September 25, 2024

Committee on the Judiciary
224 Dirksen Senate Building
Washington, DC 20510

Dear Chairman Durbin, Ranking Member Graham, and esteemed members of the Senate Judiciary Committee,

On behalf of our organizations and the millions of Americans we serve, we are writing to express strong opposition to S. 2140, the Patent Eligibility Restoration Act (PERA), which would abrogate established Supreme Court precedent and expand patent-eligible subject matter to encompass abstract ideas, laws of nature, and natural phenomena.

As written, PERA would allow patents on abstract ideas, laws of nature, and natural phenomena. This would cause significant public harm by hindering competition and innovation in a variety of areas, but most important to our community, in the fields of genetics and medicine. It would restrict the use of the "basic tools of scientific and technological work."[1]

The Supreme Court has consistently held that laws of nature, natural phenomena, and abstract ideas are not patent-eligible under the Patent Act.[2] Multiple decisions between 2010 and 2014 affirm these important patent eligibility exceptions. In Mayo v. Prometheus, for example, the Court found that the naturally occurring relationship between certain metabolite levels in the blood and the prospect of a specific drug dosage being effective was not patent-eligible.[3] The biological relationship between the metabolite level and the appropriate drug dose is a natural law, not one invented by the patent holder. In AMP v. Myriad Genetics, a unanimous Court extended its reasoning to human DNA removed ("isolated") from the body, finding that the genes are not significantly altered by isolation, and that such patents restrict access to genetic information, preventing others from scientific and medical work.[4]

These decisions profoundly affected families throughout the country, ending a monopoly on the BRCA1 and BRCA2 genes, which occur naturally in the human body. The link between BRCA gene mutations and heritable cancer syndromes was discovered and patented in the mid-1990s. Myriad's monopoly on the BRCA genes resulted in exorbitant costs and a lack of competition, ultimately hindering access to critical health information for many patients.

Before the Supreme Court's 2013 ruling, companies were able to patent human genes under a policy that allowed patents on DNA once "isolated"—essentially extracted or removed—from the cell. These patents, including those on the BRCA genes, permitted the patent holder to stop all other analyses of the patented gene. Patent holders often threatened other labs with lawsuits, even when they used different testing methods. Only one laboratory in the U.S. provided testing for BRCA genes, compared to dozens of labs in Europe.

Following the Myriad decision, dozens of labs immediately entered the genetic testing marketplace[5] and there are now more than 300 clinical tests for BRCA1 and for BRCA2 being performed.[6] Not only did the labs begin testing for BRCA mutations, but thanks to next-generation sequencing, they

were able to expand testing to include mutations in many other genes linked to hereditary cancers (ATM, CHEK2, PALB2, RAD51, etc.). This fostered tremendous growth in personalized and precision medicine, revolutionizing genetics and oncology while making gene testing more affordable and accessible. In 2013, Myriad's test for mutations in the BRCA genes cost approximately $4000; no other lab was permitted to test for cancer-causing mutations in these genes. After the Supreme Court decision, prices dropped to hundreds versus thousands of dollars.

Analyzing dozens of genes linked to hereditary cancers, multigene panel genetic testing is now the standard of care. The ability to patent genes/DNA would derail efforts to identify genetic mutations that cause increased cancer risk by excluding certain genes from these "comprehensive" tests. Concert Genetics reported that 374 tests included the BRCA1 and BRCA2 genes in 2018,[7] compared to just one before June 2013.[8] This dramatic increase in testing for hereditary cancer mutations not only provides opportunities to prevent or detect cancer earlier when it is easier to treat, but the competition ultimately leads to savings for patients and the healthcare system at large.

Current law promotes innovation and competition by ensuring that the fundamental building blocks that result in invention cannot be monopolized. One review of venture capital investments in genetic testing companies, before their initial public offering, found that funding nearly tripled in the three years after the Myriad decision and that venture capital investments in private companies reached $294 million in 2020 compared to $1 million in 2013.[9] This is proof that investments in the life sciences are robust and that the field of precision medicine is thriving under current law.

The COVID-19 pandemic illustrates the innovation possible under existing law. The American public rapidly had access to COVID-19 diagnostics, vaccines, and therapies. This innovation would not have been possible if a company had been allowed to patent COVID-19. In fact, during the 2003 outbreak of severe acute respiratory syndrome (SARS)—because the Supreme Court had not yet clarified that naturally occurring genetic sequences are not patent-eligible—biopharmaceutical companies raced to file patent applications for exclusive rights to the virus and its genetic sequence.[10] To facilitate access to the fundamental research needed to fight SARS, the CDC filed its own patent applications to "give the industry and other researchers reasonable access to the samples."

Innovation in life sciences is stronger than ever. S. 2140 threatens not only to derail future progress but also to reverse many important gains. We oppose any legislative effort that would allow gene patents. PERA will return us to a time when abstract ideas, laws of nature, and natural phenomena are patentable. This will increase healthcare costs while harming innovation and consumers.

We urge you to vote "No" on this legislation and look forward to working with you and your colleagues to ensure that DNA and other naturally occurring phenomena remain ineligible for patents. Please contact Lisa Schlager, Vice President of Public Policy at FORCE, with any questions – lisas@facingourrisk.org.

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[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).
[5] After Patent Ruling, Availability of Gene Tests Could Broaden - https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-testscould-broaden.html
[6] Data accessed from Genetic Testing Registry - https://www.ncbi.nlm.nih.gov/gtr/
[7] 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
[8] 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
[9] Comments Submitted by Invitae Corporation - https://www.regulations.gov/comment/PTO-P-2021-0032-0053
[10] Paul Elias, Race to Patent SARS Virus Renews Debate, ASSOCIATED PRESS (May 5, 2003), https://apnews.com/article/145b4e8d156cddc93e996ae52dc24ec0.