



Statement of  
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On behalf of  
**Invitae Corporation**

Before the  
**Subcommittee on Intellectual Property**  
of the  
**Committee on the Judiciary**  
**United States Senate**

Hearing on  
**The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to  
the U.S. Patent System**

January 23, 2024

Dear Chair Coons, Ranking Member Tillis, and other members of the Subcommittee:

Thank you for the opportunity to appear before the Subcommittee at the hearing on The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System. On behalf of Invitae Corporation (Invitae), I greatly appreciate the opportunity to submit additional written testimony expressing the company's concern that the Patent Eligibility Restoration Act (PERA), as introduced, will unintentionally stifle innovation and harm patient care in the fields of diagnostic genetic testing and precision medicine.

I am a partner with the law firm Pillsbury Winthrop Shaw Pittman LLP and have been a practicing attorney since the mid-1990s. I have been corporate and intellectual property counsel to Invitae since its formation in 2010. My testimony today is solely on behalf of Invitae and does not necessarily represent the views of Pillsbury or any of its other clients.

Invitae is a leading medical genetics company, delivering genetic information that supports a lifetime of patient care. Our tests and services primarily combine next-generation sequencing genetic and clinical information to improve health care decision-making and enable research across many care journeys like cancer and rare diseases. Invitae's mission is to improve healthcare for everyone, including by making genetic testing more accessible to all who may benefit. Invitae has served over four million patients since the company was created allowing those patients the opportunity to personalize and improve their clinical care. Invitae's success in providing critical genetic information to these patients was enabled, in part, by the current patent eligibility jurisprudence in the United States.

### **PERA as proposed would cause substantial harm to the research and clinical community as it relates to genetic testing**

When Invitae's former CEO, Dr. Sean George, appeared before this subcommittee in 2019 and ever since then, we have often heard the suggestion that the publication of the human genome has rendered moot the need for concern about patents related to human genes. The argument rests on the idea that the risk of patenting human genes has passed with the publication of the human genome because the sequences of human genes are no longer new. This represents a fundamental misunderstanding of the risks to science and patient care posed by permitting natural phenomena to be patented.

Under current law, natural phenomena are not patent eligible subject matter. Nor are applications of conventional technology to natural phenomena. No person has the "standard" human genome. All of us have variants in our genetic sequences. Some of these variants are clinically significant. A well-known example is a collection of variants in the sequences of the *BRCA1* and *BRCA2* genes that, when present, indicate a substantially elevated lifetime risk of suffering from breast cancer. Variants such as these are natural biomarkers and this information including its association with disease risk is an unpatentable natural phenomenon. Similarly, application of conventional technology (such as Sanger sequencing or next generation sequencing) to detect the presence or absence of such biomarkers is an unpatentable conventional application of natural phenomena.

The purpose of clinical genetic testing is not the detection or sequencing of whole genes as such, but rather the detection of biomarkers that are specific variations in a patient's genes that

are indicative of the patient's disease risk or suitability for certain treatments. These biomarkers can be simple such as single nucleotide polymorphisms (or SNPs) or larger insertions, deletions, transpositions or copy number errors in the relevant genetic sequence. While some important biomarkers have been discovered the human genome is vast and far more important biomarkers remain to be discerned. Our increasing sophistication in understanding these biomarkers and their clinical relevance is essential to the practice of precision or personalized medicine tailored to the unique needs of the individual patient.

The absence of patents on natural phenomena has not impaired innovation in the genetic diagnostics industry. Quite the opposite is true. In the last decade, the genetic testing industry has thrived. The cost of genetic sequencing and therefore the barrier to innovation in detecting new clinically relevant biomarkers has fallen dramatically. New biomarkers are being recognized on a routine basis.

PERA would slam the door shut on such innovation and also its clinical application in medicine. PERA would permit the privatization of natural phenomena in the form of knowledge of new biomarkers and their clinical relevance. Because the discernment of new (to us) biomarkers is highly distributed, patent filing on each new biomarker would proliferate with a very large and internationally dispersed group of patent applicants. Any one of those new patentees could stand in the way of a clinician's effort to conduct an analysis of a patient's genetic information because testing for a broad panel of possible variants would require permission from all of a large group of patentees, none of whom would be required to grant such permission.

From a policy perspective, we urge the subcommittee to think of natural phenomena such as biomarkers as pre-competitive information that is discovered and not invented and should be available to all. As noted above, this information is rapidly being developed now and privatization of such information is unnecessary to its discernment. Moreover, such privatization of natural phenomena biomarkers would impair patient self-knowledge about their own genetic make-up and critically an understanding of some of its implications.

PERA would impose effectively no limits on the patenting of genes and other natural materials and natural phenomena. While PERA contains exclusions from patentable subject matter for human genes and natural materials, PERA also contains substantial exceptions to those exclusions such that the "exclusions" of genes and other natural materials are so narrow as to be almost meaningless. Specifically, the bill excludes from patentability both "an unmodified human gene, as that gene exists in the human body," and "an unmodified natural material, as that material exists in nature." However, the bill expressly states that any gene or natural material that has either been "isolated, purified, enriched, or otherwise altered by human activity," or "otherwise employed in a useful invention or discovery" (where useful is defined in PERA to mean anything that has a specific and practical utility) is not "unmodified" and therefore would be eligible for patenting. Such a claim allowed under PERA would permit the privatization of newly observed biomarkers as detection of the presence or absence of a biomarker routinely involves the isolation, purification, or enrichment of a fragment of a genetic sequence embodying the natural variant that is the biomarker. Moreover, the last exception to these exclusions is telling because even if the natural material is completely unmodified and is existing exactly as it is found in nature it would *still* be patentable under PERA in the context of any alleged practical use for it. People do not seek to patent things as they exist *in situ* naturally, but instead seek to claim natural materials in the ways that humans may try to exploit them. PERA could permit patenting of natural materials that would prevent people from engaging in research on or engaging in any practical use of such natural material.

Thus, PERA would threaten the ongoing discovery of new biomarkers relevant to personalized or precision medicine that depends on the characterization of the specific variants of a patient's genes. PERA would permit all such new discoveries to be patented and privatized. The result would be the great proliferation of patents covering the many genetic variants for which clinicians would want to test a patient. A patent thicket would emerge that would impede patient care by making it very hard to conduct genetic testing comprehensively for a patient.

However, the threats to the life sciences research, innovation and patient care are not limited just to concerns about our unfolding appreciation of additional biomarkers and their effective incorporation into precision medicine. Had PERA been the law at the start of the COVID-19 pandemic it would have severely interfered with and almost certainly impeded the progress of COVID-19 diagnostics and vaccines. The severe acute respiratory syndrome (SARS) coronavirus 2 was new at the time and therefore its characteristic DNA and protein sequences would have been patentable under PERA. Indeed, the virus itself, for example in an attenuated (or "killed") form would have been patentable as a traditional vaccine. And the sequences needed to make an RNA vaccine would also have been privatized and constrained research and development of the vaccines that were the cornerstone of the response to the pandemic. The opportunity to patent would translate into a competitive imperative to patent and would have dramatically curtailed sharing of information which was critical to the rapid public health response in the development of diagnostics and vaccines.

