PREPARED STATEMENT

For the

SENATE COMMITTEE ON THE JUDICIARY

On

INTELLECTUAL PROPERTY –DRIVER OF INNOVATION: MAKING OUR LIVES HEALTHIER, SAFER, AND MORE PRODUCTIVE

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Chairman Grassley, Ranking Member Feinstein, and distinguished members of the Senate Judiciary Committee, thank you for the opportunity to testify this morning. Thank you also for your leadership in focusing on innovation. Innovation has been a hallmark of Intel since its founding 49 years ago. A quote from our co-founder Robert Noyce marks the entrance to Intel's headquarters "Innovation is Everything." Last year, Intel spent more than $12 billion on R&D and Intel owns over 90,000 patent assets. Simply put, innovation and intellectual property are critical elements of our business. And we are uniquely positioned to power every segment of a new innovation revolution, from the data center to the cloud to the device, and everything in between.

As General Manager of Health & Life Sciences in the Data Center Group of Intel Corporation, I am here to highlight the tremendous advances that big data analytics and artificial intelligence are bringing, and will continue to bring, to precision medicine—advances that will save lives and foster a healthier population. It has been a deep honor to serve on the Health IT Standards Committee of the Office of the National Coordinator for Health Information Technology since 2016. I have appreciated the opportunity to continue Intel's long-standing commitment to promoting policies that foster the digitalization and exchange of health data to improve health and healthcare, and protect the privacy and security of personal health information.

Progress in the health and life sciences sector depends, in part, on having a strong, but balanced patent system—one that promotes innovation but also prevents misuse of the system. In this process, it is important that we focus on high patent quality. Strong patents benefit scientific progress. Weak ones hurt it. As the high-tech and medical fields increasingly converge—and as the pace of innovation speeds up—this will be even more essential. We must protect real advances. And, equally important, we must have efficient mechanisms for removing bad patents from our books. By focusing on high patent quality, we enable a bright and innovative future for our country.

The Convergence of Medical Science, High Performance Computing and Data Analytics for Precision Medicine

Every year, 14 million people around the world are diagnosed with cancer. Many suffer through months or years of invasive procedures, trial-and-error diagnoses, and one-size-fits-all treatments, often fraught with complex side effects for patients and with anxiety, uncertainty, and lost productivity for patients and their families.

Precision Medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle. Sequencing a cancer patient's genome can enable scientists to pinpoint where a cancer-causing mutation has occurred. With a more precise diagnosis, clinicians may be able to prescribe treatments that target exact mutations rather than basing treatment on a generic category (such as all kidney cancers or all thyroid cancers). This targeted treatment can produce better outcomes with fewer side effects.

I'd like to share only a few of the many examples where Intel technology has driven medical advancement.

Speed matters in cancer treatment. Intel, Dell and TGEN partnered to support the Neuroblastoma and Medulloblastoma Translational Research Consortium personalized medicine clinical trial, enabling faster diagnosis and treatment for some of the most aggressive types of cancer in children for whom time is extremely precious. Neuroblastoma, a malignant tumor of immature nerve cells accounts for approximately 50% of all cancers in infants less than one year old. Its aggressive tumors are unique to each child. Using Intel and Dell high-performance computing technology, TGEN cut the time to sequence and re-sequence children's genes from 7 days to 1 day, significantly minimizing the time it takes to discover the genetic flaws in the 3-billion-letter DNA code of these patients. In the battle against aggressive forms of cancer, each day reduced can make a difference for these young patients and their families.

But too often in cancer, there's no treatment for a particular mutation. While sequencing capabilities are evolving rapidly, there's an urgent need to expand the universe of targeted treatments — a long and costly process. It takes an average of 12 years for a drug to move from research idea to approved clinical use. A 2016 report published in the *Journal of Health Economics* puts the average cost to develop and gain marketing approval for a new drug at USD $2.558 billion.

Computational biomedicine is beginning to transform this scenario. Life science researchers are bringing together analytic and simulation workloads that were previously in silos. They're combining them with an exploding world of biological data — generated by everything from genome sequencers and ultra-high-tech lab instruments, to patients' medical records and lifestyle data. There is great promise with deep learning and other artificial intelligence techniques to analyze, explore, and visualize their massive data sets in exciting and fruitful ways.

