Statement of

Debra Leonard, M.D., Ph.D.
Professor Emerita, Department of Pathology and Laboratory Medicine
Robert Larner, M.D. College of Medicine at University of Vermont

Before the
Committee of the Judiciary
United States Senate

Hearing on
From Genes to Machines: the Patent Eligibility Debate

July 14, 2026

Chairman Grassley, Ranking Member Durbin, and other Members of the Committee:

Thank you for the opportunity to testify today. My name is Dr. Debra Leonard, and I have spent my career as a molecular pathologist developing and overseeing clinical genetic testing that physicians rely on to diagnose disease and guide treatment. I am a proud member and Past President of the Association for Molecular Pathology, which was the named plaintiff in the *Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad)* case. This important unanimous Supreme Court decision held that naturally occurring human DNA is not patent eligible. Together, with the additional decisions in *Mayo Collaborative Services Inc. v. Prometheus Laboratories Inc. (Mayo) and Alice Corp. v. CLS Bank International (Alice),* the Supreme Court established an important principle: products of nature, laws of nature, and abstract ideas should not be patented, including human DNA.

I know from firsthand experience that abrogating the *Myriad, Mayo,* and *Alice* decisions is bad for patients, bad for providers, and bad for precision medicine. I am greatly concerned that the Patent Eligibility Restoration Act, or PERA, as written, would bring us back to a time in which patient care was greatly restricted and potentially harmed by patents on human genes, as I discuss in depth below. As the Committee considers reforms to patent eligibility, I respectfully urge Congress to preserve the Supreme Court's decisions in *Myriad, Mayo*, and *Alice* and reject all efforts to make naturally occurring genetic sequences and other products of nature, as well as their association with human health conditions, patent eligible once again.

Clinical Laboratory Medicine Practice Prior to 2013

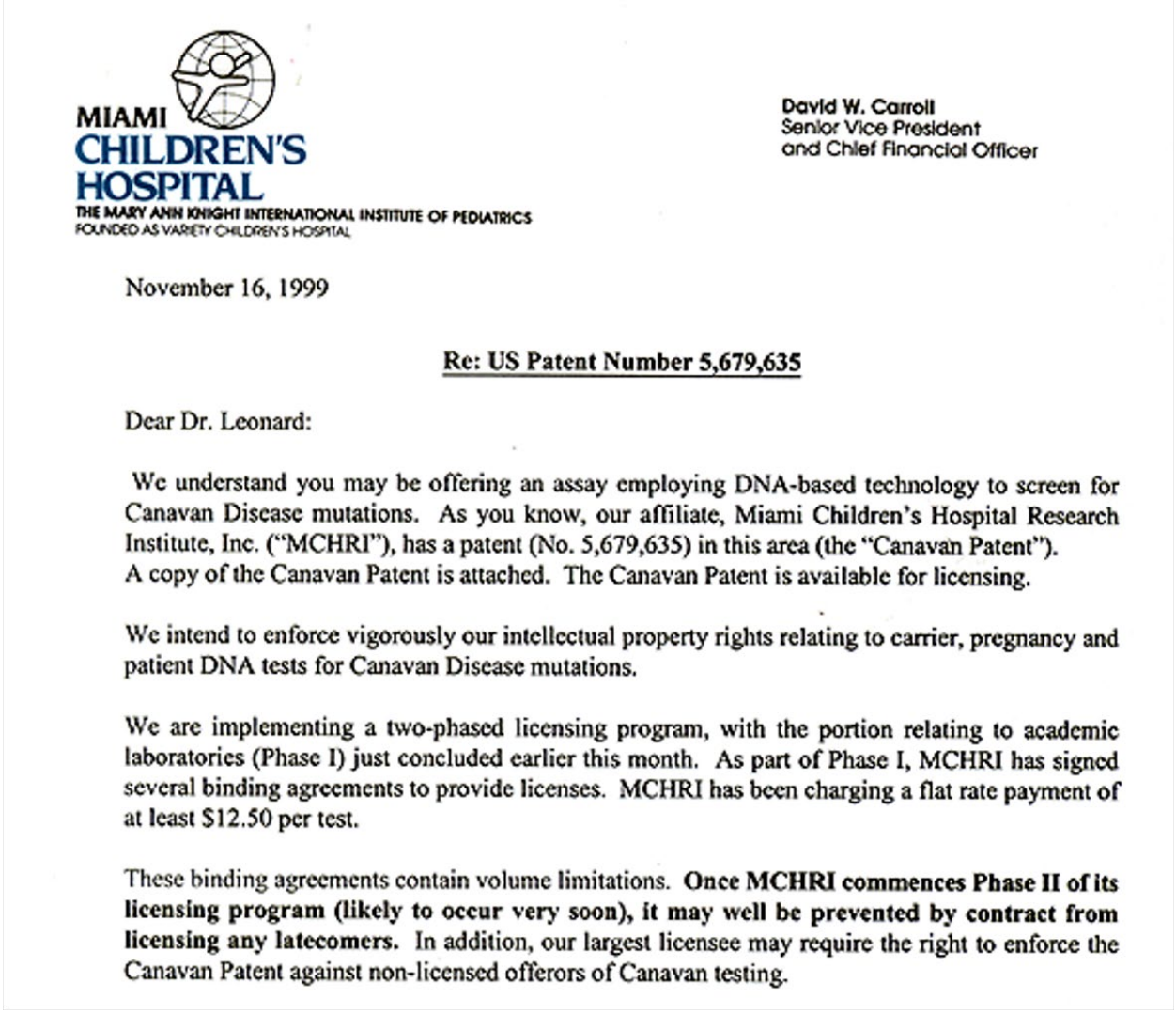
Prior to the 2013 *Myriad* decision, my laboratory received numerous patent enforcement letters demanding licensing fees or threatening infringement if we continued performing certain genetic tests essential to caring for our patients. To further illustrate the handcuffs placed on my medical

