Responses from

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to

Questions for the Record

"The State of Patent Eligibility in America: Part II"
United States Senate Committee on the Judiciary
Subcommittee on Intellectual Property

Question from Senator Tillis

Mr. Francer, in several of our roundtables participants from your organization repeatedly made the point that the current state of patent eligibility isn't working for the generics industry. Their point was simple: uncertainty prevents the development of new medicines, which ultimately prevents the entry of new generics. Your organization made similar comments in a May 7 letter submitted to Chairman Graham where you said, and I quote, "Senators Tillis and Coons have held several stakeholder roundtables on the issue of patent eligible subject matter under Section 101. We think the Committee should continue those efforts . . . ." Now that Senator Coons and I have produced a draft product, what do you like about it and what do you not like? What changes should we consider making?

As I discussed in detail in my testimony at the hearing, AAM is deeply concerned about the ability of generic and biosimilar manufacturers to break through brand-name drug companies' patent thickets, which are a major barrier to competition and lower prices. Patent thickets often consist of a number of patents that would be found invalid if challenged; they do not reward true innovation, but through sheer volume they serve to raise the cost of breaking into the market with a cheaper generic or biosimilar alternative. For the reasons I explained in my June 5 testimony, expanding patent eligibility in the manner proposed in the current draft legislation would make this already significant patent-thicket problem worse. To take but one example, by abrogating the Supreme Court's decision in *Myriad* and allowing patents on human genes isolated through "human intervention," the draft legislation would once again allow companies to control diagnostic testing and medical research—stifling innovation, raising costs, and putting human lives at risk. Before *Myriad*, the owner of an ineligible patent was charging $3,000 for genetic tests for the BRCA1 and BRCA2 genes, and sending cease-and-desist letters to scientists seeking to study these genes and develop lifesaving innovations.

AAM's specific concerns with the proposed legislation are addressed in detail in in section IV of my written testimony. Two changes to the proposed legislation are particularly important. First, AAM strongly urges that the exceptions to patent eligibility that have been recognized by courts

for more than 150 years — exceptions for "abstract ideas," "laws of nature," and "natural phenomena" — be maintained. Those exceptions have been a vital bulwark against patents that stifle, rather than promote, innovation and cutting-edge scientific research. Those exceptions do not need to be maintained unmodified, as there may be some need to clarify their scope. But AAM firmly believes that those exceptions must be the starting point, and that there is absolutely no reason to abandon them altogether. Second, AAM urges the committee to require more than just any "human intervention" in order to obtain a patent related to a law of nature. Allowing a patent on a law of nature modified by *any* human intervention would allow, for instance, a patent on DNA fragments, methods of sequencing, DNA primers, and other minor, well-known gene modifications and methods of study and analysis. Transforming patent-ineligible natural laws and compounds into patent-eligible inventions should require significant innovation, not minor human intervention.

To be clear, we disagree with one premise in your question. AAM does not take the position that uncertainties in current Section 101 jurisprudence are preventing the entry of new generics. To the contrary, Section 101 is a useful tool in pruning patent thickets relatively early and inexpensively. The uncertainties that prevent generics from coming to market, and lowering prices, would only be compounded if brand drug companies were able to obtain patents on natural phenomena and the like.

Question from Senator Blumenthal

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?*
b. *What impact will broadening the subject matter that can be patented have on consumers?*
c. *Could these reforms increase consumer prices? If so, in what industries or on what products?*

The current limitations on patent eligibility—limitations that the proposed amendments would abrogate—are necessary to ensure that, among other things, patents claiming laws of nature and natural phenomenon are not used to stifle innovation, and that thickets of questionable patents cannot artificially shield brand-name drugs from generic and biosimilar competition, increasing health-care costs for consumers and the public.

In my testimony, I gave numerous examples of the types of questionable patents that would be authorized by broadening patent eligibility in the manner currently proposed. For instance, allowing patents on any law of nature modified by any "human intervention" would allow companies to effectively control the use of human genes. In *Myriad*, Myriad Genetics obtained a broad patent on an isolated DNA sequence for two genes associated with breast cancer, BRCA1 and BRCA2. Myriad obtained those exclusive rights from the Patent and Trademark Office (PTO) even though the only purported "invention" was snipping the naturally occurring genes from the surrounding DNA using standard techniques that Myriad did not invent. The effect of these patents was to stifle innovation—numerous university researchers studying these genes received cease-and-desist letters, and many *actually stopped studying* the BRCA genes associated with breast cancer. The Supreme Court unanimously held that patents claimed ineligible subject matter, but the current proposal to broaden patent eligibility would authorize these patents and would stifle research and innovation.

