Testimony of

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"The State of Patent Eligibility in America: Part III"

Chairman Tillis, Ranking Member Coons, and Members of the Subcommittee:

OVERVIEW

We appreciate the opportunity to testify on this important issue and look forward to working with the Committee to develop and advance this policy. Our company, Caris Life Sciences ("Caris"), provides precision medicine services and cancer diagnostic tests that save lives and reduce the cost of health care.

Under the current state of the law, whether an invention is or is not patentable has become murky. This uncertainty deters the substantial investment necessary to develop new healthcare technologies and emboldens competitors—both domestic and foreign—to disregard patents in this space and exploit the hard-earned innovation of others because they know they can challenge the patent's validity with a good chance of succeeding. Therefore, Caris supports the proposed changes to Section 101, which we believe would clarify what is patentable. This would encourage companies like Caris to continue investing the substantial resources necessary to develop paradigm-shifting technologies with the promise of revolutionizing cancer treatment.

PRECISION MEDICINE

Caris' Chairman and CEO, David D. Halbert, is a Texas-based entrepreneur with a strong track record of growth and value creation in the energy, financial and healthcare industries. In 2008, Mr. Halbert used his personal resources to form Caris Life Sciences, which was the first company to offer comprehensive tumor molecular profiling services to help cancer patients by better informing their course of treatment by understanding of their unique tumor biology. Mr. Halbert is a passionate advocate of precision medicine and believes that more precise and individualized information will lead to dramatic improvements in the quality of care patients receive. Mr. Halbert has been tremendously influenced by his mother's passing over a decade ago due to cancer, as evidenced by his personal investment, commitment, and unwavering dedication to making precision medicine a reality for cancer patients today.

Traditional cancer treatment relied upon one-size-fits-all therapeutic regimens that were largely dependent on tumor origin. For example, lung cancer patients would be treated similarly, colorectal cancer patients would be treated similarly, etc. The problem with this approach was that treatment options were limited. A lung cancer patient, for example, could exhaust all conventional treatment options for lung cancer, and have little rationale for further treatment selection. We didn't want to accept this. We looked for a way to identify unconventional treatment options that could more effectively treat the patient's

disease. Our method used characteristics of the patient's own tumor to suggest treatment options independent of tumor origin or location within the body. Today, our approach is commonly referred to as "precision medicine." In the early days of our company, molecular profiling received a great deal of skepticism in the medical community. A decade later, it is becoming standard of care.

Precision medicine, which is also referred to as personalized medicine, aims to help treating physicians optimize treatment regimens for their cancer patients by correlating characteristics of an individual patient's own tumor with likely treatment benefit. In the general approach, we perform molecular testing of a tumor sample from a patient. We use the molecular test results to suggest treatments that are more or less likely to benefit the patient.

Precision medicine provides better patient outcomes and concomitant reductions in the cost of health care. Based on the analysis of thousands of cancer patients profiled over the last decade, we have shown that treatment with agents identified according to our approach leads to better patient outcomes. At the same time, we also identify treatments of unlikely benefit to the patient, thereby reducing disease progression, side effects, and costs.

I would like to highlight the real-life story of cancer patient Sandra Fehrman. In 1992, Mrs. Fehrman was diagnosed with metastatic breast cancer. At the time, she was 44 years old, otherwise healthy, and had three children, aged 16, 15 and 11. She was successfully treated with surgery and standard therapy for breast cancer and remained disease free for over 10 years. However, in 2003 at age 55, Mrs. Fehrman was diagnosed with a recurrence that had spread to both of her lungs, her liver, and five bone sites. She underwent several additional years of chemotherapy, with sometimes serious side effects. Unfortunately, by 2007, all conventional treatments for breast cancer were exhausted. Her oncologist, Dr. Larry Gluck, then suggested tumor molecular profiling to be performed by Caris. We identified several characteristics of Mrs. Fehrman's cancer that suggested additional treatments that would have otherwise not been considered. Mrs. Fehrman responded well to these treatments and was able to watch her children graduate and get married and have children of their own. Unfortunately, Mrs. Fehrman passed away last summer at age 70. All told, she survived the diagnosis of stage IV breast cancer for 26 years during which time she was treated with 27 different chemotherapy treatment regimens. We are proud to have played a role in her courageous story.

PATENTS PROMOTE INNOVATION

Caris supports the proposal by Senators Tillis and Coons. Precision medicine is based on the application of various types of genetic testing and advanced data analysis, and thus our work falls squarely into the uncertain gray areas that has been created by judicial interpretations of the law regarding patentable subject matter.

We have invested more than $400 million in order to develop and continue to optimize our tumor profiling services. Not only does this work require substantial financial resources, into also necessarily requires a great deal of time. For example, it takes years to obtain the patient outcomes data that we use to innovate. To address this, we have created a growing consortium of almost 30 universities and cancer treatment centers with hundreds of oncologists to collaborate on improvements in patient care, including tracking patient outcomes. In addition, analyzing years of outcomes data for thousands of cancer patients requires substantial investment in computing architecture to support the innovative analysis methods necessary to fully make use of the data.