In the 10 years since the completion of the Human Genome Project (HGP), advances in genome technology have led to an exponential decrease in sequencing costs (more than 16,000-fold). Patients have benefited from major biological insights and medical advances, including the development of more than 132 drugs whose labels now include pharmacogenomics information for targeted personalized applications.[i]

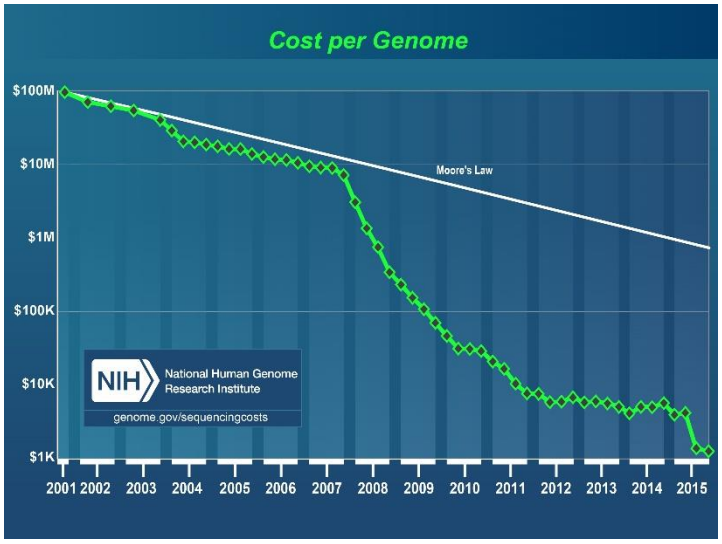
Intel is addressing big data issues associated with genomic medicine. For example, the enormous size of the genomic data, as well as privacy concerns, makes it very difficult for data to be pooled in a common repository. Additionally, due to the multidisciplinary nature of research, data and analysis tools must be made available to a variety of geographically dispersed researchers. Rather than copying the large data sets, Intel recommends federated data exchange models. We have piloted this approach with Oregon Health & Science University, Dana Farber Cancer Institute and Ontario Cancer Institute. The focus is to help cancer centers worldwide — and eventually centers for other diseases — share with one another the insights that reside in their private clinical and research data without having to

share the data itself. This approach is designed to protect data privacy and the business models of the research centers while at the same time unlock the insights from far larger datasets to benefit research and inform the specific treatment of individual patients and enabling providers throughout the country to use insights to help their patients even if they are not at a major academic medical center.

Another example of innovation involves the Internet of Things and artificial intelligence. Dramatic reductions in the cost of sensors, computing and bandwidth — coupled with the drive for improved cost and efficiency — will lead to transformation of energy grids with smart homes and buildings, transportation grids with autonomous vehicles, and new health technology with smarter wearable sensors to encourage healthy behaviors, monitor symptoms, and, eventually, detect health problems at earlier and more successfully treatable stages.

An example of using the medical IOT and artificial intelligence together to help researchers and healthcare providers identify better treatments for patients is Intel's collaboration with the Michael J. Fox Foundation for Parkinson's Research (MJFF). This effort is an important step in enabling researchers and physicians to measure progression of the disease, improve medication adherence and speed progress toward breakthroughs in drug development. With wearable technology, the potential to collect and analyze wearable sensor data from thousands of individuals on measurable features of Parkinson's, such as slowness of movement, tremors and sleep quality, provides researchers with very large amounts of objective data on the clinical progression of Parkinson's. Wearables can unobtrusively gather and transmit objective, experiential data in real time, 24 hours a day, seven days a week. With this approach, researchers could go from looking at a very small number of data points and burdensome pencil-and-paper patient diaries collected sporadically to analyzing hundreds of readings per second from thousands of patients and attaining a critical mass of data to detect patterns and make new discoveries. It is a dramatic shift from data-poverty to data-wealth — and in my view it signals the future of research and discovery.

We've reached a pace of innovation we've never seen before. As Intel, we can say that it's even outpaced Moore's law.



Innovation in a Converged World of Digital Health and Big Data Analytics

As the above examples show, innovation in precision medicine and the medical Internet of Things requires an interdependent and connected environment where various products from different companies and industries work together. To function properly, the medical monitoring and diagnostic equipment described above must operate in a seamless interconnected world—collecting, processing, and transmitting data to other devices through constantly updated networking technologies. If any part of that system breaks down because of a legal action associated with low-quality patents underlying the various technologies, the entire system can be brought to a standstill. This would jeopardize the groundbreaking advances that the introduction of high performance computing and data analytics would otherwise make possible.

Adding to the existing compelling use cases, the 21st Century Cures legislation presents new models for the convergence of health science and big data from the integration of clinical, genomic, wearable and other data. The Act requires the FDA to develop a framework and guidance for evaluating real world evidence ("RWE") – data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials

to be used in the context of drug regulation to support approvals of new indications for previously approved drugs, and to support or fulfill post-approval study requirements. This will include information on healthcare that is derived from multiple sources outside typical clinical research settings, including electronic health records, claims and billing data, product and disease registries, and data gathered through personal devices and health applications."

Drug discovery is moving from a petri dish and personal journal to computational science which is faster, more precise and enabled by the new world of data analytics, For example, we have transformed the world of Parkinson's studies from subjective journaling to wearables that collect and analyze 300 data points per minute. This is the power of big data.

