May 16, 2022

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

Sent electronically to brad watts@tillis.senate.gov

Dear Senator Tillis,

On behalf of the organizations below, we write to express our concerns regarding the ongoing stakeholder negotiations on the topic of revising Section 101 of the U.S. Patent Act. As you are aware, this process was meant (i) to explore concerns raised by certain stakeholders with respect to the current patent eligibility requirements, (ii) to consider whether all or part of current jurisprudence on patent eligibility requirements should be upheld, and, (iii) to strive to reach consensus among the very divergent groups participating in the negotiations in the hope of advancing legislation that could be supported by all stakeholders. For more than a year, we have actively engaged in the roundtable meetings and met all deadlines for requested written exercises in support of those meetings. Further, we have done so sincerely with a good faith effort and a willingness to meaningfully engage with those in support of changing the terms of Section 101 despite our organizations' continued belief that the public interest would be best served by leaving current jurisprudence largely unchanged.

Unfortunately, we do not believe that the discussions are making any substantive progress towards consensus for any legislative proposals. In reviewing the set of proposed "principles" put forth by the group of pro-change stakeholders, we have been forced to conclude that their proposals are substantively equivalent to the failed 2019 proposal to abrogate existing caselaw regarding patent eligibility standards. These principles, provided and discussed at the past two roundtable meetings, in no way reflect a consensus view. It was clear from their content that the pro-change side had neither considered nor incorporated any of our organizations' positions, principles, and priorities that we had previously raised both in writing and verbally at roundtable meetings, especially as they pertain to the life sciences. At this point we question whether this is a productive use of the significant time and resources your staff and our organizations have dedicated to this process as the proposals of the pro-change side reflect effectively stalled progress in reaching consensus.

Out of respect for you and your team who are diligently and thoroughly exploring this policy issue, we will continue to actively engage in this process in good faith. However, we felt it was important to express our concerns that we do not believe the pro-change side is advancing the discussions towards any potential consensus proposal.

To be clear, our continued participation in no way commits us to or guarantees that we will accept, support, or endorse the outcome of these negotiations. As we have consistently

communicated throughout this process, we believe the current state of subject matter eligibility allows innovators to protect their inventions while avoiding patents on products of nature and laws of nature. For those reasons, we will oppose any patent reform proposal that narrows the scope of the *Myriad*, *Mayo*, *and Alice* Supreme Court decisions in conflict with that core principle. Still, we are committed to this endeavor as we believe any policymaking process should be informed by the work of the industries, professionals, and patients that we represent. Thank you for your attention to this matter and for additional information or questions regarding this letter, please contact Jennifer Leib at jennifer@ipolicysolutions.com.

Sincerely,

American Civil Liberties Union
American College of Medical Genetics and Genomics
Association for Molecular Pathology
BioReference Laboratories
College of American Pathologists
Helix
Invitae Corporation