

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.”  
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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 inventors and investors are denied at least some appropriate 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 exists." 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.