September 20, 2022

Kathi Vidal
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Comments submitted electronically via *FederalRegister*.gov

Re: PTO-P-2022-0026 Submission of Comments Regarding the Patent Subject Matter Eligibility Guidance

Dear Director Vidal,

Thank you for your July 25th blog post on "Providing Clear Guidance on Patent Subject Matter Eligibility" and the ongoing opportunity to submit comments as you consider modifications to the Manual of Patent Examining Procedure (MPEP) 2106 guidance which was last updated in 2019. Invitae believes that the existing guidance accurately reflects jurisprudence, sets appropriate guidelines for subject matter eligibility, and fosters American innovation in the diagnostics and precision medicine industries.

Invitae is a leading medical genetics company, delivering genetic information services that support a lifetime of patient care — from inherited disease diagnoses and family planning to proactive health screening and personalized diagnosis, treatment and monitoring of cancer — combining genetic and clinical information to improve health decision-making and drive research. Invitae's mission is to improve healthcare for everyone, including by making genetic testing more accessible and more affordable to all who may benefit. Invitae's tests primarily rely on next-generation sequencing-based genetic technology to provide health information throughout the entire patient's care journey. Our digital health tools help support clinicians and patients' knowledge and use of genetic information for their care. By pioneering new ways of sharing, understanding and applying genetic information and relevant clinical information, we are transforming the field of genetics from a series of one-time, one-dimensional queries to a lifelong clinical dialogue using comprehensive genetic analyses and information management to improve medical decisions and optimize health interventions.

Our success in providing critical genetic information to over three million patients was made possible by the current patent eligibility jurisprudence in the United States. We agree with recent Supreme Court decisions that biomarkers, including DNA, and their association with a health

status are naturally occuring phenomena and natural laws, respectively, and hence, are not patent eligible. Indeed American leadership in the explosive growth of the modern clinical genomics industry has benefited greatly from current patent eligibility jurisprudence, which wisely precludes patenting the human genetic code and its interpretation.

We appreciate that your colleagues considered and referenced our response to the Request for Information for the Patent Eligibility Jurisprudence Study (docket number PTO-P-2021-0032) in the subsequent report released earlier this summer. To further inform your work in this area of policy, we wanted to provide additional data and evidence affirming that recent patent eligibility jurisprudence has led to unprecedented growth in both the precision medicine and molecular diagnostic fields. More specifically, it has ushered in a rich diversity of companies offering a wide range of innovative genetic tools, increased funding in research and development, and improved patient outcomes. We offer the following comments and data to support the critical importance of upholding these legal decisions to further foster innovation in the life sciences in the United States and request that any future modifications to the MPEP guidance reflect these Supreme Court decisions.

Innovation in Precision Medicine and Diagnostics Continues to Soar

The golden age of precision medicine and diagnostics has arisen in no small part due to the current patent eligibility jurisprudence articulated in three unanimous Supreme Court decisions: *Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad*), *Alice v. CLS Bank International,* and *Mayo Collaborative Services v. Prometheus Laboratories, Inc (Mayo).* Previously, 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. Absent current patent eligibility jurisprudence, multiple parties could hold patents relevant to the interpretation of a patient's genomic health even with respect to a single gene and therefore reading and interpreting a patient's full genome would be impeded by an impenetrable "patent thicket." This barrier to the conduct of genomic testing not only harms individual patients who are denied knowledge and understanding of their own health status, it also hobbles the progress of precision medicine which relies upon the conduct and analysis of genomic testing for large numbers of patients to generate new knowledge. Patient care has improved and innovation in genetics has thrived because of the lack of patents on DNA, not in spite of it. With the patent thicket locking up the human genome now cleared, a vibrant industry has sprung up that has led to better patient care, reduced costs to the healthcare system, and increased jobs and revenue for communities.

Illumina, the US-based powerhouse at the center of the genomics revolution, has experienced considerable growth in the past 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%.