Action is needed to realize the promise of Health IT innovation for all Americans:

1) **High-Quality patents are needed to drive innovation.** The preceding examples demonstrate how high tech innovation continues to revolutionize medicine -- advances in which Intel is proud to play a critical role. We are here, however, not just to describe this revolution, but also to discuss how the US intellectual property system can continue to foster this new and exciting progress. At Intel, we believe that continued innovation depends on a balanced patent system that produces high-quality patents.

   While the PTO and the courts have taken steps to mitigate the problem of weak patents, there are still thousands of vague and overly broad patents in the system. A recent study found that 42% of patents challenged in federal court are found to be invalid. A patent system flooded with so many low-quality patents can actually slow innovation. In an ideal world, any patent granted by the PTO would never be challenged because everyone would be completely confident that the patent was valid and properly granted. Of course, this is not the case in the real world. The PTO makes mistakes because it does not have the time or resources to perform the same detailed scrutiny that a patent undergoes during patent litigation. Nevertheless, there are

always ways that the PTO can do better and produce higher quality patents. Intel supports those efforts.

2) **Facilitate the right mechanisms and incentives for managing and reducing cyber security risk.** Open collaboration and communication among regulators, industry medical and healthcare practitioners are key to managing and reducing cyber security risk. Public-private partnerships have proven to be successful in helping a wide range of industries improve their cyber security readiness and overall capabilities in the past. More recently, the NIST Cybersecurity Framework has provided a tool for healthcare organizations to review their security posture with a focus on risk management. Collaboratively developed efforts such as the NIST Cybersecurity Framework provide real benefits to healthcare organizations wishing to better understand and improve their organization's cyber risk management processes and posture.

3) **Ensure privacy as an enabler of innovation**. Intel believes that privacy is a key enabler of innovation in this sector. If individuals are to feel at ease with these technologies and data uses, they must trust that their devices are secure and data about them is protected and used in privacy respectful ways. Intel endorses the application of long recognized, proven principles of fair information practices to address concerns about data practices and privacy. Intel further endorses implementation of "privacy-by-design" — that is, addressing privacy and building in privacy solutions throughout the design cycle of technologies and data applications. Privacy and progress in this sector are not values to be balanced or traded off — they are goals that must be pursued in tandem if we are to realize the benefits these technologies promise.

4) Sustain momentum toward standards and interoperability for today and tomorrow: 21st Century Cures provides the legislative framework to ensure interoperability of health information. A standards-based approach for health information technology enables quicker and more efficient deployments to share data from different sources. Tying certification to real world testing and ensuring that data can be exchanged

without special effort on the part of the user will be key to future medical discoveries. Intel invites policymakers to consider standards and interoperability efforts beyond EHRs and into the domain of genomics sequencing and Internet of Things.

5) **Clarify a fair payment for genomic medicine.** Cancer researchers found that because routine genomic testing of all patients has not become the standard of care in the United States, oncologists are reluctant to order genomic tests unless they are confident the results will contribute to an actionable outcome — ideally a clear indication for an accepted treatment that will be covered by insurance or other funding. Payers are reluctant to cover the costs of Next Generation Sequencing (NGS) until they have clear evidence of the tests' benefit. But since oncologists aren't ordering the tests, the data to build a case for genomic testing as part of an evidence-based standard of care isn't being accumulated. And since NGS testing is not the standard of care for most cancers, payers feel justified in not covering it. It's a vicious circle. And it is compounded by the need for education and expertise to interpret diagnostic results and counsel patients, and the lack of mature, trusted tools.

6) **Accelerate the model for Real World Evidence in FDA drug approvals.** The potential for drug discovery to include the wide array of data points to impact the patient's health is dependent on the integration of genomics, clinical, wearable and other data to be available for researchers to collaborate and innovate for the future of medicine.

7) **Building trust for data analytics.** Clinicians and patients must have confidence that recommendations generated by data analytics are based on relevant, validated, and vetted data and that the data – often from multiple sources, public and private– has been analyzed appropriately.

To close, I would like to highlight the importance of a legal system that generates high-quality patents. When a system is flooded with invalid patents, it hinders research and slows development. Intel supports efforts to enable the Patent & Trademark Office to produce higher-quality patents.

This is especially important in our increasingly connected world. Long gone are the days when new technologies are introduced as stand-alone products. Today's new solutions operate in an interconnected web, collecting, processing, and transmitting data to other devices and solutions. If one part of the chain breaks down because of a weak patent, it can break down the entire system.

Today, we are on the cusp of massive advances in medical and computing technologies. Whether advancing the speed of diagnosis or enabling innovation for novel approaches to data analytics and scientific collaboration, a high-quality patent system is critical to realize these benefits.

Thank you for inviting Intel to address this important topic.

[i] *The Personalized Medicine Report, 2017 Opportunities, Challenges and the Future*, PMC p. 47