practice by patent holders, consider a few real-world examples of how patents have tied the hands of healthcare providers caring for patients.

Canavan Disease*:* Canavan disease is a hereditary neurological disorder in which the brain progressively degenerates into spongy tissue marked by microscopic, fluid-filled spaces. Affected children typically lack head control, show reduced visual responsiveness, and display abnormal muscle tone, ranging from stiffness to floppiness. As the disease advances, they may develop seizures and experience paralysis, developmental delay, blindness, deafness, and difficulty swallowing. Canavan disease results when a child inherits two mutated copies of the *ASPA* gene, and genetic testing is essential for establishing a clinical diagnosis to guide medical management.

Miami Children's Hospital previously held the patent on the sequence of the *ASPA* gene associated with this fatal, pediatric, inherited neurological disease. I received a letter in 1999 requiring a licensing fee of at least $12.50 per test. In other words, the cost of each test provided for a patient would increase by $12.50 (about $25 today). Because of incredible advances in science, this test is now often offered as part of a panel. If a laboratory had to pay even $25 per variant, sequence, gene, etc., on a panel, it could add hundreds, if not thousands, of dollars to the cost of the test per patient. In today's era of bipartisan efforts to rein in rising healthcare costs, it is unconscionable that there are efforts to advance PERA, which would again allow gene patenting and exacerbate the problem.

In addition to the testing costs imposed by patent holders, the licensing agreements for Canavan disease contained caps on the volume of tests we could perform on that gene. This prevented us, as physicians, from performing tests in accordance with the recognized standard of care for a patient's clinical need. Given that this tactic was used in 1999, it's reasonable to anticipate that, if enacted, PERA would also lead to inappropriate interference with the practice of medicine and restricted patient access.



MIAMI CHILDREN'S HOSPITAL
THE MARY ANN KNIGHT INTERNATIONAL INSTITUTE OF PEDIATRICS
FOUNDED AS VARIETY CHILDREN'S HOSPITAL

David W. Carroll
Senior Vice President
and Chief Financial Officer

November 16, 1999

Re: US Patent Number 5,679,635

Dear Dr. Leonard:

We understand you may be offering an assay employing DNA-based technology to screen for Canavan Disease mutations. As you know, our affiliate, Miami Children's Hospital Research Institute, Inc. ("MCHRI"), has a patent (No. 5,679,635) in this area (the "Canavan Patent"). A copy of the Canavan Patent is attached. The Canavan Patent is available for licensing.

We intend to enforce vigorously our intellectual property rights relating to carrier, pregnancy and patient DNA tests for Canavan Disease mutations.

We are implementing a two-phased licensing program, with the portion relating to academic laboratories (Phase I) just concluded earlier this month. As part of Phase I, MCHRI has signed several binding agreements to provide licenses. MCHRI has been charging a flat rate payment of at least $12.50 per test.

These binding agreements contain volume limitations. **Once MCHRI commences Phase II of its licensing program (likely to occur very soon), it may well be prevented by contract from licensing any latecomers.** In addition, our largest licensee may require the right to enforce the Canavan Patent against non-licensed offerors of Canavan testing.

