

# WAIVER OF THE WTO'S INTELLECTUAL PROPERTY RULES (TRIPS): AN INDISPENSABLE TOOL TO FIGHT THE COVID-19 PANDEMIC.



*This is part of a Global Trade Watch series on the TRIPS Waiver.*

## Facts vs. Commons Myths

### Introduction

The COVID-19 public health disaster and resulting economic crises won't end anywhere unless people everywhere are vaccinated. Despite this obvious truth, rich countries with only 14% of the global population have secured preferential access to over 50% of projected global vaccine supplies. Ongoing outbreaks anywhere allow the virus to mutate, threatening the whole world with vaccine-resistant variants or more deadly or easily spread variants. Governments invested billions to create the vaccines. But now, pharmaceutical corporations control where and how much vaccine and other COVID-19 medicines are made. And, current production levels are not nearly enough to cover the world. Annual capacity is about 3.5 billion, according to the new World Trade Organization (WTO) Director General, while minimally 10 billion doses of vaccine are needed, assuming some vaccines will require two doses and 70% population coverage. And given that these will likely not be one-time vaccines, but like the flu shot must be [administered regularly](#), the only way to control COVID-19 is to build global production capacity. In every region, there are existing firms that could gear up production and governments willing to invest in expanding supply. But WTO rules require countries to guarantee pharmaceutical corporations monopoly control. More than 100 countries support a temporary, emergency suspension of these WTO rules, so more vaccines, treatments and diagnostic tests can be manufactured in as many places as possible. The United States and a handful of other WTO members are blocking the waiver: They won't even agree to negotiate about waiver language to address whatever concerns that they may have with the current text. Donald Trump started this self-defeating blockade. President Joe Biden must reverse it to speed the end of the COVID-19 pandemic.

### **A WTO TRIPS Waiver is a Critical First Step to Gearing Up the Production Level of Vaccines, Treatments and Diagnostic Tests Needed to Crush COVID-19**

In the press and on Capitol Hill, Big Pharma is pushing a Big Lie. The claim is that a lack of manufacturing capacity, not pharmaceutical corporation's monopoly intellectual property (IP) protections, are thwarting greater production of COVID-19 vaccines. A related argument, with decidedly racist overtones, is that COVID-19 vaccines are too complicated for producers in developing countries to make successfully. The reality is that in every region of the world, there are multiple producers that could be greatly increasing global vaccine supplies if the technology and know-how were shared.

Just in Africa, "Biovac and Aspen in South Africa, Institute Pasteur in Senegal, and Vacsera in Egypt could rapidly retool factories to make mRNA vaccines," notes a group of medicine-production experts in a [recent Foreign Policy article](#). Indeed, a former Moderna director of chemistry revealed that with enough technology transfer and know-how-sharing, a modern factory should be able to get [mRNA vaccine production online in, at most, three to four](#)

[months](#). The Serum Institute in India already is slated to produce the Johnson & Johnson vaccine, while Moderna declined to partner with a qualified Bangladeshi vaccine maker, claiming its engineers were too busy to focus beyond U.S. and EU production. In Latin America, existing facilities in Brazil, Argentina and Mexico under contract to monopoly holders are already pumping out vials, and in countries like Chile and Colombia, the pharmaceutical industry has expressed willingness to kickstart vaccine production.

Existing and planned contract manufacturing arrangements prove facilities in developing countries certainly can produce COVID-19 vaccines. But unless technology and know-how are shared more openly, the monopoly holders maintain absolute control over how much can be produced, what the price is and where it will be sold. So, 91% of the Johnson & Johnson vaccine that South African firm Aspen will manufacture must be shipped for sale outside South Africa, according to South Africa's WTO Counselor. And the [Serum Institute is barred from supplying upper-middle-income and high-income countries with the AstraZeneca vaccines](#) it makes, meaning AstraZeneca can artificially segment the global market and ensure that it is the only supplier of the Oxford vaccine in the most profitable national markets, according to Doctors Without Borders.