The fact that the pandemic preceded PERA does not mean that PERA would not pose future harm. Under PERA, one could patent an unpublished viral gene by claiming the gene in its isolated, purified or enriched form. Note that practically all genetic sequencing involves an enrichment step and thus such a patent would cover anyone sequencing a sample of the virus's DNA for research or diagnostic purposes. Even the whole virus could be patented if its virality is attenuated or killed. A traditional form of vaccine is made of attenuated virus which could hinder the development and access to necessary vaccines. The potential to patent newly observed viruses would impede public health goals reliant upon data sharing because there would be an incentive to make a patent filing before disclosing publicly a newly observed virus. This could even apply to new variants of the SARS coronavirus 2 that may yet emerge.

### **The current Supreme Court jurisprudence on patent subject matter eligibility does not impede innovation in the diagnostics industry**

As noted above (and discussed more below) the current state of the law has not impeded the rapid pace of innovation in the discernment and clinical application biomarkers in the form of genetic variants associated with certain disease risks and suitability for certain treatment regimens thereby advancing the progress of personalized medicine. Nor is genuine innovation in the diagnostic industry itself threatened by the current state of the patent subject matter eligibility. The exclusion of natural phenomena, natural materials, and abstract ideas from patenting in no way has stopped the patenting of innovations in the machinery and techniques for genetic sequencing or the development of new platforms for diagnostic testing. It is only the natural phenomena and natural materials, which by definition are not inventions, which are excluded. They should be viewed as pre-competitive information available to all for use in the creation of actual innovations that productively exploit such new knowledge.

## **PERA will not improve America's global competitiveness in the life sciences.**

Patent law is a species of government regulation of the economy within the U.S. A patent is not a fundamental property right. Rather it is a limited right defined by and granted by the federal government. Notably, the innovation giving rise to a U.S. patent can occur anywhere in the world and therefore a more permissive U.S. patent policy would encourage and reward innovators outside the U.S. as much as within the U.S. By contrast, the constraint on economic activity resulting from a U.S. patent occurs almost entirely within the U.S. Broadening patent eligibility to produce more U.S. patents means greater constraints on domestic economic activity but the beneficiaries could just as easily be foreign patent-holders who reside in countries that are economic competitors and who could then have a meaningful impact on American healthcare economy through their patent position. If this subcommittee has an industrial policy goal of improving American competitiveness with respect to China or other countries in the field of genomics and medical diagnostics, there are many possible productive opportunities to explore, but PERA is not one of them.

## **PERA is unnecessary as the law on patent subject matter eligibility does not require the wholesale changes it proposes.**

Invitae agrees with recent Supreme Court decisions concerning patent subject matter eligibility, including the *Association for Molecular Pathology v. Myriad Genetics, Inc. (AMP v. Myriad)*, *Alice v. CLS Bank International (Alice v. CLS)*, and *Mayo Collaborative Services v. Prometheus Laboratories, Inc. (Mayo v. Prometheus)* and believe that biomarkers, including DNA, and their association with a health status are naturally occurring phenomena and natural laws, respectively, and hence, are not patent eligible. Moreover, we believe that any efforts to reform or revise Section 101 of the U.S. Patent Act should maintain these protections and continue to prohibit patents on biomarkers, even in their isolated form, and their association with a disease or health condition.

The Patent Act of 1952 largely codified and clarified longstanding caselaw related to the U.S. patent system. Congress would do well to follow the example of the Patent Act of 1952 and seek to codify and clarify existing caselaw on patent subject matter eligibility rather than the approach embodied in PERA which is the wholesale abandonment of decades of Supreme Court jurisprudence coupled with ambiguous standards that will destabilize the field of patent subject matter eligibility for many years while the courts work out new tools applying the new standards.

Some commentators on the state of Supreme Court jurisprudence on patent subject matter eligibility since the *Mayo v. Prometheus* decision in 2013 have complained, sometimes literally, that the “sky is falling.” Here we are ten years later and the sky has most definitely not fallen. The life sciences industry has thrived, entire new classes of therapeutics and vaccines have been approved such as CRISPR-based gene therapies and the RNA vaccines that are the foundation of the nation's response to the COVID-19 crisis. As discussed below, the genetic testing industry has blossomed and we are beginning to reap the fruits of precision medicine and will continue to do so unless we take a misguided step backward by jettisoning the standards for patent subject matter eligibility that have been articulated by the Supreme Court in the unanimous *Mayo*, *Myriad*, and *Alice* decisions.

## **The current state of the law has been instrumental in unlocking the potential of precision medicine**

Prior to 2014 and the important Supreme Court decisions referenced above (*Mayo*, *Myriad* and *Alice*), people could, and did, patent not just genes but also each mutation or variation they detected along with its perceived significance for a patient's health status. These numerous patents created a thicket preventing laboratories from analyzing and interpreting genetic information relevant to a patient's health. This not only denied many patients the ability to access knowledge about their own health status but also hobbled innovation in precision medicine. At the time of Invitae's founding in 2010 many investors questioned the viability of Invitae's ambition to provide broad panels of genetic tests at an economical price precisely because of the existing patent thicket. Scores of patentees held numerous patents that claimed genes and mutations in genes covered by just the first modest panel planned by Invitae. For many, the patent thicket posed both economic and practical barriers to proceeding with even a small panel of genes to test. Testing the entire genome of a patient in the face of all of the then existing patents claiming aspects of human genes would be an impossibility as no one party would be able to assemble the rights to do so.

Invitae has long been committed to greatly expanding patient access to their genetic information, and in keeping with this commitment, Invitae filed an amicus brief in 2013 on behalf of the plaintiffs in *AMP v. Myriad*. When the *AMP v. Myriad* decision was handed down in June 2013, it unleashed a new era of precision where information gleaned from the Human Genome Project and other research could be more rapidly translated into medical approaches that work better for patients and their clinicians. It put an end to the practice of privatizing each incremental bit of knowledge about the significance of individual variations in a multitude of genes relevant to patient cancer risk or other diseases.

Since 2013, access to and the availability of genetic testing has increased dramatically. The day before the *AMP v. Myriad* decision in 2013, only one laboratory offered testing for hereditary breast and ovarian cancer. The day after the decision, at least five companies began offering testing for this indication.<sup>1</sup> Today, according to the Genetic Test Registry housed at the National Institutes of Health, there are nearly 500 clinical tests available for the *BRCA* genes.<sup>2</sup> The *AMP v. Myriad* decision also resulted in a reduction in the cost of genetic testing for both private and public payers as well as improvements in the quality of the tests – the cost of testing plummeted from \$4,400 in 2013 to only a couple hundred to the patient at Invitae today. Further, the turnaround time for results fell from months to days, which is essential for healthcare providers and patients to plan and make time-sensitive decisions about life-altering surgery, such as a risk-reducing mastectomy to reduce the risk of developing hereditary breast cancer.

Importantly, single-gene testing utilized in 2013 is now known to be inferior to large multigene panels to evaluate a person's hereditary cancer risk. Panel testing, as we provide at Invitae, is now the standard of care -- progress that would have been nearly impossible if licensing to overcome an entire patent thicket across scores of genes were required. Moreover, new information about relevant genetic variants and their implications for developing cancer is discovered every day. Had these important court cases not enabled the ability to conduct research, translate the findings into clinically actionable information, and perform diagnostic testing, patents on laws and products of nature would have severely limited the progress in precision medicine that we see today. For instance, the company that held exclusive testing

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<sup>1</sup> <https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html>

<sup>2</sup> [https://www.ncbi.nlm.nih.gov/gtr/all/tests/?term=672\[geneid\]&filter=testtype:clinical](https://www.ncbi.nlm.nih.gov/gtr/all/tests/?term=672[geneid]&filter=testtype:clinical)

rights under their *BRCA* patents originally used a testing approach (short-range polymerase chain reaction followed by genomic sequencing) that only accounted for the five most common types of rearrangements in the *BRCA1* and *BRCA2* genes. Thus, the test that launched in 2002 did not test for 12% of genomic rearrangements that can be detected using a different technology.<sup>3</sup> Due to the patent, it took another four years for a test able to detect all known large rearrangements to be made clinically available.<sup>4</sup> During that time, it remains unknown how many families may have received incomplete results and subsequently, missed opportunities to diagnose their cancer early or prevent it altogether.

