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Re: Patent Eligibility Jurisprudence Study
Docket number: PTO-P-2021-0032

Thank you for the opportunity to comment on the U.S. Patent and Trademark Office Patent Eligibility Study (PTO-P-2021-0032). The Coalition for the Life Sciences (CLS) is an alliance of eight professional organizations working together to foster public policies that advance basic biological research and its applications in medicine and other fields.[1]

We are submitting these comments in support of the existing prohibitions against patenting laws of nature, products of nature, and abstract ideas. These exclusions from patent eligibility play a crucial role in fostering scientific research and innovation that benefit the public interest. We note in particular that the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* that invalidated patents on naturally occurring DNA sequences has had an overwhelmingly positive impact on scientific research, clinical diagnostic testing, and health innovation. Proposed changes to Section 101 of the Patent Act that would effectively reverse the Court's decision would likely have a chilling effect on research and stifle innovation in genetic testing. Such harms could create barriers for patients to access life-saving knowledge about their own genomic information and would slow down the development of key innovative fields, including precision medicine.

1. Since *Myriad,* the Court's decision to invalidate gene patents has catalyzed research and health innovation

In the landmark 2013 ruling in *Association for Molecular Pathology v. Myriad Genetics, Inc.* ("*Myriad*"), the Supreme Court unanimously invalidated patents on naturally occurring DNA, finding that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated." [2] The effect of this decision was to invalidate all existing claims to naturally occurring DNA sequences, including 4,300 patents on human genes.

We are not aware of any evidence that this decision has slowed progress in gene discovery or the development of diagnostics and treatments. To the contrary, since the Supreme Court's decision, there has been a proliferation of innovation and healthy competition in genetic testing, and overall investment in genomics increased from $6.21 billion in 2013 to over $17 billion in

[1] CLS Board of Directors & Member Organizations
[2] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* 2012. US Supreme Court. 132 U.S. 1794 (2012).

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2018.[3] Within 24 hours of the Supreme Court's ruling, 5 laboratories announced they would immediately begin offering testing for the BRCA1 and BRCA2 genes.[4] Today, more than a dozen genetic testing companies offer more affordable, comprehensive, and innovative breast and ovarian cancer risk testing programs that have saved countless lives. Color Genomics, for example, has developed a clinical grade testing program that provides patients with access to testing and delivery of health information at home, and at a cost that is more than an order of magnitude lower than the cost of Myriad's test.[5] Empowering people with their health information in an efficient and meaningful way has paved the way for broader and more inclusive access to precision medicine and data-driven health care.

Current doctrine has also aided the development and deployment of testing and treatments for COVID-19. Public access to the genetic sequence of the virus responsible for COVID-19 and ongoing sharing of information by scientists from around the world about new and emerging coronavirus strains have made it possible for researchers and companies to develop and commercialize a wide variety of diagnostic tests and vaccines at unprecedented speed. The result has been more access, more competition, and more innovation. By contrast, when severe acute respiratory syndrome (SARS) emerged in 2003, the Supreme Court had not yet clarified the legal prohibition on patenting isolated 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. [6]

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 that people desperately need now more than ever.

2. There is substantial evidence that gene patents stifled research and innovation

When undertaken appropriately, the patenting of medical products and treatments that result from fundamental discovery can be an effective component of a broader strategy to bolster and reward innovation. But unlike these innovations, DNA —referred to by Nobel Prize-winning scientist, John Sulston, as "the most fundamental information about humanity" — is not a product of human invention. A patent holder that is granted exclusive rights over all uses of a gene can preempt scientific access and use of those genes in research, diagnostic testing, and care.

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[3]The State of Patent Eligibility in America: Part II Before the S. Subcomm. on Intellectual Property, 116th Cong.(2019) (statement of Sean George, CEO, Invitae Corp.)

[4] Pollack, Andrew. 2013. "After Patent Ruling, Availability of Gene Tests Could Broaden." *New York Times*, 13 June.

[5]Othman Laraki, Proposed patent legislation would block research, stifle innovation, and harm patients, STAT (June 6, 2019).

[6] *See* Paul Elias*, Race to Patent SARS Virus Renews Debate,* ASSOCIATED PRESS (May 5, 2003), https://apnews.com/article/145b4e8d156cddc93e996ae52dc24ec0

Prior to this ruling in *Myriad*, more than 4,300 human genes were patented. Several studies—including a major analysis undertaken by The Secretary's Advisory Committee on Genetics, Health and Society in 2010[7] —concluded that patents on genes undermined the development of new and promising testing technologies and documented multiple cases where gene patents directly interfered with patient access to testing and care.

In the case of the Myriad patents, Myriad Genetics used its patents on BRCA1 and BRCA2—two genes linked with breast and ovarian cancer risk—to shut down or prevent university researchers and other laboratories from offering genetic testing for both research and clinical purposes. Myriad Genetics' exclusive right over the genes allowed the company to maintain a monopoly on BRCA testing for many years, effectively dictating the standard of care for BRCA testing and blocking others from offering testing at more affordable price points and from developing methods to improve the accessibility, efficiency, and reliability of the tests.[8]

Returning to the days of gene patents would create barriers to genomic tests, eliminate access to confirmatory testing, and likely increase the cost of testing. Research is considerably slowed when scientists need to license or pay for patented technologies. Thus, the CLS supports the 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.

Sincerely,

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[7] Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS). "Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests." April 2010.
[8] Tania Simoncelli, Sandra S. Park; Making the Case Against Gene Patents. Perspectives on Science 2015; 23 (1): 106–145. doi: https://doi.org/10.1162/POSC_a_00161