IP AND STRATEGIC COMPETITION WITH CHINA: PART II—PRIORITIZING U.S. INNOVATION OVER ASSISTING FOREIGN ADVERSARIES

HEARING

BEFORE THE

SUBCOMMITTEE ON COURTS, INTELLECTUAL PROPERTY, AND THE INTERNET

OF THE

COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

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C O N T E N T S

TUESDAY, JUNE 6, 2023

IP AND STRATEGIC COMPETITION WITH CHINA: PART II—PRIORITIZING U.S. INNOVATION OVER ASSISTING FOREIGN ADVERSARIES

Tuesday, June 6, 2023

HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON COURTS, INTELLECTUAL PROPERTY, AND THE INTERNET

COMMITTEE ON THE JUDICIARY

Washington, DC

The Subcommittee met, pursuant to notice, at 10:05 a.m., in Room 2141, Rayburn House Office Building, Hon. Darrell Issa [Chair of the Subcommittee] presiding.

Present: Representatives Issa, Massie, Fitzgerald, Cline, Kiley, Lee, Johnson, Lieu, Ross, Schiff, Dean, and Ivey.

Mr. ISSA. The Subcommittee will come to order.

Without objection, the Chair is authorized to declare a recess at any time.

We welcome everyone here today for a Hearing on Intellectual Property and Strategic Competition with China. I will now recognize myself for a brief opening statement.

We are here today because intellectual property protection is vital. In fact, the United States is and remains a—or has been and remains a leader in intellectual property, but also in respect for intellectual property. In fact, second only to the United Kingdom, we are the oldest country to incorporate intellectual property in the underpinning of our law and, in fact, in our Constitution.

The medical innovations and scientific rigor that developed COVID–19 vaccines, for example, are no less an invention than anything else that we would invent now or in the future. In fact, those inventions find themselves at risk because of Executive action under TRIPS by the President of the United States.

In May 2020, the Trump Administration announced Operation Warp Speed to provide billions in taxpayer dollars to companies developing COVID–19 vaccines. Those companies, in many cases, moved from other projects to doing this project to save lives here and around the world. Unfortunately, during the COVID–19 pandemic, the WTO voted to permit member Nations, including the People's Republic of China, to waive IP protections on COVID–19

vaccine technology, much of which was developed in the United States and Europe, by our taxpayers.

The Biden Administration regrettably endorsed this action, one that I believe goes to very core of that Constitutional protection, not just the Constitutional protection of the right to have works of art and inventions be protected but, in fact, the taking of real property without compensation. This means that, in fact, there are two Constitutional principles at risk here.

The abuse, as I would frame it, came without reason, though, and not one Nation has acted on the waiver. That's the good news. The good news is that, in fact, there is no direct damage as we speak today. We are speaking more about future consideration of TRIPS waiver.

Arguably, we should be here today—arguably, we should be here today to push for waivers of rescission on a bipartisan basis before or unless China was to take advantage of their opportunity and seize the technology in a nonrecoverable way.

As we know, it is irresistible for countries around the world to buy at the lowest possible price medicines and other products, and they do so without, per se, disrespect for invention, but knowing that often intellectual property has not been respected in the production of it.

This is why I'm proud to introduce No Free TRIPS Act today with Senator Marsha Blackburn of Tennessee. The bill would simply require any Presidential Administration to receive congressional approval to waive targeted portions of the agreement on trade relations aspects of intellectual property—short reason we call it TRIPS—for all members of the World Trade Organization.

This commonsense idea that the underlying body should have to confer, and the body that can, in fact, appropriate funds to compensate those who might have a taking, must be considered. Presidents could do a great many things. They cannot appropriate money to compensate for a taking of this magnitude.

Any expansion of the TRIPS waiver agreement will undermine the very innovation, record-breaking rapid development that we saw for COVID–19. For that reason, we are here today to talk not just about the risk of helping China, but the very risk to the innovation that we all enjoy here in the United States if we do not speak strongly in favor of respect for intellectual property.

With that, I'm pleased to yield back and introduce the Subcommittee Ranking Member, Mr. Johnson.

Mr. JOHNSON of Georgia. Thank you, Mr. Chair, for holding this hearing.

The U.S. intellectual property system is one of our crown jewels and is essential to promoting innovation and driving economic growth in this country. To ensure that our IP rights are respected around the world, the U.S. has entered into the World Trade Organization agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS.

The TRIPS agreement has successfully fostered protection of IP for nearly three decades, and we should approach any encroachment on these rights with caution. When extraordinary circumstances exist, sometimes we must take extraordinary measures.

The COVID–19 pandemic, which has taken the lives of nearly seven million people to date and which continues to rage across the globe, is one such extraordinary circumstance. That's why I supported a limited waiver of the TRIPS Agreement to help developing countries gain access to the lifesaving vaccines that they need to protect their citizens.

Not only do we have a moral imperative to help those in need, but we must also recognize that COVID–19 knows no borders. We cannot protect Americans from this deadly virus if we do not help other countries reduce the spread of the disease in their midst.

I want to thank the Biden Administration for undertaking the hard work of negotiating a narrow but important waiver under difficult circumstances. I know that this was not a decision that they undertook lightly, and I appreciate the careful balance that they struck between respect for intellectual property rights and the need to take extraordinary measures to end a global health emergency.

I do not dismiss the concerns of those who oppose the TRIPS waiver, particularly those who fear that the Chinese government will take advantage of the waiver to access American technology and to use this technology to compete with American companies.

We know that the Chinese government has a history of using theft and strong-armed tactics to acquire foreign intellectual property, which hurts our inventors' ability to compete and succeed. While we should not allow these concerns to stand in the way of protecting lives during a public health emergency, we should also ensure that proper guardrails are in place so that we do not facilitate placing our technology in the hands of our foreign competitors.

As the Biden Administration considers whether to support a proposal to expand the TRIPS waiver to include diagnostics and therapeutics, I hope that they will keep these important concerns in mind. I appreciate the careful and thoughtful process that they are undergoing, including requesting a study by the International Trade Commission, and I will reserve judgment on an expansion until the ITC completes its work.

In the meantime, I appreciate the opportunity to hear from our distinguished witnesses today, and I look forward to hearing their thoughts on the important issues before us.

Thank you, Mr. Chair, and I yield back.

Mr. ISSA. I thank the gentleman.

We will enter into the record the opening statements of the Chair, Mr. Jordan; the Ranking Member, Mr. Nadler; and all other members who wish to make an opening statement.

Without objection, those opening statements are placed in the record.

Mr. ISSA. We will now introduce the witnesses.

Mr. Marc Sedam is the Vice President of Technology Opportunities and Ventures at NYU Health and New York University. He has 30 years of experience as an inventor, Biotech Chief Operating Officer, and in commercializing intellectual property generated at universities. Prior to his current position, he served as Vice Provost for innovation and new ventures and Managing Director at UNH Innovations.

Next, we have Mr. Dennis Shea. Mr. Shea is the former Deputy U.S. Trade Representative and U.S. Ambassador to the World

Trade Organization. At the WTO, he led an interagency team charged with advancing U.S. interest on issues ranging from trade in goods and services to e-commerce and, of course, intellectual property protection, and agriculture. Mr. Shea previously was a member of the U.S.-China Economic and Security Review Commission and served as an interim Chair—as either the Chair or Vice Chair of that commission between 2012–2017.

Next, we have Professor Marc Busch. Mr. Busch is the Karl F. Landegger Professor—sorry about that—of International Business Diplomacy at Georgetown University of Foreign Service. He is also a global Fellow at the Wilson Center, and that Institute for Strategic Competition, and previously taught at Queen's University School of Business and Harvard University.

Mr. Edward Gresser is the Vice President for Trade and Global Markets at the Progressive Policy Institute. He previously served as Assistant U.S. Trade Representative for Trade Policy and Economics during the Obama Administration. He also is an adjunct Professor at Johns Hopkins University, where he lectures on intellectual economic policy.

We want to welcome our witnesses. We're very pleased to have a bipartisan distinguished group of intellectuals and knowledgeable actors in this area, including the expertise in trade and the WTO.

As is required by the Committee, would you please all rise to take the oath. Usual raising of the right hand.

Do you solemnly swear or affirm under penalty of perjury that the testimony you're about to give is the truth and correct to the best of your knowledge, information, and belief, so help you God?

Please be seated.

Let the record reflect that all witnesses answered in the affirmative.

As you know from watching C-SPAN, your entire opening statement will be placed in the record, so please limit yourself to five minutes so that we can get to questions and answers. I won't gavel somebody who's wrapping up, but, again, 20 minutes, 30 minutes, 40 minutes, no matter how long your current opening statement, nor extraneous material you may choose to add as a result of questions today, it will all be included in the record. So, nothing will be left out.

Additionally, it is the Committee's desire that you agree to take additional questions that may come from Members who are unable to get here today or who served on the Full Committee and are not here to ask questions.

Would all of you agree to do that?

Thank you for that free service. It is greatly appreciated, because you'll find that our questions will lead to your answers which will lead to other questions.

With that, we go in that order, starting with Mr. Sedam.

Now, the secret of turn on the mike and get very close to it. Thank you.

STATEMENT OF MARC SEDAM

Mr. SEDAM. Chair Issa, Ranking Member Johnson, and Members of the Committee, thank you for having me today. I'm Marc Sedam,

former Chairperson of AUTM. I also serve as Vice President for Technology Opportunities and Ventures at Langone Health in NYU, although I do want to make clear I'm here under my personal capacity.

So, I've been in the tech transfer business for almost 30 years as an inventor, as a startup COO, and as a university leader, and have firsthand experience in what it takes to move these nascent technologies into market. As you might be aware, AUTM represents the tech transfer community across the Nation and around the world. Over my career, I have worked with over a hundred companies that are bringing new products and ideas to market for the betterment of humanity.

By way of background, technology transfer refers to how innovations are taken from the lab, evaluated for commercial potential, and then developed by a patent or other IP rights to be licensed to a company for future development and commercialization. Ever since the Bayh-Dole Act was passed in 1980, universities and their partners have created over $1.3 trillion in economic benefit for the Nation, including thousands of patents, hundreds of new drugs, and other new technologies, and millions of jobs. It's also led to thousands of startup companies, most of which stay in the region around the university where they're formed. University tech transfer is a key component to regional economies.

If there's one overriding principle, I've learned during my time is that the patent is the key building block to innovation. Without strong IP rights, inventors have little chance of attracting the capital to develop that invention into a useful drug, technology, or product. The startup company I once ran, Qualyst, was able to operate successfully for over a decade, employing 15 people with high-paying jobs, on the backs of just a few patents and was sold in a successful exit.

Given the massive importance of patenting to innovation, particularly for university research, it's easy to see why universities, in general, are not supportive of TRIPS waiver that was issued last year by the WTO. The pandemic presented unprecedented challenges and laid bare inequities of access to vaccine technology globally. The vaccines which were developed in less than a year to fight COVID were the direct result of patent-based research done before the pandemic and expanded on to fight COVID. The problem with reaching worldwide populations with vaccines has been about distribution and not intellectual property.

Three of our Nation's leading higher education associations, including AUTM, recently filed comments before the ITC regarding a second proposal to expand the TRIPS waiver beyond vaccines into therapeutics and diagnostics. In those comments, we noted that since the approval of TRIPS waiver nearly one year ago, not one country declared its intent to take the waiver. The lack of use or intent to use TRIPS is a strong indicator that a further expansion of the waiver for diagnostics or therapeutics would yield a similar result. Thanks to those strong patent rights we sit here in this room, the pandemic declared over, without a single use of the TRIPS waiver.

The waiver of TRIPS is troubling on other levels. If future pandemics emerge, will the precedent of the WTO's action cause

less willingness by investors and pharma manufacturers to jump in to solve the crisis? Let's be clear, the WTO is already signaling that it may want to consider TRIPS waivers for other technologies. Leaders have discussed whether clean energy might be another appropriate use, agriculture. Where does it end?

Talk to early stage investors, as I do every day, and you'd understand the less risk we can create around funding already risky early technologies, the more likely those investors will be to make those investments. It's a simple calculation. Investors and university tech transfer leaders can handle known risks: Technical risk and market risk. Those things we understand. We can use our best judgment to figure out how to protect them, commercialize them, and get them to reach market.

When you add uncertainty to a risky situation, you'll stifle innovation, investment, and opportunity. Whether it's at the Patent Office or the WTO, patent uncertainty is an innovation killer. We simply must have a patent system both here and around the world that provides inventors and investors with the tools they need to move discoveries forward, with a clear understanding of those rights, once secured, cannot be arbitrarily taken away.

It's also why AUTM has raised serious concerns about potential misuse of "march-in provisions" of the Bayh-Dole Act. There is a process ongoing by the government to review march-in, and we believe loosening those provisions beyond limited exceptions in the original act could simply have a similarly negative effect on the willingness of partners to work with universities on any of the number of research projects.

My take-home message is that we all want to see new products and services developed to improve human health and create economic growth. Adding headwinds to the process of protecting and commercializing IP only increases the chances that those early ideas die on the vine and never progress into lifesaving opportunities.

Universities and medical research institutions have created a significant number of drug discoveries in the past 30 years. With the support of NIH and other agencies, our Nation has led the world in high-impact science, leading to many of the drugs Americans rely on every day. Actions like the TRIPS waiver put that process at risk. The potential expansion of such decisions to other technologies is simply wrong-headed.

Ultimately, we believe further waivers will simply mean fewer discoveries, new drugs, or new solutions to global problems in the future, and that it serves no one's best interest. We urge the Subcommittee to share its views in opposition to further expansion of the TRIPS waivers. I thank you for your time today and look forward to any questions.

[The prepared statement of Mr. Sedam follows:]

TESTIMONY OF

MARC SEDAM

BEFORE THE

HOUSE JUDICIARY COMMITTEE
SUBCOMMITTEE ON COURTS, INTELLECTUAL PROPERTY AND THE INTERNET

TUESDAY, JUNE 6, 2023

Chairman Issa, Ranking Member Johnson, members of the subcommittee:

I am Marc Sedam, former chairperson of the Association of University Technology Managers (AUTM). I also serve as Vice President for Technology Opportunities and Ventures at NYU Langone Health and New York University, though I want to make clear that I am appearing in my personal capacity. I have been in the technology transfer business for almost 30 years, as an inventor, university startup COO, and university leader and have first-hand experience at what it takes to move nascent technologies from lab to the marketplace. As you may be aware, AUTM represents the tech transfer community across the nation and around the world. Over my career I've worked with well over 100 companies who brought new ideas into society for the betterment of humanity.

