September 7th, 2021

United States Patent and Trademark Office
Department of Commerce
Washington, DC

Re: Request for information regarding state of patent eligibility jurisprudence in the US.

To whom it may concern,

As molecular pathologists who are involved in clinical molecular diagnostics, we support existing laws and Supreme Court decisions that prohibit patents on laws of nature, natural phenomena, and abstract ideas. Weakening those laws would endanger public health, impede scientific research, and imperil our ability to recover fully from the COVID-19 pandemic.

Today's laws against patenting abstract ideas, laws of nature, and natural phenomena are critical to supporting the development of innovative fields of research, like precision medicine and genetic testing. The advancement of precision medicine is a widely embraced humanitarian effort with extensive private and public investment. Genes and their natural characteristics are basic tools that are the foundation of personalized genomic testing for the diagnosis, prognosis and therapeutic management of infectious diseases, cancers and genetic disorders. Advances in genomic research rely heavily on gene sequences are largely available in the public domain, including databases hosted through the National Center for Biotechnology Information. Restricting access to gene sequences would represent an extreme impediment to academic and commercial innovation. Recent events related to the ongoing pandemic, provide evidence that public access to the genetic sequence of the virus responsible for COVID-19 made it possible for researchers and laboratories, to develop a wide variety of diagnostic tests and vaccines at unprecedented speed. In our own laboratory, located in New York state, at the epicenter of the pandemic in early 2020, we were able to develop testing to rapidly protect the health of our patients and our community. By contrast, when severe acute respiratory syndrome (SARS) emerged in 2003, the Supreme Court had not yet clarified the legal prohibition on patenting genetic sequences. Because pharmaceutical and biotechnology companies raced to get patents on the virus and its genetic sequence, the U.S. Centers for Disease Control and Prevention was forced to defensively file its own patent applications to protect patients' access to essential medicine and researchers' access to essential tools[1].

Additionally, we need to keep the ban on patenting abstract ideas, laws of nature, and natural phenomena to ensure that innovative treatments and diagnostic tests remain affordable and accessible to the people who need them. For many years, Myriad Genetics held patents on two genes associated with a high risk of breast and ovarian cancers that allowed it to control a monopoly on all testing. The company had the sole right to examine how likely patients were to get cancer based on the genetic information harbored in their bodies. The subset of cancer patients who needed this testing were held captive to the test offered by this one company, with no accountability for quality assurance, no options for second opinion, and potentially many women misdiagnosed due to bad results. After the Supreme Court clarified the law against

patenting naturally occurring gene sequences in 2013, competitors quickly developed and commercialized more affordable and comprehensive tests that have saved countless lives[2].

As these examples show, scientific researchers, health care providers, and patients depend on access to abstract ideas, laws of nature, and natural phenomena. We oppose changing the law that ensures public access to them because doing so would threaten future innovation, healthy competition, and affordable access to quality health care.

The views expressed are our own and do not express those of our employer.

Thank you for your consideration,


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| Helen Fernandes PhD | Susan Hsiao MD PhD | Mahesh Mansukhani MD |
| Professor | Assistant Professor | Professor |
| Assistant Director | Assistant Director | Director |

Laboratory of Personalized Genomic Medicine
Columbia University Irving Medical Center
New York.


[1] *See* Paul Elias, *Race to Patent SARS Virus Renews Debate*, ASSOCIATED PRESS (May 5, 2003), https://apnews.com/article/145b4e8d156cddc93e996ae52dc24ec0.
[2] *See* Andrew Pollack, *After Patent Ruling, Availability of Gene Tests Could Broaden*, N.Y.TIMES (Jun. 13, 2013), https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html.