Cleveland Clinic

**Questions for the Record – "The State of Patent Eligibility in America: Part III"**

**Senator Tillis**

1. **What is the public policy value in encouraging investment, research, development and innovation in life sciences and precision medicine? In other words, can you explain to this committee in layman's terms why precision medicine is the future?**

As a national leader in health care delivery, it is part of Cleveland Clinic's mission to bring the latest advances in medicine to patients - including precision medicine. Even though the human genome has been mapped for years, the field of precision medicine is just beginning to see research identify useful applications of that knowledge to change the way healthcare is delivered to individual patients. The ability to tailor a treatment to a specific patient based on the patient's genomic or other patient-specific features has profound implications to improve effectiveness and cost of how healthcare is delivered.

Those advances are the product of a lengthy and deliberative process that necessitates significant resources. Cleveland Clinic's Lerner Research Institute employs 187 principal investigators, 240 research fellow, and 166 graduate students, driving many ongoing research initiatives that hold promise for improvements in health care delivery. In addition, many of our clinicians also engage in meaningful research work. Federal investments in medical research, including funding from the National Institutes of Health and the Department of Defense, are critical to driving innovation in health care.

However, research is just the first step in making health care advancements available for patient care. Bringing a new product to market for patient care requires regulatory approval, clinical demonstration, production scale-up, sales growth, and countless other steps, all of which require significant investment. Intellectual property, including patent protection, is a critical part of that process and often is a key criterion which investors consider when deciding to make an investment in a new technology.

A public policy supporting advances in medicine must address this question of intellectual property and patentability. As I stated in my written testimony, certainty in the marketplace should not come at the expense of barriers to progress for ground-breaking, and potentially life-altering, research.

2. **Some have claimed we want to allow the patenting of human genes as they exist in the body. That's false. However, I do think there's value in promoting researchers and innovators to isolate human genes and apply that isolation to personalized treatment. Can you explain for us why that's valuable? In other words, what advancements in treatment occur because of such innovation?**

As discussed in my June 11th testimony, Cleveland Clinic is a national and worldwide leader in healthcare innovation and research, including genetic medicine and research. While I am not involved in genetic medicine or research myself, I am fortunate to call these specialists my colleagues.

We support the Committee's stance that isolated naturally recurring human genetic sequences are not patentable.

Personalized treatment (or targeted treatment) is the practice of detecting a genetic cause or driving factor for disease in an individual, and then using that information to identify a treatment for the disease that is specific to the genetic makeup.

This practice has become especially beneficial in the oncology setting, where information about the genetic makeup of an individual's cancer tumor can indicate which specific chemotherapy or immunotherapy drugs are likely to shrink the patient's tumor. This practice allows the patient and their physicians to utilize treatments that have the highest likelihood of shrinking or stabilizing cancer tumors, as opposed to spending time trying treatments that the cancer tumor will not respond to.

We are learning that cancer tumors continue to develop genetic changes over time, which can be helpful for patients with a cancer recurrence. In these situations it is important to know that a treatment that was effective the first time is no longer a viable option, and that additional treatments should be considered. The targeted treatment options will continue to increase as we learn more about the genetic makeup of different cancer tumors and develop therapies specifically to treat these genetic variants.

The specialty of pharmacogenomics also falls into the category of personalized treatment. Pharmacogenomics utilizes genetic testing to identify how an individual metabolizes, or breaks down certain medications. This information can then be used to ensure that the patient is on an appropriate dose of medication, such as pain medication or psychiatric medication. One size does not fit all. An individual needs a higher dose of medication if their body metabolizes it faster than the general population, and would need a lower dose if their body metabolizes it slower. The goal of pharmacogenomics is the same as targeted treatment for cancer: to provide each individual the appropriate healthcare management for the specific condition for which they are being treated.

As we continue to learn more about the genetic risk factors for cancer, cardiovascular disease, neurological disorders, and medication metabolism, personalized treatment options are more likely to become a reality for more patients.

**3. Looking forward ten to fifteen years, if we don't correct the current state of patent eligibility what is the negative impact that American patients will experience?**

At Cleveland Clinic Innovations, our job is to translate the research and inventions of Cleveland Clinic caregivers into devices, diagnostics, treatments, and other products that can be made available for patient care. Intellectual property, including patents, are a cornerstone of that work;

without the promise of protection for an innovative idea, the investments necessary to bring that product to market are unlikely to materialize.

Under the status quo, there is significant uncertainty about what technologies are eligible for patents that can withstand legal challenges. The award of a patent based on patent eligible subject matter from the United States Patent and Trademark Office (USPTO) no longer carries the assurance of intellectual property protections, as we have seen from our legal experience in recent years.

That uncertainty makes it more difficult to bring new products to market, where they can be available for patient care. Particularly in the area of diagnostics in the life sciences, where Cleveland Clinic patents have been challenged and overturned in court, the uncertainty of patent protection makes it less likely we and other inventors will make the investments to make new advances commercially available.

Intellectual property is also a critical tool for small businesses seeking to disrupt the marketplace. Consider the case of Cleveland HeartLab, as discussed in my testimony. As a result of the intellectual property Cleveland HeartLab held, the company was successful in growing to more than 200 employees who delivered products to help hundreds of thousands of patients. Without patents, it would not have been possible to secure the investment required to grow the company.