Most critically, there simply is not enough supply to go around now or for every year in the future during which the whole world will need regular COVID vaccination to keep the virus under control. Thankfully, scores of countries are ready to invest in building [new](#) or repurposing existing production capacity. That is why more than 100 countries support a waiver of the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). These countries seek certainty that if they adjust their domestic laws and practices to support that investment by providing access to the necessary technology, they will not get dragged into expansive WTO litigation or face retaliatory sanctions from countries claiming WTO violations. The waiver will also serve as a worldwide buffer against the political pressure and legal harassment to which Big Pharma subjects countries that seek to promote affordable access to medicines.

In many countries, the regulatory authorities that had to approve domestic use of various vaccines and other COVID-related medical products have significant information from the firms that they could share with skilled teams from local universities, government agencies and pharmaceutical manufacturers — if they were not obliged by WTO rules to guarantee monopoly control of it. And world class pharmaceutical firms already are making generic versions of new cutting-edge HIV-AIDS medicines and pumping out vaccines based on the platform that, for instance, the Johnson & Johnson vaccine uses.

At issue is not manufacturing capacity or skills, but rather control: Big Pharma has a monopoly over vaccine knowledge and technology platforms that will determine life and death for millions of people in rich and poor countries alike and decide the fate of the global economy. These corporations stand to make a lot of money. Pfizer and Moderna recently revealed COVID-19 vaccine expected revenue of [\\$15 billion](#) and [\\$18.4 billion](#) respectively in 2021 alone. Speaking at the virtual Barclays Global Healthcare Conference in mid-march 2021, [Pfizer's senior VP of investor relations](#) described how the firm planned to raise prices and profit richly by selling vaccines annually to rich countries that can pay. Big Pharma firms may have no interest in sharing the vaccines created thanks to billions in tax-payer funding. But the health and economic futures of billions of people around the world require urgent access to the formulas and technology needed to massively scale up production worldwide for use in every corner of the globe.

## **A WTO TRIPS Waiver Is Not an All or Nothing Proposition: U.S. MUST Stop Blocking Discussions of Waiver Text and Engage in Negotiations so a Text Can Be Agreed**

In October 2020, South Africa and India proposed a [waiver](#) from certain WTO rules during the COVID-19 crisis. Countries would not have to comply with TRIPS terms on patent, copyright, industrial design and undisclosed information exclusivities in so far as these rules hinder the production of health products and technologies for prevention, treatment and control of the COVID-19 pandemic. Under this proposal, countries' domestic patent and other intellectual property laws would still apply. However, the TRIPS waiver would provide countries freedom to adjust their policies and practices to be responsive to the pandemic, for instance temporarily removing domestic intellectual property restrictions to support vaccine manufacturing. Temporarily waiving some TRIPS and domestic

rules during the COVID-19 health emergency is critical to facilitate investment in more vaccine production capacity and can help address deadly supply shortages caused both by insufficient production volumes and countries being outbid by the wealthiest for limited supply. Instead of discussing possible changes to the October waiver text so as to address any legitimate concerns, the United States and a handful of other mainly wealthy WTO members have simply blocked any and all text-based discussions. If some countries think that the current waiver text is too broad in its coverage or the duration of the waiver is not clear, then the answer is to engage in negotiations on the text to address those concerns. Moreover, if some countries, are intent on protecting Big Pharma’s precious “intellectual property incentives” for innovation, they can pay compensation for the suspended rights and for technology transfer, though they should take care to allow export of IP protected components to manufacturers in other countries.

