# Protect Medical Research and Health Care

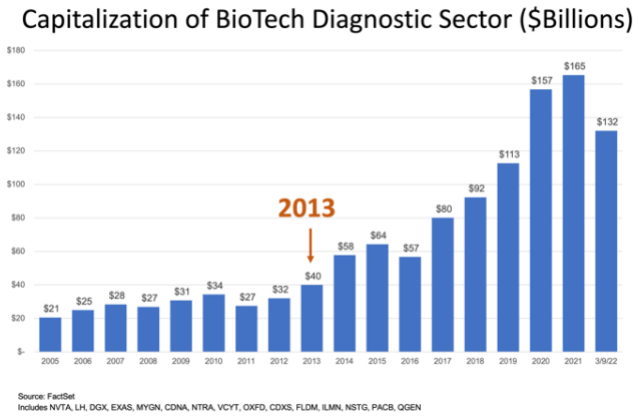
***Current State of Patent Eligibility***

In 2013, the Supreme Court unanimously decided in the *Association for Molecular Pathology v. Myriad Genetics Inc.* case that DNA is a product of nature and cannot be patented. Writing the opinion for the court, Justice Thomas said:

> ***"A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated…"***
>
> ***"Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention."***

This pivotal decision along with other landmark decisions means that today all biomarkers and their associations with health status are considered natural phenomena and cannot be patented. On the 10th anniversary of this decision, the CEO of Myriad Genetics said, "The Supreme Court, I believe, ruled correctly that genes found in nature should not be patented."

These decisions have had a tremendously positive impact:




***Investment in the diagnostics sector has grown substantially since the 2013 Myriad decision (see graph to the left).***

***The cost of testing for hereditary breast cancer has dropped from over $3400 to sequence two genes to under $300 to sequence more than 30 genes.***

***Medical research has proceeded without expensive licensing requirements.***

***S. 2140 is Bad for Innovation and Bad for Public Health***

The Patent Eligibility Restoration Act (S. 2140), would overturn 150 years of Supreme Court precedent and allow patents on laws of nature, products of nature, and abstract ideas. For healthcare, this would be a radical upheaval that would threaten the significant progress made in precision medicine, reduce patient access to lifesaving genetic tests, and slow medical innovation. The bill would also create testing bottlenecks during public health emergencies. As of January 2024, the FDA lists 276 active emergency use authorizations for molecular tests for COVID-19. If one entity had owned a patent on the virus' genetic sequence, then only that patent holder would have been able to develop a PCR-based test and they would get to decide if and when they would grant licenses to other labs, greatly hampering the country's ability to meet its testing capacity needs and respond to the pandemic.

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***The Bill's Exemptions Are Nothing More than a Distraction***

The bill includes an exemption for unmodified products of nature, but also states that the act of isolating a gene from the human body modifies the gene. *Everything* found in nature is altered by human activity in order to be useful when it's removed from its natural environment, which renders this exemption meaningless. To perform a genetic test on a patient, their DNA is first isolated from their sample. To test a patient for COVID-19, the virus' RNA is first isolated from the sample. Further, claims that the full sequence of the human genome is publicly available making it unpatentable are another distraction – there are thousands, if not millions, of DNA segments and variants whose significance still remain unknown. If the Patent Eligibility Restoration Act is enacted, any useful, newly identified association between a gene or mutation (even if the actual sequence was already known) and a health condition would be patentable. The truth is that this bill would allow patents on natural phenomena, creating countless barriers to patient care and medical research.

***More Than 150 Organizations Oppose Changes to Patent Eligibility***

When similar legislation was proposed in 2019, more than 150 civil rights, medical, scientific, patient advocacy, and women's health organizations wrote to Congress about the dangers of amending Section 101 of the Patent Act. In 2021, several dozen organizations sent a letter to President Joe Biden highlighting the importance of limiting patent eligibility in order to encourage innovation, competition, and advancement for the benefit of patients and the American public.

***We ask you to protect patient access to genetic testing and investment in medical research by opposing S. 2140 and similar changes to Section 101 of the U.S. Patent Act!***