

United States Senate
WASHINGTON, DC 20510

VIA ELECTRONIC TRANSMISSION

October 7, 2021

The Honorable Katherine C. Tai
United States Trade Representative
600 17th St. N.W.
Washington, D.C. 20508

Dear Ambassador Tai:

I write you again today for the fourth time about the Biden Administration's waiver of international obligations under the Trade-Related Aspects of Intellectual Property Rights, or TRIPS agreement.¹

Last week, several open-content organizations wrote to President Biden and argued that your proposed TRIPS Waiver should cover not just patents, but also copyright and other intellectual property rights.² These organizations ask that you include copyright simply because it may apply to software, medicine labels, manuals, or "tools" associated with vaccines. The letter fails to address the importance of these protections to the economy, trade, and employment, the limitations placed on protections to ensure a balanced system, and how copyright protection facilitates the very innovation, creativity, and knowledge sharing that will make it possible for us to end this once in a lifetime pandemic. The inclusion of copyright is both unsubstantiated and unwarranted, and would impose devastating consequences on American creators, businesses and workers, while doing nothing to advance the objective of combatting COVID.

Our laws, as guided by our Constitution, recognize the importance of intellectual property rights, including copyright.³ Our laws also implement international agreements which help form a global innovation infrastructure, such as the Senate-ratified Berne Convention which protects copyright internationally. The United States, led by the US Trade Representative, has historically played a leadership role in establishing adequate and effective protection of intellectual property

¹ A group of 16 Senators, including myself, asked for information about this disastrous decision in May, and Senator Cotton and I followed up in May. We have yet to receive any formal response from USTR. See Annexes 1 and 2. In April, I sent a letter expressing concerns. See Annex 3.

² InfoJustice, *Civil Society Letter to President Biden: TRIPS Waiver Must Apply to All Intellectual Property Rights, Not Just Patents*, September 27, 2021, <http://infojustice.org/archives/43686> (last accessed, Oct. 6, 2021).

³ Article I, Section 8, clause 8 provides Congress with the power to promote the "Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

rights worldwide, including through its annual Special 301 report which specifically names countries that fail to adequately protect copyright and thereby harm our economic interests.⁴

The proposed TRIPS Waiver ignores these important laws and commitments.⁵ We bind ourselves to these international intellectual property treaties for a purpose, and waiving obligations is not an exercise that should be taken lightly.

Our nation's copyright system supports creators and industries that collectively add over \$1.5 trillion dollars to the American economy, employ 5.7 million hard-working Americans, and contribute more than \$200 billion in exports.⁶ Yet a handful of organizations with no apparent particular medical industry expertise assert that copyright "hinders the use of critical tools for manufacturing and repairing medical equipment to treat patients."⁷ Nor do they provide any evidence beyond speculating that the "tools" may be subject to copyright to suppose that this poses a problem to the industry.

They point to evidence of only one company attempting to enforce its rights by sending "take down notices to those who share critical service information." Copyright law does not prohibit sharing critical service information. Instead it establishes that such sharing must be done with authorization, either by the law or the copyright holder. "Sharing" that which isn't yours or which you don't have the right to share is simply "theft". By ignoring the value in the underlying copyrighted works, and stigmatizing rights holders' legitimate attempts to address a dispute, the examples referenced in the letter reveal the letters writers' broader anti-copyright bias. Nor does their letter establish why a wholesale revocation of copyright or other intellectual property law is the solution to the COVID-19 pandemic.

I have established that I am firmly committed to making necessary reforms to our nation's intellectual property system. If reform is needed to address certain issues, like a right to repair for medical diagnostic equipment, then such reforms should take place in Congress and in a transparent manner that accounts for different perspectives. It is alarming that the TRIPS waiver should be pursued with no public discussion. As of the date of this letter, we have received no response or formal acknowledgement of our earlier request for responses from USTR.

This race to cure COVID is our generation's equivalent of landing a man on the moon. The solution will require the innovation and expertise of thousands of American companies and millions of hard-working, creative, and innovative Americans. We cannot undermine this innovation and creativity by weakening our nation's strong intellectual property rights, the very rights which have led to the rapid development of new treatments and diagnostics. I urge you to consult with the intellectual property experts within the Biden Administration, to respond to Congress's letters, and provide the American public with answers to the many questions

⁴ See, e.g. Office of the United States Trade Representative, 2021 Special 301 Report, [https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20\(final\).pdf](https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf)

⁵ The TRIPS Waiver would appear to apply only to Part II of the TRIPS Agreement, leaving in place the recognition that "nothing shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention..."