Similarly, prescription drug labeling often indicates a method of determining whether a given patient is a candidate for treatment, and brand-name manufacturers have recently begun patenting these methods. Because generic drugs are required—with limited exceptions—to have the same labeling as the brand drug, the brand manufacturers assert that a generic drug's required inclusion of the claimed method on its label constitutes induced infringement, and hence bars generic competition for as long as that patent is in force. Courts have held that such patents are invalid under Section 101,[1] but such arguments would be unavailable under the current proposal.

Expanding patent eligibility and allowing these types of patents would negatively impact consumers and public health in numerous ways. Most obviously, it would significantly raise prices. As I described in detail in my June 5 testimony, the price of genetic tests for the BRCA genes associated with breast cancer was as high as $3,000 per genetic test before the Supreme Court and the Federal Circuit invalidated the patents related to the isolated gene sequence and the

[1] *E.g., Mallinckrodt Hospital Products IP Ltd. v. Praxair Distribution, Inc.*, No. 15-cv-170, 2017 WL 3867649, at *14-*20 (D. Del. Sept. 5, 2017).

method of comparing that sequence to that of a given patient.[2] As one researcher explained, "[y]ou could say people are dying of breast cancer because of this patent."[3] Limiting access to genetic screening also removes the possibility of prophylactic treatment, increasing the number of people who ultimately get sick, and dramatically increasing public health costs. Similarly, Celgene's *14 patents* directed to its REMS plan for Thalomid®, a drug for treating certain types of cancer, are part the reason that the price of the drug has more than doubled from $6,195 for a month's supply in 2006 to $16,691 in March 2018.[4]

Such exorbitant prices—based on potentially non-innovative modifications of natural phenomena or FDA-mandated drug safety practices—would become far more common if the grounds for patent eligibility were expanded in the manner proposed. The increase in prices would be exacerbated by the patent thickets brand-drug manufacturers can create by combining numerous patents directed to concepts like natural phenomena and basic mental processes. Brand manufacturers know that bringing obviousness or other validity challenges to entire patent thickets is often prohibitively expensive, and these patent thickets can therefore survive—preventing competition and increasing prices—even if many of these patents would be found invalid if challenged.

Stifling innovation through patents on natural laws and phenomena and basic research methods would also harm consumers by slowing medical research. When private companies can obtain a monopoly on basic research tools, they can prevent anyone else—including academic researchers—from conducting the scientific research necessary to develop innovative new treatments. For instance, as I discussed in my June 5 testimony, before the Supreme Court invalidated the patents on the isolated DNA sequences at issue in *Myriad*, the owners of those patents sent cease-and-desist letters to researchers studying those genes, and many researches actually stopped studying them.[5] Allowing such a roadblock to scientific advancement negatively impacts consumers, as it delays or prevents the work needed to develop new technologies and new treatments for many of the most important diseases.

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[2] Josh Dzieza, *Why the Supreme Court's DNA Decision Is A Big Deal*, available at https://www.thedailybeast.com/why-the-supreme-courts-dna-decision-is-a-big-deal?ref=scroll.

[3] *Id.*

[4] Alison Kodjak, *How a Drugmaker Gamed the System to Keep Generic Competition Away*, available at https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

[5] Josh Dzieza, *Why the Supreme Court's DNA Decision Is A Big Deal*, available at https://www.thedailybeast.com/why-the-supreme-courts-dna-decision-is-a-big-deal?ref=scroll.

Questions from Senator 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?

AAM does not believe that Section 101 currently requires a Congressional fix. Some aspects of the Section 101 inquiry could usefully be clarified by the courts through case-by-case adjudication. For instance, AAM believes that the Supreme Court should clarify that the Federal Circuit erred in exempting methods of medical treatment from Section 101's requirements.[6] But the fact that there are some issues that need judicial clarification does not mean that Congress needs to intervene. And it certainly does not mean that Congress should entirely jettison more than 150 years of carefully-considered judicial precedent limiting patent eligibility, as the proposed legislation would do. The law as it currently stands allows life sciences companies to patent genuine innovations—if anything, lower courts have erred on the side of *upholding* patents in the face of strong Section 101 challenges.

