



**Association of
American Medical Colleges**
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June 14, 2019

Senator Thom Tillis
113 Dirksen Senate Office Building
Washington D.C., 20510

Senator Chris Coons
218 Russell Senate Office Building
Washington D.C., 20510

Representative Doug Collins
1504 Longworth House Office Building
Washington D.C., 20515

Representative Steve Stivers
2234 Rayburn House Office Building
Washington D.C., 20515

Representative Hank Johnson
2240 Rayburn House Office Building
Washington D.C., 20515

Dear Senators Coons and Tillis, and Representatives Collins, Johnson, and Stivers:

On behalf of the Association of American Medical Colleges (AAMC), thank you for the opportunity to provide stakeholder feedback on the draft proposal released May 22 to amend Section 101 of the Patent Act.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 154 accredited U.S. medical schools, nearly 400 major teaching hospitals, more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents more than 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

Our member institutions are major drivers of discovery and innovation in health care, performing more than half of the extramural research funded by the National Institutes of Health (NIH), and generating many of the discoveries from federally funded research that lead to patented drugs, vaccines, devices, and other inventions. The AAMC supports a strong and fair patent system, both as a national economic priority and as a mechanism for attracting private investment to better develop and implement university-generated findings.

At the same time, the AAMC believes that law and policy must protect and balance the public good with proprietary rights in support of science and technology, particularly in the fields of medicine and public health. The draft proposal would nullify settled law about the validity of issued patents in the life sciences by abrogating the current prohibitions on patenting human DNA sequences and certain methods used by clinicians to administer drugs to patients.

The consequences of this draft proposal could be especially troublesome for patients whose clinicians rely on DNA sequencing for diagnosis and individualized treatment development. Academic providers and researchers regularly use published information on disease-causing genes to interpret and adapt existing tests to care for patients. It would be a setback in patient care to provide clinicians with incomplete information from a patient's whole genome sequence, for example, because a laboratory feared a charge of patent infringement would result from evaluation and adaptation of a patented gene sequence. While protecting the rights of true inventors is a core value of academic medicine, we should not direct our nation's medical system to serve the needs of patents over patients. For these reasons, we cannot support amending Section 101 of the Patent Act as described in the draft proposal. We do appreciate remarks from the June 11 Senate

Judiciary Subcommittee on Intellectual Property hearing that there may be an opportunity to mitigate the impact to research, and hope the input from this letter will help to inform changes for the final bill.

In 2011, the AAMC joined with the American College of Medical Genetics and Genomics and other medical and research organizations in an amicus brief to the U.S. Supreme Court on the landmark case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* In *Mayo*, a clinical laboratory associated with an academic medical center had been alleged to infringe a patent by reaching a medical diagnosis based on measured correlates of blood metabolites, consistent with information available in the medical literature. Central to the amici's concern was that the patents in question claimed the naturally occurring relationship itself, a correlation, rather than embodying that relationship in a human-made method, machine, manufacture or composition of matter.

The Supreme Court unanimously ruled the patents invalid in *Mayo* based on long-established judicial precedent excluding natural laws or processes from patentable subject matter. The AAMC agrees with that decision and believes a hallmark of the patent system is to promote innovation by incentivizing inventors to find new ways for harnessing natural phenomena in useful ways. If processes (or products) of nature are themselves held patentable, "inventors" could exclude others from seeking further applications, which would encumber, not catalyze, innovation. The Supreme Court acknowledged this paradox in its opinion, which invalidated patents that incorporate laws of nature:

*Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention... The Court has repeatedly emphasized this ... concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature... For these reasons, we conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. **The claims are consequently invalid.***

It has been argued that new legislation could seek a broader scope for patent eligibility and rely on other provisions of the patent law, e.g., novelty, non-obviousness, and utility, to sufficiently prevent the patent system and courts from over-extending patent protections to natural phenomenon. But the medical literature is replete with discoveries that are new, not obvious, and useful, which exist entirely in nature and would not fit a common understanding of "invention." A defined scope for patent subject matter eligibility, as currently interpreted by the courts, prevents a proliferation of patents claiming what have been considered natural relationships and are therefore generally available to all physicians and scientists to improve patient care.

In summary, the AAMC believes that the science and practice of medicine, and the benefits for patients and communities, could be especially vulnerable if eligible subject matter is extended too broadly into principles and products of nature that are considered unpatentable under settled law. The AAMC appreciates your efforts to gather perspectives and information on eligible subject matter under the Patent Act, and to assist the U.S. Patent and Trademark Office and the courts in promoting trust and clarity in the patent system, but opposes the draft proposal released May 22 to alter Section 101 of the Patent Act. We would be glad to provide further information regarding the AAMC's concerns as discussion on the draft bill progresses. If you have further questions, please contact Christa Wagner, PhD (chwagner@aamc.org).

Sincerely,



Karen Fisher, JD
Chief Public Policy Officer