By way of background, technology transfer refers to how innovations are taken from the lab, evaluated for potential commercial application, and then developed via a patent or other intellectual property rights to be licensed to a commercial entity for future development and commercialization. Ever since the Bayh-Dole Act was passed in 1980, universities and their commercial partners have created over $1.3 trillion in economic benefit for the nation, including thousands of patents, hundreds of new drugs and other new technologies, and millions of jobs. It has also led to thousands of startup companies, most of which stay in the region around the university where they are formed. University tech transfer is a key component to regional economies.

If there is one overriding principle I have learned during my time in tech transfer, it is that the patent – the acknowledgement of the value of an invention or idea – is the key building block to innovation. Without a strong patent and strong patent rights, inventors have little chance of attracting the venture capital that will develop that invention into a useful drug, technology, or product. The startup company that I ran, Qualyst, was able to operate successfully for over a decade, employing 15 people with high paying jobs, on the back of just a few strong patents until it was sold in a successful exit.

Given the massive importance of patenting to innovation – particularly for university research – it is easy to see why universities in general are not supportive of the TRIPS waiver that was issued last year by the World Trade Organization for COVID-related vaccines. The pandemic presented unprecedented challenges and laid bare inequities of access to vaccine technology globally. But the fact is that the vaccines which were developed in less than a year to fight COVID were the direct result of patent-based research done before the pandemic, which was expanded upon to fight COVID-19. The problem with reaching worldwide populations with vaccines is about distribution infrastructure, not intellectual property.

Three of our nation's leading higher education associations, including AUTM, recently filed comments before the International Trade Commission regarding a second WTO proposal to expand the TRIPS waiver beyond vaccines to include therapeutics and diagnostics. In those comments, we noted that since the approval of the TRIPS waiver for vaccines nearly one year ago, NOT ONE COUNTRY has declared its intent to make use of the waiver. The lack of use or

intent to use the TRIPS waiver is a strong indicator that any further expansion of the waiver to diagnostics or therapeutics would yield a similar result. Thanks to strong patent rights we sit here in this room, slightly more than three years since the COVID pandemic began, with that same pandemic declared over without a single use of the TRIPS waiver.

The waiving of TRIPS is troubling on other levels. If future pandemics emerge, will the precedent of WTO's action cause less willingness by investors and pharmaceutical manufacturers to jump in to solve the next crisis? And let us also be clear. WTO is already signaling that it may want to consider TRIPS waivers for other technologies beyond COVID. Leaders there have discussed whether clean energy technologies might be another appropriate use of TRIPS to help fight climate change. Agricultural advances have also been mentioned. Where does it end?

Talk to any investors in these technologies, as I do every day, and you understand that the less risk we can create around funding already-risky early technologies, the more likely those investors will be to make the investments needed to advance new discoveries. It's a simple calculation, really. Investors and university tech transfer leaders can handle known risks. Technical risk, market risks, development risks. We understand this and are trained to use our best judgement to file patent applications, sign licenses, and start companies with these "known unknowns". But add in *uncertainty* to an already risky situation and you'll stifle innovation, investment, and opportunity. Whether at the U.S. Patent Office or at the WTO, patent uncertainty is an innovation killer. We simply must have a patent system both here and

around the world that provides inventors and investors with the tools they need to move scientific discoveries forward and a clear understanding that those rights, once secured, cannot be arbitrarily taken away or ignored.

This is also why we have raised serious concerns about potential misuse of the "march-in provisions" of the Bayh-Dole Act. There is currently an ongoing process by the government to review its march-in procedures. We believe any loosening of those provisions beyond the limited exceptions included in the original act could have a similarly negative impact on the willingness of our corporate partners to work with us on any number of research projects. The key message to take home is that we all want to see new products and services developed to improve human health and create economic growth. Adding headwinds to the process of protecting and commercializing intellectual property only increases the chances that those early ideas never progress into life changing solutions.

American universities and medical research institutions have helped create most of the major drug discoveries of the past thirty years. With the strong support of the National Institutes of Health and other agencies, our nation has led the world in creating compounds that ultimately have become many of the drugs Americans depend upon every day. But actions such as the TRIPS waiver put that process at risk, and the potential expansion of such decisions to other technologies is simply wrong-headed.

Ultimately, we believe further waivers will simply mean fewer new discoveries, new drugs, or new solutions to global problems. And that serves no one's best interests.

We urge this subcommittee to share its views in opposition to any further expansion of TRIPS waivers. Thank you for your time today and I look forward to any questions you may have.

Mr. ISSA. Thank you, Mr. Sedam.
Mr. Shea.

STATEMENT OF THE HON. DENNIS SHEA

Mr. SHEA. Chair Issa, Ranking Member Johnson, and Members of the Subcommittee, I appreciate the opportunity to appear before you today. At the outset, let me emphasize I am speaking solely in my personal capacity.

In my testimony, I will share some thoughts on last year's decision at the WTO 12 Ministerial Conference waiving IP protections provided by the TRIPS Agreement for COVID–19 vaccines, as well as the possible extension of the waiver to COVID therapeutics and diagnostics.

The TRIPS Agreement requires WTO members to provide certain minimum standards of IP protection. Over the years, these protections have played an essential role in supporting innovation and the development of lifesaving medicines, diagnostics, and therapies. More recently, they have enabled researchers to safely share technology and data across borders in ways that help power the development of multiple COVID vaccines in record time.

The TRIPS Agreement also provides for a limited set of flexibilities under certain extraordinary circumstances, including the use of a patent without authorization of the patent holder, a practice commonly referred to as compulsory licensing. Striking the careful balance between encouraging voluntary agreements while allowing for the unauthorized use of patents only in extraordinary circumstances was a result of the hard work and skill of U.S. trade negotiators.

As we approach the first anniversary of the 12th Ministerial Conference, we can now safely describe the TRIPS waiver for COVID vaccines as a solution in search of a problem. No compelling evidence has been put forward to show that IP protections have hindered global access to these vaccines. On the contrary, factors such as trade barriers and customs bottlenecks, lack of storage capacity, last-mile distribution challenges, and high levels of vaccine hesitancy have been the primary impediments.

With billions of COVID–19 vaccine doses produced globally since the pandemic's onset, it's clear that a lack of supply was never the issue. By supporting the TRIPS waiver for vaccines, the United States has helped set an unfortunate precedent.

According to press reports, country eligibility was a major point of contention during the negotiations leading up to the Ministerial Decision. Chinese and U.S. negotiators ultimately agreed on language designed to incorporate a binding commitment made by China's representative at a May 10th WTO General Council meeting that China would not seek a waiver. This language appears in footnote 1 of the Ministerial Decision.

Footnote 1, in my judgment, regrettably endorses the notion that China, the world's second largest economy and largest trading Nation, is a developing country. During my tenure as U.S. Ambassador to the WTO, changing the system in Geneva, in which some of the world's largest and most sophisticated economies, most notably China, can claim developing country status as a right was one of our leading reform initiatives.

Footnote 1 also appears inconsistent with H.R. 1107, the PRC Is Not a Developing Country Act, which recently passed the House of Representatives by a unanimous vote. H.R. 1107 states that, quote:

> It should be the policy of the United States to oppose the labeling or treatment of the PRC as a developing country in any treaty or other international agreement to which the United States is a party.

In addition, in light of China's well-documented noncompliance with WTO rules, I do not believe that China will feel the least bit bound by a statement made by one of its officials at a WTO General Council meeting, which is indirectly referenced and characterized as binding in a footnote to a WTO Ministerial Decision.

I'm not suggesting that China will be seeking to avail itself of the TRIPS waiver anytime soon, but Chinese industrial and military actors will continue to feel no compunction about engaging in IP theft and violating both the spirit and letter of the TRIPS Agreement.

Another concern arises from the massive investments China is making in the developing world. Chinese business arrangements with developing countries might serve as an access point for theft of COVID-related technologies if these countries were to avail themselves of a TRIPS waiver.

Extending a TRIPS waiver to COVID–19 diagnostics and therapeutics is now under consideration at the WTO. As was the case for vaccines, there appears to be no shortage of COVID–19 treatments with supply far outstripping demand. In November, Mexico and Switzerland highlighted this fact in a WTO communication which pointed out that, quote, "No shortage of therapeutics exists, and that large part of innovators' production capacity remain idle due to a lack of demand."

Unfortunately, the adoption of COVID–19 TRIPS waiver might have inspired calls to weaken IP protections in other areas. The WTO Director General, who took an usually active role in the lead-up to MC–12 to encourage the WTO membership to adopt a waiver for COVID–19 vaccines, has indicated she would support a similar waiver for climate change mitigation technologies. If this issue gets traction in Geneva, we can expect India, a leading proponent of an expansive COVID–19 waiver, to be in the forefront of these efforts as well.

Each day the U.S. is engaged in a global competition for technological leadership, maintaining a robust intellectual property right system, both domestically and in our international arrangements, is critical to nurturing our Nation's innovators and winning this competition.

Thank you, Mr. Chair.

The prepared statement of the Hon. Shea follows:]

TESTIMONY OF DENNIS C. SHEA
BEFORE
THE U.S. HOUSE OF REPRESENTATIVES JUDICIARY COMMITTEE
SUBCOMMITTEE ON COURTS, INTELLECTUAL PROPERTY, AND THE INTERNET
"IP AND STRATEGIC COMPETITION WITH CHINA: PART II – PRIORITIZING U.S. INNOVATION OVER ASSISTING FOREIGN ADVERSARIES"
JUNE 6, 2023

Chairman Issa, Ranking Member Johnson and members of the Subcommittee, I appreciate the opportunity to appear before you today. At the outset, let me emphasize that I am speaking solely in my personal capacity and not on behalf of any organization.

In my testimony, I will share some thoughts on last year's decision at the World Trade Organization ("WTO") 12th Ministerial Conference waiving IP protections provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 vaccines as well as the possible extension of this waiver to COVID-19 therapeutics and diagnostics. I will also highlight what I see as some of the implications of these actions for U.S. strategic competition with the People's Republic of China.

My views on these subjects are informed by my 11 years as a member of the bipartisan U.S.-China Economic and Security Commission ("USCC"), which has routinely documented the pervasive nature of Chinese-directed intellectual property theft and cyber-enabled economic espionage targeting the United States. In fact, the USCC was one of the first organizations within the U.S. government to publicly sound the alarm on China's cyber espionage against U.S. commercial firms and how it poses a significant threat to U.S. business interests and competitiveness.

I commend to the subcommittee the USCC's most recent annual report, which highlights another major concern: our nation's dangerous dependence on China for the production of life-saving and life-sustaining medications and their active pharmaceutical ingredients.

My views are also informed by my service from 2018-2021 as the U.S. Ambassador to the WTO. This experience has led me to reach the following conclusions:

First, China's economic system – with its unique melding of public, private, and Chinese Communist Party resources, all harnessed to advance industrial policy objectives – is incompatible with the WTO norms of market orientation, transparency, non-discrimination, and reciprocity.

Second, the WTO has proven itself wholly incapable of restraining the trade-disruptive effects of China's non-market economic practices, a fact that jeopardizes the continuing relevance of the WTO as an institution that serves U.S. interests.

Third, despite generally expressing support for "WTO reform," China does not want change at the WTO as the status quo in Geneva serves its interests quite well.

TRIPS Waiver for COVID-19 Vaccines

The TRIPS Agreement, which entered in force at the time of the WTO's creation in 1995, is a multilateral agreement establishing a minimum set of intellectual property protections covering copyrights, trademarks, patents, and trade secrets. Over the years, the IP protections it provides have played an essential role in supporting innovation and the development of life-saving medicines, diagnostics, and therapies. More recently, these IP protections have enabled researchers to safely share technology and data across borders in ways that helped power the development of multiple COVID vaccines in record time.

The TRIPS Agreement also provides for a limited set of exceptions or "flexibilities" under certain extraordinary circumstances, including the use of a patent "without authorization of the patent holder," a practice commonly referred to as "compulsory licensing." Under TRIPS, compulsory licenses "may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms." This condition, in turn, may be waived "in the case of a national emergency or other circumstances of extreme urgency." Striking this careful balance between encouraging voluntary arrangements while allowing for the unauthorized use of patents only in extraordinary circumstances was the result of the hard work and skill of U.S. trade negotiators.

We are approaching the first anniversary of the WTO's 12th Ministerial Conference. In hindsight, we can now safely describe the TRIPS waiver for COVID-19 vaccines as a solution in search of a problem.

No compelling evidence has been put forward to show that IP protections have in any way hindered global access to these vaccines. On the contrary, factors such as trade barriers and customs bottlenecks, lack of storage capacity, last-mile distribution challenges (particularly in rural areas), a shortage of well-trained front-line workers, and high levels of vaccine hesitancy in both the developed and developing world have been the primary impediments to vaccine access and vaccinations.

Prior to the adoption of the TRIPS waiver, support for removing some of these impediments by eliminating tariffs on vaccines and their ingredients; enhancing regulatory cooperation; scaling back export restrictions; and fully implementing the WTO's Trade Facilitation Agreement was expressed in various international forums, including the G7 and G20. But the WTO membership opted instead for a TRIPS waiver. The Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, also adopted at MC12, is nothing but a series of recollections and reaffirmations without any binding commitments expected of the WTO membership.

With billions of COVID-19 vaccine doses produced globally since the pandemic's onset, it's clear that a lack of supply was never the issue. In fact, many countries destroyed expiring COVID vaccine doses because of an inability to administer them in a timely fashion. In Nigeria, nearly 1 million doses of the AstraZeneca vaccine expired in November 2021 before they could be used. The Africa Centers for Disease Control previously called for a pause in vaccine donations because of distributional roadblocks and vaccine hesitancy. More recently, in December 2022, the board of Gavi, a nonprofit alliance of public and private entities that supplies vaccines to low- and middle-income countries, voted to halt supplying COVID-19 vaccines to most nations because of a lack of demand.