⁶ International Intellectual Property Alliance, Copyright Industries in the U.S. Economy, the 2020 Report (2020).

⁷ See Letter, n.2 above.

surrounding your May policy statement, and to abandon this disastrous and ill-conceived waiver of our nation's intellectual property rights.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Thom Tillis
Thom Tillis
United States Senator

ANNEX 1

Letter from Senators Cotton, Tillis, Grassley, Crapo, Lankford, Lee, Ernst, Sasse, Sullivan, Cramer, Young, Burr, Wicker, Blackburn, Rounds, and Daines

to

Ambassador Tai

(May 19, 2021)

United States Senate

WASHINGTON, DC 20510

VIA ELECTRONIC TRANSMISSION

May 19, 2021

The Honorable Gina M. Raimondo
Secretary
United States Department of Commerce
1401 Constitution Ave. N.W.
Washington, D.C. 20230

The Honorable Katherine C. Tai
United States Trade Representative
600 17th St. N.W.
Washington, D.C. 20508

Dear Secretary Raimondo and Ambassador Tai:

We write you today regarding President Biden's disastrous decision to support the waiver of the Trade-Related Aspects of Intellectual Property Rights or TRIPS agreement in relation to the prevention, containment, or treatment of COVID-19. The waiver, which is not limited to vaccines, will do nothing to end this global pandemic. Instead, it will undermine the extraordinary global response that has achieved historically remarkable results in record time and our nation's global leadership in the technologies, medicines, and treatments of the future.

Intellectual property rights provide the legal basis for our innovation and creative economy. Simply put, strong intellectual property rights are why the United States leads the world in IP intensive industries like the life sciences, biopharmaceuticals, precision medicine, and diagnostics. As we work to meet the challenge of the COVID-19 pandemic, this leadership has benefited our country and the world. As you both know, last year America's innovative biopharmaceutical companies developed life-saving vaccines. These companies spent substantial sums to develop these treatments and, as of this writing, have produced billions of vaccine doses for the world. Their innovation, ingenuity, and commitment to global health is responsible for the dramatic decline in the pandemic we are seeing both in America and across the globe.

Unfortunately, almost immediately after these vaccines were proven to work, China and other countries which regularly steal American intellectual property—like India and South Africa—began urging the World Trade Organization to grant a TRIPS waiver. These nations are falsely claiming that granting such a waiver would speed the development of new vaccine capacity. Nothing could be further from the truth.

The reason why there are not enough vaccine doses at this time is simple: the supply chain lacks the technological capacity. Vaccine production is a complex technical and logistical process, with limited technical resources (e.g., skilled scientists and technicians at companies). At best, all President Biden's giveaway to China and India and others will do is foster uncoordinated vaccine nationalism, as countries jump in to try to coerce technology transfer and manufacturing locally. At worst, this action will provide a boost to the Chinese Communist Party's "vaccine diplomacy"

and enable Beijing to undercut American leadership on vaccine distribution throughout the developing world.

It is not surprising that China, India, and South Africa want to steal our intellectual property and medical technology. What is surprising is that an *American* president, especially one who claims to be a “jobs” president, would force American companies to give their medical technology and manufacturing processes to foreign adversaries like China. Simply put, the Biden Administration’s support for a TRIPS waiver puts America’s interests last and China’s interests first.

Our concerns with the Administration’s decision are serious, and the American people deserve to understand exactly how President Biden reached this conclusion. Accordingly, and in order to help us better understand this decision to support intellectual property theft and forced technological transfer, we ask that you answer the following questions by no later than June 19, 2021:

1. Will you provide and describe a list of all meetings with foreign officials where the TRIPS waiver was discussed? Specifically, did anyone in the Administration speak with any Chinese, Indian, or South African officials regarding the TRIPS waiver and, if so, what were the contents of those discussions?
 - a. Did President Xi ask that the Administration grant a waiver when he spoke with President Biden in March?
 - b. Did the Administration coordinate its decision to negotiate a waiver with key allies including the United Kingdom, Germany and the European Union?
2. As you both know, the proposed TRIPS waiver merely *allows* member nations to waive domestic IP protections and enforcement. Does the Biden Administration plan on waiving American intellectual property laws? Does the Biden Administration plan on waiving domestic intellectual property enforcement, including enforcement against intellectual property and trade secret theft?
 - a. Under this scenario, what would happen if a Chinese national is found to have stolen trade secrets? Under the waiver, if adopted, would they not be prosecuted? And, what of the Chinese nationals currently being prosecuted? Would those cases now be dropped?
 - b. How would this be implemented -- would private citizens be denied their ability to protect or enforce intellectual property rights in U.S. courts?
 - c. Does this Administration plan to merely ignore its obligations at the World Intellectual Property Organization?
3. Please quantify how many countries have ever used the TRIPS flexibilities since 2001, including the TRIPS amendment on compulsory licensing for export.
4. Was the Biden Administration’s support for a TRIPS waiver premised on China, Russia, South Africa, India, or any other nation state supporting other foreign policy priorities of the Administration? Specifically, was support for a TRIPS waiver predicated on foreign countries supporting any of the Administration’s international climate priorities?