Patents also greatly hindered the development of testing for familial long QT syndrome, an inherited heart rhythm disorder that can lead to sudden cardiac death. Some of the relevant genes to familial long QT syndrome were patented by the University of Utah as early as 1997 (U.S. 5599673), which granted an exclusive license to their patents shortly after. However, company acquisitions and refusals to let other laboratories perform testing<sup>5</sup> contributed to the significant delay (approximately 9 years) between the granting of the first patent and the commercialization of more comprehensive multi-gene testing in 2004.<sup>6</sup> It was yet another two years before a second lab was able to secure a license to offer another testing option. The lack of patient access to this test due to the patents likely contributed to a number of preventable deaths from sudden cardiac arrest. Furthermore, when testing was finally introduced in 2004, according to a report from the Secretary's Advisory Committee on Genetics, Health, and Society in 2010, it cost \$5,400.<sup>7</sup> Today, in the post-*AMP v. Myriad* era, Invitae offers panel testing for familial Long QT syndrome at a fraction of that cost to the patient.

Conversely, during roughly the same time period, genetic testing for Lynch syndrome illustrated testing could be brought forward to help patients more quickly when those patents were not enforced. Lynch syndrome is a hereditary syndrome associated with a high risk for developing pancreatic, colon, uterine, ovarian, and other types of cancer. It is just as common as Hereditary Breast and Ovarian Cancer syndrome and making a diagnosis is just as impactful for patient care. Two of the genes most commonly implicated in the syndrome were patented (US 5922855 and US 5591826) in the late 1990s by two different entities, which would have required laboratories to obtain two different licenses. However, the organizations holding these patents did not enforce them. As a result, the commercialization of Lynch syndrome testing was successful and rapid and enabled patient access to genetic panel testing currently recommended by all professional clinical guidelines.<sup>8</sup> As compared to one company providing testing for hereditary breast cancer, in 2008, at least nine laboratories were offering testing for Lynch syndrome allowing laboratories to compete by making improvements to quality, turnaround time, convenience, and cost, and providing patients a choice in testing.

Nonenforcement of patents is rare and dependent on a company forgoing its market exclusivity opportunities, so it is not a reliable strategy for ensuring patients can continue to benefit from

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<sup>3</sup> Walsh T, Casadei S, Coats KH, et al. Spectrum of Mutations in *BRCA1*, *BRCA2*, *CHEK2*, and *TP53* in Families at High Risk of Breast Cancer. *JAMA*. 2006;295(12):1379. doi:10.1001/jama.295.12.1379

<sup>4</sup> House Judiciary Committee, Subcommittee on the Courts, the Internet and Intellectual Property; oversight hearing on Stifling or Stimulating?—The role of gene patents in research and genetic testing.

<sup>5</sup> Feature Story: A case of limited clinical access. *Cap Today*, February 2010. Available at: [http://www.captodayonline.com\\_Archives\\_0210\\_0210ab\\_limited\\_clinical\\_access.pdf](http://www.captodayonline.com_Archives_0210_0210ab_limited_clinical_access.pdf)

<sup>6</sup> Angrist, M., et al. Impact of gene patents and licensing practices on access to genetic testing for long QT syndrome. *Genet Med* 2010;12(4):S111–S154.

<sup>7</sup> Secretary's Advisory Committee on Genetics, Health, and Society, Department of Health and Human Services. Gene patents and licensing practices and their impact on patient access to genetic tests. [https://osp.od.nih.gov/wp-content/uploads/2013/11/SACGHS\\_patents\\_report\\_2010.pdf](https://osp.od.nih.gov/wp-content/uploads/2013/11/SACGHS_patents_report_2010.pdf). Published April 2010. Accessed June 7, 2019.

<sup>8</sup> National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®), Genetic/Familial High-Risk Assessment: Colorectal. Version 1.2018

genetic discoveries. Instead, legislative efforts should continue to prohibit patents on biomarkers and their association with diseases and health conditions, especially in light of the positive impact of the current eligibility jurisprudence on innovation in recent years.

### **Innovation in precision medicine and diagnostics continues to soar**

Since 2013, a vibrant genetic testing industry has flourished. Reports indicated that there are over 175,000 clinically available genetic tests<sup>9</sup> overall, with 14 new tests introduced daily.<sup>10</sup> Thanks to the *AMP v. Myriad* decision, patients and their providers have vast choices in selecting appropriate clinical testing. As the Subcommittee considers PERA, we urge you to also explore the potential unintended negative consequences stemming from this policy change, especially in the nascent and still expanding precision medicine industry. Invitae is concerned that reverting back to the pre-2013 state of patent eligibility would stifle innovation, create barriers to access, and harm the post-pandemic fragile economy. We offer the following data to support the fact that the diagnostic industry and precision medicine more broadly has benefited greatly in the past decade.

Illumina, the US-based powerhouse at the center of the genomics revolution, has experienced considerable growth in recent years, in large part fueled by the expanding market for genetic sequencing for which the current patent eligibility jurisprudence has provided freedom to operate. Just five years after the 2013 *Myriad* decision, in 2018, Illumina reached \$3.3 billion in revenue while sustaining a gross margin of about 70%.

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<sup>9</sup> <http://www.concertgenetics.com/wp-content/uploads/2023/11/Concert-Genetics-2023-Genetic-Test-Price-Transparency-Report-07Nov2023.pdf>

<sup>10</sup> [http://www.concertgenetics.com/wp-content/uploads/2018/04/12\\_ConcertGenetics\\_CurrentLandscapeOfGeneticTesting2018.pdf](http://www.concertgenetics.com/wp-content/uploads/2018/04/12_ConcertGenetics_CurrentLandscapeOfGeneticTesting2018.pdf)



