RICK BRANDON

SENATE JUDICIARY SUBCOMMITTEE ON INTELLECTUAL PROPERTY
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Chairman Tillis, Ranking Member Coons, and other members of the Committee – thank you for the opportunity to be here today to discuss the important topic of patent eligibility.

I am Rick Brandon, Associate General Counsel at the University of Michigan. I am here today representing the Association of American Universities, which represents the sixty largest research universities in the nation.

Let me begin by applauding the work you have already done on this issue. As patent counsel at one of the nation's leading research institutions, I can tell you that patents are the lifeblood for many of our scientific discoveries, and the key to moving those discoveries from the lab to the marketplace. In 2017 (the year of the most recent data), America's universities produced over 68-hundred patents, created one thousand startup companies, and generated millions of dollars of economic benefit and many new medical breakthroughs. At the University of Michigan, we generated over 484 discoveries, 169 new U.S. patents and 21 new startups last year.

In recent years, our federal courts have made the determination of what is or is not patentable an increasingly murky process, particularly in the life sciences area. The complicated framework of the *Alice* and *Mayo* decisions have muddied the waters and threaten to derail many legitimate new technologies that could benefit our nation. Patent examiners and courts have often been put in an untenable spot in trying to figure what sort of inventions are patentable. And many U.S. patents have been invalidated on Section 101 grounds that are thinly-veiled prior art rejections based on limited analysis.

While recent caselaw, such as *Vanda*, permits the patenting of medical treatments in combination with a diagnostic, the law on divided infringement unfortunately often renders such claims impractical or unenforceable.

American research universities have a front row seat to the incentives provided by our patent system. Whether medical diagnostics, software or other technology, inventors and investors often require the protection of a period of exclusivity in order to assume the substantial risk of investing the significant resources needed in order to bring a product to the public. In the case of products that require FDA approval, including diagnostics, this can take years and millions of dollars. The public benefits from both public disclosure and a greater assurance of new products and services. If we do not allow for U.S. patenting of medical diagnostics, we'll miss out on better patient outcomes, cost savings through screening methods that predict disease or the most appropriate course of treatment, as well as other foundations for precision medicine. We may even push investment overseas.

In the past several years, we have seen the incentive system break down in the case of medical diagnostic technologies due to the uncertainty around the patent eligibility of these technologies. At the University of Michigan, we have seen several recent examples of the problems caused by this uncertainty, where investment was based on a presumption of patent protection. In AAU's view, Section 101 issues have put at risk our licensees' investments and therefore the availability of some diagnostics.

Public universities with large health systems share the concerns that have been expressed about patient access to breakthrough medical diagnostics. Indeed, we are fully aligned on this topic with groups advocating for broad patient access. However, the question of broad access to a technology only becomes relevant once the technology has been brought to market. And since the patentability of medical diagnostics is unpredictable, there are technologies that are not being brought to market in the first place. Patients have no access to these technologies at all.

We are not arguing that any given isolated and purified gene or other molecule should be patented. We believe that *where inventive*, any molecule, even a gene or other chemicals discovered from nature, should be eligible, for the reasons stated above. We further believe that the analysis of whether a molecule is patentable belongs with Sections 102 and 103. Indeed, the prior art on genes and biomedical diagnostics is much stronger than it was years ago.

We do not believe that the patenting of chemicals discovered from nature will stifle research and innovation, and we do not believe it did so prior to *Mayo* and *Alice*. We simply do not see a prevalence of patent lawsuits against universities and others performing basic and translational research. There are many ways that research is protected from patent suits, such as the exemption under Section 271, the Hatch-Waxman system, immunities, and optics, just to mention a few.

So, we believe the current unpredictability must be rectified. Although PTO Director Iancu has sharpened PTO guidance and made other systemic changes, true correction can only occur through legislation that clearly defines for the courts what is patentable and what is not.

AAU very much supports the draft legislation you have created. We have thoughts on a couple of the sections.

In new Section 100(k), we worry about what "specific and practical" means. If one construes "specific" to be the opposite of "abstract," this might mistakenly bake the "abstract idea" notion back into law. It is also unclear how specific an application would need to be. A diagnostic could detect a condition, predict an outcome, or recommend treatment. Any uncertainty about what "specific" means could hinder investment in innovation.

Similarly, the phrase "field of technology" is also somewhat ambiguous. For instance, does it include business methods?

As for new Section 101, we agree that it is key to remove the notion of "newness" from the determination of patentable subject matter, as that concept belongs in Sections 102 and 103, as discussed.

Under Section 112, we wonder how this would work with method claims or chemical claims. We would be happy to work with you to refine that a bit more.

In Section 100(k), we like the phrase "through human intervention." Inferences drawn from the presence of a biomarker in the body clearly ought to be patent eligible, subject of course to Sections 102 and 103. But does it include a process being run on a computer or other machine?

In Section 101(a), the language still uses the phrase "whoever invents or discovers … may obtain," but it seems that this phrasing may be outdated given that an assignee, as opposed to the inventor, can, and often does, file and obtain a patent.

In Section 101(b), it seems that "limitation" should be "element" to better track the term in Section 112.

In Section 101(b), it seems that the language could be slightly improved by deleting "only while," and instead adding "only" before "as a whole." As a technical matter of drafting, the question is literally more than just looking at the claimed invention as a whole; the substantive question must be analyzed.

In Section 112(f), we wonder why "for a combination may be expressed" was removed?

In the paragraph stating that certain cases are "abrogated," will it be clear that this just applies in the future (but even to applications or patents filed in the past)?

In the final paragraph citing 102, 103, and 112, we suggest considering whether "addressed" might possibly be more logical and easier to interpret than "relating to."

Overall, however, we believe the thrust of this legislation moves us toward a patent eligibility process that will favor the widest initial view of eligibility under Section 101, while using the other provisions of the law, such as obviousness, to narrow the definition of what is patentable.

We stand ready to work with you and your Committee to develop this important legislation that will ensure that the benefits of America's research enterprise are fully realized, and not left behind in the lab because unnecessary confusion about what is or is not patentable prevents investment in products that benefit the American public.

Thank you for the opportunity to appear here today, and I look forward to any questions you may have.