January 27, 2026

The Honorable Thom Tillis
Chair, Senate Subcommittee on Intellectual Property
United States Senate
113 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Chris Coons
Member, Senate Subcommittee on Intellectual Property
United States Senate
218 Russell Senate Office Building
Washington, DC 20510

The Honorable Kevin Kiley
U.S. House of Representatives
2445 Rayburn House Office Building
Washington, DC 20515

The Honorable Scott Peters
U.S. House of Representatives
2369 Rayburn House Office Building
Washington, DC 20515

Dear Senator Tillis, Senator Coons, Congressman Kiley, and Congressman Peters:

The 103 undersigned patient advocacy, medical, scientific, technology, and civil rights organizations are writing to express opposition to S.1546 / H.R. 3152, the Patent Eligibility Restoration Act, which would overturn established Supreme Court precedent and expand patent-eligible subject matter to encompass abstract ideas, laws of nature, and natural phenomena. Current law promotes innovation and competition by ensuring that the fundamental building blocks that result in invention cannot be monopolized. The legislation, as introduced, would authorize patents locking up abstract ideas, laws of nature, and natural phenomena. This would cause harm to patients, consumers, and others by stymieing competition and thwarting innovation in areas ranging from medicine to software, and agriculture by restricting the use of "the basic tools of scientific and technological work."[1]

For over 150 years, the Supreme Court has held that laws of nature, natural phenomena, and abstract ideas are not patent-eligible under the Patent Act.[2] Multiple decisions from 2010 to 2014, all issued by a unanimous Supreme Court, affirm these important exceptions to patent-eligibility. For example, in *Mayo Collaborative Services v. Prometheus Laboratories (Mayo)*, the Court unanimously held that a naturally occurring relationship between certain metabolite levels in the blood and the likelihood of whether a drug dosage is effective was not patent-eligible.[3] The biological relationship between the metabolite level and the appropriate drug dosage was a natural law, not one invented by the patentee. In *Association for Molecular Pathology v. Myriad Genetics (Myriad)*, a fully united Court extended its reasoning in *Mayo* to human DNA isolated from the body, finding that the genes were not significantly altered by isolation, and that such patents lock up genetic information, preventing others from scientific and medical work.[4] In *Alice Corp v. CLS Bank*, the Court, again unanimously, rejected a patent

[1] Gottschalk v. Benson, 409 U.S. 63, 67 (1972).
[2] Bilski v. Kappos, 561 U.S. 593 (2010).
[3] Mayo Collaborative Services v. Prometheus Labs., 566 U.S. 66 (2012).
[4] Assoc. for Molecular Pathology v. Myriad Genetics, 569 U.S. 576 (2013).

on a computer system that did little more than employ the well-known concept of using a third party to mitigate risks of financial settlement because the patent was directed at obtaining exclusivity over that abstract idea itself.[5]

These cases 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.[6] 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.[7] The data and trends are confirmation that investments in the life sciences are robust and the field of precision medicine is flourishing under current law.

The recent COVID-19 public health emergency further illustrates the rapid and incredible innovation possible in the life sciences under prevailing law. During a crisis when every hour, day, week, and month counts, the American public rapidly had access to diagnostics, vaccines, and therapeutics specifically for COVID-19. At the end of 2022, the Food and Drug Administration had issued emergency use authorizations (EUA) for 440 tests and sample collection devices, including 297 molecular tests, of which 79 may also be used for home-collected samples.[8] In less than a year since the public health emergency was declared in the United States, patients had access to vaccines for COVID-19, and soon thereafter, vaccines that were adapted to address emerging variants. This awe-inspiring innovation could not have occurred in the United States if an entity had been allowed to patent the COVID-19 genome(s), as was possible before the *Myriad* decision. Indeed, during the 2003 outbreak of severe acute respiratory syndrome (SARS), because the Supreme Court had not yet clarified that naturally-occurring genetic sequences are patent-ineligible, pharmaceutical and biotechnology companies raced to file patent applications to obtain exclusive rights to the virus and its genetic sequence.[9] In an effort to preserve access to the fundamental research needed to combat the SARS crisis, the U.S. Centers for Disease Control and Prevention was forced to defensively file its own patent applications in order to "give the industry and other researchers reasonable access to the samples."