# Illumina – Key statistics

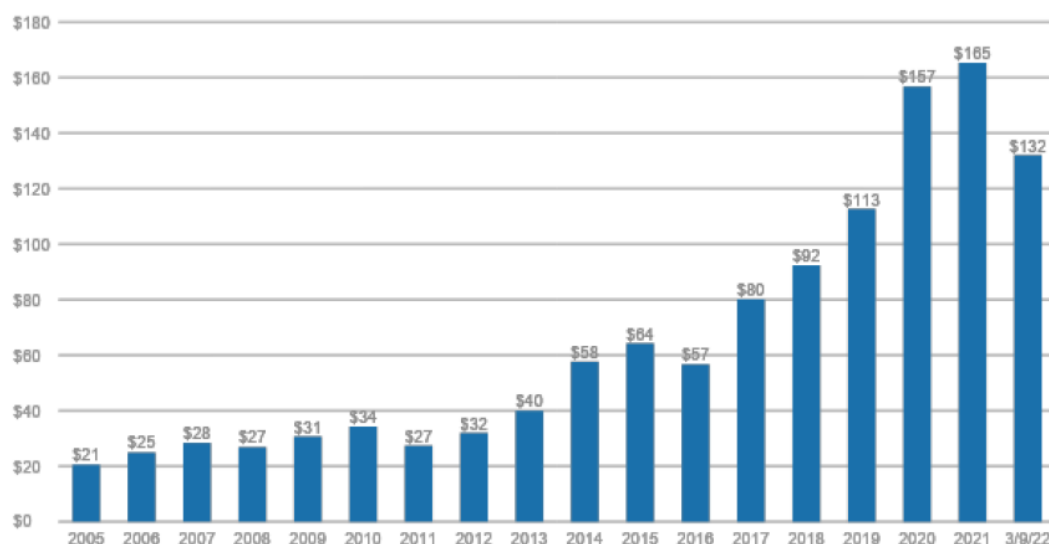
\$mm, except per share data	2014	2015	2016	2017	2018
Net Sales or Revenues	1,861.4	2,219.8	2,398.4	2,752.0	3,333.0
Growth	30.97%	19.25%	8.05%	14.74%	21.11%
Cost of Goods Sold	451.1	544.1	591.0	752.0	854.0
% of Sales	24.23%	24.51%	24.64%	27.33%	25.62%
Gross Profit	1,297.7	1,549.3	1,666.4	1,844.0	2,300.0
Gross Margin	69.72%	69.80%	69.48%	67.01%	69.01%
Selling, General & Admin Expenses	850.1	926.2	1,087.4	1,215.0	1,417.0
% of Sales	24.90%	23.64%	24.31%	24.49%	23.82%
EBITDA	603.1	751.7	735.3	1,236.0	1,130.0
EBITDA Margin	32.40%	33.86%	30.66%	44.91%	33.90%
Operating EBITDA	560.2	749.5	719.9	785.0	1,062.0
Operating EBITDA Margin	30.10%	33.77%	30.02%	28.52%	31.86%
EBIT	490.5	625.3	594.4	1,080.0	951.0
EBIT Margin	26.35%	28.17%	24.78%	39.24%	28.53%
Operating EBIT	447.6	623.1	579.0	629.0	883.0
Operating EBIT Margin	24.05%	28.07%	24.14%	22.86%	26.49%
Pretax Income	448.8	583.1	561.2	1,043.0	894.0
Pretax Margin	24.11%	26.27%	23.40%	37.90%	26.82%
Net Income to Common Shareholders	353.4	461.6	462.6	876.0	837.0
Net Margin	18.98%	20.79%	19.29%	26.38%	24.78%
Price per share	\$318.56				
Market capitalization	\$46,766.6				
Cash	\$3,512.0				
Debt	\$1,997.0				
Enterprise value	\$45,251.6				
2018 EV/Revenue <sup>1</sup>	12.7x				
2018 EV/EBITDA <sup>1</sup>	37.6x				

Source: ThomsonOne; market data as of 6/6/19

<sup>1</sup> As of 12/31/18

Similarly, companies in life sciences and diagnostics have been increasing in value significantly since 2013, with genetic medicine companies outpacing the rest. Even as the healthcare industry slowed at the outset of the COVID-19 pandemic and now as the country faces economic challenges, the cumulative market cap for the precision medicine industry continues to grow, gaining \$19 billion more than it was in 2019. Reflecting the significant surge in testing for COVID-19 in 2020 and 2021, the diagnostic industry reached a cumulative market cap of \$165 billion. Unsurprisingly, this was not sustainable as the demand for PCR based testing for COVID-19 dropped in 2022 reflecting a new phase in COVID-19 response efforts.

## Precision Medicine Cumulative Market Cap (\$bn)



Source: FactSet  
Includes NVTA, LH, DGX, EXAS, MYGN, CDNA, NTRA, VCYT, OXFD, CDXS, FLDM, ILMN, NSTG, PACB, QGEN

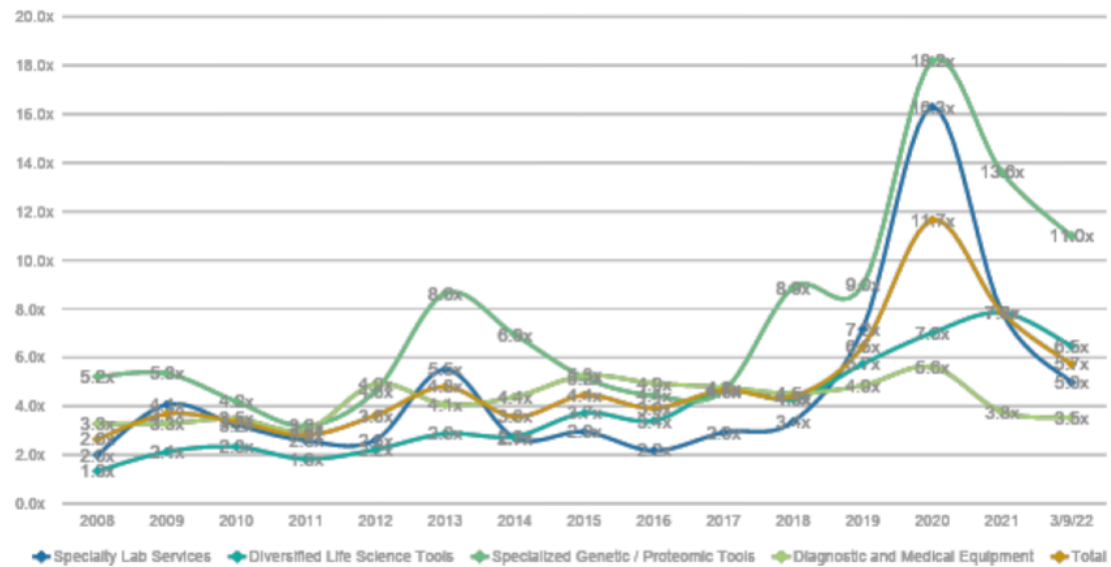


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Although, had the RNA sequence of the SARS-CoV-2 virus been patent eligible, we anticipate that we would not have seen such growth in the industry in 2020-2021. Thankfully, the *Myriad* decision meant that the sequence was not eligible and hence, innovators were able to rapidly develop and deploy countermeasures such as vaccines, diagnostics, and therapeutics specific for COVID-19. Moreover, they were able to modify diagnostics and vaccines as the virus mutated and new variants circulated. A patent on the sequence itself, its association with disease, patents on novel variants, etc. would have greatly stunted the country's ability to adequately respond to the pandemic as a result of monopolies on biotechnology, expensive testing and therapeutics, and limited access to patient care, much like what patients experienced with hereditary cancer testing before 2013. As Sandra Park wrote in her analysis, "the current ongoing public health crisis is an excellent example of what's at risk if these patent law changes move forward."<sup>11</sup>

<sup>11</sup> <https://www.aclu.org/news/privacy-technology/the-dangers-of-expanding-what-can-be-patented-in-the-age-of-covid-19>

