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Testimony of Peter O'Neill, Executive Director of Cleveland Clinic Innovations, to the Subcommittee on Intellectual Property of the Senate Judiciary Committee

June 11, 2019

Chairman Tillis, Ranking Member Coons, and Members of the Subcommittee, thank you for the opportunity to testify today. Thank you, as well, for your leadership on the very important issue of patent protection.

Cleveland Clinic is an internationally-recognized leader in the delivery of health care. US News and World Report ranked Cleveland Clinic as the #2 hospital in the nation, and Newsweek recently ranked Cleveland Clinic #2 in the world. Each day, our patients look to us to provide the best possible care for them. Part of providing the best possible care is leading innovations that improve the care available to patients. Cleveland Clinic Innovations was formed in 2000 to help translate the advances made by Cleveland Clinic staff into products available to patients and consumers.

In recent years, decisions from the federal courts have cast a cloud of uncertainty over our work in the field of diagnostic tests and life sciences. On multiple occasions, the federal courts have ruled that patents we received from the United States Patent and Trademark Office (USPTO) were invalid, even arguing that guidance issued by the USPTO did not carry legal weight. These decisions have created uncertainty that can deter investment from new products that could have a significant impact on patient care.

Leaders of this Subcommittee, along with partners in the House, are doing critically important work by shining a light on this issue in a deliberate, bipartisan manner. I am hopeful that the Cleveland Clinic story can help illustrate the need to assess the existing federal statute, and provide greater support to innovators across the country working to bring new products to market.

Cleveland Clinic Foundation vs. True Health Diagnostics

In 2001, researchers at Cleveland Clinic filed the first patent applications for a test they developed that measures a patient's risk for cardiovascular disease by analyzing the inflammation of the blood vessels. The test was called Myeloperoxidase or "MPO" testing. MPO is an enzyme released by white blood cells when inflammation occurs and is involved in the immune response bacteria in the blood stream. When tested using the methods discovered by Cleveland Clinic, the presence of certain levels of MPO is an indicator of cardiovascular disease. Cleveland Clinic received a patent for MPO testing in 2007. The patent was challenged twice in reexamination proceedings before the USPTO and found valid, most recently in 2011.

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In 2009, Cleveland Clinic launched a spinoff company known as the Cleveland HeartLab that began the process of making MPO testing commercially available. The HeartLab performs lab analysis of patients' blood samples, and also can manufacture MPO testing kits for sale to other labs.

In 2015, Cleveland Clinic took legal action against True Health Diagnostics in the United States District Court for the Northern District of Ohio for infringing several Cleveland Clinic patents – including the patent from 2007 that was reexamined twice by the USPTO – for MPO testing. In response, the Ohio district court found three of our patents invalid, citing the Supreme Court's well-known *Mayo* and *Alice* decisions that created the current analytical framework for evaluating whether patents directed to "laws of nature, natural phenomena, and abstract ideas" are eligible for patenting under 35 U.S.C. § 101. Cleveland Clinic filed a subsequent appeal to the United States Court of Appeals for the Federal Circuit in 2016, but that appeal was unsuccessful. A final appeal to the United States Supreme Court was not taken up for consideration.

In 2016, USPTO issued updated guidance to patent examiners that provided meaningful clarification for evaluating patent claims involving naturally occurring phenomena. In the guidance, USPTO asserted that certain claims directed to methodology for detection, measurement and analysis of naturally occurring phenomena are eligible for patent protection.

Following this new guidance, the Cleveland Clinic returned to the USPTO and obtained additional patents covering laboratory methods developed with human ingenuity for MPO testing that conformed carefully with the USPTO's guidance. It's important to note that diagnosing the risk of cardiovascular disease using the MPO biomarker is method dependent. The USPTO agreed and issued new patents in early 2017. Cleveland Clinic again sued True Health Diagnostics for infringing the new patents, this time in the United States District Court for the Eastern District of Virginia. The district court again found the patents on MPO testing ineligible under Section 101, relying on the rulings from the Ohio case. Cleveland Clinic again appealed to the Federal Circuit, which rejected our appeal, finding that "while we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance." We received this final decision about two months ago.

Impact of the Court Decisions

The courts' decisions in Cleveland Clinic vs. True Health have created new levels of uncertainty for Cleveland Clinic Innovations, and, I believe, for innovators across the country. That uncertainty has a very meaningful impact on our ability to develop and bring new advances to market for use with patients and consumers.

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Bringing a new health care product to market is an expensive and time consuming proposition – for good reason. The government has created a regulatory infrastructure intended to protect consumers and ensure the safety of the product. Innovation in health care therefore faces a steeper climb to commercialization than some other fields.

The resources for this process generally come from outside of Cleveland Clinic Innovations, working with the investment community. That investment community takes into account a number of factors when deciding whether to support commercialization – including whether a product is likely to be able to acquire intellectual property protections, like patents.