Interestingly, it appears that not a single country has attempted to exercise a waiver or expressed an intention to do so. Paragraph 5 of the TRIPS Ministerial Decision requires WTO members to notify the

WTO TRIPS Council of "any measure related to the implementation of this Decision." My understanding is that no such notification has occurred.

As the subcommittee knows, the United States ultimately supported the TRIPS waiver for COVID-19 vaccines, despite the unfortunate precedent it has set. As a result of the waiver, eligible WTO members can now authorize domestic manufacturers to produce the vaccines without the permission of the patent rights holder and to export those vaccines to other countries.

According to press reports, country eligibility was a major point of contention during the negotiations leading up to the ministerial decision. The U.S. apparently sought a clearly circumscribed definition of eligibility that would prevent China from utilizing the waiver. Under this definition, only those "developing country" members that accounted for less than 10 percent of world exports of COVID-19 vaccine doses in 2021 would be eligible for the waiver. Such a definition would have allowed India and South Africa, the initial proponents of weakening TRIPS protections who also happen to be among the world's largest producers of generic drugs, to be able to seek a waiver but not China whose exports exceeded the 10-percent threshold. China argued that the proposed definition unfairly targeted it. In response, Chinese and U.S. negotiators agreed on more nuanced language designed to incorporate a "commitment" made by China's WTO representative at a May 10 WTO General Council meeting that China would not seek a waiver. This language, which apparently sealed the deal for U.S. negotiators and led to U.S. support for the waiver decision, appears in footnote 1 of the ministerial decision and reads as follows:

> For purposes of this decision, all developing country Members are eligible members. Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision. Such binding commitments include statements made by eligible Members to the General Council, such as those made at the General Council meeting on 10 May 2022, and will be recorded by the Council for TRIPS and will be compiled and published publicly on the WTO website.

Let me share a couple of thoughts about footnote 1:

First, it regrettably endorses the notion that China, the world's second largest economy and largest trading nation, is a "developing country." At the WTO, any country can self-designate as a "developing" member and automatically be entitled to "special and differential" treatment that can include benefits like exemptions from the rules and longer time periods for implementing WTO commitments. During my tenure as U.S. Ambassador at the WTO, changing this misguided system in which some of the world's largest and most sophisticated economies – most notably China – can claim "developing country" status as-of-right was one of our leading reform initiatives. The fact that so many advanced economies claim developing-country status has been a major obstacle to achieving trade-liberalizing negotiated outcomes at the WTO.

Footnote 1 also appears inconsistent with H.R. 1107, the "PRC is Not A Developing Country Act," which recently passed the U.S. House of Representatives by a unanimous vote. H.R. 1107 states that it "should be the policy of the United States…to oppose the labeling or treatment of the People's Republic of China as a developing country in any treaty or other international agreement to which the United States is a party…and in each international organization of which the United States is a party." It is important for the Senate to take up H.R. 1107 and send it to President Biden for his signature. Enactment of this bipartisan legislation would be a critical source of guidance to U.S. representatives at the WTO and

other international organizations and could act as a brake on future negotiations that may lead to outcomes detrimental to U.S. interests.

Second, each year, the Office of the U.S. Trade Representative releases a report to Congress on China's compliance with its WTO commitments. As in past years, the latest such report provides an extensive analysis of how China has fallen short of meeting its WTO obligations and assesses that its record of compliance is "poor." According to the USTR report, "China…has a long record of violating, disregarding and evading WTO rules to achieve its industrial policy objectives. China continues to use numerous and constantly evolving unfair, non-market and distortive trade policies and practices in pursuit of harmful and anticompetitive industrial policy objectives. At the same time, China has sought to frustrate WTO oversight mechanisms, such as through its poor record of adhering to its WTO transparency obligations."

Count me as a realist: In light of China's well-documented non-compliance with WTO rules and its repudiation of WTO norms, I do not believe that China will feel the least bit bound by a statement made by one of its officials at a WTO General Council meeting which is indirectly referenced and characterized as "binding" in a footnote to a WTO Ministerial Decision. It is unfortunate that the U.S., as a global leader in innovation and technology, sacrificed its own considerable interest in strong IP protections on this flimsy reed of a footnote.

I'm not suggesting that China will be seeking to avail itself of a TRIPS waiver anytime soon. But actors within the Chinese military and economic systems will continue to feel no compunction about engaging in intellectual property theft and violating both the spirit and letter of the TRIPS Agreement.

In fact, in May 2020, more than two years before the TRIPS waiver decision was adopted, the FBI issued a warning that it was "investigating the targeting and compromise of U.S. organizations conducting COVID-19-related research by PRC-affiliated cyber actors and non-traditional collectors." According to the FBI, "these actors have been observed attempting to identify and illicitly obtain valuable intellectual property (IP) and public health data related to vaccines, treatments, and testing from networks and personnel affiliated with COVID-19-related research." In 2020-2021, China also tried to force Moderna to hand over the technology behind its mRNA vaccine as a condition of accessing the Chinese market, a request that Moderna refused.

Of course, these activities – attempted theft, espionage, and forced technology transfer – are part of a much broader effort by China to leapfrog the United States technologically. As FBI Director Christopher Wray put it: "China is engaged in a whole-of-state effort to become the world's only superpower by any means necessary." Years ago, Chinese authorities concluded that stealing intellectual property and other forms of proprietary information and conditioning market access on technology transfer was more cost-effective than investing in their own R&D programs to meet national science and technology development objectives. The cost to the U.S. economy has been immense, with estimates ranging in the tens and even hundreds of billions of dollars annually, and the loss of millions of jobs.

Another concern arises from the massive investments that China is making in the developing world. Chinese business arrangements with developing countries might serve as an access point for theft of COVID-related technologies if these countries were to avail themselves of a TRIPS waiver.

In 2018, for example, UNAIDS and the China Chamber of Commerce for Import and Export of Medicines and Health Products published a joint report highlighting "the vast opportunities for Chinese

pharmaceutical companies to relocate their manufacturing to African countries[.]" The report provides "Health Market Profiles" of 21 selected African countries, including the available incentives for Chinese companies to locate production there. Notably, for each surveyed country, the report explicitly notes the extent to which "any Intellectual Property flexibilities [are] incorporated in the national legislation to favour local production" and discusses past instances where these countries have used TRIPS flexibilities such as compulsory licensing. This makes clear that Chinese pharmaceutical firms are interested in investing in countries that are willing to use TRIPS flexibilities.

Potential TRIPS Waiver for COVID-19 Diagnostics and Therapeutics

The WTO Ministerial Decision establishing a TRIPS waiver for COVID-19 vaccines also contemplates that WTO members will decide on an extension of the waiver to cover COVID-19 diagnostics and therapeutics. The proposed timeline for deciding on such an extension, six months from the date of the decision, has since passed but has been indefinitely extended. Last December, United States Trade Representative Katherine Tai requested that the United States International Trade Commission (ITC) investigate the issue of access to COVID-19 diagnostics and therapeutics and issue a public report no later than October 17, 2023. The ITC has since opened an investigation and requested comments from stakeholders and the interested public.

As was the case for vaccines, there appears to be no shortage of COVID-19 treatments, with supply far outstripping demand. In November, Mexico and Switzerland highlighted this fact in a WTO communication, which pointed out that "… no shortage of therapeutics exists and that large parts of innovators' production capacity remain idle due to a lack of demand." The communication concludes: "We do not face a situation where we have an IP-induced lack of access to or a lack of manufacturing capacity of COVID-19 therapeutics and diagnostics. As a consequence, no adjustments to the IP system seem to be required."

Over the past few years, dozens of voluntary licensing agreements have been entered into by drug inventors and generic manufacturers worldwide. Knowing that their IP rights are secure gives considerable assurance to companies that their inventions will not be stolen and allows them to enter into productive manufacturing partnerships. When it issues its final report later this year, the ITC will hopefully recognize that extending the TRIPS waiver to COVID-19 diagnostics and therapeutics is not the solution to any access concerns and, in fact, would greatly disincentivize the significant investments necessary to research and develop life-saving medicines, including medicines needed to respond to future pandemics.

An extension of the TRIPS waiver to COVID-19 diagnostics and therapeutics may be on the agenda for the WTO's 13th Ministerial Conference scheduled for late February 2024 in Abu Dhabi. WTO Director-General Ngozi Okonjo-Iweala has urged the WTO membership to step up the pace of various negotiations to ensure that MC13 delivers "meaningful outcomes." It is incumbent on the Biden Administration to uphold the TRIPS Agreement and resist any attempt to include among those "meaningful outcomes" an extension of the TRIPS waiver to COVID-19 diagnostics and therapeutics.

Unfortunately, the adoption of the COVID-19 TRIPS waiver may have inspired calls to weaken international IP protections in other critical areas. For example, Director-General Okonjo-Iweala, who took an unusually active role in the lead-up to MC12 to encourage the WTO membership to adopt a waiver for COVID-19 vaccines, has indicated that she would support a similar waiver for climate-change mitigation technologies, a position apparently shared by UN Secretary-General Antonio Guterres. If this

issue gets traction in Geneva, we can expect to see India, a leading proponent of an expansive COVID-19 waiver, to be in the forefront of these efforts as well.

Conclusion

Each and every day, the United States is engaged in a global competition for technological leadership. Maintaining a robust intellectual property rights system both domestically and in our international arrangements is critical to nurturing our nation's innovators and inventors and winning this competition. Doing so is essential to U.S. national security. Through our experience battling the COVID-19 pandemic, we have also been reminded that strong IP protections are critical to enabling innovators to share knowledge and technology securely and in ways that can lead to life-saving medical breakthroughs.

For these reasons, actions that may erode the system of intellectual property rights must be undertaken with extreme care and caution.

Mr. ISSA. Thank you, Mr. Shea.
Mr. BUSCH.

STATEMENT OF MARC BUSCH

Mr. BUSCH. Chair Issa, Ranking Member Johnson, and Members of the Subcommittee, my name is Marc Busch, and I teach at the School of Foreign Service at Georgetown University. It's a pleasure to appear before you to discuss the TRIPS waiver and its implications for both commerce and national security at home and abroad. I applaud you for taking on this very important topic.

Let me be succinct. The TRIPS waiver was a mistake. Expanding it will make things worse. It won't help fight COVID, but it will hurt U.S. innovation. It will contribute to other countries realizing their industrial policy goals. Moreover, it will potentially lead to the U.S. facing greater efforts, not least on the part of China, at economic coercion.

The waiver also has two knock-on effects. As has already been pointed out, there are pleas to expand the waiver to things like clean tech, maybe even agricultural technologies, et cetera. This is very disconcerting. A less known knock-on effect is that, for some reason this year, in particular, the USTR has taken a very soft line on compulsory licenses writ large. This has nothing to do with the waiver and everything to do with the fact that, for years, other countries have been abusing compulsory licenses, and now the USTR in the 2023 Special 301 Report has gone silent. This cannot be.

As has already been pointed out, IP is the lifeblood of our innovative economy. The data are remarkable. Sixty-five days from sequencing the RNA of the virus to a vaccine. MRNA, 32–34 patent families pre-2019. In fact, for all vaccines, 83 percent of the patents on which they are built preexist COVID.

Rather than celebrate IP as having turned the tide on COVID, the members of the WTO rushed to embrace a false narrative, peddled by India and South Africa, with not a shred of evidence. They argued, moreover, that it wasn't their job to come up with evidence that somehow IP was keeping jabs out of arms. In fact, they said that it was on those who would disagree with the waiver to prove otherwise.

The waiver works through compulsory licenses. As my colleague just pointed out, it does two things. It takes away the need to invoke them only under extraordinary circumstances, and it removes the obligation to first engage with the patent owner. This is the wrong step at exactly the wrong time. In a world awash in voluntary licenses, most of which include technology sharing arrangements, this doesn't make any sense.

The focus instead—because we all want responses to COVID—should be on tariffs, taxes, fragile healthcare systems, and the like. Even when COVID vaccines have been free, they have not always found their way to patients. Keep in mind, in Congo, they had to destroy 1.7 million vaccines because they had expired. Nigeria, one million for exactly the same reason.

This fall, the WTO will look to the Biden Administration to react to that U.S. ITC study to decide whether to expand the waiver to diagnostics and therapeutics. Something to keep in mind: We have

no idea what either of those two categories entail. It is hard to believe that we are here at this moment with no definitions of either COVID-related diagnostics or therapeutics.

Second, the China question. Will China avail itself of whatever is negotiated? It said no to vaccines; it did not say no to whatever came next.

China is on the ascent in biopharma. McKinsey estimates that by 2028, it will be the leader in certain segments. It also at the moment is a leader in monoclonal antibodies, has the ability to ramp up at a very cheap cost on antibodies in general, and is a leader in gene editing and synthetic biology.

India, also a big player in generics, undoubtedly with two of the top five generics producers on Earth and the nickname "the pharmacy to the world," will likely weigh in on and use these waivers. If it doesn't use them, just the mere ability to use will deter a lot of innovations and inventions from coming to market.

We need to keep in mind that compulsory licenses have been abused, are being abused, and there is nothing new about this to make the burden less. Under the TRIPS waiver is the wrong thing at the wrong time.

So, again, let me conclude by saying, the COVID waiver, expanded or not, will not roll back COVID any more than it's already been rolled back. It will not foster U.S. innovation. It will help foreign countries realize their industrial policy goals, and through economic coercion, it will hurt the national security of this country.

Thank you.

[The prepared statement of Mr. Busch follows:]

Testimony of Marc L. Busch
Before the Subcommittee on Courts, Intellectual Property, and the Internet,
of the Committee on the Judiciary, Hearing on
"IP and Strategic Competition with China: Part II—Prioritizing US Innovation
Over Assisting Foreign Adversaries."
June 6, 2023

Chairman Issa, Ranking Member Johnson, members of the Subcommittee, I appreciate the opportunity to appear before you to discuss the "TRIPs waiver," and how its expansion could undermine US innovation, help China and other countries realize their industrial policy goals, and put America's national security at risk. My name is Marc L. Busch, and I am the Karl F. Landegger Professor of International Business Diplomacy at the Georgetown's School of Foreign Service. I applaud the Subcommittee for taking up this extremely important issue.