5. Does the Administration plan on making any additional intellectual property concessions to foreign nations?
6. What evidence did the Administration rely on to conclude that IP was a barrier to vaccine manufacturing and that the benefits of waiving IP protections outweighed the potential costs, which include, but are not limited to: diminished incentives for investment, increased supply chain competition, and the ability for manufacturers to negotiate voluntary licenses?
7. What impact will the TRIPS waiver have on America's domestic intellectual property industries, specifically biopharmaceutical manufacturing? Biopharmaceutical manufacturing provides good-paying jobs for hundreds of thousands of American workers, whose livelihoods will be adversely impacted by this decision. What will you do to support these workers and how do you reconcile this decision with the Administration's desire to be a "jobs" president?
8. What impact will this decision have on the long-term health of our nation's innovation economy? Do you believe this decision will detrimentally impact America's continued leadership in biopharmaceutical innovation?
9. Does the Administration intend to replicate this action with other vaccines or biotechnologies in the future, such as treatments for malaria, Alzheimer's, or Parkinson's that are currently in development? Have you considered how this decision will adversely affect the financing of future vaccines due to the lack of confidence in this Administration to defend American intellectual property protections?
10. Does the Administration plan to submit the text of any waiver to TRIPS that it negotiates at the WTO to Congress for approval? Will the Administration commit to respecting the role of legislative branch and refrain from unilaterally overriding or amending the terms of a Congressionally-approved agreement without approval from Congress?

Thank you for your prompt attention to this matter. We look forward to your responses and we hope you will advocate a reversal of this disastrous policy to President Biden. If you have any questions, please do not hesitate to contact us.

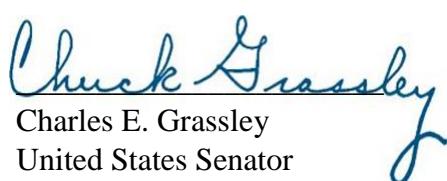
Sincerely,



Tom Cotton
United States Senator



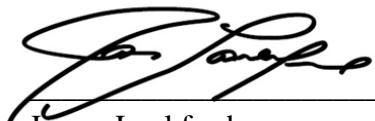
Thom Tillis
United States Senator



Charles E. Grassley
United States Senator



Mike Crapo
United States Senator



James Lankford
United States Senator



Mike Lee
United States Senator



Joni K. Ernst
United States Senator



Ben Sasse
United States Senator



Dan Sullivan
United States Senator



Kevin Cramer
United States Senator



Todd Young
United States Senator



Richard Burr
United States Senator



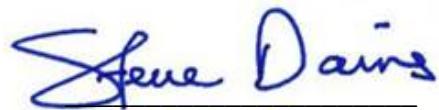
Roger F. Wicker
United States Senator



Marsha Blackburn
United States Senator



M. Michael Rounds
United States Senator



Steve Daines
United States Senator

cc: The Honorable Joseph R. Biden
President of the United States
1600 Pennsylvania Avenue NW
Washington, D.C. 20500

ANNEX 2

Letter from Senators Cotton and Tillis

to

Ambassador Tai

(July 14, 2021)

United States Senate
WASHINGTON, DC 20510

VIA ELECTRONIC TRANSMISSION

July 14, 2021

The Honorable Gina M. Raimondo
Secretary
United States Department of Commerce
1401 Constitution Ave. N.W.
Washington, D.C. 20230

The Honorable Katherine C. Tai
United States Trade Representative
600 17th St. N.W.
Washington, D.C. 20508

Dear Secretary Raimondo and Ambassador Tai:

We write you today regarding the letter we sent with twelve of our colleagues—including the Ranking Members of the relevant committees of jurisdiction—about the Biden Administration’s disastrous proposed waiver of Trade-Related Aspects of Intellectual Property Rights, or TRIPS agreement. In that letter, we posed ten specific questions about the proposed TRIPS waiver and asked for answers by June 19. We have attached a copy of that letter and the corresponding questions for your reference.

As of the date of this letter, we have not received a formal response to our letter answering our specific questions. We have received a cursory, perfunctory, and dismissive response from your offices. This response was totally inadequate and failed to respond to congressional oversight.