## **Existing WTO “Flexibilities” Not Suited to Realities of COVID-19 Pandemic Context**

In the late 1990s, millions of people in developing countries were dying from AIDS because pharmaceutical firms refused to provide affordable access to the medicines that were saving those who could afford them. After needless millions died, a global campaign targeting the WTO finally forced the 2001 “Doha Declaration” that clarified flexibilities for governments to mitigate some negative impacts that intellectual property rules may have on public health. The flexibilities are largely premised on countries experiencing a public health emergency issuing compulsory licenses to override patents so that domestic companies can produce equivalent medicines. The flexibilities were not designed for – nor do they function effectively in – a global pandemic where vaccines and other critical technologies are protected by multiple forms of IP and where production relies on complex global supply chains. Indeed, pharmaceutical firms have made it harder to effectively use compulsory licensing by creating broader intellectual property “thickets” of numerous patents, copyrights, industrial design, undisclosed data and trade secrets protections for COVID-19 technologies – each of which would require a license. For instance, mRNA vaccines include 100-plus key components manufactured in over a dozen countries that may be subject to patents, in addition to copyright protections on software, algorithms and training material used to make the drugs and on storage and use guidelines as well as undisclosed data protections covering some trade secrets plus perhaps industrial design protections for key machinery used to mix lipids and genetic materials for mRNA vaccines. Non-mRNA vaccines that rely on biologic technologies to produce the active vaccine ingredient rely on secret, proprietary cell-lines. To develop markets attractive to new producers, multiple countries would have to try to coordinate national compulsory licensing strategies that would allow prospective producers to import the needed components, machinery and more. In contrast, a TRIPS waiver would simply clear the thorny IP thickets and related investment-chilling liabilities. But even then, the existing WTO flexibilities may not encompass elements of IP critical to COVID-19 vaccines and biologic medicines. Neither the TRIPS Agreement nor the “Doha Declaration” describes explicit mechanisms for easily overcoming trade secrets and undisclosed confidential information with respect to complex manufacturing processes, formulas, bespoke equipment, and biologic resources. Similarly, TRIPS copyright protections, which apply to software embedded in instrument-based diagnostics and other medical devices, in e-health technologies, and in production manuals and industrial blueprints, do not allow for easy override, nor are there such provisions for industrial designs.

The compulsory licensing process for patents is cumbersome and slow under any circumstance, but the “product-by-product” and “country-by-country” compulsory licensing at the heart of the current TRIPS flexibilities are not suited to products relying on complex supply chains. In order to manufacture a “generic” COVID-19 mRNA vaccine using TRIPS flexibilities, the relevant producer would have to seek compulsory licenses for each IP-protected commodity in its country of manufacturer and export, which would require the compulsory licensing cooperation of the exporting country. It would likewise have to seek a compulsory license allowing for import of each such component and allowing for production of the vaccine. Restrictive WTO production-for-export rules make compulsory licensing in a global pandemic context even more complex and unworkable. Under WTO rules, compulsory licenses are to be issued predominately for the supply of the domestic market. WTO rules covering export of compulsory-licensed products to a country lacking its own production capacity are so complex that this flexibility has only been used once in the past 20 years. Finally, countries attempting to invoke the existing TRIPS

flexibilities in the past have been subject to criticisms and trade pressures from the United States and the European Union in efforts to discourage them from doing so. The U.S. government [2020 Special 301 List](#) explicitly targets countries seeking compulsory licenses with possible investigations and sanctions. The 2021 Special 301 submissions from industry include explicit attacks on compulsory licensing in the context of the COVID-19 pandemic.

## **COVAX, C-TAP and Other Programs Need TRIPS Waiver to Succeed, Are Not a Substitute for Waiver**

In the race against time to ensure a critical mass worldwide is vaccinated to quash outbreaks that could spawn vaccine-resistant, more deadly or infectious variants, the answer is “Yes, And!” The TRIPS waiver is a critical first step to getting more manufacturing geared up around the world. Efforts to expand supply through voluntary efforts have not panned out to date. The World Health Organization COVID-19 Technology Pool (C-TAP) was established last May, but as of January 2021 [not a single pharmaceutical firm has donated rights](#) for a single COVID-19 medical technology. The waiver is not a substitute for C-TAP. They are complementary global initiatives, both key to bolster vaccine and medicine manufacturing worldwide. The waiver would remove legal and political obstacles for rich countries’ governments to compel corporations to commit technological resources and know-how to C-TAP. Adding a capacitated technology transfer hub and providing supports for tech transfer and absorption would expedite needed vaccines even more. Similarly, while U.S. participation in programs like COVAX is important, unless production is quickly ramped up around the world to meet global demand, there simply will not be enough supply for COVAX to provide to countries in need. Moreover, COVAX — which is a joint initiative of the World Health Organization, the Global Vaccines Alliance (Gavi), and the Coalition for Epidemic Preparedness Innovations — has as its goal providing vaccines for the 20% of populations at highest risk, such as healthcare workers and people over 65. Even if it meets its full ambition, it would not provide vaccines for the vast majority of people and not enough to establish herd immunity.

