

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 Director-General's "New" Proposal Would Consolidate Big Pharma Control Over COVID Vaccine Supply and Prices: "Third Way" Is the Same Old Way, Rebranded..

Key Takeaways

- By design, what has been dubbed the "Third Way" of relying on contract manufacturing and voluntary licensing leaves Big Pharma in control of the supply of life-saving vaccines and treatments, allowing firms to control if, where and when supply will be manufactured as well as where those vaccines and treatments can be sold or distributed and at what prices.
- The "Third Way" is the status quo that has failed to close the chasm between global vaccine supply and demand. Firms in many developing countries have asked for licenses or contract manufacturing arrangements. Instead of agreeing to boost global production, the vaccine originators have used their intellectual property monopolies to artificially segment the global market to prioritize corporate earnings over global access. Recently Pfizer announced plans to focus on producing profitable boosters for rich nations, while many in poor nations have not had access to an initial vaccine.
- Many multilateral initiatives already underway and even those by national agencies are better suited than the WTO to identify potential COVID-19 vaccine production capacity and facilitate developer-manufacturer matches. But missed connections are not the main issue: Until policies change so as to deny pharmaceutical corporations monopoly control over production, such as a WTO TRIPS waiver and related government actions to pressure for technology transfers, sufficient supplies of vaccines and treatments will remain.
- The role of the WTO and its Director-General is to facilitate negotiations among WTO member nations to fix a problem, caused by existing WTO rules on intellectual property, by creating a TRIPS waiver text that can gain wide support.

Introduction

Most countries in the World Trade Organization (WTO) support a temporary, emergency [waiver](#) of certain WTO rules during the COVID-19 crisis to boost worldwide production of COVID vaccines, treatments and diagnostic tests. The waiver would empower countries to adjust their domestic policies and practices to most effectively battle COVID-19 by suspending some exclusivities otherwise required by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) with respect to patents, copyrights, industrial designs and undisclosed information in so far as they hinder the production of health products and technologies for prevention, treatment

and control of the COVID-19 pandemic.

While two-thirds of WTO member nations, including many nations that to date have had no access to vaccines, support the waiver, large pharmaceutical firms fiercely oppose it and insist on maintaining their monopoly control over how much and where COVID medications can be produced, how they are priced and to whom they are sold. The Trump administration, joined by a handful of other WTO members, blocked the waiver, refusing to even engage in negotiations to ascertain whether countries could agree on language that is acceptable to all. So far, President Biden has not reversed Trump's position.

Many hoped that the arrival of the new WTO Director-General (DG), economist Ngozi Okonjo-Iweala, might move countries currently blocking the waiver. Because South Africa introduced it and the WTO Africa Group supports it unanimously, some WTO member countries and activists worldwide expected that the first African WTO DG could help facilitate progress. However, Okonjo-Iweala did not endorse the waiver. Instead, she diverted attention away from it by [suggesting](#): *"a third way to broaden access through facilitating technology transfer within the framework of multilateral rules, so as to encourage research and innovation while at the same time allowing licensing agreements that help scale up manufacturing of medical products."*

Yet that is the same old way that pharmaceutical development, production and sales have functioned for decades: Corporations determine where and how much vaccines and other drugs are produced through highly restrictive voluntary licenses and contract manufacturing arrangements, with the monopoly-holding firms deciding if, how much, where and under what terms chosen partners may produce. One example of what the WTO DG proposes is South African firm Aspen's contract manufacturing arrangement with Johnson & Johnson (J&J). Johnson & Johnson controls the terms under which Aspen will only perform elements of production and then can ship finished product in compliance with J&J's instructions. [According to South Africa's WTO Counselor](#), 91% of the doses produced in South Africa must be sent for sale in Europe, while the South African firm is only allowed to provide 9% of its output for use in South Africa.

In early March, Australia, Canada, Chile, Colombia, New Zealand, Norway and Turkey echoed the DG's call to maintain the status quo of Big Pharma control in a WTO [submission](#) calling for the WTO to convene vaccine developers and manufacturers to identify and activate unused or underutilized production capacity and facilitate licensing agreements. These countries assert that this can be done without a waiver through voluntary agreements between companies.

Of course, if WTO intellectual property dictates were not an obstacle, manufacturers all over the world would already have begun to organize more production to fill the chasm between supply and demand. Instead, there are a limited number of market-segmented contract manufacturing arrangements, as determined by the developers who restrict access to the technology. As a result, there is a huge gap between needed global supply and the production levels that vaccine developers deem useful for their business strategy, which is focused mostly on selling at higher prices to rich and upper-middle-income countries. Moreover, the WTO has neither authority nor expertise or capacity to serve as a matchmaker for pharmaceutical firms. Rather, the WTO's role is to provide a forum for negotiations among countries on international rules, for instance to agree on a transformative TRIPS waiver. Indeed, the so-called "third way" is a distraction and impediment to the TRIPS waiver proposal, a truly transformative initiative that falls squarely within the WTO's actual remit.