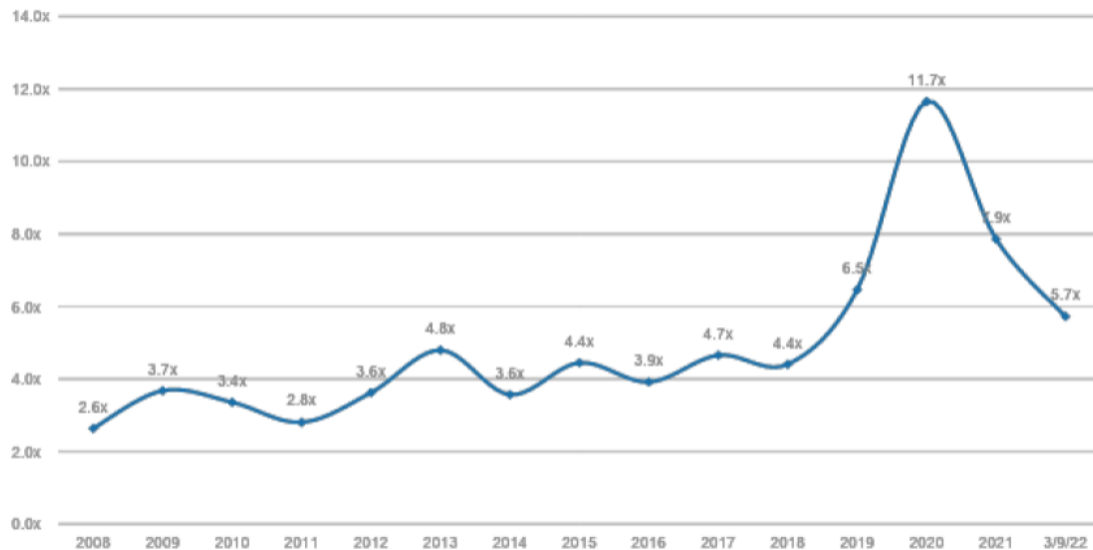
# Life Science Tools / Dx revenue multiples



Source: FactSet, median EV/Revenue multiples shown  
 Specialty Lab Services includes NVTA, LH, DGX, EXAS, GHDX, MYGN, CDNA, NTRA, VCYT, OXFD  
 Diversified Life Science Tools includes A, BRKR, DHR, MTD, PKI, WAT, TMO  
 Specialized Genetic / Proteomic Tools includes CDXS, FLDM, ILMN, NSTG, PACB, QGEN  
 Diagnostic & Medical Equipment includes HOLX



## Life Science Tools / Dx revenue multiples (2/2)



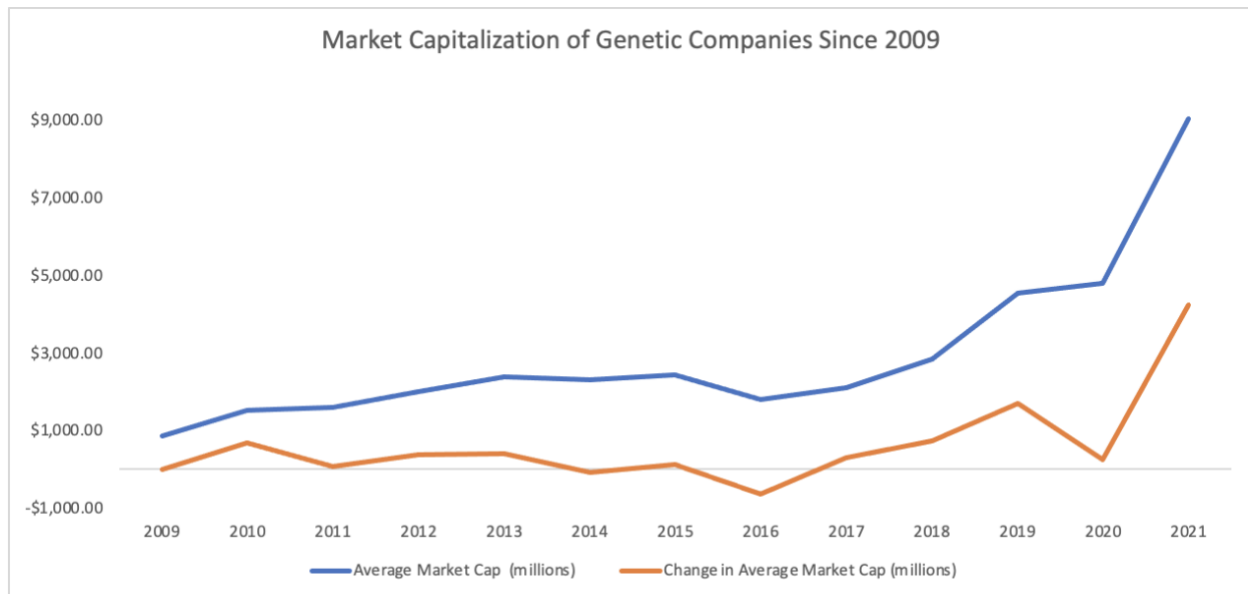
Source: FactSet, CapIQ, median EV/Revenue multiples shown  
Companies included: NVTX, LH, EXAS, CDNA, GDX, NTRA, MYGN, OXFD, VYCT, BRKR, DHR, PKI, WAT, TMO, CDXS, FLDN, ILMN, NSTG, PACB, QGEN, HOLX, A, MTD



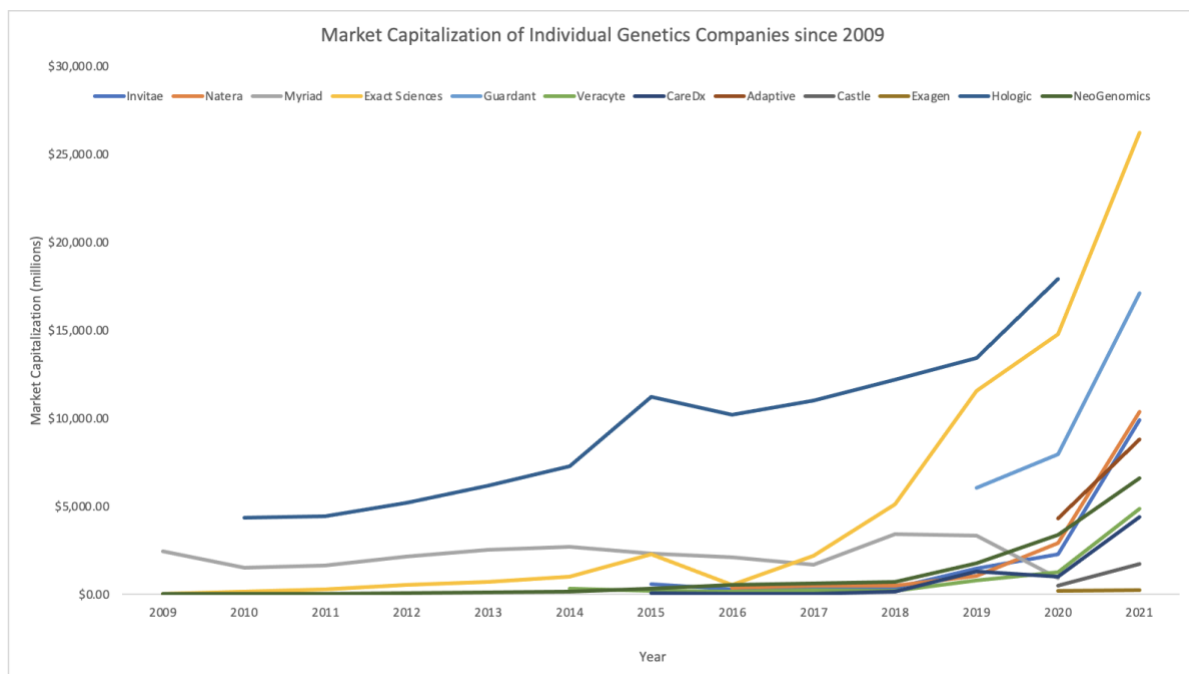
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By examining and aggregating data from the 10-K filings and NASDAQ valuations of twelve publicly traded genetic testing companies,<sup>12</sup> we found that market capitalization has increased since the *Myriad* and *Mayo* decisions, indicating that they did not have a negative impact on growth in this sector. Notably, testing for COVID-19 was a boon for the industry, indicating that the lack of patents on the RNA sequence and its association with disease actually led to a surge in revenue for genetic testing companies.