## **A TRIPS Waiver Will Boost, Not Cost U.S. Jobs or Undermine U.S. Economic Interests**

The market for COVID-19 vaccines is literally the entire world. Even with technology transfer, any successful vaccine maker stands to profit handsomely. It is critical to understand that waiving WTO rules does not prevent governments from paying royalties or providing other compensation for research and development costs, data rights and trade secret resources under national laws. There simply is not, and in the medium term will not be, sufficient U.S. production capacity to manufacture here the full volume of vaccines and other COVID treatments needed worldwide. Even if every U.S. manufacturing facility is working 24-7-365 with extra shifts of U.S. workers and new facilities are brought on line as quickly as possible, U.S. production cannot win the race against time to produce the minimally needed 10 billion doses of vaccine annually, when now global annual capacity is about 3.5 billion, according to the WTO’s new Director General. And, without widespread vaccination in developing countries, the world economy stands to lose more than \$9 trillion, according to a [study issued by the International Chamber of Commerce](#). Wealthy countries like the United States would bear nearly half of that hit. This economic loss resulting from failure to vaccinate the world would mean fewer jobs and lower wages for Americans as well as resurgent risks of infection with vaccine-resistant variants.

## **Speedy Creation of COVID-19 Vaccines and the Innovations Underlying Them Were Made Possible by Billions in Taxpayer Funds, Not by IP Protections**

The standard Pharma claim is that their monopoly rights and high prices are necessary to support innovation. But the speedy development of COVID-19 vaccines proves the opposite point: Every leading COVID vaccine, on the market or in final clinical trials, has benefited from [substantial public investment](#). The miracle of speedy COVID vaccines resulted from taxpayers providing pharmaceutical firms billions to develop and test COVID-19 vaccines and then [billions more in pre-orders](#), not from pharmaceutical firms investing monopoly-gained profits. By one

estimate, during the pandemic governments already have transferred more than \$112 billion to pharmaceutical firms, mainly for COVID-19 vaccine development. Before that, the U.S. [National Institutes of Health](#) (NIH), military and other agencies invested in coronavirus research for decades. Governments have invested our tax dollars far more than pharmaceutical corporations have spent their own funds in developing these medicines. Why should pharma corporations have monopoly control over COVID-19 vaccines they took little risk or expense in developing?

Indeed, the COVID vaccine situation proves the opposite point that Big Pharma interests claim. This is the third time in the last 20 years that a coronavirus has made the leap from animals to humans: Sars coronavirus in 2002, Mers coronavirus in 2012, and Sars-CoV-2 in 2019. Yet the patent protections of the pharmaceutical industry have yielded little investment in our pandemic preparedness. Why? “Because there is [no real incentive to do this](#), no financial incentive,” Johnson & Johnson’s chief scientific officer [admitted](#) back in January.” Under our current IP paradigm, firms that did not use past profits from their monopolies to prepare for the next outbreak obtained billions in public dollars to develop vaccines for this crisis. Yet under the current IP paradigm, they are given absolute control over the production and distribution of these drugs that will literally determine who lives and dies and the fate of the global economy.

## **U.S. Position at WTO Cannot Be That Millions Should Die Globally and U.S. Public Be Exposed to Unnecessary Health and Economic Risk to Protect Pharma Monopolies**

The Trump administration led opposition to the WTO TRIPS COVID-19 waiver when South Africa and India first proposed it in October 2020. Because WTO decisions are taken by consensus, the United States and very few other WTO members were able to block the waiver even though the proposal has support from 100 WTO countries. But even after the inauguration of the new U.S. president, U.S. officials in Geneva at the WTO maintained the old, self-defeating Trump position. The Biden administration must reverse Trump’s blockage of the emergency WTO COVID-19 TRIPS waiver. That means engaging immediately with the rest of the world to finalize a waiver text. Supporting this waiver is the right thing to do in and of itself. But doing so would not be only altruistic. Ending the COVID-19 pandemic as quickly as possible is also necessary to protect Americans’ health and reboot the global economy on which so much of the U.S. economy relies. And, with so many of the world’s nations supporting this emergency waiver, the Biden administration can also help restore America’s place in the world by siding with the majority prioritizing saving lives over pharma corporation profits.

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