Katherine M. Hiner
Acting Secretary to the Commission
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

Re: Investigation No. 332-596, *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*.

EDIS Filing Date: May 5, 2023

Dear Madame Secretary,

Thank you for the opportunity to provide our written commentary to the public record for the above-referenced investigation on COVID-19 diagnostics and therapeutics. We, the undersigned higher education associations, wish to express our shared views concerning any further agreement by the U.S. Trade Representative to the expansion of the TRIPS waiver with the World Trade Organization.

Our associations represent multiple university perspectives in relation to the U.S. innovation cycle. The Association of American Universities (AAU) is an organization of 65 leading U.S. and Canadian public and private research universities on the leading edge of innovation, scholarship, and solutions that contribute to scientific progress, economic development, security, and well-being. AUTM is the non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward. COGR is an association over 200 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

America's universities and medical research institutions have helped create most of the major drug discoveries of the past thirty years. With strong support from the National Institutes of Health and other research agencies, America has led the world in creating compounds that ultimately have become many of the drugs Americans depend upon every day. [1]

One key to that pipeline of drug discovery is the patent for the compound that was created. That intellectual property then attracts the commercial investment needed to take that initial discovery, perform additional extensive research, and then conduct lengthy drug trials before any new pharmaceutical is approved for human use. Attempts to weaken or remove intellectual property protections for compounds, drugs, or other medical therapies or tests threatens the willingness of our corporate partners to invest in these potentially life-saving innovations. And when that happens, we will see fewer new treatments and other innovations to fight and cure disease.

[1] Stevens, A.J., Benson, D.E., Dodson, S.E. *et al.* Role of global public sector research in discovering new drugs and vaccines. *J Technol Transf* (2023). https://doi.org/10.1007/s10961-023-10007-z

The global COVID-19 pandemic presented unprecedented challenges and laid bare major inequities of access to vaccine technology globally. Responding to the pandemic required global solutions, of which vaccine innovation was a singular part of the equation of fighting COVID-19. For our part, our organizations provided licensing guidelines to our respective memberships in support of humanitarian licensing to help accelerate the work of our research organizations and technology transfer offices to combat the pandemic effects broadly. "Administering COVID-19 vaccines across a population requires significant healthcare infrastructure which some developing countries lack, such as refrigeration to keep vaccines at low temperatures and a well-trained healthcare workforce…[t]o increase global vaccination rates, efforts should focus on building healthcare infrastructure and distribution capacity, not facilitating additional vaccine production."[2]

While the WTO is to be commended for seeking to address the crisis of the pandemic, we believe that the original decision to waive TRIPS rules for COVID-19 vaccines did not result in an outcome that now warrants expanded waivers of intellectual property protections for COVID-19 therapeutics and diagnostics. We note that, since the approval of the TRIPS waiver for COVID-19 vaccines, and close to a year after approval by the WTO, no country had declared intent to make use of the TRIPS waiver. The lack of use or intent to use the TRIPS waiver is a strong indicator that an expansion of the waiver to therapeutics and diagnostics would yield the same result, while damaging the innovation ecosystem through the injection of uncertainty for intellectual property protections. In our view, that damage to prospective innovation cycles overall is not worth an expansion that may not be utilized after its passage. Strong intellectual property protections are vital to the research enterprise and the cycle of innovation, such that any uncertainty can stymie future research endeavors and investment.

We are also strongly concerned that, once these precedents are set, we could see similar actions to strip intellectual property protections from other technologies, such as clean energy and agriculture. Weakening the protection of intellectual property is simply not the way forward, in our view, to obtain the desired outcomes of greater access and distribution of COVID-19 diagnostics and therapeutics in the Global South.

We would urge the United States and other members of the WTO to reject any further waivers of TRIPS. Thank you for your consideration of our views.

Sincerely,

Association of American Universities (AAU)
Council on Government Relations (COGR)
AUTM

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[2] Borges, Christopher, TRIPS Waivers and Pharmaceutical Innovation, Center for Strategic and International Studies (CSIS), March 15, 2023, https://www.csis.org/blogs/perspectives-innovation/trips-waivers-and-pharmaceutical-innovation.