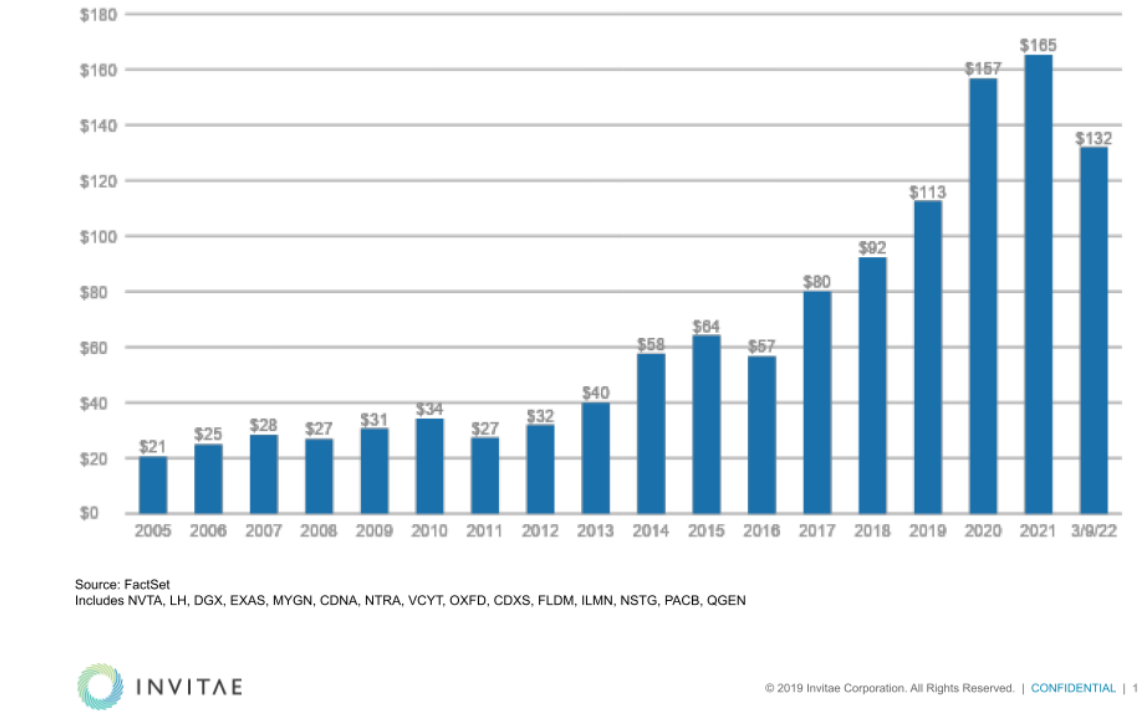
Illumina – Key statistics

$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[1]	12.7x
2018 EV/EBITDA[1]	37.6x

Source: ThomsonOne; market data as of 6/6/19
[1] As of 12/31/18

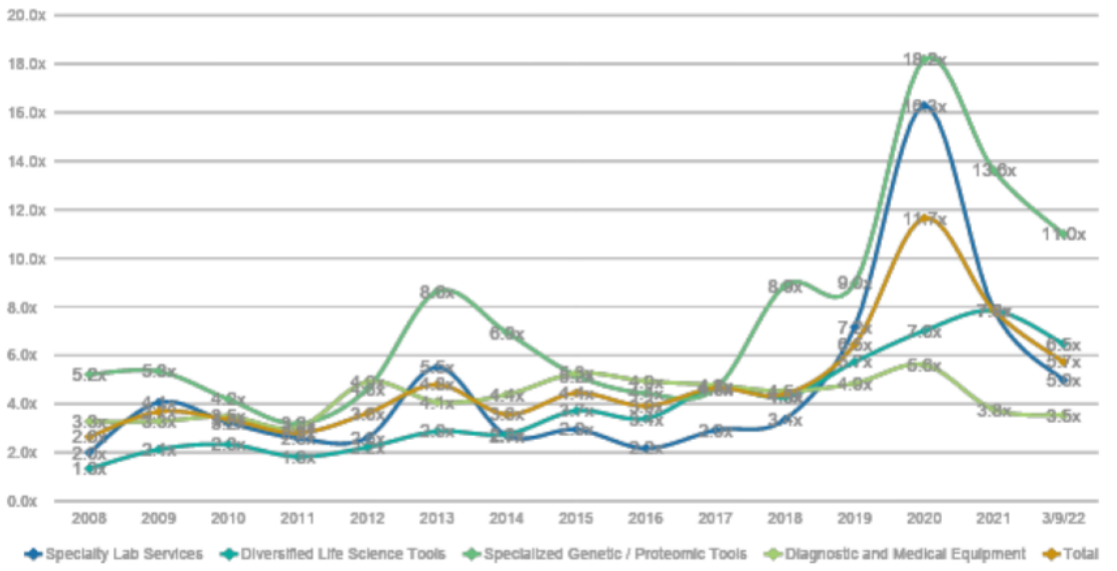
Similarly, companies in life sciences and diagnostics have been increasing in value significantly since 2013, with genetic medicine companies outpacing the rest. Even as the healthcare industry slowed at the outset of the COVID-19 pandemic and now as the country faces economic challenges, the cumulative 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.