We must be able to protect these investments that required the support of hundreds of millions of dollars for development and validation. We and others cannot continue to invest such time and resources into advancing personalized medicine, thereby improving patient outcomes and reducing healthcare costs, if we are unable to recoup our investments because others copy our innovations. Under the current state of the law, competitors, both domestic and foreign, have been emboldened to copy our innovations, disregard patents, and then challenge the validity of those patents in court.

Moreover, the murky state of the current patent laws inhibits the sharing of scientific information. For example, Caris has a unique wealth of knowledge gained from molecular profiling of over 150,000 cancer patients for more than 10 years. We are only free to share this information with the medical and scientific communities if we have adequate protection over our intellectual property. Accordingly, patent protection facilitates the dissemination of scientific knowledge to the benefit of all, as it is intended to do.

PATENTS DO NOT RELIABLY PROTECT PRECISION MEDICINE INNOVATIONS UNDER THE CURRENT STATE OF THE LAW ON PATENTABLE SUBJECT MATTER

Patents are our only realistic mechanism of protecting our innovations. Because of compelled disclosures, trade secret protection is inadequate in our field. We cannot simply provide molecular profiling reports with cancer treatment information without also providing the underlying rationale. Treating physicians will not trust a black box approach

to therapeutic intervention for their patients. In addition, regulatory agencies such as the United States FDA require disclosure for regulatory approval.

Yet, patent protection for precision medicine is uncertain under the current law. Any invention relying even in part upon the relationship between a gene and disease, or a gene and treatment benefit, may be characterized as an unpatentable "natural law." And any invention relying even in part upon analyzing large amounts of molecular data may be characterized as an unpatentable "abstract idea."

REAL WORLD EXAMPLES

I would like to offer two examples of innovations we are making to precision medicine that may lack adequate protection given the current state of the laws on patentable subject matter.

As a first example, we are developing systems and methods to optimize cancer treatment decisions. Standard first line therapy for colorectal cancer comprises a choice between the combination therapies "FOLFOX" and "FOLFIRI." An individual patient may respond to one regimen or the other, but currently there is no ideal way to predict response *a priori*. This may result in the initial choice of an ineffective therapeutic regimen, thereby delaying beneficial treatment and increasing healthcare costs. We have applied advanced machine learning algorithms to our molecular profiling data and outcomes data—which we have compiled and analyzed over many years—to identify a signature of genes that accurately predicts response to FOLFOX. An oncologist can prescribe FOLFOX if a patient is identified as likely to respond. Conversely, a predicted non-responder may be initially treated with FOLFIRI.

As another example, we are developing systems and methods to identify the origin of a tumor sample based on molecular analysis. The origin of 5-10% of tumors is unknown, which leads to difficulty in choosing a treatment regimen, sub-optimal treatment selection, and/or delay in treatment. This results in worse patient outcomes and increased healthcare costs. We have applied advanced machine learning algorithms to our molecular profiling data for over 60,000 patients to identify signatures of genes to accurately predict tumor origin for >90 percent of cases analyzed. Such predictions can be used together with our molecular profiling to optimize treatment options for individual cancer patients, thereby improving patient outcomes and reducing costs.

However, under the current state of the law, the systems and methods we have developed to inform treatment decisions may be alleged to be unpatentable natural laws, abstract ideas, or both, even though they are man-made, highly innovative, and provide numerous societal benefits. Without patent protection, others may copy such signatures

as soon as they are published or made publicly available during regulatory review. Such copying reduces the incentives to invest in advances in precision medicine and therefore inhibits our ability to improve patient care and reduce healthcare costs.

ADDRESSING THE CONCERN OF "GENE PATENTING"

We well understand the concern with "gene patents" and the Myriad decision. However, there are better ways to deal with one company's unpopular business practices than imposing limitations on patentable subject matter—ways that will not stifle investment in life-saving innovations.

It is important to understand what "gene patenting" means and what it does not mean. First, we do not believe that a product of nature *per se,* such as a gene as it exists in nature, should be patentable as it is not a man-made innovation. And we do not believe that it would be patentable under the proposed legislation. However, the knowledge gained from a product of nature or uses thereof that are novel and non-obvious may very well deserve patent protection. Second, if Myriad's patents had survived and competitors had been found to infringe, the Courts could have imposed a licensing regime upon Myriad that aligned with the public's interest in having access to the patented technology. Thus, the U.S. patent system already has built-in mechanisms to deal with so-called "blocking" patents. Finally, the human genome is known today. The isolated BRCA1 gene would not be patentable today because it either lacks novelty or is obvious given what is presently known.

Indeed, we believe that other requirements of the patent laws are better equipped to deal with technological changes over time. For example, it goes without saying that what is considered new will change over time. But what is considered to be obvious also changes over time: at the time of Myriad's patent filings, genes were new and difficult to discover and isolate, but this is not the case today. In contrast, subject matter eligibility should not depend on the current state of the art and should remain anything under the sun that is made by man. Patentable subject matter should remain constant.

CONCLUSION

We believe that the proposed changes to the laws regarding patentable subject matter would clarify what is patentable and restore robust patent protection for innovations in healthcare. This would encourage companies like Caris to continue investing in research and development to innovate paradigm-shifting technologies with the promise of revolutionizing cancer treatment.

We thank the Subcommittee for allowing us to participate today. We look forward to continuing the discussion of this important area and working with the Committee on any new language that may be proposed.