

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”
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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.