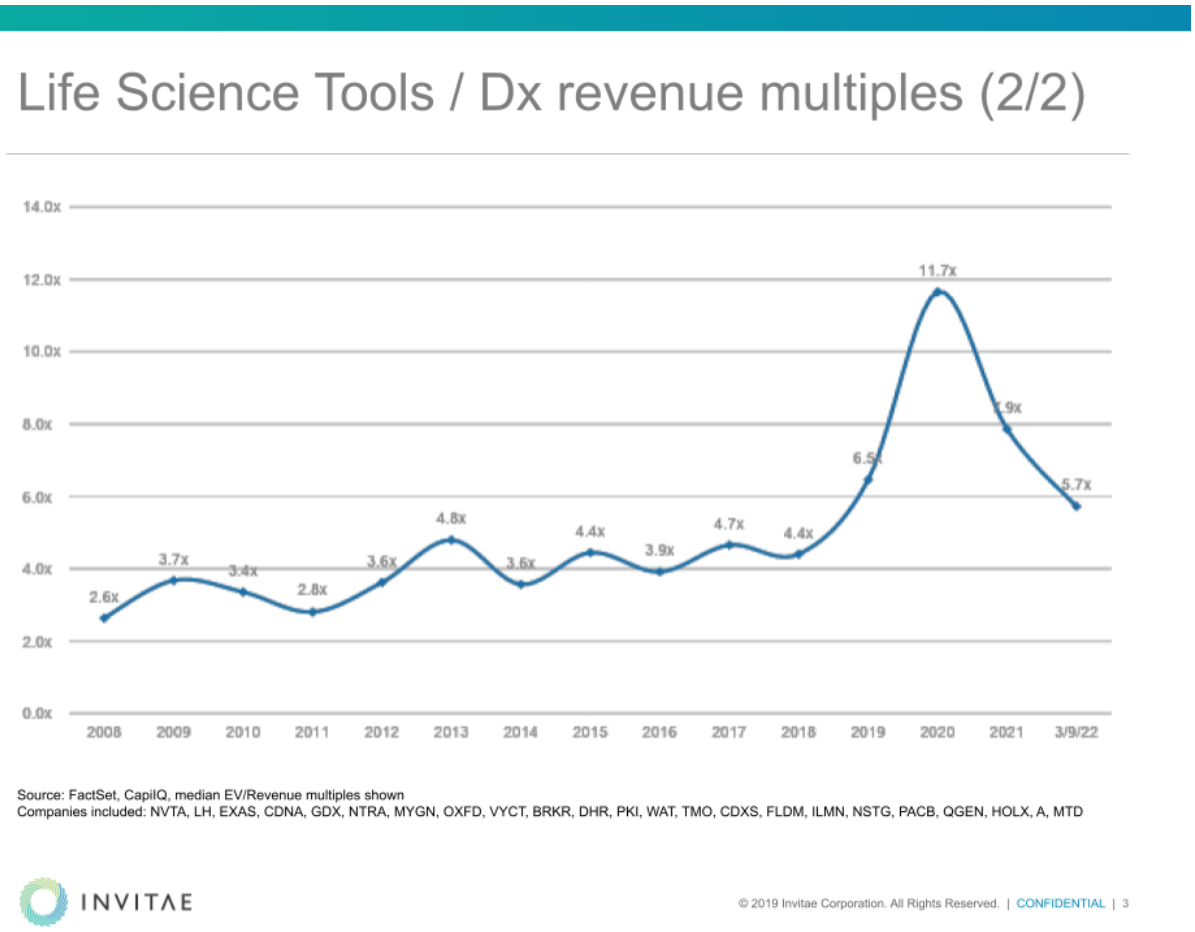
Had the RNA sequence of the SARS-CoV-2 virus been patent eligible, we anticipate that we would not have seen such growth in the industry in 2020-2021. Thankfully, the *Myriad* decision meant that the sequence was not eligible and hence, innovators were able to rapidly develop and deploy countermeasures 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."[1]