Beyond COVID-19, erasing the Supreme Court precedent through legislation will harm patients and their families and fuel sky-rocketing healthcare costs. Prior to the *Myriad* ruling, companies were able to patent thousands of human genes under a PTO policy that granted patents on DNA once "isolated" from the cell. These patents, such as those obtained on the BRCA1 and BRCA2 genes, permitted the holder to stop *all* other analysis of the patented genes by threatening other labs with lawsuits, even when they used different testing methods. As a result,

---

[5] Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 216 (2014).
[6] Source: FactSet includes NVTA, LH, DGX, EXAS, MYGN, NTRA, VCYT, OXFD, CDXS, FLDM, ILMN, NSTG, PACB, QGEN
[7] https://www.regulations.gov/comment/PTO-P-2021-0032-0053
[8] https://www.fda.gov/news-events/press-announcements/fda-roundup-december-23-2022
[9] Paul Elias, *Race to Patent SARS Virus Renews Debate*, ASSOCIATED PRESS (May 5, 2003), https://apnews.com/article/145b4e8d156cddc93e996ae52dc24ec0.

only one laboratory in the U.S. provided testing for *BRCA1* and *BRCA2*, two of the genes linked to hereditary breast and ovarian cancers, compared to dozens of laboratories in Europe. Immediately after the *Myriad* decision, five American companies began offering testing,[10] and nearly a decade later, there are 300+ clinical tests for *BRCA1* and for *BRCA2* being performed in CLIA-certified laboratories according to the Genetic Test Registry at the National Institutes of Health.*[11]*

The standard of care now demands that laboratories offer testing that analyzes the dozens of genes linked to hereditary breast and ovarian cancers. Concert Genetics reported that there were 374 panel tests that included these two genes in 2018,[12] more than double what existed merely two years earlier in 2016 (172 panels).[13] This dramatic increase in patient access to testing for hereditary risk of cancer not only provides opportunities to prevent cancer or detect it early enough to save countless lives, but this competition leads to savings to the healthcare system. The cost of testing decreased from over $4000 per test in 2012 – when only the patentholder Myriad performed testing on the *BRCA1* and *BRCA2* genes[14] -- to $675 as priced on Medicare's Clinical Laboratory Fee Schedule in 2024.[15] 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.[16]

The software industry, also, has continued to thrive in the years following the Supreme Court's decisions clarifying patent subject matter eligibility limitations, suggesting that the current restrictions do not harm software developers or businesses. Investment in research and development for the software industry doubled in 2018,[17] four years after *Alice*

---

[10] https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html

[11] Data accessed on August 17, 2021 from Genetic Testing Registry; https://www.ncbi.nlm.nih.gov/gtr/

[12] 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.

[13] 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.

[14] 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.

[15] https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/files/24clabq1

[16] https://www.genomeweb.com/molecular-diagnostics/decade-after-scotus-gene-patents-ruling-precision-medicine-and-test

[17] *The State of Patent Eligibility in America: Part II Before the S. Subcomm. on Intellectual Property*, 116th Cong. (2019) (statement of David W. Jones, Exec. Dir., High Tech Innovators All.), https://www.judiciary.senate.gov/imo/media/doc/Jones%20Testimony1.pdf; strategy&, *PWC 2018 Global Innovation 1000 & What the Top Innovators Get Right* (Oct. 2018), slide 28, https://www.strategyand.pwc.com/gx/en/insights/innovation1000/2018-global-innovation-1000-fact-pack.pdf.

"clarif[ied] that the addition of a generic computer was not enough" for subject matter eligibility,[18] and venture capital funding for software start-ups rose.[19] Courts have fostered competition by ruling that basic abstract ideas such as storing scanned data,[20] content streaming,[21] and sending money transfers[22] cannot be patented.

The evidence is clear that innovation in software and life sciences is more robust than ever. As introduced, S.1546 / H.R. 3152 threatens not only to halt future progress but to potentially reverse so many of these important gains. We oppose any legislative effort that would allow patents on abstract ideas, laws of nature, or natural phenomena, which are the building blocks of innovation.

We look forward to working with you and your colleagues on addressing our concerns in future iterations of this bill. For any further questions, please contact Annie Scrimenti, Associate Director of Public Policy and Advocacy at ascrimenti@amp.org.