Accordingly, we write today to ask when we will receive a formal response to the ten specific questions we asked in our May 19 letter. Please formally reply to this correspondence by no later than July 31, 2021 with an exact deadline of when we will receive answers to our questions. Failure to give specific answers to our questions—and the questions of twelve of our colleagues—will result in us taking appropriate action to ensure congressional oversight of this important matter.

The choice is yours. We look forward to your reply. If you have any questions, please do not hesitate to contact us.

Sincerely,



Tom Cotton
United States Senator



Thom Tillis
United States Senator

ANNEX 3

Letter from Senator Tillis

to

Ambassador Tai

(April 16, 2021)

VIA ELECTRONIC TRANSMISSION

April 16, 2021

The Honorable Gina M. Raimondo
Secretary
United States Department of Commerce
1401 Constitution Ave. N.W.
Washington, D.C. 20230

The Honorable Katherine C. Tai
United States Trade Representative
600 17th St. N.W.
Washington, D.C. 20508

Dear Secretary Raimondo and Ambassador Tai:

I write you today in my capacity as the Ranking Member of the Senate Judiciary Committee Subcommittee on Intellectual Property. I write specifically regarding a disastrous proposal by India and South Africa to waive the Trade-Related Aspects of Intellectual Property Rights or TRIPS agreement in relation to prevention, containment, or treatment of COVID-19.

I am concerned the Biden Administration is being urged to support this broad and open-ended waiver in the mistaken belief that it will promote broader access to vaccines needed to halt the spread of this terrible pandemic. The waiver, which is not limited to vaccines, would do nothing of the sort. Rather, it would undermine the extraordinary global response that has achieved historically remarkable results in record time and undermine our nation's global leadership in the technologies, medicines, and treatments of the future.

Intellectual property rights provide the legal basis for our innovation and creative economy. Simply put, strong intellectual property rights are why the United States leads the world in IP intensive industries like the life sciences, biopharmaceuticals, precision medicine, and diagnostics. As we work to meet the challenge of the COVID-19 pandemic, this leadership has benefited our country and the world. Of the more than 800 global development projects to create vaccines, treatments and diagnostics launched around the world, approximately half were generated from the United States and, significantly, about three-quarters are from small- and medium-sized enterprises.

A disastrous TRIPS waiver can do nothing to speed the development of new capacity, which requires the active cooperative involvement of the vaccine originator companies, which need to transfer not just patents but specific know-how. This is a complex technical and logistical process, with limited technical resources (e.g., skilled scientists and technicians at companies),

that is best coordinated collectively. A TRIPS waiver would foster uncoordinated vaccine nationalism, as countries jump in to try to coerce technology transfer and manufacturing locally. Companies could not possibly comply with all the potential mutually contradictory requests, nor would it be an efficient means of creating new global manufacturing capacity.

Equally as important, this proposed waiver is not “limited”. It contains no time or technology limits and it does not require governments to consult in advance with companies nor compensate them. Any such limits are non-enforceable in any case, since the waiver exempts countries from WTO dispute settlement. This means that foreign nations—nations which did not invest in the research and development of revolutionary vaccines and treatments—can demand any technology with the loosest connection to COVID without recourse.

The waiver’s main concrete impact would therefore be to legitimate the transfer of American technologies to foreign competitors. China and India, for example, lag in or totally lack in the development of mRNA technologies and applications. The waiver, without limits on scope, creates an uncontested opportunity for them to demand such technology transfers. These technologies are not just used for COVID vaccines. Their transfer would allow for the creation of entire industries in these countries that will compete with American companies in the development of cutting-edge health care technologies.

This competition would be allowed without any compensation to the American innovators and, with the explicit acquiescence of our government, make it virtually impossible to undo them in any future trade negotiations over intellectual property rights. As much as we have protested forced technology transfer and outright intellectual property theft in recent years, it makes no sense for the Biden Administration to support the disastrous waiver of all intellectual property rules that would allow our foreign competitors to gain free and unfettered access to our most advanced technologies. That is hardly the worker-centric, job-centric trade policy the President has advocated and promised to hardworking taxpayers.

For all these reasons, I ask that you oppose any and all efforts aimed at waiving intellectual property rights. You must continue the longstanding, bipartisan American policy of supporting strong intellectual property rights. America’s innovation economy is depending on you to support the continued enforcement of the TRIPS agreement. Thank you for your attention to this matter. I look forward to your response, and I hope that I can count on your support in this matter.

Sincerely,



Thom Tillis
Ranking Member
Subcommittee on Intellectual Property