The court's decisions have created new questions about whether patents that apply naturally occurring phenomena will stand in court. Regardless as to how innovative or unique a new product might be, the courts seem to suggest that a product that utilizes a naturally occurring phenomena – like diagnostic tests – could be subject to invalidation in court.

Furthermore, the Federal Circuit has outright questioned the weight of policy issued by USPTO. Its decision would seem to undermine the very notion that guidance issued by the USPTO has any legal weight. Under that direction, it remains unclear in the innovation community what protections a patent actually provides in the life sciences space.

These questions about patents hurt the ability of Cleveland Clinic Innovations and other innovators to bring new products to market that involve the life sciences. At Cleveland Clinic Innovations, we have an established process to assess inventions, based on their likelihood to be able to be developed into commercial products. Ability to get protectable intellectual property (usually in the form of a patent) is the first, and most influential factor in our assessment. If an invention can't get intellectual property protection, usually that is a fatal flaw and the invention is abandoned at that point.

Financial supporters of new products put significant weight on intellectual property rights, including patents, when issuing support. Those financial supporters are following federal court cases like ours, and weighing whether a patent is likely to withstand a court challenge. The absence of that financial backing can make it nearly impossible to bring products to market.

Take the example of Cleveland Heart Lab, the company formed to bring to market the MPO testing that was the subject of our recent litigation. Highly skilled researchers at Cleveland Clinic identified MPO as a biomarker that identifies people at an increased risk of developing cardiovascular disease. This research, conducted through the use of inventive steps (according to USPTO guidelines) was just the beginning of the work. We invested in preparing and subsequently obtaining a number of patents, which it should be noted is not an easy process. We pursued commercial investment through a company started by Cleveland Clinic to further develop the diagnostic test and materials necessary for regulatory approvals before the product could come to market. Each of these steps took time and resources that were made possible only by the promise of return on investment enabled by patent protections.

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The end result was meaningful: a new company that brought 200 skilled new jobs to Northeast Ohio, and access to a novel diagnostic test that identifies people at increased risk for cardiovascular disease. The success of Cleveland HeartLab, including the jobs the company created and the many thousands of patients served, was only possible because of the certainty around the patent that existed when the company was formed that enabled the company to raise the required investment funding

The Cleveland HeartLab story is just one example of the work we do. Cleveland Clinic Innovations has a history of significant results translating innovation into products helping patients. We have helped form dozens of other spin-off companies and licensed hundreds of other technologies that have led to the creation of thousands of jobs and impacted countless patients. Patents and intellectual property were an essential part of all this work.

Patents and the protection of intellectual property are a critical and necessary part of the process of bringing groundbreaking new advances in health sciences to patients. Medical research can and will continue across the country, supported by governmental and non-governmental entities. Translating that research into products available for patient care necessitates a reliable and predictable patent system.

The Balancing Act

There is a balancing act at play in the world of patents. Certainty in the marketplace should not come at the expense of barriers to progress for ground-breaking, and potentially life-altering, research.

At Cleveland Clinic, we are fortunate to have some of the nation's leading experts in genetic research on staff. Our researchers join others around the nation in advancing the field of medicine, and bringing new hope to many impacted by terrible diseases. Their research is critical, and should be supported.

Parts of the research community have expressed concern that the proposal put forward by the Committee could become a barrier to progress, by allowing entities to attain patents on the very genes they seek to research. These concerns are important to Cleveland Clinic and the researchers we support. In particular, we share concerns about any scenario in which individual genes would be eligible for patenting.

While we remain pleased the Committee is looking at the challenges created by uncertainty in the realm of patents, the Committee should move with caution, and ensure that the concerns of the research community are heard and reflected in any legislative solution.

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Recommendations

Decisions made by federal courts in recent years have made a significant impact on the field of innovation, particularly in the field of life sciences. Patents are an integral part of the process of developing new products and bringing them to market. Without the confidence that patents will withstand the test of legal challenges, their effectiveness is removed.

As the Committee deliberates on how to approach any potential changes to the federal statutory scheme, we offer the following considerations:

1. **Give greater standing to guidance from the USPTO** – the USPTO is the federal entity that provides guidance on patentable subject matter and issues patents. Innovators track closely any guidance or direction from the USPTO with respect to what products are eligible for patents. A patent issued by USPTO should represent the approval of the federal government that a product meets the standards of the federal statute, not the beginning of a protracted legal battle.

2. **Clarify the eligibility of life science and diagnostic products for Section 101 patents** – the federal court decisions, including *Mayo* and *Alice,* have called into question whether any innovative product we develop that involves the human body would be eligible for patents that would not be overturned in court. This uncertainty has a chilling effect on this field absent some greater clarity.

3. **Protect the ability of genetic researchers to continue their work** – while patents are an important part of the field of innovation, those patents should not stand in the way of crucial research into life-saving technology.

Again, we applaud the work of the Committee to bring focus to these changes in our federal patent system. In addition to any questions before the Committee, we look forward to serving as a resource for the Committee going forward.