current practice in the U.S. China's SIPO is very focused on the importance of patenting cutting edge technology like AI and 5G and through their patent examination guidelines, both China and India have shown they are more permissive in their eligibility jurisprudence than the US.¹

In his article, "Software Patent Law: United States and Europe Compared," Michael Guntersdorfer lays out some history of the patentability of software in the U.S. and in Europe.² In the late 90s, following the decision in State Street, Mr. Guntersdorfer noted the following regarding the patenting of software in Europe:

"It is notable that, especially in the beginning, the majority of European software patents were not issued to European companies, but mostly to companies from the United States and also Japan. Ironically, this result seems to stem from the fact that Europeans, accustomed to clear statutory laws, simply assumed that computer programs weren't patentable because they were literally excluded in § 52(2), while Americans, weren't discouraged as easily."

While over time the EU has worked through some of the confusion surrounding "technological arts," European practitioners will readily admit that the advent of new technologies like AI cause major confusion as participants in their patent system attempt to understand what aspects of the new technology are "technological".

¹ http://www.perlaw.ca/en/newsroom/publications/2018/2/1/china-india-make-software-patenting-easier-adrian

² https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1075&context=dltr

We can see from this that where there is uncertainty in a jurisdiction, the participants of that jurisdiction react accordingly, and are disadvantaged. European practice has come around and, up until the uncertainty from the Mayo/Alice cases, there has been more parity. So any backsliding we do, or overcorrection of *State Street*, will have a similarly negative impact on U.S. companies for some time into the future.

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?

Answer:

The Bilski hedging method was stipulated by the parties to not be performed on a computer, however in that decision the Court, while finding the method ineligible, declined to categorically declare business methods ineligible. We do not believe a categorical requirement for implementation on a computer is necessarily the only way to confer patent eligibility to a business method. Like the Bilski Court, we prefer not to affix eligibility to a particular current state of technology.

Your reference to in a "field of technology" mirrors the current 101 proposal in which useful is defined as "any invention that provides specific and practical utility in any field of technology through human intervention". The term "field of technology," as proposed, sets a limit for inventions that requires that they be in a field of technology. We believe this is not appropriate. First, per our other comments, we believe the term technology is unclear and has a problematic history in U.S. patent legislation and jurisprudence, but in addition if technology were to be a limitation to the term useful it should only be a limitation on the type of invention or discovery and not on the on the field in which that invention is applied. Clearly, inventions can and are regularly applied to all fields of endeavor whether those fields are technological or not.

Opponents of the proposed legislation have raised concerns about patents in aesthetic areas like dance moves. But clearly real technological inventions can be applied to dance moves. For example, in 1992 entertainer Michael Jackson invented a special pair of shoes to achieve the gravity defying illusion in his "Smooth Criminal" video. He was awarded US patent number 5255452. This is a technological innovation applied to the field of dance moves. Clearly an eligible patent and clearly applied to a non-technological field. Furthermore, even without involving any particular item, such as shoes, dance moves themselves may be worthy of patents in medical applications. If a distinct set of movements were discovered to have measurable therapeutic benefits for certain neurological disorders or conditions, those should also be patent eligible, whether or not they could be described as dance moves. The character of the invention as claimed, when properly construed as would be done under Section 102, should be determined on its own to have utility that is of a benefit or not, and categorical bans on areas of the arts or sciences should very rarely be instituted and only if narrowly tailored and if there is a genuine need to do so.

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

- e. Answer: I believe if we are to abide by the guiding principles of the drafting effort, we either cannot use the word "technology" as it has been made problematic by the courts, or we would have to provide a proper and definition that does not make the mistake of inadvertently excluding future technologies technology if used at all, should refer to the implementation of the invention not the area or field of useful arts and sciences. The language would need to make clear that any past use of the term by the courts is being expressly abrogated.
- 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?

Answer: Eligibility should only be adjusted for policy considerations if absolutely necessary after full deliberation of the need and the consequences of such action, and then only narrowly excluded to meet the necessity, and no more. The Constitution empowers the Congress to develop patent laws to promote the progress of science and the useful arts. Categorical exclusions from patent eligibility are not directed at that objective. In the past, Congress has addressed concerns over the use of patents and their relation to other policies such as social or economic policy by passing laws limiting the use of patents in certain areas while not circumscribing eligibility. The laws regarding enforcement of patents on surgical techniques is an example of how Congress addressed a legitimate public health concern about the possibility of patents hindering a physician's performance of life saving procedures, by altering the damages available for infringement by certain parties and not by tinkering with eligibility.