Alzheimer Disease*:* Over 7 million Americans are living with Alzheimer disease, and the *APOE* gene has been central to understanding Alzheimer disease risk and genetic susceptibility. Athena Diagnostics previously exclusively licensed a patent on the *APOE* gene and enforced its patents to such an extent that it didn't even offer licensing options, establishing itself as the sole provider of the test. The company charged $195 per test, but my laboratory at the University of Pennsylvania charged $100.50 per test. The patent on the *APOE* gene meant that patients, insurance companies, etc., would incur unnecessary costs to obtain this important risk information. As of July 2026, the Genetic Test Registry shows 38 tests across 17 laboratories in the United States currently offering this testing. The patent on the *APOE* gene served only to establish a monopoly and increase the cost of care, rather than to foster innovation.

athena diagnostics
TM formerly Genica Pharmaceuticals Corporation

Athena Diagnostics, Inc.
Four Biotech Park
377 Plantation Street
Worcester, MA 01605
Tel 508 756 2886 Fax 508 753 5601

March 21, 1997 SECOND NOTICE

RE: U.S. Patent Number 5,508,167

As part of our effort to be at the forefront of developments in diagnostic testing, I would like to advise you that Athena Diagnostics has acquired exclusive rights to certain tests in the diagnosis of late onset Alzheimer's disease. These tests are covered under U.S. Patent number 5,508,167 a copy of which is enclosed.

The patent covers methods of diagnosing for increased risk of late onset Alzheimer's disease by testing for the presence of the ApoE 4 allele.

We understand that University of Pennsylvannia may be offering a diagnostic test covered by this patent. Any such testing would infringe on the above patent under which Athena has exclusively licensed.

This diagnostic testing service is available through Athena's facilities, and it is only by using Athena's facilities that other laboratories can offer this patented diagnostic test without infringing the patent.

If University of Pennsylvannia is interested in continuing to offer this patented testing service to its customers, Athena would be pleased to perform the services on University of Pennsylvannia behalf. Our currently published price is $195 per specimen.

