



# COLLEGE of AMERICAN PATHOLOGISTS

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February 28, 2024

The Honorable Chris Coons  
Chair  
Senate Subcommittee on Intellectual Property  
United States Senate

The Honorable Dick Durbin  
Chair  
Senate Judiciary Committee  
United States Senate

The Honorable Thom Tillis  
Ranking Member  
Senate Subcommittee on Intellectual Property  
United States Senate

The Honorable Lindsay Graham  
Ranking Member  
Senate Judiciary Committee  
United States Senate

Dear Senator Coons, Senator Tillis, Senator Durbin and Senator Graham:

On behalf of the College of America Pathologists (CAP), I write to express our strong opposition to S. 2140, the Patent Eligibility Restoration Act. We firmly believe that abstract ideas, laws of nature, and natural phenomenon are fundamental tools of scientific and technological work, and that established Supreme Court precedent protecting these categories from patent eligibility has directly and positively fostered significant growth and innovation in the healthcare space. Enacting S. 2140 would represent a large step backwards, limiting the exchange of basic scientific knowledge and stifling innovation. This legislation would also immediately erect barriers to quality healthcare by limiting clinical laboratories' ability to provide confirmatory testing, substantially increase costs to patients for diagnostic tests, and amplifying disparities.

The CAP is the world's largest organization of board-certified pathologists and a leading provider of laboratory accreditation and proficiency testing programs, serving patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Being responsible for diagnostic laboratory testing, pathologists have a vested interest in ensuring that patent reform does not restrict the ability of physicians to provide quality diagnostic services to the patients they serve.

### **Impede Patient Care**

Clinical practice has significantly changed over the last decade; innovations in genetic/genomic testing have directly led to improved care options, and now this testing is required for an innumerable number of medical conditions. The new technologies and staggering growth in medical genetic diagnostics were made possible by the protections afforded in section 101. Patents over genes, their sequences, and naturally occurring associations between genes and diseases pose a serious threat to patient care, medical advancement, and medical education. Allowing commercial entities to patent genes will impede the provision of genetic-based clinical testing and patient care through exclusive license agreements, excessive licensing fees, and restrictive licensing conditions.



### **A. Increase Costs for Patients**

Our country has suffered through the negative consequences of gene patenting before. About 1 in every 500 women in the United States has a mutation in either her BRCA1 or BRCA2 gene, which substantially increases their risk of developing breast, ovarian, and other cancers. Prior to 2013, innumerable women were held captive to one company that held corporate ownership of diseases related to the BRCA1/2 genes through gene patents. A woman could only learn if she had this increased risk by taking a test provided exclusively by Myriad Genetics at a cost of more than \$3,000. Not only was this test costly, but their initial offerings failed to detect mutations in about 12% of breast cancer patients – leaving many (who had no other option for second-opinion/confirmatory testing) to discover their carrier status the hard way. The Supreme Court's unanimous 2013 decision against Myriad created much needed academic and commercial freedom to create novel tests and rapidly offer more competitive test options on previously patented genes. Now there are tests for BRCA1, BRCA2, and a litany of other pathologically significant genes for as little as \$249. If S. 2140 is enacted, we will be returning patients to a time of limited diagnostic options, and stifling development in clinical laboratories with cease-and-desist letters.

In another example, the company Sequenome filed for patent-infringement against other companies claiming that it alone had §504 patent rights over cell free fetal DNA circulating in maternal blood. In fact, methods to isolate and utilize this material for diagnosis were well known. Fortunately for patients, the §504 patent was invalidated in litigation because it claimed a judicially-protected natural phenomenon. The use of cell-free fetal DNA represents a substantial testing area in clinical prenatal genetics. If the Sequenome patent-ineligible claims were reverted, the price of non-invasive prenatal testing (for chromosomal abnormalities like Downs syndrome) would spike, and the other commercial and academic labs who had developed tests would have difficulties performing their tests at significant detriment to medical research and patient care.

### **B. Threaten Treatment**

Additionally, S. 2140 would eliminate the patent protections related to natural correlations, again overturning another unanimous Supreme Court ruling in *Mayo vs. Prometheus* (2012). The ruling clarified that ascertainment of a reference range simply describes the relationship between an analyte and a physical condition – “setting forth a natural law”. Normal test measurement boundaries (reference ranges) are critically important to healthcare providers, as they allow for the interpretation of test results. Pathologists are responsible for ensuring that reference ranges are established or verified to be applicable to their patient population, for every applicable analyte and specimen source proffered in the laboratory test menu, and this skill is an essential part of a pathologist's training and duty to patient care. *Mayo vs. Prometheus* freed clinical pathologists to practice their medical specialty and ensured that no entity could monopolize these natural correlations of the human body to impede improvement in medical knowledge and treatment. S.2140 would eviscerate that protection.