The “Third Way” Is the Old Pharma-Controlled Voluntary Licensing Model That Has Not Led to Needed Boost in Production, Lower Prices or Equitable Distribution of Vaccine and Therapeutics

One year ago, the World Health Organization (WHO) declared the [COVID-19 pandemic](#). Ever since, governments, civil society groups and people worldwide have demanded that pharmaceutical firms share their know-how, technology and intellectual property over vaccines and other medicines to ramp up production so every country in the world can fight COVID-19. [Costa Rica proposed](#) the creation of a global pooling mechanism to facilitate access to and use of intellectual property for technologies that are useful for the detection, prevention, control and treatment of COVID-19. In May 2020, the WHO launched the COVID-19 Technology Pool (C-TAP). But as of January 2021, [not a single pharmaceutical firm had donated rights](#) for a single COVID-19 medical technology.

Most vaccine developers headquartered in developed countries have been reluctant to broadly license recipes, know-how and technology to manufacturers in the developing world. [Moderna declined to partner up with producers in Bangladesh](#), arguing that its engineers are fully occupied expanding European production and that focusing more tech transfer now could undermine existing production. Pfizer/BioNTech’s manufacturing operation is also based in the [United States and Europe](#). Big Pharma claims that the mRNA platform used both by Moderna and Pfizer/BioNTech is a novel technology that vaccine manufacturers in developing countries cannot master. **Yet, 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 lines going, at most, three to four months.** Indeed, while COVID-19 shone a spotlight on the mRNA platform, for two decades researchers around the world have attempted to harness it for vaccines and therapies.

Even when companies enter limited voluntary licensing agreements with manufacturers in developing countries, more accurately called contract-manufacturing or manufacturing-and-distribution agreements, the monopoly-rights-holding corporation controls price, terms and conditions and where vaccines can be sold. Johnson & Johnson’s limit on South African use of J&J vaccines that are manufactured there is not unique. AstraZeneca has licensed production of the vaccine developed by Oxford University in Argentina, Brazil, China and Indonesia and has made a deal with the Serum Institute of India to make one billion doses. However, according to Doctors Without Borders, the [Serum Institute is barred from supplying upper-middle-income and high-income countries](#). By retaining monopoly control, 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.

Public awareness of the conditions imposed on contract manufacturers is the exception rather than the rule. The licensing agreements are generally subject to non-disclosure obligations that prevent governments and the public from knowing whether production capacity is actually being fully utilized or if supply is being restricted to keep charging monopoly prices. For instance, when Sanofi and GlaxoSmithKline (GSK) [temporarily gave up on](#) efforts to create their own vaccine, Sanofi contracted with BioNTech to manufacture [125 million doses of Pfizer/BioNTech’s vaccine for the European Union](#). GSK made a similar arrangement to [produce 100 million doses of CureVac’s vaccine](#). However, the projected production capacity of the Sanofi/GSK vaccine candidate was [500 million doses](#). Why Sanofi and GSK did not devote their entire projected production capacity to produce other firms’ effective COVID-19 vaccines is unknown. Was it so they could reverse capacity to produce their own vaccine candidate once it might belatedly pass Phase 3 trials and thus increase their profits even if that involved limiting supply? It is plausible that the gap relates to having to retool their facilities to replicate all the production processes necessary to manufacture these vaccines, or it is also possible that monopoly-holding firms — Pfizer/BioNTech and CureVac — only allowed Sanofi and GSK to make the agreed, lesser amount. Contract manufacturing schemes are obscure by nature and do not permit governments or the public to hold pharmaceutical firms accountable if they are intentionally limiting supply and artificially raising prices.

Voluntary licensing also does not ensure widespread or equitable access. Consider Doctors Without Borders' [case study](#) of Remdesivir: *“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 WHO withdrew support for Remdesivir use, it is authorized as a COVID-19 treatment in many countries, including the United States. Gilead’s tight controls over where it can be made or sold mean many nations in many regions of the world that seek to use it have no supply. Pakistan and Indonesia raised this example in 2020 as the debate on the COVID-19 emergency TRIPS waiver began.

Likewise, despite multiple voluntary contract manufacturing agreements, rich countries are still securing the vast bulk of vaccine supplies shipped thus far.

Overall, industry-controlled voluntary licensing/contract manufacturing schemes, while contributing to increased supply, cannot alone remedy either supply shortages or unfair distribution in the context of a deadly pandemic that is ravaging every nation in the world. By design, this system leaves Big Pharma in control of the supply of life-saving vaccines and treatments, allowing firms to artificially segment the global market and control manufacturing supply, access and prices.

The “Third Way” Approach Would Insert the WTO Into a Pharma Matchmaker Role for Which Is it Not Qualified and That Other International and National Initiatives Are Already Undertaking

During the course of the pandemic, a plethora of multilateral initiatives to increase production capacity and supply of treatments, medical equipment and vaccines sprouted. At the WHO, the already mentioned C-TAP was created in May, although it is still chronically underused when it comes to Big Pharma committing to sharing their proprietary information. C-TAP works through partner organizations to implement its agenda, of which the [Medicines Patent Pool](#) and the [UN Technology Bank-hosted Technology Access Partnership](#) are especially noteworthy. Both programs have as their core missions helping to scale up the local production of and increase access to life-saving medicines, medical equipment and personal protective equipment in the developing world. Both programs facilitate connections with manufacturers in developing countries, patent pooling, voluntary licensing, information sharing and technical guidance. These programs have been working on expanding access to medicines for developing countries for years.