[1] 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

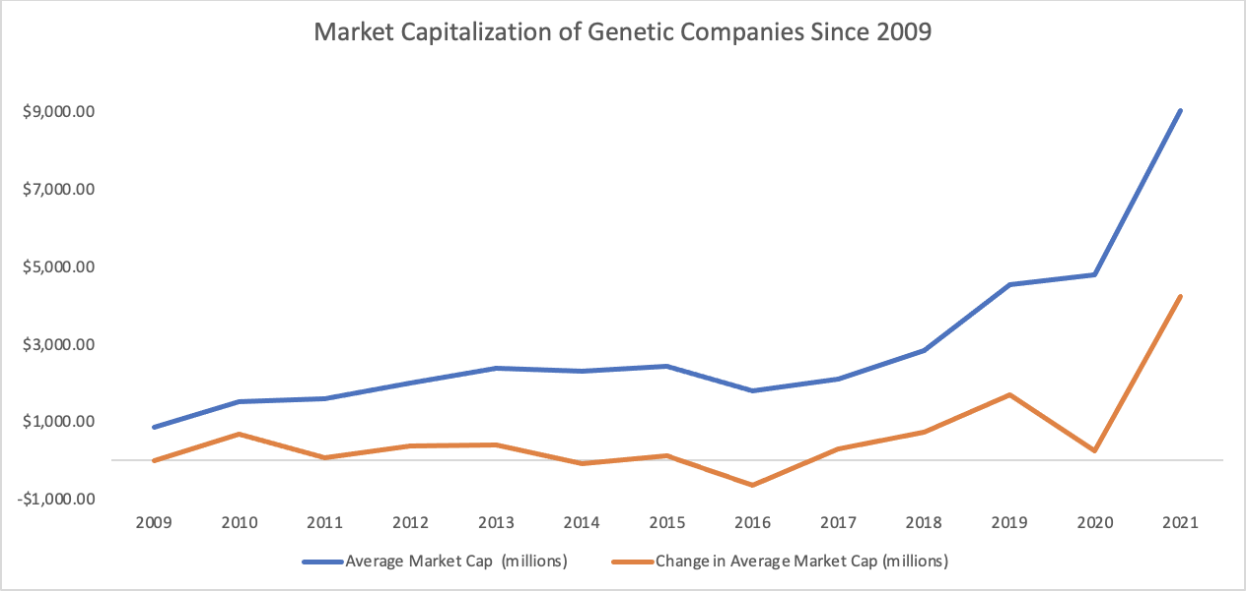


Source: FactSet, median EV/Revenue multiples shown
Specialty Lab Services includes NVTA, LH, DGX, EXAS, GHDX, MYGN, CDNA, NTRA, VCYT, OXFD
Diversified Life Science Tools includes A, BRKR, DHR, MTD, PKI, WAT, TMO
Specialized Genetic / Proteomic Tools includes CDXS, FLDM, ILMN, NSTG, PACB, QGEN
Diagnostic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

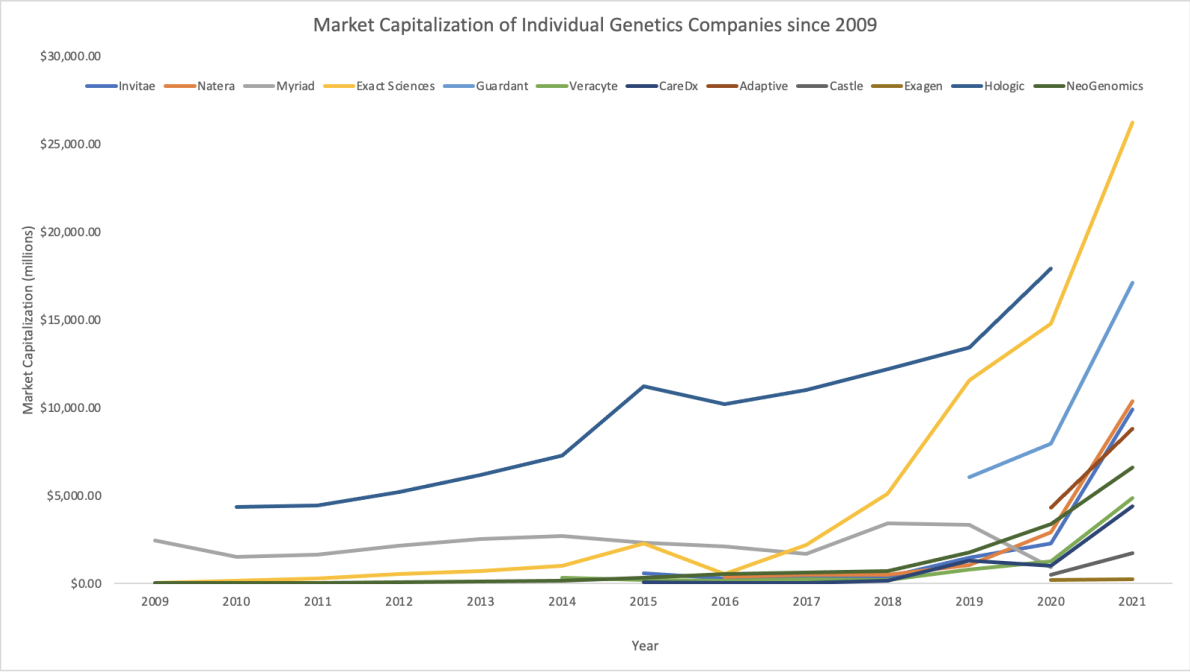


By examining and aggregating data from the 10-K filings and NASDAQ valuations of twelve publicly traded genetic testing companies,[2] we found that market capitalization has increased since the *Myriad* and *Mayo* decisions, indicating that they did not have a negative impact on growth in this sector. 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.

