

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.

WTO-Required Monopolies for Pharmaceutical Corporations Obstruct Global Production of COVID-19 Vaccines & Treatment: US Blocking 100-Nation Consensus to Waive WTO Rules for COVID Crisis

Introduction

Many Americans are hopeful that the Biden administration will improve COVID-19 vaccine production and deployment in the United States. But there will be no end to the public health disaster and resulting economic crises anywhere if people in developing countries are not vaccinated and cannot get testing and treatment. Ongoing outbreaks anywhere allow the virus to mutate, threatening the whole world with variants that could evade vaccines or are more deadly or easily spread.

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, it is not nearly enough to cover the world. In every region, there are existing firms that could gear up needed production and governments willing to invest in expanding supply. But World Trade Organization (WTO) rules require countries to guarantee pharmaceutical corporations' monopoly control. More than 100 countries are calling for a temporary, emergency suspension of these exclusive rights, so greater volumes of 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. Donald Trump started this self-defeating blockade. President Biden must reverse it to speed up the end of the COVID-19 pandemic.

Production and Supply of COVID-19 Vaccines and Treatments Are Not Close to Meeting Needs

It is obvious that current production capacity cannot supply enough vaccines for the entire world. Many people in low- and middle-income countries around the globe will not get vaccinated until at least 2022 unless the world manufactures many more doses, [according to the British Medical Journal](#). The world's poorest countries may wait until 2024 for mass immunization, if it happens at all, [reports the Economist Intelligence Unit](#).

The global vaccine apartheid unfolding right now could cost millions of lives and push tens of millions more into poverty. The devastation will be felt for a generation. A [new International Chamber of Commerce report](#) concluded that the world could face economic losses of more than \$9 trillion under the scenario of wealthy nations being fully vaccinated by mid-2021, but poor countries largely shut out. Wealthy countries like the United States would bear

nearly half of that hit. Vaccinating just half of low- and middle-income countries' populations could reduce global losses by \$5.5 trillion.

To avoid the worst outcomes, the global supply of all COVID-19 medical goods — vaccines, treatments, and diagnostic tests — must be greatly increased. The good news is that countries with existing drug manufacturing capacity and expertise, such as South Africa, Argentina, Indonesia and others, could ramp up manufacturing of COVID vaccines and treatments to bolster global shortfalls. While the technologies for some COVID-19 vaccines are new, existing producers in the developing world may be able to scale up manufacturing relatively quickly, if the needed know-how and technology is transferred to them. The ability of producers in developing countries to manufacture complex vaccines has been [repeatedly and wrongly dismissed](#). Existing vaccine production lines can be switched to making COVID-19 vaccines, and existing facilities can add new production lines. Clearly regional, pharmaceutical manufacturing hubs in developing countries could vastly expand global supply well before 2024.

But that will only happen if there is global cooperation, including among qualified manufacturers, to share vaccine recipes, technology and know-how. And that is why the WTO “Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19” is so important. For more producers and governments to succeed in boosting the supply of COVID-19 vaccines and treatments, the steely web of intellectual property protections must be temporarily removed. That is because, as [Doctor Without Borders \(MSF\) revealed](#) in a report identifying barriers to global production of newer vaccines, at issue is no longer one monopoly patent on a medicine but thickets of patents on every aspect of vaccine development, production and use. That includes vaccine-production materials such as chemical reagents, host cells, vectors, and DNA/RNA sequences; vaccine compositions; process technologies; vaccination age groups; methods of using vaccines; and vaccine schedules and presentations. And in addition to patents are copyrights on computer programs related to production and trade secret or undisclosed information protections on various manufacturing practices or know-how. Legal claims by holders of any of these rights can result in a court order to stop production. That is precisely [what happened](#) repeatedly with pharma firms Inovio, GeneOne and VGXI as they battled over intellectual property rights for the COVID-19 vaccine they partnered to develop and a specialized vaccine dispenser. Their serial lawsuits — just among firms that agreed to collaborate — led to temporary injunctions and delays.

“Patent activity in the field of vaccine development and manufacturing has been increasingly recognised as problematic over the past 15 years, according to manufacturers interviewed for this report. International organisations with vaccines expertise such as WHO and Gavi, the Vaccine Alliance, have similarly noted that patent thickets are an increasing concern for vaccines. For medical products such as PCV [Pneumococcal conjugate vaccine] and HPV [human papillomavirus] vaccines, patent barriers can slow the development process, increase costs, increase uncertainty and deter or even block other manufacturers considering entering the market. A recent analysis by Chandrasekharan et al. found 106 Patent Cooperation Treaty (PCT) applications “potentially relevant to the manufacturing of pneumococcal vaccines” and 93 patents applications “relevant to the manufacturing of HPV vaccines.”

—Doctors Without Borders, [A Fair Shot for Vaccine Affordability: Understanding and Addressing the Effects of Patents on Access to Newer Vaccines](#) (2017)

The TRIPS Waiver is a Critical Tool in the Fight for Timely Global Access to COVID Vaccines and a Faster End to the Pandemic

The WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires WTO signatory countries to provide pharmaceutical corporations a broad array of lengthy monopoly protections for medicines, diagnostic tests and the technologies used to produce them. Unlike many international agreements, TRIPS like all WTO agreements, has strong enforcement. Any WTO member government can challenge other government as having violated TRIPS’ requirements. Often industry interests “recruit” governments to pursue such disputes. WTO

enforcement cases are heard by a tribunal of three trade officials who can order a government to eliminate or alter a domestic policy. Countries that do not comply are subject to trade sanctions — tariffs against their exports — until the WTO-illegal policy is ended or changed.