The TRIPs waiver was a *mistake*. Expanding it would make things worse. US intellectual property (IP) is the DNA of our country's innovative economy. Watering down IP won't help fight COVID, but it will result in a suboptimal level of investment in new ideas, and leave the US more vulnerable to economic coercion by foreign adversaries. China is especially well positioned to take advantage of an expanded waiver. It is poised to become a leader in segments of the global biopharma industry, and an expanded waiver could help it get there faster. This would pose a commercial threat to the United States, and by extension, a national security one.

Basics of the TRIPs waiver

COVID is in the rearview mirror thanks to IP. Patents made it possible to bring a vaccine to market 65 days after the virus' RNA was sequenced. Vaccines based on mRNA technology build from 34 patent families, 32 of which are *pre*-pandemic. All told, 83% of the patents in all COVID vaccines were filed *before* 2019. Government research and funding helped to seed important basic science, but three-quarters of the patenting related to COVID vaccines was carried out by the private sector.

Rather than celebrate IP for having turned the tide on COVID, governments have been determined to weaken it. Acting on a false narrative that IP made it too expensive to get more jabs in arms, the US, together with other members of the World Trade Organization (WTO), agreed last June to the "TRIPS waiver," which temporarily suspends certain patent obligations on COVID vaccines in the WTO's Agreement on Trade-Related Aspects of Intellectual Property.

The waiver works by relaxing some of the steps required to use a *compulsory license* (CL). A CL involves a government forcing the patent-owner to share its innovation with a generic producer for a royalty. The waiver gets rid of important measures which ensure CLs aren't used inappropriately, such as where the generic is re-exported, or diverted to more lucrative markets.

The key, for the sake of this hearing, is that the TRIPs waiver almost didn't happen because of two issues. The first was that it originally included COVID-related diagnostics and therapeutics, which caused dissent. The second was that China, as a "developing country," would have been allowed to use the waiver, and this was deemed unacceptable by the United States.

To deal with the first, a decision on COVID-related diagnostics and therapeutics was set aside until December. It has since been postponed again until the fall, in order to give the Biden administration time to study the costs and benefits of expanding the waiver.

To address the second, WTO members engaged in a lengthy debate over which countries might be eligible. China objected to this effort, but said that if its concerns were addressed, it wouldn't "avail itself" of the waiver. This pledge was only made with respect to *vaccines*. If the waiver is expanded to include COVID-related diagnostics and therapeutics, China will undoubtedly see it as fair game.

Why the TRIPs waiver is misguided

In the fight against COVID, there is *no evidence* that IP is the problem, nor that CLs are the answer.

Without strong IP to incentivize investments in vaccines, diagnostics and therapeutics, there would be nothing for generics to copy. Proponents of the waiver *assume* that innovation will happen, but the reality is that ideas aren't brought to market if inventers and investors are denied at least some appropriable return.

The pandemic made clear that there are many factors at play in determining patient access to medicines. One is that developing countries place sizable tariffs on patented drugs; 20 have no ceiling on these tariffs at the WTO. The average tariff on vaccine inputs is 28.6%. The WTO says that 23 of the 27 top vaccine-producing countries have tariffs of at least 5% on five of the 13 inputs used to make them. Encouraging more developing countries to join the WTO's "zero-for-zero" agreement on pharmaceutical tariffs should be a priority in this regard.

There are also many so-called "last mile" issues to address. A lack of distribution channels, fragile health care systems, taxes and excessive red-tape all conspire to keep COVID-related technologies out of the reach of those who need them. There are no easy answers to solving these, but that does *not* mean that acting on a false narrative about IP is the answer.

Congress isn't buying it, either. For example, 10 Senators wrote to US Trade Representative Katherine Tai to complain that there is "little data or other evidence" that shows the need for the waiver, and that its expansion "could face similar issues."

They're not alone in voicing this concern. America's allies have questions too. In a communication to the WTO, Mexico and Switzerland explain that the "[a]vailable information shows that no shortage of therapeutics exits." As for diagnostics, they conclude that "there is a high level of product surplus to order," and that the challenges that remain "*are not IP-related*." Accordingly, they conclude that "*no adjustments to the IP system seem to be required*."

In fact, India and South Africa, the coauthors of the original TRIPS waiver, have never once given evidence that IP rights undermined patient access to COVID vaccines, diagnostics or therapeutics. Quite the opposite. In meetings held at the WTO in January 2021, India and South Africa said that it wasn't their responsibility to back up their claims, but rather that the burden of proof was on the countries that opposed the waiver. In short, even the waiver's coauthors knew there's no evidence.

The companies doing the actual work to fight COVID have argued this too. Gilead Sciences, which invented remdesivir, explains that "IP is a *prerequisite* to access, not a barrier, so a TRIPS Waiver is not the answer" (emphasis added). Keep in mind that remdesivir was developed to treat Ebola back in 2015, and recently earned a patent for humanity award from the US Patent and Trademark Office.

Even *if* IP was the problem, CLs are counterproductive. The Information Technology & Innovation Foundation testified, for example, that innovators granted 140 voluntary licenses (VLs) to generics to make vaccines in developing countries. Moreover, 91% of these CLs include a technology transfer clause. CLs, according to the Alliance for Trade Enforcement, can undermine the odds of negotiating VLs, and thus prevent the sharing of "know how." This helps explain why CLs are rarely used (including under the waiver): VLs deliver more benefits to recipient countries.

Finally, generics aren't free, and can actually be more expensive than patented drugs had through international government procurement mechanisms. Sadly, even when COVID vaccines were free for certain developing countries, patients never got them. The Congo, for example, had to destroy 1.7 million vaccines it bought at a big discount or got for free from donors, because they were past their expiration date. Nigeria was forced to discard 1 million vaccines for the exact same reason.

Given these considerations, it should come as no surprise that not a single country has notified the WTO of having initiated any activity in conjunction with CLs, never mind actually filing for a CL.

The TRIPs waiver and US innovation

Expanding the waiver will help China and others realize their industrial policy goals. There is no agreement on which technologies fall under COVID-related diagnostics and therapeutics, such that the waiver could end up reaching far and wide across the US economy. Patients with COVID often have respiratory problems, for example. To care for them, physicians use a variety of technologies patented for other purposes. Which of these technologies would an expanded waiver likely cover?

A report by McKinsey predicts that Chinese biopharma companies will "likely have greater influence" by 2028. The country already has clear strengths in monoclonal antibodies, for example, and can boost production of antibodies quickly and cheaply. China also leads in processes for gene editing and synthetic biology, as well as technologies that will play a crucial role in preventing and treating COVID. An expanded waiver could hasten China's ascent in these fields, courtesy of CLs.

The US has complained for years about countries abusing CLs. Concerns about India, for example, date back to at least 2012. Chile, Indonesia and Malaysia have all been named in prior *Special 301 Reports* for being overly eager to use CLs, without first making every effort to obtain authorization from the patent owner. None of these cases involved a public health emergency. Malaysia sought to use CLs to build up its medical tourism industry. An expanded waiver will make this even easier.

Not surprisingly Congress has expressed reservations about the waiver, let alone an expanded one. For example, 14 House Democrats wrote to US Trade Representative Tai to warn that expanding the waiver could have "unintended adverse consequences, such as hampering American

manufacturing and shifting jobs to foreign countries." More generally, the Congressional Research Service notes that "some policymakers and stakeholders remain concerned about the risk of theft by China of US COVID-19-related technologies." These concerns are all well-founded.

The TRIPs waiver and US national security

An expanded waiver would also present a national security risk. Several Congressional bills speak to this concern. For example, in H.R. 7430, *Protecting American Innovation Act*, much like in S. 1683, *Preventing Foreign Attempts to Erode Healthcare Innovation Act*, warn that China will use COVID technologies as the centerpiece of its strategy to undermine the competitiveness of the US and its allies. The Federal Bureau of Investigation and Britain's MI5 agree, explaining this strategy is already playing out.

The pandemic showed the fragility of medical supply chains. Many countries erected export and import restrictions on items from soap to masks. Talk of "vaccine nationalism" sparked widespread fears that governments would hoard shots. A few countries moved in the opposite direction. Singapore and New Zealand, for example, pledged to keep their medical supply chains open to each other. Australia and Canada joined in too. But these countries were the exception, and not the rule.

The more common reaction was to prepare for economic coercion. The age-old reality is that "hold up" problems in trade are more likely among adversaries than allies. The European Union explains, for example, that because of the "rise of protectionism and increasing deployment of the economy as a geopolitical tool," it has seen fit to craft an *anti-coercion instrument*. It targets actions ranging from "explicit" to "disguised" and "silent" coercion, and arms Brussels with a wide variety of trade and investment sanctions to use in response.

The European Union points to China's trade war with Lithuania as an example of economic coercion. Lithuania allowed Taiwan to open a *de facto* embassy in Vilnius. China responded by placing import bans on goods and services from Lithuania, and from those countries that used Lithuanian imports.

China has also been involved in similar trade disputes with Australia and Canada. Both began over political tensions, and quickly escalated to include import and export restrictions on items deemed to be politically and strategically important to the target country. Barley from Australia, and canola oil from Canada, were among these.

Expanding the waiver will help China practice economic coercion through export bans. Using CLs to access American technologies, and strengthen its grip on more of the global biopharma industry, will considerably enhance these prospects. China has used this strategy before. It banned the export of rare earths, which are crucial in producing countless high-technology goods. In 2012, the United States challenged these restrictions at the WTO, and secured a ruling that led China to back down.

Yet, in China's recent trade disputes with Australia, Canada and Lithuania, Beijing has shown less interest in having the WTO intervene. In response to a complaint filed by the European Union over China's treatment of Lithuania, for example, Beijing said a WTO case would not solve anything, because "[t]he issue between China and Lithuania is a political one, not an economic one." Therein

lies the rub: the whole point of economic coercion is to use commercial means to leverage political outcomes.

Economic coercion has always been a feature of international relations. But this does not mean the US should help China build out its toolkit by issuing CLs on COVID-related diagnostics and therapeutics.

Conclusion

To expand the TRIPs waiver is to buy into a false narrative about IP. It won't help to fight COVID, but it will hurt US innovation, assist China and other countries realize their industrial policy goals, and put America's national security at risk.

Mr. ISSA. Thank you.
Mr. GRESSER.

STATEMENT OF ED GRESSER

Mr. GRESSER. Mr. Chair, Ranking Member Johnson, thank you very much for soliciting our participation in this hearing.

You're posing some important questions. Specifically, how does the WTO's TRIPS Agreement relate to U.S. interest in innovation and technological progress? Was the Biden Administration correct to support a temporary waiver of some of its provisions for COVID–19 vaccines last year? Will this be to the advantage of China vis-à-vis the United States? Should this waiver go further to cover diagnostic and therapeutic technologies?

Let me make four points to summarize my views here.

First, promotion of scientific research and defense of American innovators against piracy and infringement are important to American national interests, and the TRIPS Agreement is an important element of policy to secure them.

American businesses, government labs, and research universities commit over $700 billion a year to research and development. The results make us a leader in fields ranging from agriculture to medicine, aerospace, automotive industry, information technology, and many other fields.

The TRIPS Agreement is a part of policy to secure these results. It imposes reasonable obligations on the 164 WTO members to maintain and enforce a basic set of patent, copyright, trademark, and other laws, with flexibilities for least developed countries in emergency situations, such as those noted in the 2001 Declaration on TRIPS and Public Health.

Since TRIPS' entry into force, R&D has risen from 2.2 percent of GDP to 2.6 percent in high-income countries, from 0.5–1.5 in middle-income countries, and from 2.4–3.4 percent in the U.S. specifically. Such figures suggest that the TRIPS Agreement is contributing as its authors hoped.

Second, however, in emergency circumstances, governments must often act in ways they would not in normal times, frequently do so on the basis of incomplete information, and take steps that should not be regarded as precedence to be sustained later on.

The COVID–19 pandemic was such an emergency. As a wholly new virus, easily transmissible, and in many cases deadly, both the Trump and Biden Administrations, with good reason, took emergency steps in many areas to address it. Often these helped save lives and support the U.S. economy in crisis.

The COVID–19 TRIPS waiver should be seen in this context. It is time limited for five years, it is limited in coverage to vaccines only, and includes a formal binding commitment for China to forego use of the waiver. This approach seems, to me, to be a reasonable decision, given the information available to the Biden Administration, the time, and was well negotiated by Ambassador Pagan in Geneva and Ambassador Tai in Washington.

The fact that no country has yet used it suggests, in retrospect, that the major challenges for distribution were related to developing the ability to mass-produce vaccines and distribute them safely rather than to intellectual property rules. At the time, gov-

ernments are acting with an emergency situation in their minds, with thousands of deaths per day, and I think had some reason to take extraordinary measures.

Looking ahead, where do we go from here? First, I would note that the Chinese commitment to forego use of the waiver means that all normal WTO patent rules remain in effect, vis-à-vis China for COVID vaccine specifically, and for all other patents as well. There is, as my colleagues have mentioned, great reason to be concerned about Chinese efforts to access and use proprietary American technologies and more generally to take illicit advantage of U.S. research to promote the Chinese economy. There is a large question and important one about how do you effectively keep WTO patent, copyright, and other IP rules effective in the case of China.

The TRIPS waiver for COVID vaccines is not one of these. It is China's decision to forego it. It is a commitment as binding as any other WTO IP rules. So, I think the administration handled this quite well.

Looking ahead, the WTO members are now considering a broader proposal to waive TRIPS rules for therapeutics and diagnostics related to COVID. This appears to be a much broader array of products and technologies than the vaccine waiver covered. As several of my colleagues have mentioned, the scope of the coverage is not yet clear. The U.S. International Trade Commission is reviewing submissions on this matter and should be issuing a report that adds more context in information in mid-October. I await this with interest.

I would note, in general, however, that with a reported 64–70 percent of the world's public vaccinated, the emergency situation of the pandemic's first two or three years has abated, and the case for emergency IP measures would need to be made very forcefully. I do not think we are in the same situation today as we were two years ago or even one year ago.

Thank you very much, and I look forward to your questions.