<sup>12</sup> Companies included in the analysis (parentheticals indicate years for which data is provided for each company): Adaptive Biotechnologies Corporation (2020-2021), CareDx, Inc. (2015-2021), Castle Biosciences, Inc. (2020-2021), Exact Sciences Corporation (2009-2021), Exagen, Inc. (2020-2021), Guardant Health, Inc. (2019-2021), Hologic, Inc. (2012-2020), Invitae Corporation (2015-2021), Myriad Genetics, Inc. (2009-2020), Natera, Inc. (2016-2021), NeoGenomics Laboratories, Inc. (2009-2021), Veracyte, Inc. (2014-2021)

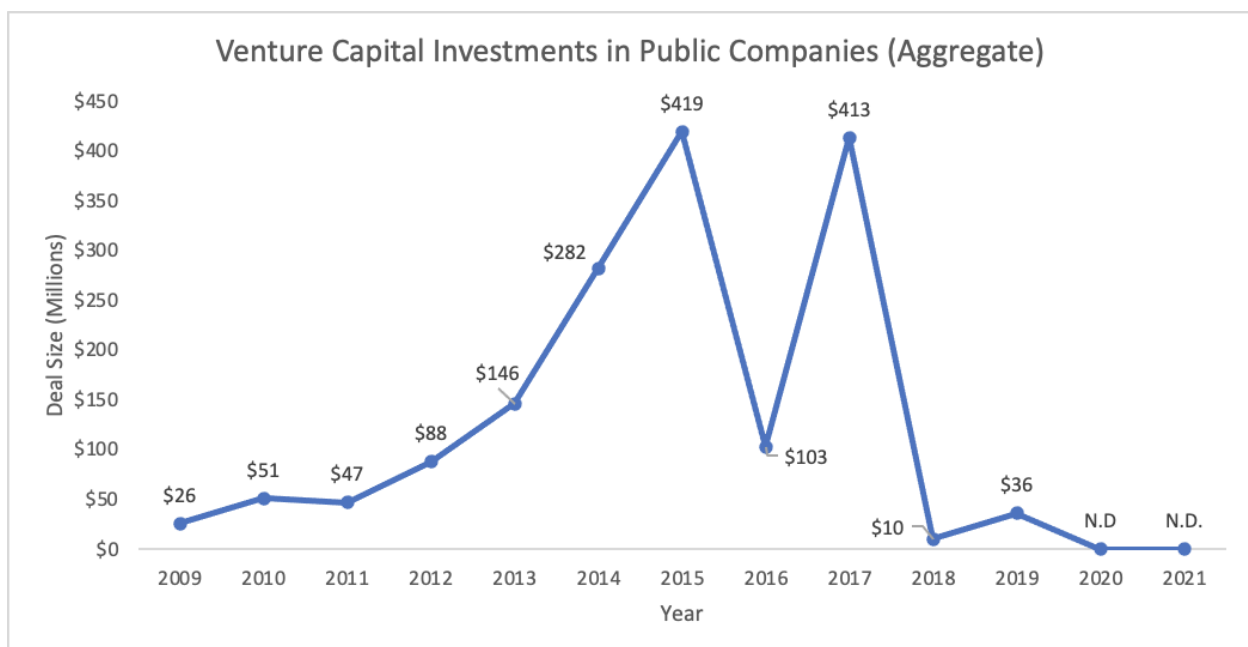


Looking at the data from individual companies, one can see the dramatic growth in these innovative companies. An interesting observation is that Myriad Genetics, Inc., which once owned the patents on the hereditary breast and ovarian cancer genes and their interpretation, saw no major change in their market capitalization from the period before the Supreme Court decision ushering in the current patent eligibility jurisprudence and after 2015 when Myriad abandoned enforcement of such patents directed to patent ineligible subject matter. The loss of those patents had at most a marginal effect on Myriad's market capitalization.

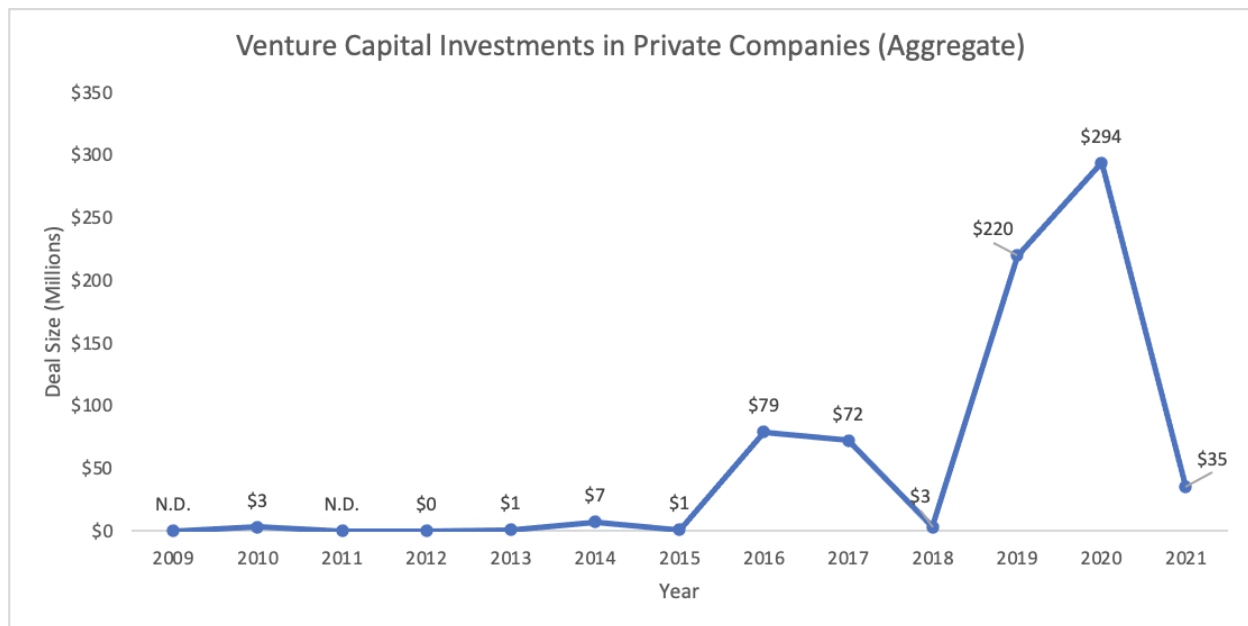


Invitae's former CEO, Dr. Sean George, testified before the Senate Judiciary Committee's Subcommittee on Intellectual Property on the State of Patent Eligibility in America in June 2019. In his written testimony, he shared that in 2012, Invitae was turned down by hundreds of

investors who said its goal to offer a comprehensive menu of the world's medical genetic tests at lower prices would never work for one reason: the DNA patent thicket. Since the *Myriad* decision in 2013 eliminated that barrier, venture capital funding in genetic testing companies has ballooned. Examining the venture capital investments in companies prior to their initial public offering, the funding more than tripled three years later to a peak in 2015 at \$419 million. These companies are widely respected and considered industry leaders in genomic testing: Adaptive Biotechnologies Corporation (2020-2021), CareDx, Inc. (2015-2021), Castle Biosciences, Inc. (2020-2021), Exact Sciences Corporation (2009-2021), Exagen, Inc. (2020-2021), Guardant Health, Inc. (2019-2021), Hologic, Inc. (2012-2020), Invitae Corporation (2015-2021), Myriad Genetics, Inc. (2009-2020), Natera, Inc. (2016-2021), NeoGenomics Laboratories, Inc. (2009-2021), Veracyte, Inc. (2014-2021). (Note: parentheses indicate years for which data is provided for each company; "N.D." means no data from any company for that year).



