Biotechnology Innovation Organization

Dr Michelle McMurry-Heath
President & CEO

June 30, 2021

The Honorable Katherine Tai
United States Trade Representative
600 17th Street, NW.
Washington, DC 20506

Dear Ambassador Tai:

We would like to provide you some updates on the U.S. and global biotechnology industry's efforts to scale-up global vaccine production to address the global imbalance in access to COVID vaccines, and to request a close working relationship with USTR now that the WTO has agreed to have text-based discussions on COVID and intellectual property (IP) rights.

First, since our last letter to you in April, our sector has continued to expand global efforts to produce COVID vaccines and therapeutics, and to make maximum efforts working with governments, multilateral organizations including COVAX, as well as other stakeholders to get those vaccines to people in low-and middle-income countries. The list of global partnerships has expanded now to almost 300 cooperative relationships, including significant partnerships (as well as capacity expansions by our own companies) in countries like India and South Africa (see updated list attached). The best estimates are that approximately 11 billion COVID vaccines doses will be manufactured globally in 2021, and billions more in the first part of 2022 (see attachment).

We welcome the Biden Administration's recent actions to significantly increase its donations of COVID vaccines to developing countries working with our companies. We are also working closely with the Administration to address supply chain bottlenecks and trade barriers, so that they do not impede the scaling-up of vaccine production.

In view of these efforts, we believe the evidence strongly supports the conclusion that intellectual property rights ***have not*** and ***will not*** stand in the way of saving lives around the world. Of course, there is still much to be done to ensure that vaccines get to the people who need them most, especially in low-and middle-income countries, and we outlined many of our ideas in our May 3 letter to President Biden which contained our SHARE proposal (attached).

Nonetheless, we understand that the WTO will now embark on "text based" negotiations of IP and COVID issues, with the explicit support of this Administration for waiving global IP rights related to COVID vaccines. We do not believe this waiver will have a beneficial impact on the actual production or distribution of vaccines globally during the COVID crisis. But in any case, we welcome USTR's announcement of "Transparency Principles" earlier this year and as a result would expect that U.S. positions in the TRIPS negotiations be articulated in a timely and transparent manner – to us and all other interested stakeholders.

We thus seek your commitment to consult with BIO and industry leaders (as well as other interested stakeholders of course) in advance of presenting U.S. positions in either informal

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or formal talks, so that you can have the best possible information about the impact of those positions on the thousands of Americans who are working to produce COVID vaccines.

While there are many technical and policy issues to discuss, an initial set of questions and issues our sector would like to raise, in view of the articulated positions of the Administration on this issue:

- We understand that the Administration supports only a "temporary waiver" of IP rights. You will understand however that there is no such thing as sharing trade secrets temporarily. Trade secrets, once made accessible to others, cease being trade secrets and lose their protection forever. What then is the position of the Administration with respect to removing the rights of American companies to protect their trade secrets and knowhow from being irreversibly appropriated by others?

- Does the Administration's support for a "temporary waiver" of IP rights for COVID vaccines mean that the Administration intends to suspend such rights also in the United States? If so, will the Administration consult stakeholders and Congress before a vote is taken at the WTO? A domestic waiver of IP protections for COVID vaccines would be incompatible with multiple U.S. statutes, and would require significant legislative action to be even partially implemented in the United States; hence it is critical that such consultations occur in a transparent manner as early as feasible.

- Specifically with respect to trade secrets, waiving TRIPS simply means that other countries that seek U.S. technology would be waiving their *own* TRIPS obligation to protect confidential data contained in drug regulatory dossiers as well as trade secrets from misappropriation. (Article 39). That does not in itself provide them with the authority to access trade secrets, proprietary biological materials, and confidential regulatory data *in other countries.* For other countries to obtain trade secrets from the U.S. (something we oppose), the United States itself would presumably need to abrogate *its* protection of those secrets. Is the Administration contemplating waiving its protection of U.S. trade secrets, and if so what is the legal authority for that?

- We understand that the Administration's position is to limit the scope of the waiver of IP to COVID-vaccines. For advanced technologies such as mRNA vaccines, however, sharing IP will require sharing the entire platform of underlying enabling technology, which can then be used to develop other products that compete with the products of American companies in areas unrelated to COVID vaccines. Does the Administration in negotiations support the compulsory sharing of such platform technologies?

- Does the Administration plan to implement its approach to the TRIPS waiver in accordance with its "worker centric" trade policy? Specifically, will its negotiating strategy work to prevent the off-shoring of existing or future U.S. vaccine capacity, and the potential loss of U.S. jobs that would result?

- Does the Administration intend to implement its negotiating strategy in a way consistent with its policy of promoting more resilient global supply chains, which includes less dependence on foreign sourcing for critical products (such as COVID vaccines)? If so, how will that be done?

This is only an initial listing of questions from America's world-leading biotechnology sector. We look forward to working with you in the coming months to address them, but most

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importantly, to take those steps that really will have an impact on ensuring that people around the world will get safe, quick access to COVID vaccines and treatments.

Yours Sincerely,

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