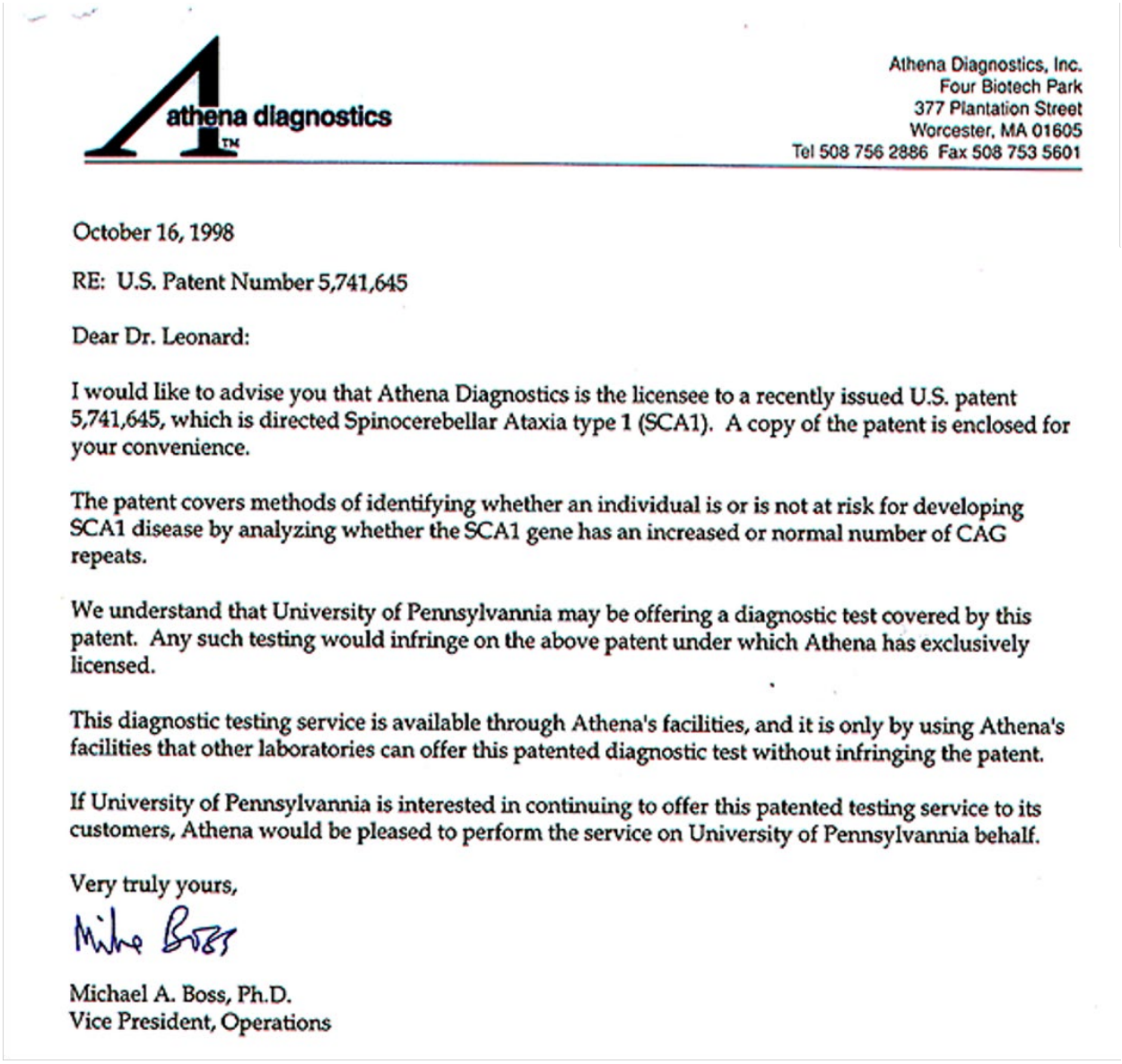
Very truly yours,

Michael A. Boss, Ph.D.
Vice President, Research and Development

MAB/cml

Spinocerebellar Ataxia (SCA)*:* Spinocerebellar ataxia (SCA) is a group of inherited, progressive neurological disorders that primarily damage the cerebellum (the part of the brain that coordinates movement) and the pathways that connect it to the brainstem, as well as the pathways in the brainstem and spinal cord. SCA causes adult-onset progressive movement dysfunction including problems walking, poor coordination, slurred speech and trouble processing and remembering information. Onset occurs earlier with each generation. This hereditary disorder is further divided into subtypes based on different disease-causing genes. Athena Diagnostics had a license to the patent on the most common SCA-causing gene, *SCA1*. The issue with a gene patent on one gene of a gene panel needed for accurate diagnostic testing, is that by stopping clinical laboratories from testing that one gene, the patent holder of the one gene basically controls testing for all the disease-causing genes. Similar to their *APOE* gene patents, Athena Diagnostics was enforcing their exclusive rights to be the sole provider of SCA genetic testing in the United States. Not only did this mean they could set the price of the test, but it also meant that patients across the country had to send their samples to the Athena Diagnostics laboratory in Massachusetts. Shipping specimens to an outside laboratory for testing increases costs and delays obtaining test results. For many types of molecular testing,

such as in infectious disease and oncology, time is of the essence. Today, SCA is associated with over 40 genes. If gene patents are again possible, clinical laboratories would need to stop testing to negotiate licensing agreements with up to 40 or more patent holders, with the added costs of legal and licensing fees. This assumes that all the patent holders or exclusive licensees would even offer a license.



athena diagnostics™

Athena Diagnostics, Inc.
Four Biotech Park
377 Plantation Street
Worcester, MA 01605
Tel 508 756 2886 Fax 508 753 5601

October 16, 1998

RE: U.S. Patent Number 5,741,645

Dear Dr. Leonard:

I would like to advise you that Athena Diagnostics is the licensee to a recently issued U.S. patent 5,741,645, which is directed Spinocerebellar Ataxia type 1 (SCA1). A copy of the patent is enclosed for your convenience.

The patent covers methods of identifying whether an individual is or is not at risk for developing SCA1 disease by analyzing whether the SCA1 gene has an increased or normal number of CAG repeats.

We understand that University of Pennsylvania may be offering a diagnostic test covered by this patent. Any such testing would infringe on the above patent under which Athena has exclusively licensed.

This diagnostic testing service is available through Athena's facilities, and it is only by using Athena's facilities that other laboratories can offer this patented diagnostic test without infringing the patent.

If University of Pennsylvania is interested in continuing to offer this patented testing service to its customers, Athena would be pleased to perform the service on University of Pennsylvania behalf.

Very truly yours,

Michael A. Boss, Ph.D.
Vice President, Operations

Hereditary Hemochromatosis*:* SmithKline Beecham exclusively licensed the patent on the gene associated with hereditary hemochromatosis, a genetic disorder in which the body absorbs and stores excessive amounts of iron, leading to major organ damage. The company sent a letter to my laboratory requesting a $25,000 upfront fee for intellectual property rights, plus a fee per test performed, making testing by my clinical laboratory cost prohibitive. The treatment for this deadly disease is quite simple: donate blood to remove excess iron from the body. However, my institution's ability to diagnose patients and provide treatment was greatly

hampered by the patent holder.

June 24, 1998

Dr. Debra Leonard
University of Pennsylvania Medical Center
3400 Spruce Street
7103 Founders
Philadelphia, PA 19104-4283

Dear Dr. Leonard:

Hereditary Hemochromatosis Assay

I would like to bring to your attention three U.S. patents, 5,705,343; 5,712,098; and 5,753,438 all relating to an assay for hereditary hemochromatosis. The '098 patent may be of most interest to you and I have taken the liberty of enclosing a copy of it for your convenience. These patents are owned by Progenitor, Inc. and licensed exclusively to SmithKline Beecham Clinical Laboratories, Inc. for use in running a home-brew assay.