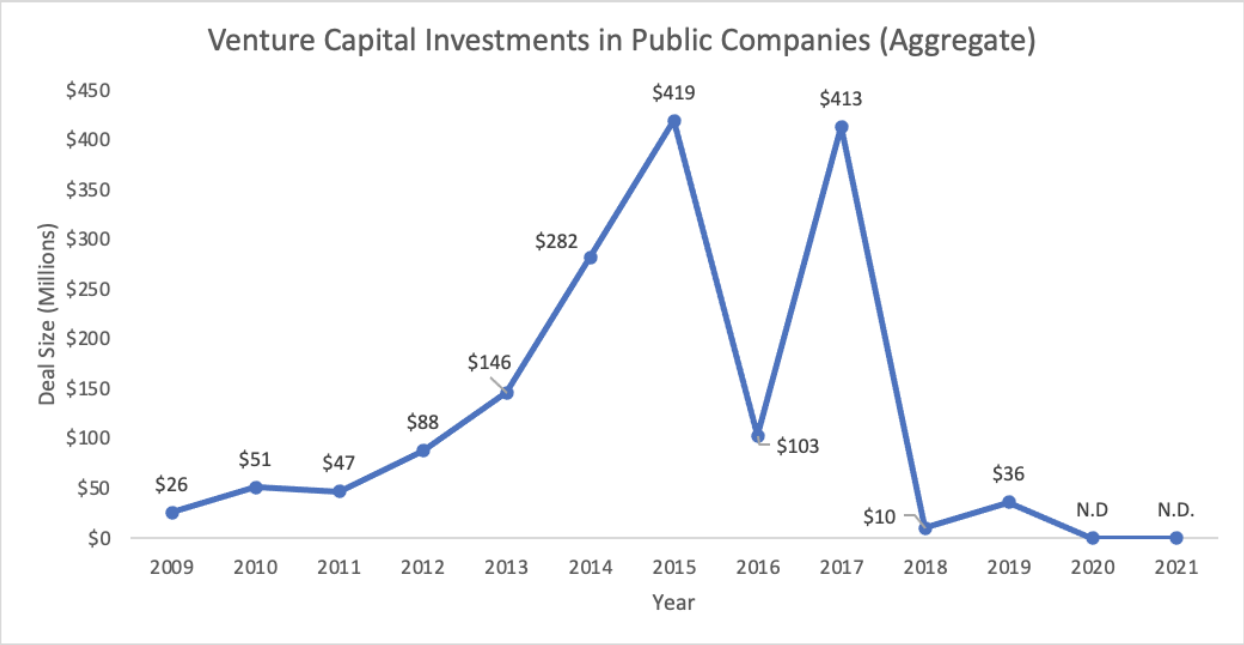
[2] Companies included in the analysis (parentheticals indicate years for which data is provided for each company): Adaptive Biotechnologies Corporation (2020-2021), CareDx, Inc. (2015-2021), Castle Biosciences, Inc. (2020-2021), Exact Sciences Corporation (2009-2021), Exagen, Inc. (2020-2021), Guardant 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)



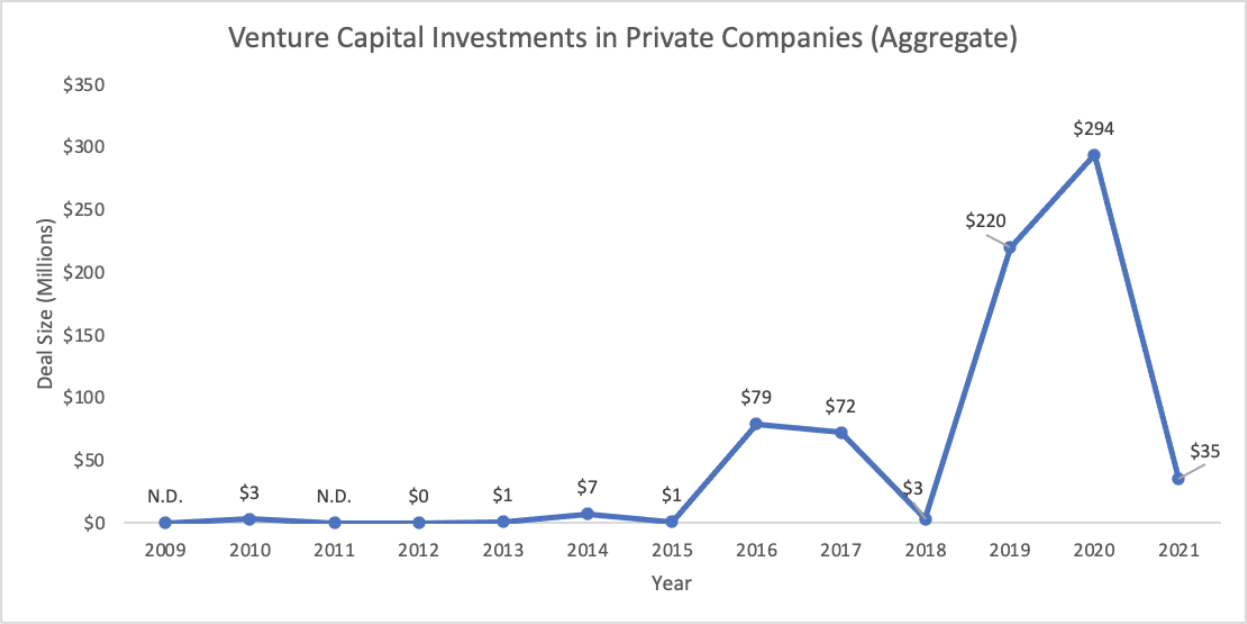
Looking at the data from individual companies, one can see the dramatic growth in these innovative companies. An interesting observation is that Myriad Genetics, Inc., which once owned the patents on the hereditary breast and ovarian cancer genes and their interpretation, saw no major change in their 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: parentheticals indicate years for which data is provided for each company; "N.D." means no data from any company for that year).