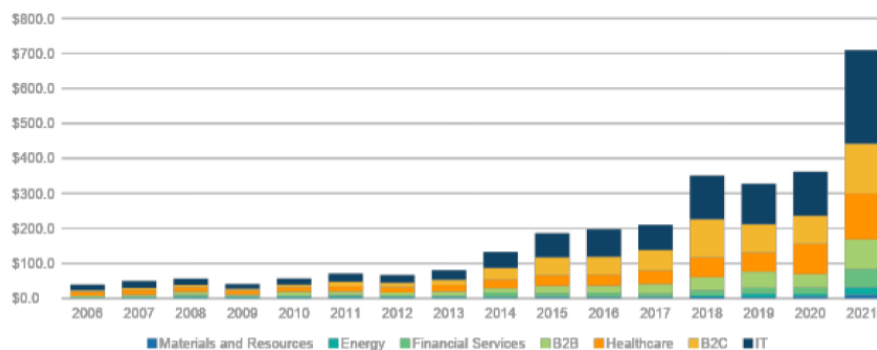
In the years after the Supreme Court's decisions giving rise to the current patent eligibility jurisprudence, venture capital funding for private genetic testing companies showed similar growth. As shown below, aggregate data for BioTheragnostics, Inc., Caris Life Sciences, Cernostics, Freenome, and Inivata, Inc. experienced almost a 300 fold increase.



Expanding to healthcare more broadly, venture capital investments have also increased each year since the Supreme Court decisions. It's also increasing at a faster rate in comparison to some other sectors such as financial services.

## Venture capital investment by sector (\$bn)

\$ in Billions	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Materials and Resources	\$ 0.4	\$ 0.7	\$ 1.0	\$ 0.8	\$ 1.0	\$ 1.4	\$ 1.5	\$ 1.6	\$ 1.2	\$ 2.2	\$ 2.1	\$ 2.2	\$ 3.8	\$ 3.3	\$ 6.1	\$ 10.8
Energy	\$ 1.9	\$ 2.7	\$ 4.4	\$ 4.3	\$ 4.8	\$ 5.7	\$ 4.4	\$ 3.9	\$ 3.9	\$ 3.5	\$ 3.2	\$ 2.8	\$ 4.2	\$ 10.3	\$ 6.5	\$ 21.0
Financial Services	\$ 0.6	\$ 1.0	\$ 4.5	\$ 0.8	\$ 1.9	\$ 2.3	\$ 1.8	\$ 2.7	\$ 11.6	\$ 10.1	\$ 11.2	\$ 8.8	\$ 15.7	\$ 16.7	\$ 18.6	\$ 52.5
B2B	\$ 4.9	\$ 5.8	\$ 8.5	\$ 4.7	\$ 11.0	\$ 10.4	\$ 9.0	\$ 11.3	\$ 12.5	\$ 19.4	\$ 19.6	\$ 27.3	\$ 36.6	\$ 46.2	\$ 38.0	\$ 83.6
Healthcare	\$ 11.1	\$ 14.4	\$ 13.7	\$ 12.7	\$ 13.5	\$ 14.1	\$ 15.7	\$ 18.9	\$ 24.9	\$ 31.1	\$ 31.6	\$ 38.8	\$ 57.2	\$ 54.8	\$ 86.7	\$ 132.6
B2C	\$ 4.4	\$ 5.2	\$ 6.1	\$ 4.5	\$ 6.6	\$ 13.6	\$ 12.2	\$ 14.8	\$ 32.8	\$ 50.9	\$ 51.5	\$ 58.0	\$ 108.8	\$ 80.4	\$ 80.3	\$ 141.2
IT	\$ 16.0	\$ 20.1	\$ 18.1	\$ 13.1	\$ 17.8	\$ 23.5	\$ 22.2	\$ 27.5	\$ 45.8	\$ 69.0	\$ 78.3	\$ 72.1	\$ 124.6	\$ 115.9	\$ 126.0	\$ 267.6
<b>Total</b>	<b>\$ 39.3</b>	<b>\$ 49.8</b>	<b>\$ 56.4</b>	<b>\$ 40.9</b>	<b>\$ 56.7</b>	<b>\$ 70.9</b>	<b>\$ 66.8</b>	<b>\$ 80.7</b>	<b>\$ 132.7</b>	<b>\$ 186.3</b>	<b>\$ 197.4</b>	<b>\$ 210.1</b>	<b>\$ 350.9</b>	<b>\$ 327.7</b>	<b>\$ 362.1</b>	<b>\$ 709.5</b>



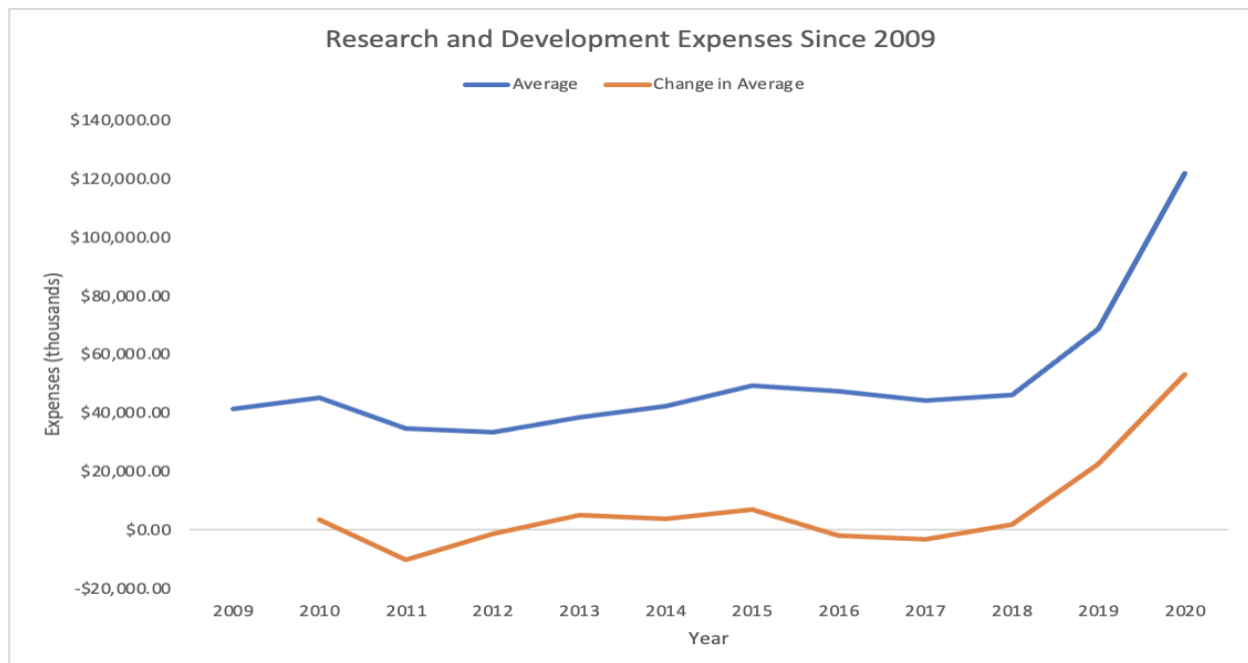
Source: Pitchbook Data.