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"?***

   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?***

   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?***

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

As I explained in my June 5, 2019 testimony, the term "field of technology" is neither clear nor well understood. To the contrary, it is open to considerable manipulation by those seeking to patent abstract ideas and natural laws and phenomena. Adding a common, non-innovative technological component—like a standard computer—should not make an otherwise ineligible concept patent- eligible. So, for example, if a method of playing bingo is not patent-eligible,

[6] *See* Brief for the Association for Accessible Medicines and Certain Individual Companies as *Amici Curiae* in Support of the Petition, *Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*, No. 18-817.

neither is a method of playing bingo *on a computer*, even though the use of a computer arguably constitutes a "field of technology."

Similarly, given that a naturally occurring substance like penicillin is not patentable, it should not become patentable simply because the claim limits it to the field of medical technology. *Bilski* provides another excellent example. Regardless whether the method for hedging against the financial risk of price fluctuations is, in the abstract, in a "field of technology," patentability certainly should not turn on whether the method is performed on a generic computer. Moreover, incorporating a "field of technology" test into the statute would likely lead to years of litigation about the precise meaning of the term. Thus, we do not believe it would result in additional clarity; if anything, it is a step in the opposite direction. My written testimony illustrates these points in more detail.

AAM does not believe that the problems with the "field of technology" approach in the current draft can be solved through clarification. A far better approach would be to maintain the current Section 101 framework, under which courts first consider whether the patent is directed to unpatentable abstract ideas or natural law or phenomena and, if so, consider whether the patent claims an inventive application of that unpatentable subject matter. Whether the inventor declares a limited field of use—like "use this natural law on a generic computer"—should not be relevant at all.

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?

The sponsors have said that, under their proposal, only genes *as they exist in the human body* would not be patent eligible, but that limitation is both crucial and problematic. Their proposal would seem to permit a patent on a gene *in isolation*, on the theory that snipping out a fragment of DNA or even breaking a single chemical bond could be "human intervention." And it would allow for patents on basic technologies used in genetic research such as DNA primers, methods of sequencing, and diagnostic tests based on a patient's genes. Indeed, one of the expressed purposes of the proposed legislation is to abrogate the Supreme Court's decision in *Myriad*, which *prevented* patenting of such basic tools of genetic research.

AAM believes that the categories that should be excluded from patent eligibility are precisely the categories that currently *are* excluded from patent eligibility, including abstract ideas, laws of nature, and natural phenomena. AAM does not believe it is productive to list specific, limited categories of patent-ineligible subject matter like "genes as they exist in the human body," especially not in conjunction with a provision stating that everything is eligible if not specifically declared ineligible. Specific, limited categories of patent-ineligible subject matter also cannot account for future innovation concerning natural laws and phenomena that may not fall in a category Congress could enumerate now, but that is as deserving of an exception to patent eligibility as the human genome. Given that it is unrealistic to foresee every specific category of

patent-ineligible subject matter now, it is far better to maintain the current, broader categories, which can far more easily account for future scientific innovation.

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?*

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

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

Your question focuses on the high-tech space, and AAM does not have a position on that issue.

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?

No. The language from Section 101 the Federal Circuit has cited as a basis for obviousness-type double patenting is an inventor's entitlement to "*a* patent" for the invention, thus "forbid[ding] an individual from obtaining more than one patent on the same invention, *i.e.*, double patenting."[7] That language is unchanged in the current proposal. That said, as your question suggests, obviousness-type double patenting is an incredibly important tool for preventing abuses of the patent system, including patent thicketing, and AAM would fully support more explicitly codifying the doctrine in the Patent Act.

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 problem with retroactively applying a new and broader version of Section 101 to already-issued patents is that it would change the rules in mid-stream for patents that the PTO never should

[7] *AbbVie v. Mathilda & Terence Kennedy Institute*, 764 F. 3d 1366, 1372 (Fed. Cir. 2014).

have issued in the first place and may even have been held invalid. A patent's validity should depend on whether it satisfied the applicable rules at the time the applicant submitted it to the PTO. Any changes to the rules of patent eligibility should only apply to new patents.

Because the proposed changes to patent eligibility would broaden—not narrow—the scope of patentable subject matter, they therefore would impose the costs of unfair retroactivity entirely on patent challengers. They would not have any Due Process or Takings implications for patent holders, because for them the legislation would be giving and not taking away.