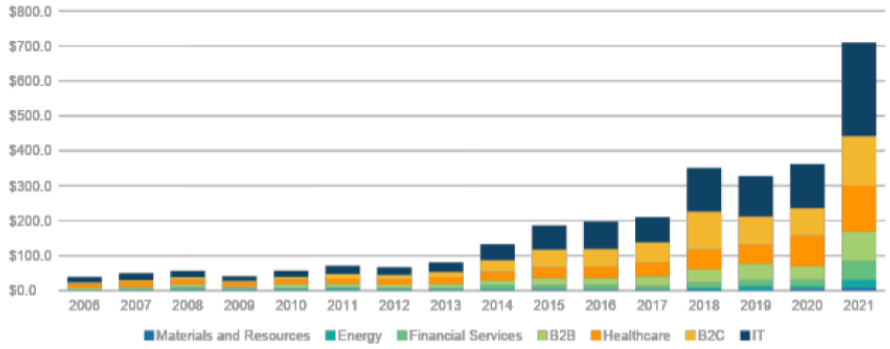
In the years after the Supreme Court's decisions giving rise to the current patent eligibility jurisprudence, venture capital funding for private genetic testing companies showed similar growth. As shown below, aggregate data for BioTheranostics, Inc., Caris Life Sciences, Cernostics, Freenome, and Inivata,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

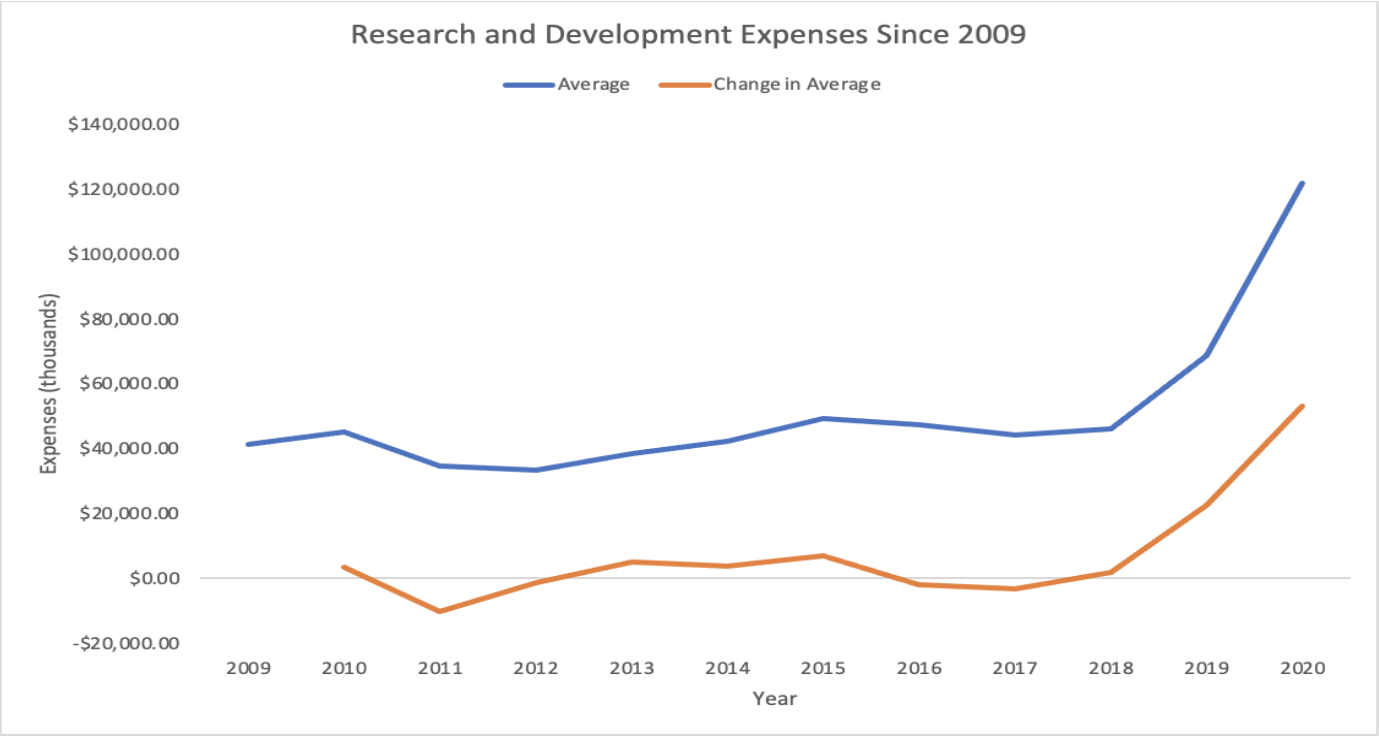
Venture capital investment by sector ($bn)