Without predictable intellectual property protections, small companies like Cleveland HeartLab would have faced competitive disadvantages to larger companies with brand recognition and ability to scale. A continued deficit in certainty around the availability and security of these patents will create challenges for smaller, disruptive innovators.

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**Questions for the Record – "The State of Patent Eligibility in America: Part III"**

**Senator Hirono**

1. **Last year, Judge Alan Lourie and Judge Pauline Newman of the Federal Circuit issued a concurring opinion to the court's denial of *en banc* rehearing in *Berkheimer v. HP Inc.*, in which they stated that "the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are § 101 problems."**

   **Do you agree with Judges Lourie and Newman? Does § 101 require a Congressional fix or should we let the courts continue to work things out?**

We would welcome any change to the status quo that will provide the innovation community with greater certainty about what products are eligible for patents, and give greater weight to the decisions of the United State Patent and Trade Office (USPTO). Under the status quo, the award of a patent from the USPTO does not carry the necessary certainty of intellectual property protection, given that the courts seem to have set their own standards. Patent protection should not necessitate lengthy and costly legal proceedings.

As new areas of innovation emerge, such as applying knowledge of the human genome to treat human conditions, the innovation community will continue to search for guidance and certainty. As the federal agency that executes federal law, the USPTO is well suited to address those evolutions and provide public information in a reasonable fashion. The courts should not be left to set policy.

2. **The Federal Circuit rejected a "technological arts test" in its *en banc Bilski* opinion. It explained that "the terms 'technological arts' and 'technology' are both ambiguous and ever-changing." The draft legislation includes the requirement that an invention be in a "field of technology."**

   a. **Do you consider this a clear, understood term? If so, what does it mean for an invention to be in a "field of technology"?**

   b. **The European Union, China, and many other countries include some sort of "technology" requirement in their patent eligibility statutes. What can we learn from their experiences?**

   c. **Is a claim that describes a method for hedging against the financial risk of price fluctuations—like the one at issue in the *Bilski* case—in a "field of technology"? What if the claim requires performing the method on a computer?**

**d. What changes to the draft, if any, do you recommend to make the "field of technology" requirement more clear?**

While we are happy to provide candor about medical innovation and the process of bringing new products to market, these questions go beyond the scope of our expertise.

3. **Sen. Tillis and Sen. Coons have made clear that genes as they exist in the human body would not be patent eligible under their proposal.**

   **Are there other things that Congress should make clear are not patent eligible? There are already statutes that prevent patents on tax strategies and human organisms. Are there other categories that should be excluded?**

We appreciate very much the comments from the Subcommittee Chair and Ranking Member about the importance of protecting genes from inappropriate patents. Cleveland Clinic is home to some of the nation's leaders in genetic medicine and research. Overly broad changes in patent law could create barriers to their work.

At this time, we do not have other specific fields we would recommend for statutory exclusions from patentability. We look forward to engaging with the Committee on this issue.

4. **I have heard complaints that courts do not consistently enforce Section 112 with respect to claims for inventions in the high tech space.**

   **a. Are these valid complaints?**

   **b. Do the proposed changes to Section 112 adequately address those complaints and limit the scope of claims to what was actually invented?**

   **c. Are you concerned that the proposed changes will make it too easy for competitors to design around patent claims that use functional language?**

While we are happy to provide candor about medical innovation and the process of bringing new products to market, these questions go beyond the scope of our expertise.

5. **There is an intense debate going on right now about what to do about the high cost of prescription drugs. One concern is that pharmaceutical companies are gaming the patent system by extending their patent terms through additional patents on minor changes to their drugs. My understanding is that the doctrine of obviousness-type double patenting is designed to prevent this very thing.**

**The Federal Circuit has explained that obviousness-type double patenting "is grounded in the text of the Patent Act" and specifically cited Section 101 for support.**

**Would the proposed changes to Section 101 and the additional provision abrogating cases establishing judicial exceptions to Section 101 do away with the doctrine of obviousness-type double patenting? If so, should the doctrine of obvious-type double patenting be codified?**

Cleveland Clinic is exceptionally concerned about the cost of drugs. The high cost of drugs impacts the ability of our clinicians to treat patients; when patients cannot afford the drugs we prescribe from them, it jeopardizes their health and our ability to help them stay healthy. The high cost of drugs also takes away resources that our institution could dedicate to patient care.

We have concerns that some of these costs may be driven by practices that slow the arrival of generic drugs to market. For that reason, we have supported the CREATES Act and other legislation designed to speed the process of bringing these drugs to market.

We do not have specific expertise to answer the question of whether the proposed changes to Section 101 would impact patent gaming or other abuses of the patent system. However, we share your concerns with the high cost of drugs.

6. **In its *Oil States* decision, the Supreme Court explicitly avoided answering the question of whether a patent is property for purposes of the Due Process Clause or the Takings Clause.**

   **What are the Due Process and Takings implications of changing Section 101 and applying it retroactively to already-issued patents?**

While we are happy to provide candor about medical innovation and the process of bringing new products to market, this question goes beyond the scope of our expertise.