Under the WTO TRIPS rules, pharmaceutical corporations are granted exclusive rights to decide where and how much production of COVID-19 vaccines, treatments and diagnostic tests occurs. This is the case even though governments, particularly the United States, providing pharmaceutical corporations billions in R&D funding, upfront payments, clinical trial support and guaranteed purchases and many precursor technologies used in new vaccines resulting from long-term U.S. government efforts, in collaboration with U.S. scientists and those around the world.

Yes, even though the pharmaceutical firms did not bear risk or costs in developing the vaccines, they control where and how much vaccine is made. And there is insufficient supply, even as some firms holding vaccine monopolies have contracted others to manufacture.

Thus, 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 countries in need. (COVAX is a joint initiative of the World Health Organization, the Global Vaccines Alliance (Gavi), and the Coalition for Epidemic Preparedness Innovations, intended for equitable global distribution of vaccines for the 20% of populations at highest risk, such as healthcare workers and people over 65.)

The WTO TRIPS corporate monopoly rights and resulting supply shortages also threaten equitable and timely global access to COVID-19 treatments. Remdesivir is among the examples provided by Doctors Without Borders, which prepared a [report](#) on how monopoly protections have limited access to COVID-19 diagnostics, medical equipment and therapeutics: “Despite having received at least US\$70.5 million of public funding to develop Remdesivir, one of the candidate drugs for COVID-19 treatment, pharmaceutical corporation Gilead has signed secretive bilateral deals with a few generic companies of its choosing that exclude nearly half of the world’s population from its licensed territories.” (While the World Health Organization withdrew support for the use of Remdesivir, it is authorized for use as a COVID-19 treatment in many countries, including the United States.) As a result of Gilead’s tight controls over where the medicine can be made or sold, many countries in many regions of the world that seek to use it have no supply.

The WTO TRIPS Waiver: What Exactly is Being Proposed?

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.

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, including to support vaccine manufacturing. Temporarily waiving some TRIPS 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.

Efforts to expand supply through voluntary efforts have not panned out to date. The WHO 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 around the globe. The waiver would remove legal and political obstacles to governments compelling corporations to commit technological resources and know-how to C-TAP.

Why is the Waiver Necessary? Doesn't WTO Allow for "Flexibilities" in Patent Rules?

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. Back then, a global campaign also targeted the WTO as a facilitator of this deadly greed.

One result was the 2001 "Doha Declaration" that clarified flexibilities in the TRIPS Agreement that enable governments to mitigate — through the enactment of appropriate legislation and regulations — some negative impacts that intellectual property rules may have on public health. However, the stringent and burdensome legal procedures required to use these WTO TRIPS flexibilities, such as "product-by-product" and "country-by-country" compulsory license procedures, make it almost impossible for any developing country to adequately use the flexibilities in the context of the COVID-19 health emergency. (Every country that seeks to produce must negotiate licensing terms for each medicine with every firm that has monopoly rights over any aspect of a medicine.) Plus, countries' attempts to exercise these rights have led to fierce U.S. opposition time and again. The U.S. government's recently published [2020 Special 301 List](#) explicitly targets countries that seek compulsory licenses with possible investigations and trade sanctions.

Countries that do not have the capacity to manufacture their own medicines must import from another country that is producing under a compulsory license. In the 20 years since WTO rules first introduced import licenses, [only one country has been able to use them](#). In contrast, in one fell swoop, the TRIPS waiver would remove key obstacles to access for all governments and all manufacturers worldwide to the technology and know-how needed to invest in producing COVID vaccines and treatments as rapidly as possible, in as many places as possible, for the billions who still need them.

Everyone is Sacrificing — While Big Pharma is Profiting Richly

The standard Big Pharma claim is that their monopoly rights and high prices are necessary to support innovation. But every leading COVID vaccine, on the market or in final clinical trials, has benefited from [substantial public investment](#). By one estimate, governments 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. The public is all paid up.

The market for vaccines is literally the entire world. So, any successful vaccine maker stands to profit handsomely, whether there is technology transfer or not. And waiving WTO rules does not prevent governments from paying royalties or providing other compensation for research and development costs under national patent laws.

People all around the world have been making extraordinary sacrifices to slow the spread of COVID-19 and protect each other. We have weathered social distance and worn masks, endured separation from our loved ones and even isolation. Many of us have lost our work. If working people around the world can sacrifice this way to help each other through the pandemic, how is it that some of the world's most profitable corporations insist that Big Pharma should have monopoly controls that limit supplies and raise prices for medicines that our tax dollars funded?

For a Speedy End to the Pandemic, Biden Must Reverse Big Pharma WTO Boondoggle

The Trump administration led opposition to the WTO TRIPS COVID-19 waiver since 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.

It is rare that one U.S. policy change can so significantly impact a global health effort that could save millions of lives. The Biden administration 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 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 pharmaceutical corporation profits. This can help erase the months of shameful attacks on the waiver and defense of Big Pharma launched by U.S. representatives in Geneva and speed global health effort to exit the pandemic, save lives and get the economy back on track.

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