

The Honorable Gina M. Raimondo
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The White House
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Jacob Sullivan
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The White House
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The Honorable Katherine C. Tai
U.S. Trade Representative
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Jeffrey Zients
Coordinator of the COVID-19 Response and Counselor to the President
The White House
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April 15, 2021

Dear Secretary Raimondo, Ambassador Tai, Mr. Deese, Mr. Sullivan, and Mr. Zients:

We thank you for your leadership and understanding in recognizing the important role the innovation and creative industries in the United States play as the world faces one of the greatest healthcare challenges in history during the COVID-19 pandemic. The Biden Administration's commitment to trust science and persevere against the challenges this global threat poses by uniting rather than dividing communities will undoubtedly save many lives and livelihoods as our nation plays a central role in the worldwide recovery. American innovators and creators have always relied on stable and enforceable intellectual property (IP) rights to incentivize and bring to market discoveries and products. Indeed, this crisis demonstrates the primary importance of protecting and promoting IP rights that can be used in the marketplace to give innovation value, thereby facilitating collaboration between researchers and manufacturers, creators and educators, and small and large firms across the country who reoriented their efforts without delay—proactively—as the pandemic began in order to solve one of the world's hardest problems.

Unfortunately, the historical debate over whether medicines and related IP should be considered a global public good during times of a health emergency has emerged in the context of COVID-19

as well. India and South Africa have proposed and members of the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) at the World Trade Organization (WTO) are considering a proposal for an indefinite waiver “in relation to prevention, containment or treatment of COVID-19” of certain TRIPS obligations for IP rights. The waiver sought is to continue “until widespread vaccination is in place globally, and the majority of the world's population has developed immunity.” Notably, it is not limited to patents or applicable only to efforts to distribute current vaccines, but specifically enumerates other IP rights, including “industrial designs, copyright, and protection of undisclosed information.”¹

While we share the laudable goal of providing safe and efficacious vaccines and other tools to support containment and treatment of the pandemic to everyone, we urge that such a drastic decision to waive IP protections indefinitely for large swaths of the innovation sector globally should not be taken lightly. Importantly, the WTO IP rules already include flexibilities adopted in 2017 allowing for compulsory licensing and the importation of generics by poorer countries during times of global health crises, and it has not been shown that those flexibilities are insufficient prior to proposing this drastic expansion. Moreover, the affected industries are already proactively collaborating and ensuring broad diffusion of knowledge and know-how both domestically and internationally.

- Scientific publishers have made crucial technological information and tools related to the coronavirus widely available to the public and to researchers in both text and machine-readable formats to allow for full text and data mining using Artificial Intelligence with rights in place for research reuse and secondary analysis. Likewise, publishers like Elsevier are also making early-stage and peer-reviewed research available with special cataloguing to meet the differing needs of researchers, clinicians, and patients, and with special resources related to anxiety and other mental health challenges associated with the pandemic. Elsevier has also launched a tool for clinical researchers that enables them to capture clinical trial data securely. This tool is being made available for free.
- Biotechnology and pharmaceutical companies have made significant investments in R&D, production, and manufacturing, devoting enormous resources and expertise to developing safe and effective vaccines, medicines, and diagnostics as quickly as possible. Creating, testing, and implementing safe solutions is a monumental task that costs hundreds of millions of dollars and countless hours of work, and it is the incentives offered by the IP system that support these vast undertakings. Rather than IP acting as a hindrance, IP has helped the innovation industries create partnerships where technical know-how is shared collaboratively through licensing agreements that speed up the R&D and manufacturing process. Given the complexity of manufacturing vaccines, the time required to ramp up production, and the difficulty in sharing know-how, we cannot know if waiving IP rights would speed up the current vaccine rollout in countries with different IP regimes than ours. What we do know is that companies are likely to be reluctant to spend substantial resources and effort in the future, if their IP can be taken after the fact.

¹ World Trade Organization, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Treatment and Containment of COVID 19: Communication of India and South Africa* (Oct. 2, 2020), available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:IP/C/W669.pdf&Open=True>.

For these reasons, we urge the Biden Administration to support American scientists, innovators, manufacturers, and creators who through their innovations and discoveries are leading the fight against the pandemic by opposing the Indian and South African request.

Sincerely,

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*Affiliations for all signatories are provided solely for identification purposes