



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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Office of Science and Technology Policy
The Executive Office of the President
1600 Pennsylvania Ave NW
Washington, DC 20500

Re: Request for Information: Accelerating the American Scientific Enterprise (Docket ID number OSTP-TECH-2025-0100)

Submitted electronically via www.regulations.gov

To Whom It May Concern:

The Association for Molecular Pathology (AMP) appreciates the opportunity to respond to the Office of Science and Technology Policy's (OSTP) Request for Information regarding policy actions needed to accelerate the American scientific enterprise. AMP is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostic industry.

AMP strongly agrees that a robust scientific enterprise relies on policies that promote innovation, competition, evidence generation, affordability, and translation of scientific discoveries into clinical practice. In that context, AMP submits this comment to emphasize that preserving existing limits and jurisprudence on patent eligibility under 35 U.S.C. §101 is essential to achieving OSTP's stated goals.

Patent Policy Is Foundational to a Healthy Scientific Enterprise

OSTP's RFI identifies the need to reduce barriers to scientific discovery, enable translation, and strengthen the innovation ecosystem. The patent system is one of the most consequential levers in influencing these outcomes. For molecular diagnostics and precision medicine, Supreme Court jurisprudence has directly advanced these goals by ensuring that biomarkers, genetic sequences, and natural disease-associated correlations remain part of the scientific commons rather than becoming proprietary assets controlled by a single entity.

AMP was the named plaintiff in *Association for Molecular Pathology v. Myriad Genetics Inc.* (“Myriad”), which confirmed that naturally occurring DNA sequences are not patent-eligible merely because they have been isolated from the human body. This decision spurred increased accessibility of genetic testing, competition among laboratories, rapid innovation in test development, and significant reductions in cost, all of which are outcomes that are central to OSTP’s vision for a high-functioning scientific enterprise.

Similarly, *Mayo Collaborative Services v. Prometheus Laboratories Inc.* (“Mayo”) ensured that natural relationships between biomarkers and health status, such as correlations between metabolite levels, gene variants, or other biological features and a disease state, cannot be patented absent a meaningful inventive application. This protects researchers, clinicians, and clinical laboratories from being blocked from using foundational scientific knowledge in patient care. Following those decisions, *Alice Corp. v. CLS Bank International* (“Alice”) affirmed that abstract ideas, laws of nature, and natural phenomena are not patentable.

Together, these three unanimous Supreme Court decisions have created a legal foundation that is promoting innovation across numerous sectors. The cumulative market capitalization for the precision medicine industry continues to grow, expanding from \$40 billion in 2013 to \$132 billion in 2022.¹ One review of venture capital investments in genetic testing companies, prior to their initial public offering, found that funding nearly tripled within three years after the *Myriad* decision and that venture capital investments in private companies peaked at \$294 million in 2020 compared to \$1 million in 2013.² These data and trends are confirmation that investments in the life sciences are robust and the field of precision medicine is flourishing under current law.

Prior to the *Myriad* ruling, due to patent restrictions only one laboratory in the U.S. provided testing for *BRCA1* and *BRCA2*, two of the genes linked to hereditary breast, ovarian, and prostate cancer. Immediately after the *Myriad* decision, five American laboratories began offering testing.³ Today, the standard of care is to offer panels that analyze dozens of genes linked to hereditary cancers to inform patient care related to cancer prevention and early detection. Concert Genetics reported that there were 374 panel tests that included these two genes in 2018,⁴ more than double what existed merely two years earlier in 2016 (172 panels).⁵ This dramatic increase in patient access to testing for hereditary risk of cancer not only provides opportunities for prevention and early and detection of cancer, but this also leads to savings to the healthcare system through increased competition. The cost of testing decreased from over \$4000 per test in 2012, when only the patent holder Myriad performed testing on the *BRCA1*

¹ Source: FactSet includes NVTA, LH, DGX, EXAS, MYGN, NTRA, VCYT, OXFD, CDXS, FLDM, ILMN, NSTG, PACB, QGEN

² <https://www.regulations.gov/comment/PTO-P-2021-0032-0053>

³ <https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html>

⁴ Concert Genetics, “The Current Landscape of Genetic Testing: Market Growth, Reimbursement Trends, Challenges and Opportunities – 2018 Edition.” 2018. http://www.concertgenetics.com/wp-content/uploads/2018/02/10_ConcertGenetics_CurrentLandscapeofGeneticTesting_2017Update.pdf Accessed August 31, 2021.

⁵ Concert Genetics, “The Current Landscape of Genetic Testing – Market size, market growth and the practical challenges of the clinical workflow.” 2016. http://concertgx.wpengine.com/wp-content/uploads/2017/02/ConcertGenetics_TheCurrentLandscapeOfGeneticTesting_March2016.pdf Accessed August 31, 2021.

and *BRCA2* genes⁶, to \$675 as priced on Medicare's Clinical Laboratory Fee Schedule in 2024.⁷ On the 10th anniversary of the decision, the CEO of Myriad Genetics stated that he believes the Supreme Court ruled correctly in reference to the need to enable science.⁸

Maintaining §101 Supports OSTP's Goals

In response to the RFI's request for policy recommendations that would accelerate scientific progress, AMP urges OSTP to:

1. Affirm the importance of maintaining existing Supreme Court precedent excluding natural phenomena, natural laws, and abstract ideas from patent eligibility to support competition, affordability, and research freedom.
2. Advise against legislative or regulatory reforms to §101 that would permit patents on biomarkers or associations between biomarkers and health status.
3. Recognize that preserving an open scientific commons is essential for rapid innovation in precision medicine, diagnostic innovation, clinical translation, and patient access.

OSTP's RFI rightly highlights the importance of reducing barriers, accelerating discovery, and strengthening American scientific leadership. For molecular diagnostics and precision medicine, maintaining the current patent eligibility policy established by the unanimous Supreme Court decisions in *Myriad*, *Mayo*, and *Alice* is indispensable to achieving those aims. AMP strongly urges OSTP to protect the existing boundaries of patent eligibility and to oppose any proposals that would allow patents on biomarkers, genetic sequences, or natural biological correlations. Preserving these principles is vital to sustaining a vibrant, competitive, innovative, and patient-centered scientific enterprise in the United States.

Sincerely,

Aaron Bossler, MD PhD
President, Association for Molecular Pathology

⁶ Clain E, Trosman JR, Douglas MP, Weldon CB, Phillips KA. Availability and payer coverage of BRCA1/2 tests and gene panels. *Nat Biotechnol*. 2015 Sep;33(9):900-2. doi: 10.1038/nbt.3322. PMID: 26348951; PMCID: PMC4625918.

⁷ <https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/files/24clabq1>

⁸ <https://www.genomeweb.com/molecular-diagnostics/decade-after-scotus-gene-patents-ruling-precision-medicine-and-test>