Topics for Public Comment

Section I—Observations and Experiences

1. Please explain how the current state of patent eligibility jurisprudence affects the conduct of business in your technology area(s). Please identify the technology area(s) in your response.
    - I am a certified genetic counselor and the President & CEO of My Gene Counsel, LLC, a digital health company located in New Haven, CT.
    - In my role at My Gene Counsel, we work with patients, clinicians, laboratories, large and small health care systems, pharmaceutical companies, and other players in the precision medicine space.
    - Since the gene patent ruling of 2013 the cost of genetic testing for BRCA1 and BRCA2 alone has decreased substantially (was $4400 and is now less than $300 at some laboratories) and continues to fall as technology improves and competition increases;
        - Competing labs improved the quality of testing offerings by adding more genes, meaning that more patients are able to find the mutations causing cancer in their families;
        - Competing labs offered more inclusive testing, including large rearrangements and deletions in the genes;
        - More patients are having testing, and more physicians and health care providers are offering testing to patients who need it;
        - Payers continue to widen inclusion criteria for genetic testing;
        - Innovation around better testing methods continue to grow in all areas of genomics.

2. Please explain what impacts, if any, you have experienced as a result of the current state of patent eligibility jurisprudence in the United States. Please include impacts on as many of the following areas as you can, identifying concrete examples and supporting facts when possible:

c. patent counseling and opinions;

- The current gene patent status has allowed competition in the area of genetic testing for hereditary cancer. This has resulted in lower pricing of genetic tests, higher quality of tests, and inclusive gene panels that are better for patients and the clinicians ordering those panels.

d. research and development;

- Clinical research has flourished since the 2013 gene patent ruling, because it is much less expensive to order genetic testing and to create research protocols that include that testing within grant budgets.
- Competition has also driven laboratories to continually improve genetic testing technology (e.g. RNA testing to determine whether variants are deleterious), leading to better testing for patients and their clinicians.

e. employment;

- Competition has led to a rich market for genetics employees and more job opportunities in our field.

3. Please explain how the current state of patent eligibility jurisprudence in the United States impacts particular technological fields, including investment and innovation in any of the following technological areas:

c. precision medicine;

- The gene patent ruling of 2013 has been critical in the rise of precision medicine. If every gene in the human genome were under patent, offering whole genome sequencing would be impossible, due to individual patents and the cost of testing.

Section II—Impact of Subject Matter Eligibility on the General Marketplace

13. Please identify how the current state of patent eligibility jurisprudence in the United States affects the public. For example, does the jurisprudence affect, either positively or negatively, the availability, effectiveness, or cost of personalized medicine, diagnostics, pharmaceutical treatments, software, or computer-implemented inventions?

- The gene patent ruling of 2013 has caused a sea change for patients and their families who need genetic testing, which can be lifesaving. In hereditary cancer families, the availability of affordable, comprehensive genetic testing allowed hundreds of families to discover the genetic alteration that was causing cancer in their DNA, and to use testing to find out which family members were at risk. Before the gene patent ruling, Myriad Genetics held the patent and charged over $4400 per patient for this testing, which did not include the dozen of other cancer genes, or large rearrangements or deletions in BRCA1 and BRCA2. I saw first-hand how their control of these patents for more than a decade damaged patients, their families, clinical care and clinical research.
- Since the gene patient ruling, there has been a rise in personalized medicine, clinical research, pharmaceutical treatments for genetic findings, and software and technology to support the precision medicine industry.