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October 15, 2021

Andrew Hirshfeld
Commissioner for Patents
US Patent and Trademark Organization
Arlington, VA
c/o www.regulations.gov

Re: Patent Eligibility Jurisprudence Study 86 FR 36257-60

Dear Mr. Hirshfeld:

On behalf of the Association of American Medical Colleges (AAMC), we are grateful for this opportunity to provide input on the Congressionally requested study of recent jurisprudence on patent eligibility (primarily relating to 35 U.S.C. § 101). The AAMC is a nonprofit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals employed across academic medicine, including more than 186,000 full-time faculty members, 94,000 medical students, 145,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

For purposes of this response, the AAMC may be described under Category 9 of the notice, a nonprofit advocacy organization. Our member institutions, academic medical research organizations, are among the world's most prolific generators of new discoveries, patents, and licenses in the biomedical and life-sciences. Our comments primarily focus on Question 13:

> *Please identify how the current state of patent eligibility jurisprudence in the United States affects the public. For example, does the jurisprudence affect, either positively or negatively, the availability, effectiveness, or cost of personalized medicine, diagnostics, pharmaceutical treatments, software, or computer-implemented inventions?*

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:

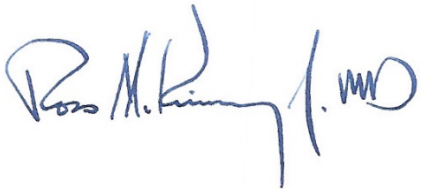
> *Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention… 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.***

The issues at stake in patent eligibility are intricately complex. While an invention that embodies or exploits some understanding of natural principles may rightly belong to its creators, the ability to discover, investigate, and teach about natural processes or natural laws themselves, which exist prior to any human invention, belong to all. The recent example of the ongoing COVID-19 pandemic and the subsequent development of several vaccines has demonstrated the importance to the global sharing of SARS-CoV-2 virus sequences and other information, while providing proprietary protections for products developed from that information.

In summary, the AAMC believes that law and policy must protect and balance the public good, including access to timely patient care, with proprietary rights in support of science and technology, particularly in the fields of medicine and public health. We believe that these principles are reflected in current jurisprudence.

The AAMC is grateful for the opportunity to provide input and appreciates your efforts to better understand the current state of patent eligibility jurisprudence in the United States. If you have any questions regarding this response, please contact Stephen Heinig, Director, Science Policy at sheinig@aamc.org or Heather Pierce, JD, MPH, Senior Director, Science Policy and Regulatory Counsel, at hpierce@aamc.org.

Sincerely,



Ross McKinney, Jr., MD
Chief Scientific Officer