[The prepared statement of Mr. Gresser follows:]

ppi radically pragmatic

1156 15th Street NW, Ste 400
Washington, DC 20005
Tel: 202-525-3926
Fax: 202-525-3941

INTELLECTUAL PROPERTY: U.S. INTERESTS, EMERGENCIES, AND THE WTO'S TRIPS WAIVER FOR COVID-19 VACCINES

Edward Gresser
Vice President and Director for Trade and Global Markets
Progressive Policy Institute

Testimony Submitted For:
House Judiciary Committee
Subcommittee on Courts, Intellectual Property, and the Internet

June 6, 2023

Mr. Chairman and Mr. Ranking Member,

Thank you very much for inviting me to testify at this morning's hearing on intellectual property, innovation, and the U.S. competition with China, focused on the World Trade Organization and its decision on waiver of patent obligations for COVID-19 vaccines and potentially for "diagnostics and therapeutics" related to COVID-19.

By way of introduction, I am Vice President of the Progressive Policy Institute (PPI) here in Washington, D.C., a 501(c)(3) nonprofit research institution established in 1989 and publishing in a wide range of public policy topics. Before joining PPI, I served at the Office of the U.S. Trade Representative from 2015 to 2021 as Assistant U.S. Trade Representative for Policy and Economics, with responsibility for overseeing USTR's economic research and use of trade data, chairing the interagency Trade Policy Staff Committee, and administering the Generalized System of Preferences. This period coincided with the beginning of the COVID-19 pandemic in December 2019 and extended through the initial WTO discussions on a temporary waiver of some elements of the 1994 TRIPS agreement relating to COVID vaccines.

The hearing poses some important questions. Specifically, how does the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) relate to U.S. interests in innovation and technological progress? Was the Biden administration correct to support a waiver of some of the TRIPS patent provisions for COVID-19 vaccines? Will this be to the advantage of China vis-à-vis the United States? I can summarize my view of this in four points:

R&D, TRIPS, AND THE U.S. INTEREST

First, the promotion of scientific research and the invention of new technologies is both an important worldwide good, and a specific area of U.S. comparative advantage. The U.S. is the world's largest investor in scientific research and development at over $700 billion per year, accounting for roughly 30% of all world R&D spending, and is home to top-tier research universities; innovative businesses in every field from agriculture to life sciences, information technology, aerospace, and automotive industry; and world-renowned government laboratories. In numbers, the 3.4% of GDP the U.S. now committed to scientific research and development ranks fourth in the world after only Israel, Korea, and Taiwan.[1] This is one of the U.S.' significant strengths and safeguarding this investment from piracy and infringement is an important national interest.

For the past three decades, the WTO's TRIPS agreement has been an important element of policy designed to secure this interest. It imposes reasonable obligations on the WTO's 164 members to maintain and enforce a basic set of patent, copyright, trademark, and other laws, with flexibility for emergency situations. While causality is always hard to determine, a few data points suggest that since the TRIPs agreement, both U.S. and world R&D commitments have grown:

- From the conclusion of TRIPS in 1994 through 2019, the data site "Our World in Data" reports that high-income country R&D spending has risen from 2.2% of GDP to 2.6%, and middle-income country R&D from 0.5% to 1.6% of GDP.[2]
- The U.S.' R&D rate has grown especially rapidly, rising according to the National Science Foundation from 2.4% of GDP in the early 1990s to 3.4% in 2020 and 2021. These last two figures are the highest levels in NSF's records.[3]

As such TRIPS appears to serve a worldwide interest in encouraging research, invention, and artistic creation and also a specifically U.S. interest in a detailed set of rights and obligations, enforceable under Dispute Settlement Understanding rules pending completion of WTO discussions on institutional reform. TRIPS, then, is an important tool for the American government, as policymakers seek ways to promote innovation and research and to defend U.S.-based researchers against infringement and piracy.

With respect to China specifically, China has a well-documented program of developing its national technological base by all available means, ranging from public investment in research, to open-source and collaborative work with foreign scientists and governments, to coercive extraction of technology from investors and exporters, to clandestine cyber-theft programs. With this as part of the landscape, the U.S. government and American

[1] "Gross Domestic Spending on R&D ," OECD , accessed June 2023, https://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm.
[2] Hannah Ritchie, Edouard Mathieu, and Max Roser, "Research and Development," Our World in Data, 2023, https://ourworldindata.org/research-and-development.
[3] 1. "National Patterns of R&D Resources: Table 1 U.S. Gross Domestic Product, R&D," National Center for Science and Engineering Statistics, 2021, https://ncses.nsf.gov/data-collections/national-patterns/2021.

businesses need to be vigilant, aware of threats, and share best practices to protect themselves. The U.S. government in addition should be using international law and organizations to defend American innovators' and researchers' rights, including the WTO and the TRIPS rules.

EMERGENCY SITUATIONS AND THEIR IMPLICATIONS

Second, in emergency circumstances, governments must often act quickly on the basis of incomplete information and in ways they would not choose to act in normal times. Their actions in these cases should be seen as *sui generis* actions that may not be useful once the emergency is ended, and need not be seen as precedents that need to be kept once circumstances return to normal.

The COVID-19 pandemic was such an emergency, as a wholly new and quite dangerous virus, easily transmissible, with no known treatment, and in many cases deadly. In the 3.5 years since its appearance, we have seen nearly 100 million known cases worldwide and 7 million deaths, including over 1 million deaths here in the United States. This was a medical emergency unique in my lifetime, and as such it required and received an extraordinary response in the United States and worldwide:

- Massive government and private-sector commitment to vaccine development, and distribution once vaccines became available in December 2020;
- Conversion of important manufacturing supply chains to produce personal protective equipment and specialized medical devices;
- Economic emergency measures, including closing much of the retail economy, developing work-from-home procedures for white-collar workers, and emergency fiscal stimulus including direct support to closed businesses.

In retrospect, this effort appears to me to have been very successful. Within less than a year, we had several new and very successful vaccines, with nearly 14 billion vaccinations and booster shots now delivered. Like many Americans, I am a personal beneficiary of this work; with vaccines and boosters, my own recent case of COVID, contracted about a week ago, has been much more like a mild cold than a severe (let alone life-threatening) illness. More generally, an early study published in the Lancet suggests that these vaccinations helped cut world COVID mortality by a range of 41% to 64%,[4] or in total numbers from a potential 20 million to 7 million. A more recent review by the Commonwealth Fund focusing on the United States estimates that vaccinations prevented more than 18.5 million hospitalizations and 3.2 million deaths.[5] This is a remarkable success story and one in which many people in the U.S. government, science and business, and non-profits and families should take pride.

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[4] Oliver J Watson et al., "Global Impact of the First Year of COVID-19 Vaccination: A Mathematical Modelling Study," *The Lancet Infectious Diseases* 22, no. 9 (2022): 1293–1302, https://doi.org/10.1016/s1473-3099(22)00320-6.

[5] Meagen C. Fitzpatrick et al., "Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths," The Commonwealth Fund, December 13, 2022, https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations.

2022 TRIPS WAIVER FOR COVID-19 VACCINES

One element of the Biden administration's (and more generally, the WTO membership's) response to this emergency was a decision to authorize a temporary, five-year waiver of several elements of the TRIPS agreement's patent rules for COVID vaccines.

Debate over the TRIPS agreement's relationship to public health crises is a familiar topic for the WTO. One point of reference is the 2001 "Declaration on TRIPS and Public Health," for example, expressed a consensus view of WTO members that:

> *"[T]he [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all… [and that] [e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."*[6]

It is not surprising that the outbreak of the COVID-19 pandemic elicited some debate over whether ordinary rules would need to be suspended as governments grappled with a fast-moving and deadly disease. Some WTO members, notably India and South Africa, proposed a very broad set of TRIPS waivers, either of the agreement's patent sections broadly or for particular products including vaccines but also extending to personal protective equipment, medical technologies such as ventilators, and larger categories of goods not specifying particular products such as "diagnostics and therapeutics."[7]

This debate continued in the run-up to the WTO's 12th Ministerial Conference, originally scheduled for December 2021 but delayed until June 2022 after the emergence of the *omicron* variant of the COVID-19 virus. At the June 2022 Ministerial, the WTO members agreed on a limited, five-year waiver specifically for Covid-vaccines (while deferring decisions on any broader range of products and technologies) as follows:

> *"[A]n eligible Member1 may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter "the Agreement") by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic" … "An eligible Member may waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market and may allow any proportion of the products manufactured under the authorization in accordance with this Decision to be exported to eligible Members" … though the member must also "undertake all reasonable efforts to prevent the re-exportation of the products manufactured under the authorization in accordance with this Decision that have been imported into their territories."*[8]

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[6] "Declaration on the TRIPS Agreement and Public Health," World Trade Organization, November 14, 2001, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[7] "Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19," World Trade Organization, October 2, 2020, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf.

[8] "Ministerial Decision on the TRIPS Agreement," World Trade Organization, June 22, 2017, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True

In effect, the "waiver" creates a time-limited option to set aside patent rights for COVID-19 vaccines to manufacture vaccines within a Member's country in the event there is no supply of vaccines, and also allows a member to export the resulting vaccine to other WTO members findings themselves short of vaccine. It does not authorize this for other products. In tandem with this, the Chinese government made a "binding commitment" not to make use of this waiver.[9]

A year later, I would make three points about this decision:

1. First, it is limited in scope and in time, meant to deal with the specific cases of a country's lacking urgently needed vaccine. As such it does not seem to me an unreasonable decision to take in an emergency, especially as the debate began at a time when there were widespread fears that vaccines might not be manufactured in sufficient quantity for the entire world.

2. Second, no WTO member government has yet used this waiver. This suggests that the major challenges for vaccine distribution in practice have been related first to developing the ability to mass-produce vaccines, and later to distribute them safely and effectively, rather than to a problem arising from intellectual property rules.

3. Third, it includes a formal statement by China foregoing the use of the waiver.

With respect to the potential use of this waiver by China, we have many reasons to be concerned about Chinese efforts to access and use proprietary American technology. The WTO TRIPS agreement is one tool to deter this, though not the only one. But the fact that China has foregone the use of the waiver means that to the extent there is reason for concern about patent rights to COVID vaccines vis-à-vis China, the relevant issue is one of enforcing current legal rules, rather than of opening a gap in those rules for China.

NEXT STEPS: "DIAGNOSTICS AND THERAPEUTICS"

Finally, the Ministerial decision on Covid vaccines is not the end of the argument. The WTO members, and the U.S. as one of them, are now considering a broader proposal to waive TRIPS rules for "production and supply of COVID-19 therapeutics and diagnostics." This suggests a much broader array of products and technologies, though therapeutics and diagnostics are not terms of art and the range of devices and medicines they might cover is unclear. The U.S. International Trade Commission is reviewing submissions on this matter, with a report that should add context and information due in mid-October.

[9] "Record in Accordance with Footnote 1 of the Ministerial Decision on the TRIPS Agreement of 17 June 2022," World Trade Organization, June 22, 2022, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W690.pdf&Open=True.

I would note as a general matter, however, that the emergency situation of the pandemic's first two years has abated. With nearly two-thirds of the world's public vaccinated,[10] the need for emergency measures seems to me harder to justify that it might have been two years ago.

CONCLUSION

In conclusion, I would emphasize again that emergency situations often require governments to take extraordinary actions in defense of public health and security, and that these actions are not necessarily ones that need to be sustained afterward or viewed as precedents for future decisions.

With this in mind, I believe the Biden administration's decisions on this topic are quite reasonable. In 2021 the incoming administration inherited a worldwide crisis posing a grave threat to life and health in the U.S. and elsewhere. In considering the requests of a number of WTO members appealed for a temporary waiver of patent rules. Its officials, in particular U.S. Trade Representative Katherine Tai and Ambassador to the WTO Maria Pagan, managed the subsequent negotiations in my view professionally and reasonably. Their work with other WTO members ended in an agreement which:

(a) Allows countries to take emergency steps in the event other measures are not able to provide them with the vaccines they need;
(b) Limits this to 5 years and to vaccines specifically; and
(c) Stipulates that China (among other things as a country producing its own version of a vaccine) will not take advantage of patent waivers under the decision.

Under the circumstances, this seems to me a reasonable outcome, and not one that should be viewed as putting at risk U.S. intellectual property broadly or undermining the commitment American businesses, research labs, and inventors make to scientific research and development.

Thank you for this opportunity to share my views, and I welcome any questions you may have.

[10] Edouard Mathieu et al., "Coronavirus (COVID-19) Vaccinations," Our World in Data, last modified June 4, 2023, https://ourworldindata.org/covid-vaccinations.

Mr. ISSA. Thank you.

I now recognize the gentleman from Virginia, Mr. Cline, for his questions.

Mr. CLINE. Thank you, Mr. Chair. I thank our witnesses for being here.

Ambassador Shea, let me start with a question about the trustworthiness of the Chinese government. How would you rate the trustworthiness of the Chinese government and Chinese Communist Party with respect to IP rights, especially considering the conduct that's been documented in the USTR Section 301 Report in recent years?

Mr. SHEA. I would say that their trustworthiness is nil. Each year, the USTR issues an annual report on China's compliance with its WTO obligations. The Biden Administration put out a very strong report saying China's compliance is poor, and goes through the litany of violations of subsidy notifications and market access requirements. That's why I find it so intriguing that we would rely on a footnote in a Ministerial Decision that indirectly references a binding commitment by an official at the WTO at the General Council. It does not seem like a very powerful commitment to me.

Mr. CLINE. What do you make of the Chinese government's silence on whether they give similar assurances with respect to an expansion of the waiver to therapeutics and diagnostics?

Mr. SHEA. Well, I think there is a possibility that they will seek that. I also think we should be passing—Senate should take up the PRC Is Not a Developing Country Act. I know it passed by 415–0 here in the House of Representatives.

As I read that footnote, it suggests—it treats China as a developing country, even though it allegedly makes a binding commitment not to seek a waiver. I think if we had that as a policy of the United States, that we do not treat China as a developing country in international agreements and international organizations, that would really, I think, help stall, or stall an effort for China to seek a waiver on other matters.

Mr. CLINE. Now, how would you compare the current debate at the WTO as to special IP waivers for COVID–19 with the debate around TRIPS flexibility for HIV/AIDS drugs from 20 years ago?

Mr. SHEA. I wasn't really paying attention 20 years ago. The issue when India and South Africa first circulated the TRIPS waiver proposal, no one took it seriously. It happened as sort of at the end of my term at the WTO, but it suddenly got legs.