If you are offering a genetic test for hereditary hemochromatosis, please provide me with an assurance that the test procedure you are running is not covered by one or more of the three mentioned patents. If your test might be covered by these patents, SBCL is willing to make arrangements to insure that your clients have continued access to this gene-based HHC test discovered by Progenitor within the context of Progenitor's issued patents. I invite you to initiate such arrangements by contacting Rose Tricoski at SmithKline Beecham Clinical Laboratories, 1201 South Collegeville Road, Collegeville, PA 19426. Please feel free to call her at 610.454.6367, by fax at 610.983.2302 or by e-mail at rose.tricoski@sb.com. She and others at SBCL can assist you with making the necessary arrangements to avoid any inconvenience or interruption of services to your clients.

I ask that you follow up with Ms. Tricoski by July 24th. Thank you.

Sincerely,

David O'Bryan

David O'Bryan, Ph.D.
Vice President and Director,
Science and Technology

***Leukemias and Lymphomas**:* In 2002, my laboratory entered into an agreement with Invivoscribe (IVS) to license a test to diagnose leukemia and lymphoma and monitor for residual disease after treatment. The agreement was incredibly unreasonable and costly, requiring payment of tens of thousands of dollars at the outset to license the test and a continuing royalty of up to $60 per test. In the end, it cost our institution approximately $300 per test. For comparison, in 2002, Medicare only reimbursed this test at $55.39, thus shifting the cost of testing to the patients.

4.0 LICENSE FOR PRIOR ACTS

Included in the License Issue Fee paid according to Section 5.01 is a retroactive License under Section 3.0 for all of LICENSEE's use of the Licensed Patent Rights prior to the effective date of this Agreement.

5.0 LICENSE ISSUE, CONTINUING ROYALTY FEES

Payment obligations will accrue during this Agreement as follows:

5.01 Payment for License Issue. In consideration of the issuance of the License granted in Sections 3.0 and 4.0 by IVS under the terms of this Agreement, and as a license issue fee, LICENSEE shall pay IVS the sum of _____ Thousand ($__,000.00) US Dollars, due and payable upon the execution of this Agreement.

5.02 Continuing Royalty. In addition to the License Issue Fee paid under Section 5.01, the following continuing Royalty (the "Continuing Royalty") shall be due and owing biannually subject to reduction as outlined in Section 7.03.

1. 1. Zero ($0 USD) dollars for each Intramural Test performed using IVS kits using the reaction volumes recommended in the Product Insert or literature accompanying the product(s);

2. 2. Forty ($40 USD) dollars for each Intramural Test performed without use of IVS kits;

3. 3. Forty ($40 USD) dollars for each Reference Test performed using IVS kits using the reaction volumes recommended in the Product Insert or literature accompanying the product(s);

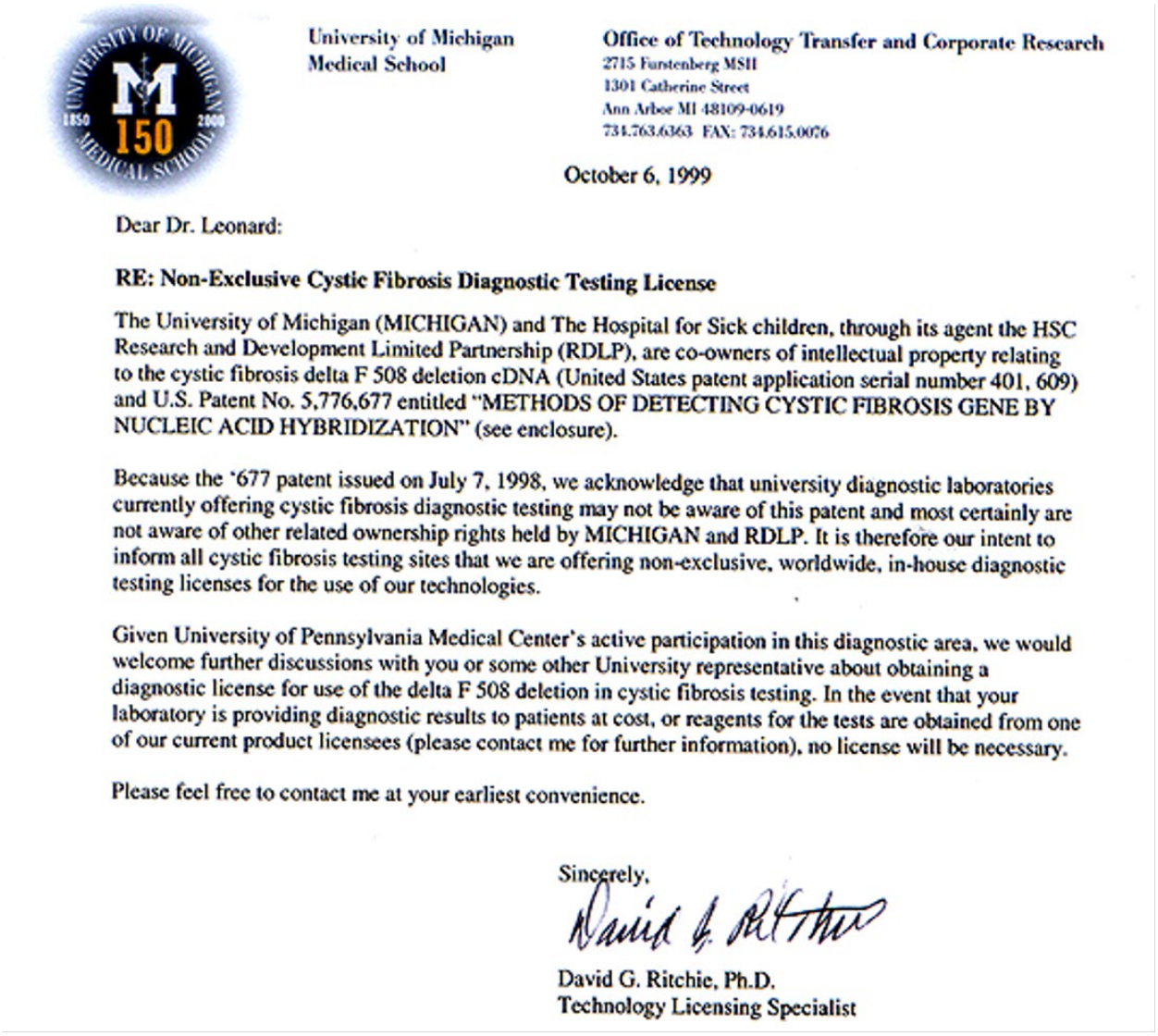
4. 4. Sixty ($60 USD) dollars for each Reference Test performed without use of IVS kits;