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When we examined data on research and development in the US-based diagnostics industry, we found that investment increased in the years following the Supreme Court decisions on patent eligibility. Specifically, as noted in the 10-K filings from the twelve publicly traded genetic testing companies discussed above, spending in research and development has dramatically increased since 2018.

(Note: not all 12 companies contributed data throughout the whole measurement period and some data points may represent the average of fewer than 12 companies.)



Prior to the emergence of the current patent eligibility jurisprudence, the Human Genome Project with a \$3 billion budget was one of the largest federal investments in research. A private entity, Celera Genomics (Celera), competed with that public effort, and Celera's efforts ended in 2001 when they published a partial sequence of the human genome,<sup>13</sup> and subsequently, they were able to claim patent rights in the genes that had not been sequenced by the public effort. In a 2013 report on the impact of Celera's intellectual property on subsequent innovation, the author noted that these protections allowed Celera to control licensing for using and commercializing innovations involving those genes which allowed the author to compare the levels of subsequent research and development between Celera's protected genes and those genes able to be freely studied as a result of their publication as part of the Human Genome Project.<sup>14</sup> Making use of this unique natural experiment, the author found that Celera's intellectual protections resulted in a 20 to 30 percent *decrease* in scientific research and product development. Therefore, having patents on the human genome actually discouraged researchers and hindered these activities.

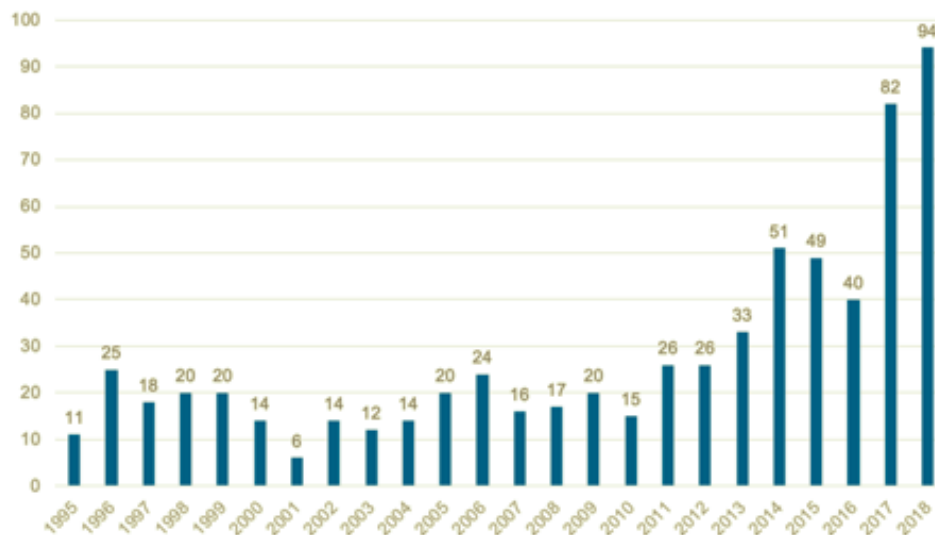
<sup>13</sup> Venter JC, Adams MD, Myers EW, et al. The Sequence of the Human Genome. Science (80- ). 2001;291(5507):1304-1351. doi:10.1126/science.1058040

<sup>14</sup> Williams, H. Intellectual Property Rights and Innovation: Evidence from the Human Genome. Journal of Political Economy. 2013;121(1):1-27. <https://www.journals.uchicago.edu/doi/pdf/10.1086/669706>



Now that the Supreme Court decisions have helped to make a genetic diagnosis more affordable and accessible, we've also seen a corresponding boom in precision therapeutics with the availability of gene-linked therapies at an all-time high. They are bringing hope to patients battling diseases like cystic fibrosis, non-small cell lung cancer, and even hepatitis C. The number of both applications and approvals for orphan drugs with the Food and Drug Administration accelerated significantly after 2013<sup>15</sup> and in 2018 when drug approvals reached an all-time high, orphan drugs for rare, often genetic, disorders accounted for more than half of all approvals.<sup>16</sup> The broad availability and low-cost of genetic sequencing is a core driver of this success because genetic screening is so often necessary to identify the patient population receptive to such drugs.

### Number of orphan indications approved in US



Source: FDA, IQVIA

It is clear that after the Supreme Court decisions giving rise to the current patent eligibility jurisprudence, investment and innovation in diagnostics and precision medicine has increased dramatically. The benefit of these advancements lies not just in maintaining American leadership in the field, but also in the improved standard of care allowing many more patients to obtain an earlier diagnosis, prevent disease altogether, or receive a tailored more effective treatment. We hope that after reviewing the data presented that you will recognize that the current patent eligibility jurisprudence has greatly benefited and accelerated both clinical availability and continuing innovation in precision medicine which is rooted in an evolving understanding of the human genome and other biomarkers. And as such, that you will proceed

<sup>15</sup> Quintiles IMS for the National Organization for Rare Disorders, Orphan Drugs in the United States: Providing Context for Use and Cost. October 2017. Available at: <https://rarediseases.org/wp-content/uploads/2017/10/Orphan-Drugs-in-the-United-States-Report-Web.pdf>

<sup>16</sup> Taylor, Phil. Orphan drugs dominate FDA's record-breaking year. PM Live. Published January 2, 2019. Available at: [http://www.pmlive.com/pharma\\_news/orphan\\_drugs\\_dominate\\_fdas\\_record-breaking\\_year\\_1273631](http://www.pmlive.com/pharma_news/orphan_drugs_dominate_fdas_record-breaking_year_1273631)

cautiously with any legislative efforts to modify patent eligibility that would allow patents on laws and products of nature.

For all of the reasons discussed above, we believe that PERA is both unnecessary and harmful to the genetic testing industry, patient access to self-knowledge regarding the significance of their genetic characteristics, and the evolution and delivery of precision medicine. Invitae would urge the subcommittee to consider instead the codification of existing Supreme Court jurisprudence on patent subject matter eligibility. Invitae stands ready to offer any assistance the subcommittee may request in order to approach patent law reform while preserving the vitality of the genetic testing industry and the promise of precision medicine and 21st century healthcare.

## **Conclusion**

Thank you again for the opportunity to serve as a witness in the Subcommittee's hearing and to provide this additional written testimony for your consideration. We believe the evidence is clear that prior to the *Myriad*, *Mayo*, and *Alice* decisions, patents restricted innovation in diagnostics and precision medicine and that since 2013, the field had grown significantly. We oppose any efforts to reverse these Supreme Court decisions due to the harm it will cause patients and to the healthcare industry.