I mean, and I would say that South Africa and India are also countries that, under a proposal we put forward at the WTO on special and differential treatment, they would also be covered because they're members of the G20. India's a huge, huge, huge economy, so why are they not abiding by all the rules of the WTO? Why do they have a right to automatically claim special and deferential treatment?

Mr. CLINE. Before the WTO's IP waiver for COVID–19 vaccine patents was put into place, many noted that the TRIPS Agreement already provided flexibilities for member Nations to implement compulsory licenses for public health emergencies, but no member Nation tried to use those flexibilities before the IP waiver was adopted.

Do you think that the IP waiver was needed, considering existing TRIPS flexibilities?

Mr. SHEA. No, it was certainly not needed.

Mr. CLINE. What are the differences between the IP waiver and the TRIPS flexibilities available before the waiver?

Mr. SHEA. Well, under TRIPS, as I think Professor Busch said in his testimony, there has to be an effort to engage the patent holder before you exercise a compulsory license. It has to be under extraordinary circumstances. You can't re-export—export the vaccine.

So, it expanded—there is also—there's a compulsory licensing regime in TRIPS. What the TRIPS decision did was expand this already reasonable system to allow the use of compulsory licenses in extraordinary circumstances.

Mr. CLINE. Professor Busch, you noted that the notice requirement was exactly the wrong requirement at the wrong time. Can you elaborate on that?

Mr. BUSCH. The idea that there wouldn't have to be a discussion with the patent holder is not only wrong for innovation, but obviously wrong for the generic provider which, under voluntary licenses, is typically getting a tech-sharing arrangement. So, it really doesn't make a lot of sense, even if you believe that IP is the link. The problem is that there is no evidence that IP is the link.

Now, let's not correlate two things here. Everyone wants cheaper drugs. Compulsory licenses don't necessarily do that. So, this is, as my colleagues said, "a solution looking for a problem." We actually have evidence that compulsory licensing doesn't come close to certain voluntary licensing prices. So, there's no magic here. It's not necessarily the case that a compulsory license eases the burden in terms of price. As I pointed out, even when these drugs had been made available for free, that has not led to more jabs in arms.

Mr. CLINE. Thank you.

Mr. ISSA. I thank the gentleman.

We now recognize the Ranking Member, the gentleman from Georgia, Mr. Johnson, for his questions.

Mr. JOHNSON of Georgia. Thank you.

Mr. Gresser, you respond to the insinuation that the Biden Administration was in error in supporting a temporary waiver of patent rules. Based on the fact that the administration was an incoming administration confronted with a grave public health emergency that threatened health and safety of people, and it actually was killing people, can you go into a little more detail on why you think that it was a correct decision to support that temporary waiver of patent rules? I would like for you to also respond to the question of whether you believe therapeutics and diagnostics should now be subject to a temporary waiver.

Mr. GRESSER. Thank you. With respect to the Biden Administration's choices in 2021 and early 2022, we need to dial back the clock a bit. Over the course of 2020, year 2020, the world fell into a massive health and economic crisis. As we recall, the former administration closed a lot of the U.S. economy. So did many State governments. We went through a period of offering PPP loans on a scale of tens of billions of dollars. We did lots of things that we

would not do in normal circumstances and would not be appropriate in normal circumstances.

In normal circumstances, the TRIPS Agreement, as I had mentioned, is serving the U.S. very well, and I believe is serving the world interest in promoting research and innovation.

There have been cases over time. Mr. Cline mentioned HIV and AIDS, which was actually quite a similar debate at the WTO 15 or 20 years ago, whose early years I witnessed while I was at the USTR at that time. It raises a question, when you have an extraordinary threat to public health, is it at sometimes necessary to make exceptions to policies you would ordinarily not make exceptions to? Sometimes it is.

In the case of COVID, government, in 2020–2022, was operating on not complete information. We don't know how many new strains will evolve, how quickly they will come, how virulent they will be. I think governments do need to at some time take extraordinary measures. The Biden Administration viewed that this might be one. In practice, no one has used it, as you say. So, it's probably, in case in retrospect, maybe it wasn't needed, hasn't done any particular harm, can move on.

With respect to therapeutics and diagnostics, this appears to me to be much wider array of products and technologies than the COVID way—the vaccine waiver, which is specifically for vaccines for the COVID–19 virus. That gives me pause.

It, also, should be recognized that we are no longer in the emergency situation of 2020–2021, so the external circumstances are different. So, I'm personally quite skeptical that this is necessary. I am waiting with some interest to see the ITC's report and what they will show. I think from what I can see right now, the case for a much broader waiver is not, at the moment, compelling to me.

Mr. JOHNSON of Georgia. Thank you. In your testimony, you say that the fact that China has foregone the use of the waiver means that, to the extent there's reason for concern about patent rights to COVID vaccine's vis-à-vis China, the relevant issue is one of enforcing current legal rules rather than of opening a gap in those rules for China. Can you expand on that point and describe what you mean?

Mr. GRESSER. Yes, that's correct. The WTO TRIPS Agreement requires all its members, with some flexibilities for these developed countries, to maintain a basic set of patent rules and patent laws and enforcement. China has these patent laws. China is a spotty enforcer. China is also an aggressive seeker-out of proprietary technologies.

The COVID vaccine waiver does not change the WTO rules vis-à-vis China, because China has foregone it. It is embodied in a WTO document. So, it is an obligation of China just as the regular patent laws are. So, what our challenge is in dealing with China vis-à-vis patent laws is to find ways to enforce the WTO rules to the extent we can; to have U.S. businesses adopt best practices to defend themselves; to help the U.S. Government—have the U.S. Government be an advocate and enforcer of these rules.

Mr. JOHNSON of Georgia. Thank you. I yield back.

Mr. ISSA. We now go to the only gentleman on the dais who a TRIPS waiver could affect his current patents, Mr. Massie, the gentleman from Kentucky.

Mr. MASSIE. I thank the Chair.

Mr. Shea, when I first heard the Biden Administration announce they were going suspend patents for vaccines, I was very taken aback, because it's a right that's enshrined in the Constitution. I've learned it's a little more complicated than that. It's not that he announced he would suspend patent protection in the United States to make users sell something here in the United States; he suspended something called TRIPS.

Can you explain to me what it is that was suspended that never got used, but it is a reciprocal enforcement mechanism? Is that what TRIPS is? Or is it reciprocal licensing agreements? What is TRIPS?

Mr. SHEA. TRIPS was adopted in 1995 or went into force in 1995 at the time of the creation of the World Trade Organization. It, as Mr. Gresser said, it establishes a min—it requires WTO members with certain flexibilities for LDCs, least developed countries, and at one point for developing countries, to use their domestic mechanisms to establish a minimum set of intellectual property protections for patents, trademarks, trade secrets, and other matters.

In TRIPS, there is a mechanism to obtain a compulsory license in extraordinary circumstances. Even to get a compulsory license, you have to engage the patent holder and potentially remunerate the patent holder. The TRIPS flexibility—the waiver of that requirement, which is what the Ministerial Decision of the WTO decided, waives that requirement.

So, an entity in WTO, a member country, can just utilize the patent without informing the patent holder or even without any kind of engagement with the patent holder.

Mr. MASSIE. Mr. Busch, when I first learned about this TRIPS thing where you can get compulsory licenses, I'm just troubled by TRIPS itself, now that I know about this, because isn't this the logical conclusion of compulsory licenses, when instead of letting a free market decide what the price of a license should be, you let politicians decide what the price of a license should be? Isn't the logical conclusion that people who don't appreciate entrepreneurship are going to set the value at zero of a patent?

Mr. BUSCH. The compulsory licenses are generally coming in with a royalty fee of between 5–7 percent. So, it's not quite zero, but it's not fantastic.

The AIDS experience really drove successive decisions on what's known as TRIPS Article 31b. That was the flexibility that allowed the members of the WTO to respond to a public health emergency. The provisions there were centered on compulsory licensing, the expectation being that when times get tough, you could have generics providers, courtesy of their government, force a patent holder to hand over their idea at a royalty fee.

We really didn't see it during AIDS, and we aren't going to see it now. Even if it's never used, however, in expectation, the fact that we had 164 countries go along with the idea is going to devalue IP and seriously raise questions about how much protection

is out there when things look tough. So that really is what has to be worked out.

Exceptions should always be narrowly construed and rarely used. We have to make sure that goes for not just the Part 1 of the TRIPS waiver, but whatever might come with a Part 2, if anything at all.

Mr. MASSIE. It sounds like eminent domain for property rights, but for patent rights. In this case with the waiver, the Biden Administration said just take it, just take what you want here from these people who've developed it.

Mr. Sedam, there's been a claim that there was no harm in this waiver since it didn't get used. Can you explain why there is harm and what the message that it sends to inventors and investors that we can just take your idea and give it away? Why is that harmful, even though it wasn't implemented.

Mr. SEDAM. Yes, I think there was no direct harm in that it wasn't used. What it adds, as I mentioned in my opening statement, was it adds uncertainty. Anytime there's uncertainty in a transaction, the likelihood of a transaction goes down. So, just the threat of having someone at a time ill-defined in the future for an event that itself is ill-defined might mean that somebody can come in and take and use your IP without reasonable compensation for you, would lead people to say, well, maybe I just simply won't make this investment.

In the area of a therapeutic, it might take $1.2–1.3 billion of investment to create a drug to have in the first place that then someone can say, well, never mind, I'm just going to use those IP rights and make it and not pay you anything. So, who on Earth would invest that kind of money if they knew that they couldn't get the return that they need even just to break even later on?

So, it's a cooling effect and a headwind on even early stage research and directing things toward really, really hard problems that are going to be there in 5–10 years.

Mr. MASSIE. Thank you, Mr. Chair. My time has expired, and I yield back.

Mr. ISSA. I thank the gentleman.

We now go to the gentleman from Maryland, Mr. Ivey, for five minutes.

Mr. IVEY. Thank you, Mr. Chair.

Good morning to the panel.

Ambassador Shea, in particular, good to see you again.

Mr. SHEA. Hey, Glenn, how are you? May I call you Glenn?

Mr. IVEY. You may. I'm going to call you Ambassador, though, sir.

Let me ask this question. Let's start with Mr. Gresser. In your testimony, you talk about China foregoing the use of the waiver. Give me your thoughts as to why that might be. Why do you think that they didn't use the waiver in this instance?

Mr. GRESSER. It's not easy for me to enter the mind of Chinese negotiators and their overseers in Beijing, but I think they may have felt (1) that they were very committed to their own vaccine, Sinovac. They had put a lot of money and a lot of kind of publicity into it and may not have been that interested in the U.S. and European vaccines. (2) Another is that they may well have seen that

the scale of vaccine production in the West was ramping up very quickly and that there would not likely be a worldwide shortage as they would need to see their own needs to use a waiver. (3) It may also be that they had their own plans to go into the U.S. technology waiver or not.

All those things I think are possible, and there may be more than one of them at work.

Mr. IVEY. Going to Mr. Sedam's point about whether there was direct harm or not, what's your sense with respect to that?

Mr. GRESSER. I don't want to characterize Mr. Sedam, but I think he agreed that there was not direct harm to research. It has always been the case within the WTO's TRIPS Agreement, there are flexibilities. Ever since 2001, there has been an explicit statement that governments have the right to take action in event of public health emergencies. That is understood. It has not been frequently used.

I think most people will say that the COVID–19 pandemic was such an emergency. I think they will look at the fact that governments have not actually used this and probably conclude, yes, there is some risk there may be another such event in the future, but that governments are pretty careful about how they do it, and they don't recklessly and willy nilly take intellectual property.

So, on balance, you can look at this experience to say this was fairly reasonable. They took a prudential decision in an emergency, found it wasn't necessary to use it, and no one has used it. So, I think that should give some confidence to R&D investors.

Mr. IVEY. Professor Busch, in your testimony just a moment ago, you said, "exceptions should be narrowly construed and rarely used." Is it your sense—I would assume that you'd think COVID would be within the range of the narrow exception scenario?

Mr. BUSCH. I definitely agree with Mr. Gresser that there was a lot that was unique about that dire moment in COVID in the early goings. The question that I have, though, is—let's just take that as given—why are compulsory licenses the answer? We all agree that we want access to medicines. We all agree that we would like cheaper drugs. Compulsory licensing is a very particular mechanism. There is absolutely no evidence that this particular mechanism is the solution to that problem. That's where things get complicated.

So, on its face, I totally agree COVID was very unique in many exceptional ways. That doesn't mean that what we do is we run with this very cogent narrative and ignore all the factors that are weighing on access to medicines, including the fact, mind you, that there are 20 developing countries with no WTO legal limit on their tariffs on pharmaceutical drugs. That is simply unacceptable.

There are quick fixes for this, including zeroing out those tariffs in these same extraordinary times and zeroing out the taxes in these same extraordinary times. There are other alternatives. This idea of a compulsory license is not a unique equilibrium.

Mr. IVEY. Let me ask you about the—I think you gave a valuation in response to Congressman Massie's question of 5–7 percent.

Mr. BUSCH. Yes.

Mr. IVEY. I don't mean to characterize your testimony, but I sense that there was a sense of regret with the numbers that you gave. I assume you think that was too low?

Mr. BUSCH. That's what Indian courts have been issuing, 5–7 percent royalty fees on compulsory licensing. I would imagine that the technologies are sufficiently heterogeneous that it's hard to pinpoint an exact number that would work across the board. I can tell you that there has been no love for these numbers on the part of those who have been essentially expropriated.

Mr. IVEY. I see my time has expired, but I look forward to another round. I appreciate your testimony.

Mr. ISSA. I thank the gentleman.

That last question, I'm sure we're going to have a followup on while we're here.

We now go to the gentleman from California, Mr. Kiley.

Mr. KILEY. Thank you, Mr. Chair.

As a quick survey, Mr. Sedam, do you believe that the COVID–19 pandemic is over?

Mr. SEDAM. It was declared over, so—and we're in this room without a mask, so pretty good.

Mr. KILEY. That's right.

Mr. Shea, do you believe the COVID–19 pandemic is over?

Mr. SHEA. I think so.

Mr. KILEY. Mr. Busch?

Mr. BUSCH. Yes.

Mr. KILEY. Mr. Gresser?

Mr. GRESSER. I have to say honestly no. I had myself contracted COVID last week. So, COVID is still with us.

Mr. KILEY. As a public health emergency, would you say it's over?