***Cystic Fibrosis**:* Many genetic discoveries are derived from NIH-funded research by academic physicians and scientists, which resulted in some gene patents being issued to universities before *Myriad*. In 1989, former National Institutes of Health (NIH) Director, Dr. Francis Collins, discovered the gene for cystic fibrosis, *CTFR*, and the most common disease-causing variant, delta F508, in his laboratory at the University of Michigan.[1] After this tremendous scientific finding, the University patented the gene variant and, as you can see below. In 1999, the University of Michigan sent a letter requesting that we obtain a license to continue to perform testing that included this delta F508 variant. Unlike other gene patent holders, the University of Michigan was offering non-exclusive, no-cost, licenses for in-house testing. We obtained a license and continued to perform cystic fibrosis testing for our patients. Recognizing the limitations that patents placed on medicine and scientific advancement, after the *Myriad* decision, Dr. Collins applauded the ruling, saying it "represents a victory for all those eagerly awaiting more individualized, gene-based approaches to medical care."[2]

Today, 213 tests are available in the United States for cystic fibrosis and are instrumental to patient care. In 2015, just 16 years after the initial discovery of the gene, the FDA approved a

[1] https://www.michiganmedicine.org/news-release/gene-discovery-changed-cystic-fibrosis-care-and-genetic-research-forever
[2] https://www.aclutx.org/news/myriad-genetics-latest-attempt-maintain-its-monopoly-our-genes-rejected/

new precision drug that specifically targets a common mutation causing cystic fibrosis.[3] In other words, genetic testing for patients with cystic fibrosis now directly determines if a patient can receive this life-changing treatment. Patients eligible for this treatment, who previously faced an average life expectancy of 31 years,[4] now have a median survival of 66 years thanks to this major therapeutic breakthrough.[5] The innovation in diagnostics and targeted therapeutics for cystic fibrosis is profound and likely would have been limited had the University of Michigan enforced its patent rights as others had done.



University of Michigan
Medical School

Office of Technology Transfer and Corporate Research
2715 Furstenberg MSII
1301 Catherine Street
Ann Arbor MI 48109-0619
734.763.6363 FAX: 734.615.0076

October 6, 1999

Dear Dr. Leonard:

RE: Non-Exclusive Cystic Fibrosis Diagnostic Testing License

The University of Michigan (MICHIGAN) and The Hospital for Sick children, through its agent the HSC Research and Development Limited Partnership (RDLP), are co-owners of intellectual property relating to the cystic fibrosis delta F 508 deletion cDNA (United States patent application serial number 401, 609) and U.S. Patent No. 5,776,677 entitled "METHODS OF DETECTING CYSTIC FIBROSIS GENE BY NUCLEIC ACID HYBRIDIZATION" (see enclosure).