Finally, as 'products of natural phenomena', gene sequence data are fundamental to the understanding of numerous diseases and must remain exempt from patent eligibility. No commercial entity should have 'exclusive ownership of a disease' through license agreements on gene-based tests. This practice has previously been used to prevent physicians and clinical laboratories from performing genetic tests as diagnostic medical procedures. Examples of where testing has been halted due to patent enforcement goes well beyond BRCA1/2, and include Alzheimer disease, Canavan disease, Charcot-Marie-Tooth disease, and others.

### **Stifle Innovation**

S. 2140 will cause the quality of healthcare to deteriorate in our country. It is empirically known that the 'state of the art' will stagnate under the duration of a patent term, and this stifled innovation will leave patients stuck with outdated/suboptimal medical diagnostics. Genomics is not a stagnant field; genes and other natural phenomena that impact normal physiology and disease can change over time. Viruses can undergo rapid adaptive evolution, knowledge of the genetic drivers of neoplastic and non-neoplastic diseases are undergoing exponential growth, and the results of genomic testing are directly altering treatment plans, clinical trial opportunities, and eligibility for targeted therapies. The state of scientific knowledge does not remain static to when a test is first developed, and this leads to relatively quick technological obsolescence in genetic testing. Involvement by a diversity of pathologists and laboratory professionals ensures the ongoing relevance and accuracy of diagnostic tests.

If gene sequences and other natural phenomena can be considered intellectual property, a company with monopoly rights over the related disease can significantly hinder critical research. We know that this will make our country's healthcare industry less productive and less competitive domestically and globally, as well as significantly increasing the cost of care for patients and society. Many of our members were on the frontline of the COVID-19 pandemic; responding to a pandemic in a situation where the exchange of critical genetic/genomic information was restricted would be disastrous. It is not in the public's interest for any single entity to hold ownership over the means to diagnose a disease or serve as the sole gatekeeper for targeted therapeutics. This approach would be bad for patient care, public health, and the U.S.' standing as a global leader in the provision and quality of health care.

### **Prohibit Confirmatory Testing**

S. 2140 would prohibit confirmatory testing. Confirmatory tests are used for test result verification. Confirmatory testing is important for rare diseases, various conditions with difficult screening/diagnostic algorithms, and for tests that carry significant/life-altering implications (e.g., results would change the choice of chemotherapy). Cancer treatment highlights the vital importance of confirmatory tests; testing results frequently affect chemotherapy selection, may avert potentially devastating short and long-term drug toxicities, and may qualify a patient for life-saving targeted therapies.



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If companies could patent genes, gene sequences and/or variations, and diseases, it would be possible for them to become a significant roadblock to patient care. For example, if a condition can only be diagnosed using one proprietary test, and the development of newer/better testing for the same disease is blocked, this poses significant harm to patients with the disease that may test negative by the patented test, and significantly stymies scientific advancement in healthcare.

### **Exacerbate Disparities**

S. 2140 would exacerbate health disparities for rural and underserved communities by limiting access to needed testing and increasing the cost of diagnostic tests. Over 30 million people in the U.S. are without health insurance. People without health insurance are less likely to have access to and may not be able to afford the health care services they need. Access to services like preventive care, cancer screenings, and treatment for chronic illnesses are essential for communities of color and other underserved populations. For example, people of color who are diagnosed with lung cancer face worse outcomes compared to white Americans because they are less likely to be diagnosed early, less likely to receive surgical treatment, and more likely to not receive any treatment. Taking that step backwards and returning to when genes, gene sequences, naturally occurring substances, and diseases could be patented will result in an anti-competitive diagnostic marketplace. Particularly in communities of color and underserved communities, patients will be priced out of the market for important life-saving diagnostic tests and subsequent treatments.

The CAP strongly opposes S. 2140. Patent reform must not condone the patenting of naturally occurring phenomena such as human genes or the associations between genes and disease. Doing so would create barriers to patients' access to lifesaving genetic/genomic tests and eliminate access to confirmatory testing. The cost of testing would also substantially increase which would hurt the provision of health care. Patients would lose benefits from recent technological advances that have otherwise reduced costs and expanded access. Therefore, the CAP strongly believes that legislation reforming the patent system must maintain the judicially created exceptions to patent-eligibility as demarcated by the *Mayo*, *Myriad*, and *Alice* decisions. Unfortunately, S. 2140 does not do that.

Thank you again for your diligence and attention to our concerns. Please contact Darren Fenwick at [dfenwic@cap.org](mailto:dfenwic@cap.org) if you have questions or comments.

Sincerely,

Donald Karcher, MD, FCAP  
President  
College of American Pathologists