Mr. GRESSER. Yes. As a serious threat to life and health around the world on a large scale, yes.

Mr. KILEY. All right. So, we'll count you as four for four.

The House of Representatives has passed a bill saying the pandemic is over. The Senate has passed a bill. The President signed it into law. Our experts here agree. So, why in the world would we be continuing and expanding a waiver that is predicated on the existence of a public health emergency? How does that make any sense?

Professor Busch, how does that make any sense?

Mr. BUSCH. It doesn't.

Mr. KILEY. So, I think that in your testimony, actually in several people's testimony, Mr. Shea, we heard about how this proposal to expand the waiver would benefit China primarily. Could you just explain again why that's the case?

Mr. SHEA. Well, I'm concerned that they might be—China might use countries that do use a waiver. The waiver extends for five years, so we have been at it for one year. China might be able to use other countries who avail themselves as a waiver as a point of access for stealing technologies.

I mean, the Chinese have identified medicines and medical devices as a key industry and made in China 2025. Biotechnology is named as a key industry, and it's one of their former plans called

the Strategic Emerging Industry Plan. They're also investing outward.

Particularly, I put in my testimony a report put out by a U.N. agency, as well as a joint report by the China Chamber of Commerce for Medicines, about how Africa might be a potentially beneficial place for China to make significant pharmaceutical investments. One of the things that is appealing is that many of the countries there avail themselves of TRIPS flexibilities.

Mr. KILEY. Thank you. So, this is now concerning to me, and it seems to be part of a pattern when we discussed at a prior hearing of the Subcommittee that the Chair convened how this administration entered the China Initiative. So, now we have several examples of administration policies with respect to IP that are potentially disadvantaging the United States vis-à-vis China.

We've also seen talk from the WTO about potentially expanding this sort of emergency waiver to other types of emergencies, such as even green technologies.

Mr. Sedam, do you see any limiting principles to this idea once we get in the habit of simply suspending IP if there's something that anyone could characterize as an emergency?

Mr. SEDAM. I think we have strong IP rights for a reason, and we should respect them.

Mr. KILEY. Thank you.

A final point, several people have mentioned how the real holdup was not IP protections when it came to global distribution of vaccines. For evidence that I think you can actually look right here in the United States where we had the same level of IP protection, but different States had a very different level of efficacy in terms of distribution.

I will say in my own State of California, our State was dead last in the entire country out of all 50 States in terms of how effectively it was able to distribute vaccines. The irony is we had a Governor who decided it was good politics to mandate vaccines left and right. He would get in front of the camera every day and announce new vaccine mandates, even did one—the only one in country for school children. Yet, when it came to getting vaccines to people who wanted them, we were the worst in the entire country because of a lack of administrative capability and effective governance.

So, I think that in preparation for future public health threats, States who didn't do well, like California, would do well to study the methods of States that did do well and that applies on an international level as well to those countries that had a difficult time getting medicines to their citizens. That's something that perhaps our international organizations should be focused on as well. Frankly, I think this idea of continuing these waivers and expanding these waivers is a destruction to that.

So, thank you. I thank the Chair for convening this hearing and I yield back.

Mr. ISSA. Thank you.

We now go to the gentlelady from North Carolina for a round of questioning.

Ms. ROSS. Thank you, Mr. Chair. Thank you to all the witnesses for your input.

I want to use my time today to turn down the temperature, maybe depoliticize this issue a little bit and make it clear that the Biden Administration has not taken a stance on whether to expand the TRIPS waivers to COVID–19 diagnostics and therapeutics. By all accounts, the administration is diligently gathering information from all sorts of stakeholders about the benefits and harms of a potential expansion.

Moreover, many Congressional Democrats, including myself, have urged the Biden Administration not to expand the TRIPS waiver. Last year, I joined over a dozen of my Democratic colleagues in sending a letter to U.S. Trade Representative, Ambassador Tai, expressing concerns with a TRIPS waiver expansion for COVID-related therapeutics and diagnostics.

Mr. Chair, I'd like to submit that letter into the record.

Mr. ISSA. Without objection, so ordered.

Ms. ROSS. Thank you, Mr. Chair.

This issue is not theoretical to me or to my constituents. Many of the companies that brought us lifesaving vaccines, therapeutics and diagnostics during the public health emergency are located in my district in North Carolina's Research Triangle Park. These companies largely choose to enter into voluntary licensing agreements with countries struggling with the COVID–19 vaccine, diagnostics, and therapeutic supply. Because they recognize that they had a duty to help other Nations address the pandemic for all our benefit.

Strong IP protections are the backbone of my district and the lifeblood of research and development. I've seen this in labs, universities, and other pharmaceuticals—other facilities in the biopharmaceutical space. Now, the Biden Administration and the WHO have ended the COVID–19 public health emergencies. People worldwide have access to U.S.-developed vaccines, diagnostics, and therapeutics.

The best way we can support our national public health infrastructure for the future is to make sure that we maintain robust incentives to innovate, and that starts with strong IP protections.

My first question is for all the witnesses so it may take up all the time. American medical innovation led the way during the COVID–19 pandemic as major vaccines and treatments were developed in our country. What IP and trade policies are needed for the United States to remain a leader in the biopharmaceutical innovation space and in research and into—and encourage making therapeutics and vaccines for emerging viruses to ensure that we are prepared for the next pandemic, which is surely coming and that we're not reliant on foreign competitors like China. I'd like to start with Mr. Gresser and then we can go down the line.

Mr. GRESSER. Thank you very much. I think your statements very well expressed.

In terms of where do we go from here? I think recognition that emergency actions are sometimes necessary in emergencies, but that they should be limited to emergencies is one principle. The U.S. should feel very good about its support and endorsement of TRIPS agreement over the years and should continue on that path. We should be careful about expanding a waiver that was designed specifically for vaccines and time limited and limited in country coverage. More generally, I think the U.S. is well set up to succeed.

We have a large industry and university research system. We have a lot of public commitment to R&D. We have a strong ability to recruit the world's talents. I think we should be feeling pretty good about ourselves.

Ms. ROSS. Mr. Busch.

Mr. BUSCH. We have to keep trade open. During the pandemic and through the early goings of early 2022, 91 countries opposed 191 export bans on COVID-related technologies. There were only two countries that bucked the trend, Singapore and New Zealand. They signed an agreement that they would keep their supply chains in medical technologies open. We have to stop thinking in this country that we can reshore every supply chain. It can't happen, but to get the maximum benefits of trade, we've got to agree with other countries to keep the lines flowing.

Mr. SHEA. Well, Congressman, I agree with your statement completely, very well stated. I may disagree a little bit with Professor Busch. I served on the U.S.-China Commission for 11 years. Last year, the Commission issued a report that has a section on how the U.S. is dangerously dependent on China for the manufacture of lifesaving medicines and advanced pharmaceutical ingredients. So, I do think we need to bring more of that production to the United States and to friendly Nations.

Ms. ROSS. Thank you. Sorry, it's up to the Chair whether we can have the last witness answer.

Mr. ISSA. Go ahead, briefly.

Mr. SEDAM. I will.

I'll keep it even a little earlier stage, which is to double-down and enforce the things that we have on the books now, like protecting Bayh-Doyle and making sure we're reinforcing Bayh-Doyle, so that their marching provisions are only used very, very—it's never been used and to keep that very limited. To look at things in our own Patent Office like post grant review that has made it actually a little problematic. It used to be patents were assumed granted—they were valid when they were granted, post grant review has led to some questions there. I would say even a little bit in our own country, there's a principle in the technology industry called efficient infringement, which is, I'll use your patents until you sue me and then come back to that. We are actually admitting that we are not respecting our own patent rights.

So, I would like to see the country think about doubling down on those things and reinforcing for patent holders that the rights that you have once granted cannot be taken away or my used by somebody who does not own them.

Ms. ROSS. Thank you for your indulgence, Mr. Chair. I yield back.

Mr. ISSA. Always.

The gentlelady from Florida who has been patiently waiting is recognized.

Ms. LEE. Thank you, Mr. Chair. Good morning, gentlemen and welcome.

Professor Busch, I would like to start with you. I could direct your attention to the part of your testimony that specifically refers to the expansion of these waivers and the implication on national security. If you would please, elaborate on how it is you perceive

that these waivers could lead to China's work at undermining the United States' competitiveness and how that affects our overall national security?

Mr. BUSCH. The flow of technologies with undermine U.S. competitiveness, but on the national security front, think about it this way, in the past few years all since COVID China has waged political trade wars on Australia, Canada, Lithuania, and the company Micron Technologies. In pursuit of levers in these trade spats, the idea of having a market concentration in any given technology will facilitate that type of economic coercion. It's not new, but it's really come online in a really big way.

I'd point out that both the FBI and Britain's MI–5 have concluded that this is already happening, and that as a result, you have the European Union recently legislating what they call an anti-coercion instrument.

These are tough times in a lot of ways. The more that China dominates certain of these sectors of Biopharma, the more leverage they will have through economic coercion, which implicates, of course, U.S. national security.

Ms. LEE. If you would elaborate for us on what are some of the strategies you think the United States should be implementing to help combat this effort and economic coercion here at home?

Mr. BUSCH. Well, first, we have to do something that kind of looks like what Europe has been up to, namely, thinking about ways to mitigate those disputes that are purely political and have nothing to do with economics. So, for example, Canada arrested a relative of a Huawei senior executive, and China banned canola exports from a given Canadian company in response.

Australia asked for a global study of the origins of COVID, and China went to a full-fledged trade war with Australia. We have to have mechanisms that allow us to respond to these coercion efforts and do so in a way that is transparent in the eyes of our allies, because the worst thing in the world would be to lose the faith of our allies as we deal with Chinese aggression.

Ms. LEE. Thank you.

Ambassador Shea, I'd like to turn back to a point that you raised earlier related to the potential scope of these waivers, if expanded. You touched on the notion that these waivers could implicate more than just COVID-related technologies or therapeutics, but could actually implicate a broader philosophical construct that covers things like climate change mitigation and other technology. Share with us more your perspective on that subject.

Mr. SHEA. Well thank you for the question. Included in my written testimony, a reference to existing—a statement by the existing WTO Director General, who took a very active role in pushing the waiver through the ministerial. Usually, the WTO is considered a member-driven organization, but I think in this instance around the waiver she seemed to have played a very active role in shaping the outcome. When she was asked in London recently about extending the waiver to climate change mitigation technologies, according to the report I read, she says, "I could not agree more." We're going to see more of this type of argument, and I hope we'll find a way because, really, trade needs to help spread green technologies.

So, there are members of the WTO, for example, India who would love to jump on that bandwagon. So, it is a slippery slope, which unfortunately this precedent with the COVID–19 vaccine's waiver has set.

Ms. LEE. You touched a moment ago on the concept of our dependence on China as it relates to lifesaving drugs. Tell us, if you will, about that dependence and what steps you think we could be taking now to try to mitigate that vulnerability?

Mr. SHEA. Well, I think we need to—I don't know if the Federal government, the Executive Branch has actually done an assessment of what you are our dependencies are. I think the first thing to do, not just on pharmaceuticals, but in other areas, is to assess what are we really dependent on? What is critical to us and what are our dependencies?

In the military, the military has subcomponents, thousands of subcomponents in very high-tech missile systems, and I don't think we know where all these subcomponents are sourced. I assume some are from China, so that is very perturbing.

If I may, I'll just go back to—if I may on the question you asked my colleague, I mean, you could have also added Philippines, Korea, and Japan to the countries that have been subject to Chinese trade coercion as a result of a political position that they've taken.

In terms of working with our allies, there is an idea that two people I respect, Rob Atkinson of ITIF and Clyde Prestowitz have floated of forming a, defense—I forget what specifically refers to, what the acronym refers to, but it is basically getting allies together to collectively respond to coercive trade acts directed at one of the members. So, I think that's something that should be explored further.

Ms. LEE. Thank you.

Mr. Chair, I yield back.

Mr. ISSA. I thank the gentlelady.

We now go to the gentleman from California, Mr. Lieu.

Mr. LIEU. Thank you, Chair. Let me first thank Chair Issa and Ranking Member Johnson for holding this hearing. I have some questions for Mr. Gresser, and I thank all the witnesses for being here today.

So, the only reason we're here today talking about intellectual property waivers for COVID vaccines is because these vaccines work. Isn't that right?

Mr. GRESSER. I think that's a fair statement.

Mr. LIEU. In fact, if these vaccines didn't work no one would care about intellectual property. Isn't that right?

Mr. GRESSER. They may be interested in how the U.S. businesses do their research, there may be things that could draw from unsuccessful approaches, but I think basically yes.

Mr. LIEU. The reason that all these witnesses are about fear of China trying to take those intellectual properties because these COVID–19 vaccines, in fact, reduce severe symptoms in people who got vaccinated, or prevented death. Isn't that right?

Mr. GRESSER. Yes. China has a well-documented record of trying to take and understand and sometimes—and make use of proprietary U.S. technologies.

Mr. LIEU. So, for folks who are watching, and you're still not vaccinated, I urge you to talk to your doctor about vaccines or read what doctors' organizations like the American Medical Association have said about vaccines.

Now, I do have a question about some of the things you said in your written statement which I read. I haven't formed a very strong opinion on these TRIPS waivers, so I just want to learn some more information. There is a huge difference between getting a patent and then producing a vaccine. There are multiple steps. You have to have the resources to be able to do that.

Mr. GRESSER. Yes. A patent is a legal proprietary right to produce a particular product.

Mr. LIEU. So, I'm just trying to understand, even if a devolving country got a patent for one of these complicated vaccines, how are they going to be able to produce that?

Mr. GRESSER. It would depend on the country, I'm sure. There are quite sophisticated scientific and medical establishments in India and in Brazil, quite a number of countries. Not all WTO members would have that capacity.

Mr. LIEU. Doesn't it suggest, though, that, in fact, one of the reasons no one took the TRIPS waiver is because they didn't really have the capacity to make one these vaccines?

Mr. GRESSER. I don't think that would be the case. I think the reason that countries have not used it is because the steps, the U.S. and others took to produce new vaccines, develop ways of manufacturing them on massive scale, and logistically, deliver them to people in need proved quite effective. So, there was actually little need for countries to use the waivers.