Because the '677 patent issued on July 7, 1998, we acknowledge that university diagnostic laboratories currently offering cystic fibrosis diagnostic testing may not be aware of this patent and most certainly are not aware of other related ownership rights held by MICHIGAN and RDLP. It is therefore our intent to inform all cystic fibrosis testing sites that we are offering non-exclusive, worldwide, in-house diagnostic testing licenses for the use of our technologies.

Given University of Pennsylvania Medical Center's active participation in this diagnostic area, we would welcome further discussions with you or some other University representative about obtaining a diagnostic license for use of the delta F 508 deletion in cystic fibrosis testing. In the event that your laboratory is providing diagnostic results to patients at cost, or reagents for the tests are obtained from one of our current product licensees (please contact me for further information), no license will be necessary.

Please feel free to contact me at your earliest convenience.

Sincerely,

David G. Ritchie, Ph.D.
Technology Licensing Specialist

My experience with patent holders restricting the practice of medicine prior to 2013 was not an isolated experience. In a survey of laboratory directors published in 1998, about 25% stopped

[3] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/0206038Orig1s000SumR.pdf
[4] https://cystic-fibrosis.com/life-expectancy
[5] https://www.cff.org/managing-cf/understanding-changes-life-expectancy

testing due to patents, and about 50% said they were not offering one or more genetic tests in their laboratories due to concern about patent enforcements.[6]

Clinical Laboratory Medicine Practice After 2013

Despite claims that current patent law has discouraged innovation in precision medicine, the evidence demonstrates exactly the opposite. Since 2013, molecular medicine has flourished. Today, more than 175,000 genetic tests are available in the United States[7] with 14 new tests entering the market every day on average.[8] This reflects over an 180% increase in the number of genetic tests since 2016.[9] In the 2025 Senate Judiciary Subcommittee on Intellectual Property hearing on PERA, one witness testified that the lack of patents has hindered the development of non-invasive prenatal testing to detect genetic abnormalities, implying that the *Ariosa v. Sequenom* decision in 2016 led to patients not having access to this innovative test.[10] However, today, at least four laboratories offer this test nationwide, including LabCorp,[11] Natera,[12] Quest Diagnostics,[13] and Myriad Genetics Inc.,[14] the named defendant in the pivotal Supreme Court decision. Clearly, the inability to patent DNA has not hindered innovation in this space. On the 10th anniversary of the *Myriad* decision, the company's then CEO stated, "The Supreme Court, I believe, ruled correctly that genes found in nature should not be patented."[15] If anything, current patent law jurisprudence ushered in an environment that made this testing widely available and now a standard of care in prenatal care.

Focusing on the genes at the center of this case illustrates this well. Before *Myriad*, a single company held a monopoly and was the sole provider of testing for the *BRCA1* and *BRCA2* genes. Today, in the United States, there are 263 clinical tests involving the analysis of *BRCA1*,

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[6] Cho, M. K. in Preparing for the Millennium: Laboratory Medicine in the 21st Century. p. 47-53 (AACC Press, 1998).

[7] Concert Genetics, "Genetic Test Price Transparency Report." 2023. http://www.concertgenetics.com/wp-content/uploads/2023/11/Concert-Genetics-2023-Genetic-Test-Price-Transparency-Report-07Nov2023.pdf Accessed January 18, 2024.

[8] Concert Genetics, "The Current Landscape of Genetic Testing: Market Growth, Reimbursement Trends, Challenges and Opportunities – 2018 Edition." 2018.

[9] 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.

[10] https://www.judiciary.senate.gov/imo/media/doc/4539f98c-f893-95c0-3976-2519d3d06087/2025-10-08%20-%20Testimony%20-%20Peschin.pdf

[11] https://womenshealth.labcorp.com/patients/pregnancy/noninvasive-prenatal-screening

[12] https://www.natera.com/womens-health/panorama-nipt-prenatal-screening/

[13] https://www.questdiagnostics.com/healthcare-professionals/about-our-tests/womens-health/pregnancy-and-fertility/pregnant-patients/noninvasive-prenatal-screening

[14] https://myriad.com/genetic-tests/prequel-prenatal-screen/

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

and 284 clinical tests involving the analysis of *BRCA2*.[16] Prior to 2013, Myriad billed about $4000 to sequence those two genes. Further, if a state's Medicaid program did not contract with the test's patent holder, those beneficiaries had to either pay out of pocket for the test or were unable to have tests that, if positive, could lead to lifesaving health care. In the 2024 Subcommittee hearing on PERA, Invitae testified that patients have access to multigene hereditary cancer panels with dozens of genes for as low as a "couple hundred dollars."[17] Moreover, coverage today is determined by the utility of the test, not its patent status. Thanks to Supreme Court decisions such as *Myriad,* competition has increased, costs have fallen, and patients have greater access to high-quality testing than ever before.

