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Association for Molecular Pathology Expresses Serious Concerns with Congress' Attempt to Resurrect Human Gene Patenting Debate and Reverse Settled Supreme Court Ruling

Draft legislation would overturn 150 years of patent case law, prevent the development of life-saving diagnostics for devastating diseases, dramatically increase drug costs, and significantly limit access to optimal patient care

ROCKVILLE, Md. – June 4, 2019 – The Association for Molecular Pathology (AMP), the premier global, molecular diagnostic professional society, expressed serious concerns with Congress' recent proposal to amend Section 101 of the Patent Act. If enacted, the draft legislation would overturn 150 years of patent case law and permit patenting of human genes and naturally-occurring associations between genes and diseases. In a recent letter to Senators Coons and Tillis, and Representatives Collins, Johnson and Stivers, AMP joined a diverse community of 169 medical, scientific, patient advocacy, women's health, and civil rights organizations, opposing the recent proposal.

For over 150 years, the Supreme Court has held that laws of nature, natural phenomena and abstract ideas are not patent-eligible under Section 101 of the Patent Act. In the landmark 2013 *Association for Molecular Pathology v. Myriad Genetics*[1] case, a unanimous Supreme Court ruled in favor of AMP and determined that "A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated." The Court concluded that such patents would lock up genetic information and prevent others from scientific and medical work.

"The Court's 2013 ruling was the culmination of many years of deep concern within the medical field and was celebrated across the greater scientific community who fought hard for the chance to be heard," said Mary Steele Williams, Executive Director of AMP. "Today, AMP is prepared to win this fight again. In this age of precision medicine, it is more important than ever to maintain the boundaries between nature and technology, so that we can continue to develop innovative diagnostics for devastating diseases and provide access to the best medical care. Since the Supreme Court's decision, multiplex gene panels that feature dozens of genes in a single test are now routine practice. Advances such as this would have been difficult if not impossible without the Court's decision."

AMP maintains its position that the authorization of patents for human genes and naturally occurring associations between genes and diseases would impede the scientific community from working together to discover novel diagnostics and treatments for rare and common diseases including cancer, muscular dystrophy, Alzheimer's disease, and heart disease. It would also create barriers to patients' access to potentially life-saving genomic tests and eliminate access to confirmatory testing. Further, these patents would create monopolies that would stifle competition and dramatically increase costs for payers, patients and the healthcare system overall.

"The fact that the new proposed legislation was drafted with input only from a select group of patent holders, lawyers, large corporations, and the pharmaceutical industry should be of grave concern to the public," said Victoria M. Pratt, PhD, FACMG, Associate Professor, Director of Pharmacogenetics and Molecular Genetics Laboratories, Indiana University School of Medicine, and President of AMP. "AMP members share a common goal of putting the patient first and we will continue to offer our collective expertise and engage key stakeholders and members of Congress to make sure this proposed legislation as currently drafted is not passed into law."

To view the full letter and list of undersigned organizations, please visit https://www.amp.org/Section101SignOnLetter.

The view the Supreme Court's full *Myriad* decision, please visit https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf.

[1,] *Association for Molecular Pathology et al v. Myriad Genetics, Inc. et al, No. 12-398, U.S. (2013)*

ABOUT AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,500+ members practice in the various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. They include individuals from academic and community medical centers, government, and industry; including pathologist and doctoral scientist laboratory directors; basic and translational scientists; technologists; and trainees. Through the efforts of its Board of Directors, Committees, Working Groups, and members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. For more information, visit www.amp.org. Follow AMP on Twitter: @AMPath.

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