Mr. LIEU. So, it turned out that there were some countries that have enough capacity to supply these vaccines.

Mr. GRESSER. Eventually, yes. I don't think that was known early on. That was one of the gaps in information that all governments were working with.

Mr. LIEU. Right. For a developing country to take the resources and just all of a sudden create a factory to start making these complicated vaccines would have taken quite a big amount of time, right?

Mr. GRESSER. For some of them, yes, and maybe for many of them.

Mr. LIEU. So, I'm just trying to understand, what is the utility of giving away these patents to countries that haven't really shown the ability to just stand up a factory—personnel and then develop—and produce these vaccines.

Mr. GRESSER. One of the aspects of this particular waiver is relatively easy right to export it to other countries. So, that a country with quite a large medical establishment, say, an India or an Israel, would probably be quite able to create a productive capacity and export.

Mr. LIEU. Now, if the vaccine manufacturers did have a capacity to produce these vaccines for people who need it then there would be no need for this waiver, right?

Mr. GRESSER. Yes. In the absence of an emergency situation which governments did not know all the information and had to—visible health emergency in their own countries, probably that

wouldn't be the same situation. There wouldn't be a real case for a waiver in those in that situation.

Mr. LIEU. Thank you. I'd like to get more information on this. It seems to me that by definition, "emergency situation" may be something that people haven't thought of or because it is an emergency, things happened very quickly and the notion that any country can just all of a sudden stand up a facility to make complicated vaccines just because they have a patent doesn't seem realistic to me.

With that, I yield back.

Mr. ISSA. I thank the gentleman.

We now go to the gentleman from Wisconsin, Mr. Fitzgerald.

Mr. FITZGERALD. Thank you, Mr. Chair. Mr. Sedam, I wanted to kind bring it back to my own State in a discussion that I know it has been happening for some time, and that is, since 1925, University of Wisconsin Madison has partnered with Wisconsin Alumni Research Foundation, we call it WARF of in Wisconsin. It sounds like you're very aware of that.

Mr. SEDAM. Vitamin D.

Mr. FITZGERALD. To commercialize patents developed through the university research. I know there is not a Member of Congress who doesn't have a similar situation with a research university in their State. This partnership has led to numerous successful commercializations in the field of biotechnology. How would an expansive WTO IP waiver effect research universities or some of these other partnerships similar to what we have in Wisconsin?

Mr. SEDAM. With a $60 billion annual investment by the Federal government a year in early stage research, that's a great question.

So, I think it, again, adds a headwind on things. The trick to all this is, as Mr. Lieu said, was you have to have a drug to then decide that you don't want it, you want to waive the patent right. If you don't get the drug, you have nothing to fight over. When we add uncertainty into the IP world, whether it's on attacks Bayh-Doyle, post parties review, things that we've talked about today, it leads people not to make the initial investment in the first place.

Remember, there are two kinds of investments at risk here, it is the Federal government's investment in its own capacity to create knowledge, and to create new ideas that lead to products and services that make humankind better. That is at risk because we need those patents. The universities file and protect those and license those and start companies around them. So, there is a significant, not only a risk to development of products, but we do create over a 1,000 startups companies a year, which leads to economic growth in our regions, much like in Wisconsin and in New York City. Then, universities clearly don't make products, right? We create and disseminate knowledge. When those products find partners, those partners have to be willing to invest $20 million, $50 million, $1 billion, $2 billion to get that idea, that a nugget of an idea that sits in a patent and make it into a product or service that we can all use. The more risk you put into that early stage, that says, Well, if you put that in, but maybe someone will take it from us or maybe somebody will be able to use it and not compensate us for it. It just reduces the likelihood that either would be able to license it to an existing company, or that we will be able to find the

sources of capital, whether it is seed investment, early stage capital, venture capital who are willing to take not a technical risk, not a market risk, not a financial risk, but a risk of the unknown, and invest in those early stage technologies. So, I think it is fairly significant, its TRIPS and those other things that I mentioned about, especially Bayh-Doyle.

Mr. FITZGERALD. Thank you very much for that answer.

I'm just going to shift very quickly to Ambassador Shea. This is a question more about it might be hard to articulate, but kind of the environment or the feel. The Biden Administration supported the initial WTO IP waiver on vaccine patents based, in part, on assurances that were given by the Chinese government that it basically would not make use of that waiver authority.

As a former Chair of the U.S.-China Economic and Security Review Commission, with many experiences, probably some good and some bad, on experiences dealing with China-related issues, do you think we should trust the Chinese when it comes to this or is—that's why I think Members of Congress have a hard time really gauging that, because that's not something we do on a daily basis, right?

Mr. SHEA. General Secretary Xi told President Obama that he would stop—China would stop cyber espionage directed at U.S. economic assets. He promised that China would not militarize the islands in the South China Sea, violated the U.K.-Sino agreement on Hong Kong.

As I mentioned earlier, each year USCR puts a report out assessing China's compliance with its WTO obligations. Again, the assessment was China's record of compliance is poor. So, I do not take much—I don't give much account to a statement made by a WTO representative of China at a general council meeting, that's indirectly referenced in a footnote in a WTO ministerial decision as binding. It does not—I don't take that too seriously.

Mr. FITZGERALD. So, I'll put you down as a no.

Mr. ISSA. I thank the gentleman.

We now get to what might end up be last and least, myself.

A number of questions, Ambassador Shea, and all of you are very qualified, but you're the most recently qualified when it comes to the actions of trade and what I would call coercion. I think you alluded—both you and Mr. Busch alluded to this earlier: The techniques that are regularly used to help negotiate lower prices include part of TRIPS. Do they not? In other words, if you, quote, "Deny a drug," a country is allowed to ignore the patent and make the drug because it's been denied. Isn't that a basic principle that you deal with?

Mr. SHEA. I haven't dealt with that extensively at the WTO, but I think you're right. Yes, sir.

Mr. ISSA. Under that TRIPS enforcement, Canada has used that to set a price that they will pay for a drug with the threat that they will make a generic if they don't get that product. That's been going on for decades. It's one of the reasons that brand drugs are slightly cheaper in Canada than they are here, while generic drugs turn out to be more expensive.

So, I'm going to go back to this specific waiver. Isn't the use of this waiver in the sense of offering it, and the threat of offering it

in the future, doesn't it inherently adversely affect the normal negotiations on licensing of companies, technology to—around the world, not just in the developing world, but even between the European and the U.S.

Mr. SHEA. I think that's accurate. It does, as my colleagues have said, it dampens the desire for investment in these products or potential products. If the threat is out there that I am going to use the waiver against you, that could have a damaging effect as well.

Mr. ISSA. Now, going back to alternatives to ever doing this again, and I bring this out for a reason because it is always good to say it's a challenge. Mr. Gresser, I'm going to probably put this to you, if, in fact, in that emergency, we had recognized that we wanted no one to die for lack of the availability of this drug, weren't there a number of other tools available to the Trump and then to the Biden Administration, including using our war powers type act to mandate the creation of additional facilities, or the repurposing of additional facilities to make additional drugs if there weren't a sufficient amount. Are those tools that are available from the U.S. around the world, and they were used, for example, on ventilators during the administration. Aren't those tools that could have been used in lieu of this because you've supported the idea of an initial waiver?

Mr. GRESSER. I guess what I would say is that the response to COVID pandemic was quite successful. The idea within a couple of years you would, from a standing start, have a safe and effective vaccine, you would produce it at a level able to serve the entire world. You would have logistics and providers able to deliver it to the patients. That's quite an impressive achievement I believe.

Mr. ISSA. So, we look at the model going forward, the use of this waiver, again, until or unless other forms that do not deny the intellectual property return or respect, wouldn't those be better to push for either in statute, or, at least, in practice by future administrations?

Mr. GRESSER. I think governments do need to reserve some right to take emergency actions in circumstances that they can't foresee, which is probably—the next pandemic will be slightly different than this one. We don't know quite what will be necessary there. So, I hesitate to say we should never do X or Y, but I think your point is a good one.

Mr. ISSA. Why don't we just say that the next pandemic is much worse, it's a new form of smallpox that a vaccine doesn't work for, and it has a 70 percent morbidity, far worse than COVID did.

Let's just say that this hit tomorrow, Mr. Massie brought up a point, and I'm going it to use it because it was extremely good. He likened this to an eminent domain, a taking of an asset by an entity that needs it. When it comes to eminent domain, have we ever seen eminent domain, even in a time of war or emergency, not lead to a reimbursement for the value of that taking?

Mr. GRESSER. I do not know nearly enough about eminent domain's history to answer that question.

Mr. ISSA. OK, but you are aware that even our Constitution calls that a taking not, even in time of war, not be without compensation?

Mr. GRESSER. Sure, yes. I guess what I would say in a circumstance like the one you're describing, I think the U.S. Government and other governments and businesses would put all the money they needed into developing a treatment, as soon as possible, and would clear up whatever messes later.

Mr. ISSA. So, one of the things that's missing, and I'll go back to our Ambassador, who is—and I saw you over there at the last administration running in and out so fast you couldn't get a second word in to a lot of people, so I know how hard you worked in a number of areas. As we are looking at global trade negotiations, isn't the TRIPS waiver even if continues to exist, doesn't it lack that fair recognition that some compensation for that taking should have been considered? The taking for purposes of people not dying on the dais, would be undeniable. The question of compensation, how would you deal with that if you were, again, the trade representatives chief go-to guy to go out there and do the work?

Mr. SHEA. I wouldn't have gone for the waiver because it was a solution in search of a problem, but I understand your point. There is compensation envisioned, as Professor Busch pointed out, with respect to the compulsory licensing regime in TRIPS. So, yes, I would be saying if we're going to go down this route, the inventors, the innovators need to receive some sort of compensation.

Mr. ISSA. Because I am last, I apologize if I go a little over.

Mr. Busch, I am going to ask you the closing question, because 5–7 percent on a drug that is a blockbuster, it might, in fact, get you fully compensated, but on a great many drugs, including orphan drugs, including drugs that are, as many of new drugs are, I don't want to call their boutique, but they are refined for a specific cancer, they are refined for a much smaller group, 5–7 percent likely is never going to make you whole. Many of these countries rely on, Oh, you were made whole in your parent country, in Europe or the United States, and thus shifting the make you whole back to the original inventor. Should we, in fact, as a matter of global policy, be trying to reform the system so that it not unfairly shifts the responsibility, if you will, in a way in which they knowingly could pay more, but choose not to, simply because they can use compulsory licensing at an amount that they determine rather than anything close to a fair market return?

Mr. BUSCH. Notice how I said in the courts delivering a 5–7 percent royalty. In other words, the generic provider probably lowballed relative to the 5–7 percent, and the two sides ended up in court. So, that doesn't bode well.

Mr. Chair, to your question, my biggest fear is that if you do something like that, then we will have proponents of a waiver of whatever mechanism you come up with. So, if you do hold hearings on that, I'm happy and ready to testify.

Mr. ISSA. Well, I can assure you that in addition to courts, intellectual property, this committee, from Chair Jordan on down, does believe that we need to protect the fair return to those who create intellectual property, and that continues to be attacked by those who believe that intellectual property only matters if it's theirs.

With that, I see no further individuals—with that I yield to the Ranking Member for a final question.

Mr. JOHNSON. Thank you, Mr. Chair.

Professor Busch, you did mention your discomfort with the compulsory licenses being the mechanism through which payment was determined. What other mechanism would you recommend?

Mr. BUSCH. My concern isn't about the payment per se, my concern is that we have gravitated to one of many mechanisms that might have produced an outcome more favorable. That in other words, I do not see the compulsory license as the go-to instrument for achieving lower prices.

There are other things, many of which are under control of the developing countries themselves and could be put into effect overnight. The idea that we sprang to this idea of a compulsory license as really the only game in town, largely because of the experience with the AIDS crisis was just wrong. So, my frustrations isn't necessarily about the 5–7 percent, or how that's determined. It's that we shouldn't have been looking at compulsory licenses first.

Mr. JOHNSON. Thank you.

Mr. Gresser, do you agree or disagree?

Mr. GRESSER. I guess I would say I agree, we shouldn't look at compulsory licenses first. We should also recognize that we don't know what the next crisis is going to be. We don't really know what the best response to it would be. So, I don't think we should disavow any particular response in advance, but we should be—as I think the dilatory members have in the past, able to recognize when we have a real emergency, and to limit whatever we do to things that are specifically necessary or seem to be necessary at the moment rather than extending it to a range of the other topics and technologies.

Mr. JOHNSON. Thank you.

Mr. Shea and Mr. Sedam, I assume you'd both agree?

Mr. SEDAM. Yes, I do. I think it was interesting with the waiver that IP was the only—it came up very quickly and it assumed that it was in the way, but it wasn't. So, it was the only part of this process in terms of solving the COVID crisis that didn't have to be proven that needed to be changed. Everybody just said IP is going to be a problem. You brought up the War Powers Act. If you know that you can't manufacture something and you say, ah, I can't manufacture it, let me use a different power to do that. With IP, it just was de rigueur that this was going to be a problem before it was even shown that it was a problem. I would hope next time we would try to prove that this is actually in the way of getting things that—there are people that stop people from dying. If it is a real problem, then address it then, don't address it in the beginning.

Mr. JOHNSON. Thank you. Thank you.

Mr. ISSA. I'm going to close, not with a full statement, but just with a remainder that Mr. Busch, you did you aptly say that it seems to make no sense to waive what is effectively the rights of the intellectual property that would have led to a royalty or a product incorporating that royalty. While a country chooses to continue to have tariffs or taxes that artificially run up the cost of the medicine to their own people.

So, I certainly think, although that's not within the jurisdiction of this Committee, it's good for us to note that in the future, or even in the near future, if there's an attempt to have a further

waiver, this Subcommittee and this Full Committee will quickly ask you to opine again in person. So, I want to thank you.

As I said in the beginning, if you want to revise and extend, you can. Of course, somewhere here I have—it tells me how many days, guys—five legislative days in which to include extraneous material, and, of course, the questions that come to you we would expect that you'd answer them timely, but we would keep the record open longer for your response.

With that, we stand adjourned.

[Whereupon, at 11:43 a.m., the Subcommittee was adjourned.]

All materials submitted for the record by Members of the Subcommittee on Courts, Intellectual Property, and the Internet can be found at: *https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=116047*.

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