

December 2, 2022

The Honorable Katherine C. Tai
United States Trade Representative
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Tai:

On behalf of patients battling illnesses such as cancer, HIV, diabetes, genetic disorders, and antibiotic-resistant infections, we write to convey our profound opposition to recent actions supported by the Biden administration regarding intellectual property (IP) protections and express our concerns with potential actions that may further erode IP protections that are necessary to produce lifesaving medicines.

Recently, the Biden administration supported at the World Trade Organization (WTO) waiving the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 vaccines. Such drastic and unprecedented action was totally unnecessary to improving worldwide access to COVID-19 vaccines and will curtail research for vaccines to stop future viruses and diseases that we do not even know about. We share in the American people's generosity and commitment to ensuring people around the globe have access to vaccines and medicines. However, it is well known that there is adequate supply of COVID vaccines, but vaccine hesitancy along with an inadequate healthcare delivery system have been the greatest barriers to vaccine uptake, especially in the African continent.¹

Now the WHO is considering relaxing the TRIPS waiver for diagnostics and therapeutics. We strongly urge the Biden administration to oppose extending the TRIPS waiver any further.

Doing so would be devastating to patients living with illnesses for which there are few or no reliable treatments or cures, and also further challenge efforts to develop and deliver new novel antimicrobials which we are in desperate need of globally given the estimated 1.2 million related deaths annually.² Similarly, 38 million people worldwide are living with HIV, the virus that causes AIDS, an illness responsible for tens of millions of deaths.³ It's also important to consider the approximately 50 million people living with Alzheimer's disease or other dementias, a

¹ https://urlisolation.com/browser?clickId=427ACE46-7C31-4258-AC63-41A3371F5EDE&traceToken=1669905628%3Bphrma_2_hosted%3Bhttps%3A%2Fgafpa.org%2Fwp-content%2Fuplo&url=https%3A%2F%2Fgafpa.org%2Fwp-content%2Fuploads%2F2022%2F05%2FGAfPA-FF-VaccinesInDevelopingCountries_May2022.pdf

² <https://www.cdc.gov/drugresistance/national-estimates.html#:~:text=Antimicrobial%20resistance%20is%20an%20urgent,resistant%20infections%20occur%20each%20year>

³ <https://www.kff.org/global-health-policy/fact-sheet/the-global-hiv-aids-epidemic/#:~:text=HIV%2C%20the%20virus%20that%20causes,the%20beginning%20of%20the%20epidemic>

number that could grow to 152 million by 2050,⁴ and more than 10 million people worldwide with cancer.⁵

Patients who live with these conditions desperately need new medicines, but breakthroughs are far less likely without the robust IP protections that enable drug manufacturers to recoup the enormous costs associated with new drug research and development. Novel drugs often take over a decade to make it to market at a cost of over \$2 billion.^{6 7}

Weakening global IP protections would punish patients at a moment when hope is just around the corner. Extending the TRIPS waiver could jeopardize many of the over 8,000 medicines currently in development, including medicines with potential dual or multiple applications beyond treating only COVID-19.⁸ Jeopardized medicines include an HIV vaccine, revolutionary Alzheimer's treatments, gene therapies, and a potential cure for hepatitis B.^{9 10 11 12} As of 2020, there were well over 1,000 treatments in the pipeline for cancer alone.¹³

TRIPS and other IP protections have bolstered, not hindered, patient access during the pandemic. International respect for IP has made possible an extensive network of voluntary licensing and manufacturing agreements around the world. These agreements include Pfizer's commitment to allow generic production of its Covid-19 therapeutic, Paxlovid, in 95 low- and middle-income countries and Merck's efforts to expand access to its Covid-19 oral antiviral, molnupiravir, in 105 low- and middle-income countries.^{14 15} These advances would not have been possible without a universal understanding and expectation that the IP manufacturers rely on would always be protected.

As patient advocates, we admire efforts to improve patient access and reduce global health inequities. But undermining IP rules is a shortsighted and self-defeating way to accomplish these critical goals. A TRIPS waiver extension inevitably would end in more unnecessary future patient suffering and stem innovation for future treatments and cures.

Thank you for your time and attention to this urgent matter.

Respectfully submitted,

⁴ <https://www.brightfocus.org/alzheimers/article/alzheimers-disease-facts-figures>

⁵ [https://www.webmd.com/cancer/how-many-cancer-deaths-per-year#:~:text=In%202021%20\(the%20latest%20year,and%20about%2080%2C000%20in%20Canada.](https://www.webmd.com/cancer/how-many-cancer-deaths-per-year#:~:text=In%202021%20(the%20latest%20year,and%20about%2080%2C000%20in%20Canada.)

⁶ <https://lifesciences.n-side.com/blog/what-is-the-average-time-to-bring-a-drug-to-market-in-2022>

⁷ <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub>

⁸ <https://phrma.org/Scientific-Innovation/In-The-Pipeline>

⁹ <https://www.biopharma-reporter.com/Article/2021/04/15/Moderna-to-take-mRNA-flu-and-HIV-vaccines-into-Phase-1-trials-this-year>

¹⁰ <https://abc7chicago.com/mrna-covid-vaccine-pfizer-moderna/10734145/>

¹¹ <https://abc7chicago.com/mrna-covid-vaccine-pfizer-moderna/10734145/>

¹² <https://www.nature.com/articles/d41586-022-00812-1>

¹³ [https://phrma.org/Scientific-Innovation/In-The-Pipeline/Medicines-in-Development#:~:text=Today%2C%20more%20than%201%2C300%20medicines,and%20Drug%20Administration%20\(FDA\).](https://phrma.org/Scientific-Innovation/In-The-Pipeline/Medicines-in-Development#:~:text=Today%2C%20more%20than%201%2C300%20medicines,and%20Drug%20Administration%20(FDA).)

¹⁴ <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-medicines-patent-pool-mpp-sign-licensing>

¹⁵ <https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countries/>

Autoimmune Association
Global Colon Cancer Association
Global Alliance for Patient Access
HIV+Hepatitis Policy Institute
ICAN—International Cancer Advocacy Network
Partnership to Fight Chronic Disease (PFCD)
Partnership to Fight Infectious Disease (PFID)
Patients Rising Now

cc: United Nations
World Health Organization
World Intellectual Property Organization
World Trade Organization