$ 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
Total	**$ 39.3**	**$ 49.8**	**$ 56.4**	**$ 40.9**	**$ 56.7**	**$ 70.9**	**$ 66.8**	**$ 80.7**	**$ 132.7**	**$ 186.3**	**$ 197.4**	**$ 210.1**	**$ 350.9**	**$ 327.7**	**$ 362.1**	**$ 709.5**



Source: Pitchbook Data.

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[3], 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 of 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.[4] 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

[3] 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

[4] 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

development. Therefore, having patents on the human genome actually discouraged researchers and hindered these activities.

Since 2013, access to and the availability of genetic testing has increased dramatically. The day before the *Myriad* decision in 2013, only one laboratory offered testing for hereditary breast and ovarian cancer and the day after the decision, at least five companies began offering testing for this indication.[5] Today, according to the Genetic Test Registry housed at the National Institutes of Health, there are 466 clinical tests available for the *BRCA* genes.[6] In 2018, Concert Genetics tallied the clinically available genetic tests at approximately 75,000 with 14 new tests introduced daily.[7] In 2020, the tally is now more than 160,000 clinically orderable genetic tests.[8] Since the barrier of patents on DNA has been removed, patients and their providers have vast choice in selecting appropriate clinical testing.

Additionally, the *Myriad* decision 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. We offer three historical examples that illustrate how patents discourage development of clinical testing with potentially deadly consequences for patients and their families.

Within hereditary breast cancer alone:

- The cost of testing plummeted from $4,400 in 2013 to a $250 cost to the patient at Invitae today.
- 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.
- The single-gene testing utilized in 2013 is now known to be inferior to large multigene panels. Panel testing, as we provide at Invitae, is now the standard of care -- progress that would have been nearly impossible if licensing an entire patent thicket across scores of genes were required.
- Research is constantly ongoing in the field of hereditary cancer. Patenting a gene will severely limit the ability to include newly discovered genes that are associated with an increased risk of cancer from being included in a panel. This will have an adverse impact on patient outcomes if panel tests cannot be updated with the most current research.

[5] https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html
[6] https://www.ncbi.nlm.nih.gov/gtr/all/tests/?term=672[geneid]&filter=testtype:clinical
[7] http://www.concertgenetics.com/wp-content/uploads/2018/04/12_ConcertGenetics_CurrentLandscapeOfGeneticTesting2018.pdf
[8] https://www.concertgenetics.com/resources/concert-genetic-testing-unit-gtu/

It has been known since 1999 that large rearrangements in *BRCA1* are likely responsible for approximately 10% of all disease-causing mutations in hereditary breast and ovarian cancer.[9] Yet, the company that held exclusive testing rights under their patent 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 potentially missed 12% of genomic rearrangements that can be detected using other technology.[10] It took another four years for a test able to detect all known large rearrangements to be made available, and it has been speculated that this was only in response to significant pressure from the scientific community to improve the methodological approaches in clinically offered tests.[11] During that time, it remains unknown how many families may have received false negative 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 a license to their patents shortly after. However, licensing was done in such a fragmented way that lab skirmishes[12] and other delays in bringing tests to market 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.[13] It was yet another two years before a second lab was able to secure a license to offer testing. Throughout this period, patients had no option to obtain this needed testing from the license holders, and even when testing became available from competitors, the license holders prevented patient access by taking legal action against those laboratories. 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 introduced in 2004, according to a report from the Secretary's Advisory Committee on Genetics, Health, and Society in 2010, it cost $5,400.[14] Today, in the post-*AMP v. Myriad* era, Invitae offers panel testing for familial Long QT syndrome at a cost of $250 to the patient.

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[9] Puget N, Stoppa-Lyonnet D, Sinilnikova OM, et al. Screening for germ-line rearrangements and regulatory mutations in BRCA1 led to the identification of four new deletions. Cancer Res. 1999;59(2):455-461. http://www.ncbi.nlm.nih.gov/pubmed/9927062.