Sincerely,

5p- Society
AliveandKick'n
Alliance for Genomic Justice
ALS Association
ALS Network
American Brain Coalition
American Civil Liberties Union
American College of Medical Genetics and Genomics
American Economic Liberties Project
American Society for Clinical Pathology
American Society of Human Genetics
AnCan Foundation
ARUP Laboratories
Association for Academic Pathology (AAPath)
Association for Frontotemporal Degeneration
Association for Molecular Pathology
Beta Cell Action
BioReference Health, LLC
BRCA Research & Cure Alliance (CureBRCA)
Brem Foundation to Defeat Breast Cancer
ClinPath Diagnostic LLC

[18] Netflix Inc. v. Rovi Corp, 114 F. Supp. 3d 927, 934 (N.D. Cal. 2015).
[19] Jones, *supra* note 17; National Venture Capital Association, Venture Monitor, 4Q 2018 at 19, https://files.pitchbook.com/website/files/pdf/4Q_2018_PitchBook_NVCA_Venture_Monitor.pdf.
[20] *See* Content Extraction & Transmission LLC v. Wells Fargo Bank, N.A. 776 F.3d 1343 (Fed. Cir. 2014).
[21] *See* Intellectual Ventures I v. Symantec Corp., 838 F.3d 1307 (Fed. Cir. 2016).
[22] *See* Integrated Tech. Sys., Inc. v. First Internet Bank of Ind., No. 2:16-cv-00417 (E.D. Tex. Jan. 30, 2017).

College of American Pathologists
Colon Cancer Alliance for Research & Education for Lynch Syndrome (CCARE Lynch Syndrome)
Colon Cancer Coalition
Colorectal Cancer Alliance
CSNK2A1 Foundation
Cure CMD
Cure HHT
CureAge Therapeutics Ltd
Damajha Systems (SDVOSB)
Doctors for America
Dravet Syndrome Foundation
Epilepsy Foundation
Evergreene Labs
EveryLife Foundation for Rare Diseases
Fabry Support & Information Group
Families Fighting Hereditary Cancer
FOD (Fatty Oxidation Disorders) Family Support Group
FORCE: Facing Our Risk of Cancer Empowered
Friedreich's Ataxia Research Alliance (FARA)
GeneDx
Genetic Alliance
Genetic ALS & FTD: End the Legacy
Genetica Consulting Services
Genome Medical
Genomic Path, LLC
Genomind
Global Genes
Hereditary Neuropathy Foundation
Hope for Stomach Cancer
Huntington's Disease Society of America
Hypertrophic Cardiomyopathy Association
IVD Logix LLC
Jscreen
Knowledge Ecology International (KEI)
Laboratory Consultants of Florida
Living Beyond Breast Cancer
M-CM Network
Male Breast Cancer Global Alliance
Man Up to Cancer
MLD Foundation
My Gene Counsel
National Ovarian Cancer Coalition
National Society of Genetic Counselors

National Tay-Sachs & Allied Diseases Association
NBIA Disorders Association
NETWORK lobby for Catholic Social Justice
Ochsner Health
Parallel Profile
Pathology Laboratory Associates
PCDH19 ALLIANCE
Phoenix Laboratory Consulting, LLC
Primary Ciliary Dyskinesia (PCD) Foundation
Public Citizen
Public Interest Patent Law Institute
PXE International
RASopathies Network
Raymond Foundation & GI Cancers Alliance
ReteoBiotech LLC
Salud y Farmacos
Seventh Generation Interfaith Inc.
SHARE Cancer Support
Sharsheret | The Jewish Breast & Ovarian Cancer Community
Society of Gynecologic Oncology
Stupid Cancer, Inc.
Susan G. Komen
Sutter Health Shared Laboratory
SynGAP Research Fund
T1International
Tharalink Technologies, Inc.
Tigerlily Foundation
Triage Cancer
Twist Bioscience
UC Santa Cruz Genomics Institute
United Vision for Idaho
Unity Fellowship of Christ Church-NYC
Usher 1F Collaborative
VOCAL-NY
Voices of Health Care Action
West Virginia Citizen Action Group
Yaya Foundation for 4H Leukodystrophy
ZTTK SON-Shine Foundation