January 5, 2021

The Honorable Thom Tillis
United States Senate
113 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Tillis,

On behalf of the organizations listed below, thank you for the opportunity to participate in the November 20th stakeholder call led by Brad Watts on your staff, as well as the opportunity to provide our very important perspective on patenting products of nature and abstract ideas. As you are aware, our members support the Supreme Court decisions in *Association for Molecular Pathology vs. Myriad Genetics Inc. ("Myriad"), Alice Corp vs. CLS Bank International ("Alice"), and Mayo Collaborative Services vs. Prometheus Laboratories Inc. ("Mayo")* and aim to preserve those rulings as you and your Senate colleagues explore modifications to Section 101 of the U.S. Patent Act ("Section 101"). We write today to follow up in regards to the process for designing legislation intended to modify Section 101 that you outlined at the end of the call on November 20th. We appreciate the meetings and conversations we have had with your staff since the Nov. 20th meeting where we discussed many of the concerns outlined below. To be sure, your staff has alleviated some of them. Given the extent of our concerns and our desire to be clear in our communication, we thought it would be beneficial to send a letter outlining our concerns as well.

**There are More than Two "Camps"**

Dividing the stakeholders into two camps, one pro-reform and the other anti-reform, inaccurately captures the range of positions of those on the November 20th call. While in fact there are those who oppose reform all together, there are others who simply want to protect the integrity of one or more Supreme Court decisions. As such, we find it inappropriate to be lumped into a group labeled anti-reform and believe that you need to create as many "camps" as needed with their own representatives at the table to accurately reflect the range of interests.

To be clear, we do not have a position on whether or not the patent system writ large needs reforming. However, we do believe that those requesting policy modifications to Section 101 can achieve their goals of clarity in the law's application without vacating more than 150 years of court decisions, including the recent decisions by the Supreme Court. The approach proposed in the draft legislation you offered in 2019 and reflected in some of the comments shared on the recent call make it clear that some stakeholders continue to advocate for the ability to patent naturally occurring DNA sequences. Overturning, narrowing, or otherwise limiting the implications of the *Myriad, Alice, and Mayo* decisions is a non-starter for us in these negotiations. Given the breadth of the expertise on the side in support of reform, we are confident that they have the creativity and thoughtfulness to craft a policy that addresses their concerns without trampling ours. We strongly encourage you to direct them to identify solutions

to achieve clarity in patent eligibility that does not allow patents on products of nature, laws of nature, or abstract ideas.

Further, we are concerned that by artificially dividing stakeholders into two camps and then only allowing 14 individuals to speak on behalf of those two camps, the process actively silences the voices of those not in the room and not at the table. We have serious concerns about this being a democratic and open process, in which everyone who has an interest also has an equal and legitimate opportunity to contribute to this discussion to formulate policy. For instance, it's unclear if you and your colleagues will accept meeting requests from those not encompassing the 14 representatives, how you will resolve the inability to reach consensus within each camp, if and how parties who did not participate in the November 20, 2020 call will be able to participate moving forward, etc.

**Process and Timeline is Unfeasible**

The expectation that the organizations, many of whom are engaged on more timely and highly critical issues, including providing the infrastructure nationwide for testing for the COVID-19 pandemic, will be able to meet quick deadlines is unrealistic. Further, asking these nonprofit organizations, many of whom focus on direct patient care and already have limited resources to devote to non-healthcare focused policy issues during the current public health emergency, to then meet every two weeks and consult meaningfully with other organizations is onerous and burdensome. We ask that you modify the timeline to reflect these needs.

**Engagement in the Process Does Not Imply Acceptance of Policy Outcome**

Despite the burdens created by the process you outlined and our concerns about silencing important voices and genuine engagement, we feel compelled to participate in these discussions to make sure our position is acknowledged. However, please understand that our participation in no way commits us to or guarantees that we will accept, support, or endorse the outcome of the negotiations. In fact, as we stated earlier, we will oppose any patent reform proposal that narrows the scope of *Myriad* and other recent Supreme Court decisions.

Thank you for your consideration of our comments about the proposed process for developing patent reform policy. We would be happy to speak with you further about these concerns and look forward to working with you to protect the interests of patients, providers, researchers, and innovators.

Sincerely,

American Civil Liberties Union
American College of Medical Genetics and Genomics
American Society of Human Genetics
Association for Molecular Pathology
Breast Cancer Action

FORCE: Facing Our Risk of Cancer Empowered