[10] 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

[11] 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.
October 30, 2007 See Appendix A, supplementary written statement from Dr. Wendy Chung, Columbia University.

[12] 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

[13] 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.

[14] 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. Published April 2010. Accessed June 7, 2019.

Conversely, during roughly the same time period, genetic testing for Lynch syndrome illustrated testing could be brought forward to help patients more quickly without patent enforcement. Lynch syndrome is a hereditary syndrome with high risk for developing 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. Thus, performing adequate Lynch testing would have required licensing from both the entities. Fortunately, licensing was not exclusive and, in fact, the holders of the patents never enforced them, enabling patient access to testing panels currently recommended by all professional clinical guidelines.[15] Because the patents were never enforced, the commercialization of Lynch syndrome testing was successful and rapid. In 2008, compared to one company providing testing for hereditary breast cancer, 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.

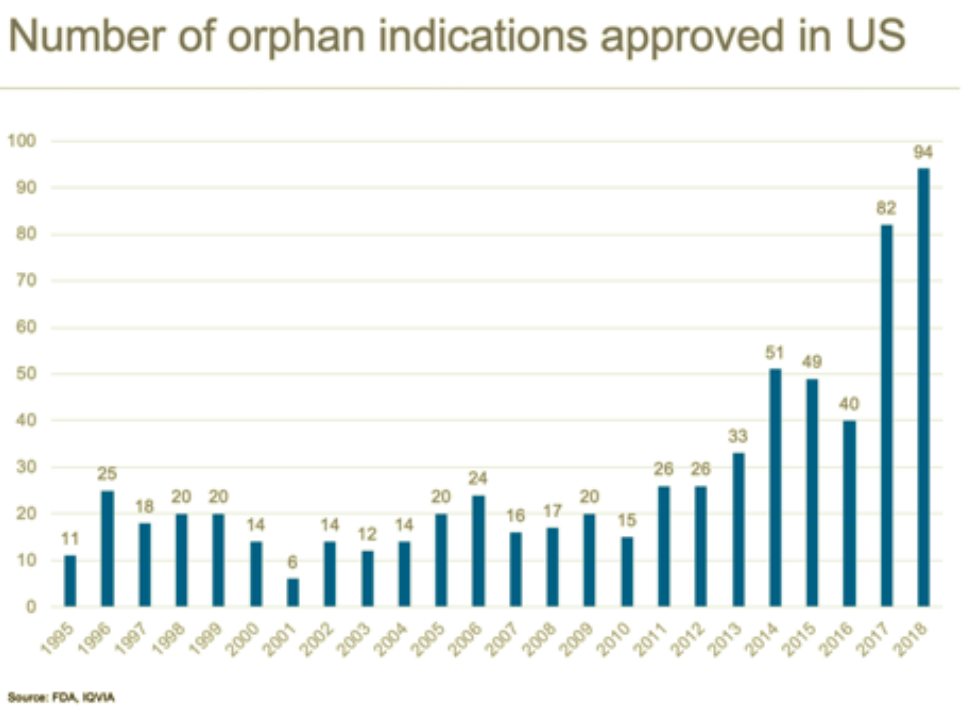
Though in this example the organizations holding the patents did not end up enforcing them — which enabled innovation and greater access to Lynch syndrome testing — nonenforcement of patents is rare and dependent on a company forgoing its market exclusivity opportunities, so it is not a reliable strategy for ensuring patients can continue to benefit from genetic discoveries.

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[16] 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.[17] 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.

[15] National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®), Genetic/Familial High-Risk Assessment: Colorectal. Version 1.2018

[16] 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

[17] 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



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.

Invitae agrees that, outside of biomarkers, their association with health status and abstract processes, a wide range of patent-eligible subject matter exists in the precision medicine and molecular diagnostic fields. Specifically, Invitae maintains a significant patent portfolio with claims directed to innovative laboratory techniques, device manufacturing, automation, and other technologies that confer commercial advantage and enable Invitae to offer higher quality services to more patients at more affordable prices. Invitae also recognizes the patent rights of others by obtaining licenses to practice the patented technology of others, where appropriate.

Thank you again for the opportunity to provide our comments and this data for your consideration. We hope that it informs your work as you update the guidance and successfully

demonstrates that patent eligibility jurisprudence has resulted in unprecedented innovation in precision medicine and diagnostics for industry and has provided remarkable improvements in health outcomes and improved access to these innovative tools for patients and their families. Given the significant investments, growth, and size of the genetic testing industry today, we do not believe that a policy change is warranted. Invitae agrees with the Supreme Court decisions that biomarkers, including DNA, and their associations with health status are natural phenomena and natural laws and therefore should not be patent eligible. If we may be of further assistance, please contact me at lee.bendekgey@invitae.com.

Sincerely,

Lee Bendekgey
Chief Policy Officer
Invitae Corporation