Alliance for Biosecurity

May 5, 2023

Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street SW
Washington, DC 20436

Dear Secretary Barton:

Please find below written comments from The Honorable Jack Kingston, on behalf of the Alliance for Biosecurity, responding to USITC Investigation No. 332-596. This submission does not include Confidential Business Information.

Sincerely,

The Honorable Jack Kingston
Squire Patton Boggs
Secretariat, Alliance for Biosecurity

The Alliance for Biosecurity (Alliance) is a coalition of biopharmaceutical companies that promotes strong public-private partnerships as a means to ensuring that medical countermeasures (MCMs) are available to protect public health and enhance national health security. As strong advocates of public policies that support these goals, we are grateful for the opportunity to comment on the proposed expansion of the intellectual property (IP) waiver under the TRIPS Agreement to include COVID-19 diagnostics and therapeutics.

The Alliance strongly urges the U.S. government to reject this expansion. Much like the original waiver, this expansion would do nothing to increase the supply of treatments and tests to developing countries, because it would not address the main issues preventing their uptake, such as infrastructure challenges in developing countries. Granting this expansion would, however, pose issues for our national security.

The primary reason that expanding this waiver would not improve the supply and distribution of COVID-19 diagnostics and therapeutics to patients around the world is that there is already an overabundance of these products. Over 70 million courses of COVID-19 antivirals have already been produced, an amount that far exceeds the 19 million needed in 2022. Additionally, the industry has built up stockpiles of more than 30 million courses of these diagnostics and therapeutics, far more than enough to exceed anticipated total global demand in 2023.

Importantly, this abundant supply of COVID-19 treatments was made possible <u>because</u> of IP rights, <u>not in spite of them</u>. That is because companies rely on IP protections when making new investments in research and development. Without IP rights, they would not risk billions of

dollars to turn that basic research into experimental treatments that may – or may not – make it to patients. To date, companies have spent over $24 billion on clinical trials for over 1,200 COVID-19 vaccines and treatments. And as you know, the costs of drug development are only increasing in the wake of COVID-19, with the average cost of developing a new drug among the top 20 global biopharmaceutical companies rising 15% in 2022 –bringing the cost to approximately $2.3 billion according to a new analysis from Deloitte.

IP protections also incentivize pharmaceutical companies to share medical technology because they prevent others from copying a treatment without a licensing agreement. In fact, IP protections underpin over 140 agreements between American companies and global partners in more than 30 countries to develop and distribute COVID-19 treatments.

The only thing that waivers such as these do is undermine the ability of government and biopharmaceutical companies, including our members, to partner with one another in developing and distributing future medical innovations and sharing relevant technology in the face of public health emergencies. In that regard, granting this expansion would weaken our response not just to COVID-19, but also to the next pandemic.

Perhaps the most concerning result of expanding the waiver would be requiring that sensitive biological research and technology be handed over to America's geopolitical adversaries – including, potentially, to state-owned companies in countries like China and Russia.

U.S. leadership has been and will remain central to global success against COVID-19. But, as noted above, undermining IP protections would do nothing to address access and distribution challenges. It would, however, compromise America's ability to prepare for the next natural or manmade disaster, without alleviating those challenges.

Already, few companies choose to be part of the enterprise that delivers countermeasures for chemical, biological, nuclear, or radiological (CBRN) threats due to its challenging business model when compared with other products they could develop – even though these MCMs are critical to national, economic, and health security. And yet, the expansion of this waiver suggests that the reward for companies that work to develop, manufacture, and scale COVID-19 treatments and bring these products across the finish line is for the government to undermine their IP rights. The United States should be working to build on the success of these breakthroughs, not undermine them.

The COVID-19 pandemic has presented the greatest global health crisis of the last hundred years. Industry responded by accelerating the production of treatments to rates unimaginable even 20 years ago, without compromising safety. Rather than undermining IP protections, policymakers should be focused on removing trade barriers and shoring up global supply chains to safely and efficiently speed up the manufacturing and distribution of these treatments.

We believe that protecting American IP will make the world better equipped to fight future pandemics and thus urge the U.S. government to oppose this expansion of the TRIPS waiver petition.

Thank you for the opportunity to submit comments and for considering our opposition to the expanded TRIPS waiver petition.

Sincerely,

The Honorable Jack Kingston
Squire Patton Boggs
Secretariat, Alliance for Biosecurity