Sen. Coons and Tills have adopted an approach to amending s101 in which they have eliminated categorical exclusions to eligibility and instead relied on a set of principles that require practical application of an invention or discovery through human intervention. This is an approach that will stand the test of time and the attendant rapid advances in technology. It does what Congress is supposed to do with the patent laws – promotes the progress of science. While it is possible for Congress to pass other laws addressing concerns over the use of patents, the patent law is uniquely authorized by Constitutional mandate to promote progress and any amendment to the law ought to only be enacted if it is consistent with that mandate.

We understand that there is subject matter such as those identified above that have been excluded, but eligibility should only be invoked if there are no other mechanisms for invalidating such claims, and Sen. Tillis was clear that human genes are not patentable because they are in the public domain. Precluding eligibility as a backstop or boot-strapping step when other means of invalidity are present is undesirable due to the chilling effects it can have on key research in the affected area.

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?

Answer: We too have heard of such complaints. We have requested examples illustrating this so that a proper description of any potential problem can be created. When such a problem definition is created, then a clear solution narrowly tailored to address the problem without causing unintended adverse consequences can be crafted. Until such a problem is properly defined, we do not believe it is wise to attempt to address an undefined problem.

We continue to request specific examples of such issues and stand ready and eager to help define any such problem and craft any needed remedies of it.

In the past 5 years, section 112 jurisprudence has not developed as section 101 has been widely used to dispose of cases under the ambiguous Mayo/Alice test, even in cases we believe involved written description, enablement, or 112 utility issues. This has retarded the proper development of 112 jurisprudence, and with the correction of 101 through this effort we believe more focus can be put on the role of 112 and its proper application to claim inventions that groups claim are problematic. It seems pre-mature to address problems with 112 at this time. But again, a showing of specific current problematic activity or holdings in this area should help determine if such a problem exists and point the way to its resolution.

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

Answer: Without knowing really what the problem is that is intended to be corrected we do not know that the proposed change to 112(f) will actually address it. What we do know from extensive patent practice and history is that the proposed change to 112(f), as proposed, would result in a sea change in the way method and process claims are reviewed for infringement. We do not believe that this was intended.

Additionally, the proposed change would result in a form of practice that would run antithetical to the history of patent practice in the U.S. Over the history of the patent system, we have assumed that we speak in our patents to people of ordinary skill in the art for the invention and therefore we would not list every detail of every part of any invention, because it is reasonable to rely on the knowledge of skilled artisans. If we were not to assume that, we would fill specifications with all of the variations of each part or aspect, no matter how ordinary and mundane, just so that we would not risk missing some part a copycat might employ to avoid a process claim. The ability to make insignificant changes to avoid claims of infringement, which is what the proposed language would result in, would allow knock off products to undermine our patent system.

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

Answer: As noted in the previous answer, we believe this is exactly what the language proposed would result in.

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?

Answer: We do not believe the current proposal and abrogation language is intended to nor does affect, either expressly or in effect, the obviousness-type double patenting doctrine. The language is pretty clear on this,

"No implicit or other judicially created exceptions to subject matter eligibility, including "abstract ideas," "laws of nature," or "natural phenomena," shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated."

Only cases creating or interpreting the judicial exceptions are abrogated.

While the statutory prohibition on double patenting from Section 101's requirement that each patent will be for only *one* invention prevents issuing multiple patents on the same invention, we believe the question rightly gets at the issue of slight claim differentiation in order to expand or extend patent protection. We believe obviousness-type double patenting is the correct tool to deal with attempts to patent such inventions that are not patentably distinct from previously patented inventions. Because obviousness-type double patenting is not abrogated by the proposal, we do not believe any codification is required.

Additionally, if indeed a new claimed invention is patentably distinct from a company's past inventions, then there really is no patent eligibility issue, but rather perhaps a behavior issue then exists that Congress is well suited to address with other statutes. Patent eligibility should only be a last resort tool used to govern and affect behavior. If Congress feels that pricing practices of certain companies is usurious, then it has substantial powers at its disposal to adjust or moderate that behavior that it should consider prior to implementing any eligibility changes that may disincentivize research for critical new drugs or therapies.

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?

Answer: Mayo/Alice and their progeny currently affect future and past patents alike. The current proposal only removes judicially created exclusions to the eligibility statute that reads, "any new and useful invention or discovery." Therefore, the holders of patent rights are not adversely affected by this.

The only parties that might make such a claim would be those who are adversely affected by the removal of such judicially created exceptions. Therefore, a party who is claiming to have a legitimate complaint would have to had infringed a patent claim, but done so with a good faith belief that it felt was within an excluded category relying on the test under Mayo/Alice, and that the clarification in the proposed legislation is a taking without due process from their right to practice the claimed invention under the judicially created exclusion. With the uncertainty as to what is and is not eligible right now, I believe it is fallacious to claim such a right to practice an exclusion, as one would not have the sort of certainty needed to claim a right, even if such a right existed.