In anticipation of the need for updated Medicare coverage policies for novel cancer screening tests coming to market, Congress recently enacted the *Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act*, which creates a new benefit category to cover noninvasive tests that screen for more than one cancer at the same time by analyzing many biomarkers at once. In 2024, FDA authorized the first blood-based screening test for colorectal cancer[18] and currently, a blood-based test that can screen for 50 cancers at once is available to patients.[19] The ability to detect cancer with a blood test, eliminating the need for CTs that expose patients to radiation and procedures that include the risk of anesthesia and possible costly complications, is revolutionary. It also promises to dramatically increase access to cancer screening for people in rural communities, who otherwise would travel long distances for more complex imaging or procedures.

This innovation extends far beyond oncology. Last year, the FDA authorized the first blood-based test that measures biomarkers to diagnose Alzheimer disease.[20] If enacted, those biomarkers and their association with Alzheimer disease would be patent eligible under PERA. Recognizing the importance of patient access to these innovative tests, bipartisan, bicameral legislation, the Alzheimer's Screening and Prevention (ASAP) Act, was introduced to ensure Medicare covers these diagnostics. Championed by the Alliance for Aging Research,[21] 40 Senators currently cosponsor the bill, including nine members on the Judiciary Committee: Senators Booker, Britt, Coons, Hirono, Kennedy, Klobuchar, Padilla, Tillis, and Welch.[22]

Again, all of this innovation in genetic diagnostics and therapeutics has occurred since 2013, within the current patent environment. This progress stands in stark contrast to assertions that gene patenting is needed for diagnostic innovation. My colleague, Dr. Harry Ostrer, the only

[16] Data accessed on July 7, 2026 from Genetic Testing Registry; https://www.ncbi.nlm.nih.gov/gtr/
[17] https://www.judiciary.senate.gov/imo/media/doc/2024-01-23_-_testimony_-_blaylock.pdf
[18] https://www.fda.gov/medical-devices/recently-approved-devices/shield-p230009
[19] https://grail.com/galleri-test/the-science/mced/
[20] https://www.fda.gov/news-events/press-announcements/fda-clears-first-blood-test-used-diagnosing-alzheimers-disease
[21] https://www.agingresearch.org/news/asap-act-offers-unprecedented-hope-for-earlier-diagnosis-treatment-of-alzheimers/
[22] https://www.congress.gov/bill/119th-congress/senate-bill/3267/cosponsors?pageSort=alpha

plaintiff with standing when the *Myriad* case reached the Supreme Court, said in his Substack, "PERA is a solution in search of a problem."[23] As it pertains to genome-based testing, I concur.

In past hearings, witnesses discussed how the human genome has been sequenced and is now publicly available. I want to stress that we are still in the nascent days of understanding the genome. Discoveries continue with new variants, new associations, and new pathogens being identified each day. For example, the NIH-funded All of Us Program announced in 2024 that its researchers have discovered over 275 million previously unreported genetic variants.[24] If PERA were enacted, those variants would be eligible for patenting, resulting in the same barriers to research and care experienced prior to 2013.

Finally, as a molecular pathology physician, I must point out that the exception for "an unmodified human gene, as that gene exists in the human body" and the following condition for it in PERA are meaningless. Any genetic test requires that the DNA be purified and enriched, i.e., altered by human activity. If the intent of this language in PERA is to protect the integrity of the *Myriad* decision, it fails to accomplish its goal. The language runs counter to *Myriad* and would allow future patents on human genetic sequences. Further, this language doesn't reflect current genomic medicine. As our understanding of genomics and other omics has advanced, we no longer focus on "genes" but on individual variants within coding and non-coding regions, interactions among them, and so on. This exception fails to address the concerns of the stakeholder community.[25] I implore you to retain the principles set forth by the *Myriad, Mayo,* and *Alice* decisions, namely that products of nature, laws of nature, and abstract ideas should not be patented, when considering patent eligibility reform.

From the examples in my testimony to the advances in gene therapy, CRISPR technology, precision oncology, and more, it's clear that the United States leads the world in genomics and precision medicine. That success has occurred under the current patent eligibility framework, not despite it. We must continue to reward true innovation through patents on novel technologies, therapies, and laboratory methods, while ensuring that the building blocks of biology remain available for researchers, clinicians, and patients alike. Having experienced both worlds, I can say with confidence that the current framework serves patients far better than the one that existed before *Myriad.*

Thank you for the opportunity to testify.

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[23] https://harryo.substack.com/p/why-are-we-talking-about-gene-patenting

[24] The All of Us Research Program Genomics Investigators. Genomic data in the All of Us Research Program. Nature 627, 340–346 (2024).

[25] https://www.amp.org/AMP/assets/File/advocacy/Stakeholder%20Letter%20Opposing%20PERA%20March%202026.pdf?pass=73