Due to the failure of C-TAP to get firms to participate, the WHO has now launched the [Covid Vaccine Capacity Connector](#), which focuses on bilateral deals as opposed to a pool of technology. The initiative is likely to become part of the [Access to COVID-19 Tools \(ACT\) Accelerator](#). It is intended to: (i) alleviate bottlenecks, particularly in the fill-finish stage; (ii) facilitate bilateral tech transfer through standardized contracts between manufacturers (notably, this objective clearly overlaps with the “third way” proposal at the WTO) and (iii) launch tech transfer hubs of low- and middle-income countries.

The Coalition for Epidemic Preparedness Innovations (CEPI) conducted a worldwide [survey](#) of vaccine manufacturers in spring 2020 to assess capacity available to meet COVID-19 vaccine demand. This project is underpinned by CEPI’s previous work evaluating potential manufacturing networks to secure capacity for manufacturing and stockpiling to ensure flexibility, affordability and reliable supply. CEPI has been using this information to matchmake vaccine developers and manufacturing capacity to maximize production of COVID-19 vaccines. In December 2020, UNICEF, which is responsible for COVAX procurement coordination, launched the [COVID-19 Vaccine Market Dashboard](#). (COVAX is a global initiative created for equitable global distribution of vaccines for the 20% of populations at highest risk, such as healthcare workers and people over 65.) This interactive tool for governments and industry provides updated information on the global research and development pipeline, projected production capacity, publicly announced bilateral and multilateral supply agreements, and reported price points.

Even at the national level there are numerous programs with considerably more experience and capacity than the WTO in identifying unused or underutilized vaccine production capacity and facilitating licensing partnerships to harness such capacity. The U.S. Biomedical Advanced Research and Development Authority (BARDA) played a [pivotal role during the H5N1 influenza epidemic](#). By partnering with the WHO, BARDA helped build facilities, train personnel, provide technical assistance and transfer technology to scale up manufacturing in 13 countries. Through this program, the WHO obtained an intellectual property license from a Russian institute on a vaccine strain so that manufacturers could more easily begin production, creating a vaccine technology hub that increased production capacity from 1 million doses in 2005 to 300 million in 2014.

Each of these organizations and initiatives has more capacity, infrastructure and expertise than the WTO to identify potential production capacity and facilitate connections. What makes the WTO think that it would add any value?

The WTO's Proper Role Is to Facilitate Consensus Among Countries on a TRIPS Waiver, Which Is a Critical First Step in Boosting COVID Vaccine, Treatment and Diagnostic Test Production

The WTO is a multilateral organization with a clear mandate: provide a common institutional framework for the conduct of trade relations among its members in matters related to the agreements and associated legal instruments negotiated under its purview (Art.II.1 of the Marrakesh Agreement Establishing the WTO). To achieve this, the organization's remit includes to: (i) facilitate the implementation, administration and operation of the agreements, (ii) be a forum for further negotiations concerning multilateral trade relations, (iii) administer the dispute settlement system created to enforce the obligations included in the agreements, (iv) review the trade policies of its members and (v) cooperate with other international organizations. The agreement establishing the WTO does not provide authority for the DG to broker deals between private firms. This activity is simply outside of its mandate. Some have even interpreted that the group of seven countries — including Australia, Canada and Norway — [acted in violation of WTO rules](#) by urging the WTO DG to conduct discussions with vaccine developers and manufacturers.

In contrast, negotiating waivers of the obligations contained in WTO agreements due to the development of exceptional circumstances is an explicitly authorized function of the organization. If the COVID-19 pandemic does not constitute the exceptional circumstances that warrant a temporary waiver so WTO rules do not undermine the global response in face of this crisis, it is unclear what would qualify as such.

Indeed, failure to enact a waiver in the face of this unprecedented health and economic crisis could be the final blow that dooms the WTO. The existential and intensifying crisis that has wracked the WTO in recent years is in no small part a consequence of the organization getting involved in or being used to dealing with issues clearly outside of its mandate. And the WTO's increasing irrelevance is related to the body not succeeding in managing problems and concerns that are directly in its remit.

The "third way" approach would double down on the same mistakes. By not prioritizing the negotiation of waiver language agreeable to all WTO member countries and desperately needed to address THE priority concern of many, the organization will become more irrelevant, while also alienating 100-plus countries that support the TRIPS waiver. If the new DG pulls the WTO — an organization devised to negotiate and administer rules — into instead pretending to become an international deal broker, it will only amplify concerns about the WTO staff and structures overstepping the authorities provided by member countries.

The way forward at the WTO is clear. The WTO's existing rules are obstacles to greatly scaling up global production and thus facilitating equitable distribution of affordable, safe and effective COVID-19 vaccines and other related medical products. Eliminating these obstacles is not the final step to greater production, but the first, so there is no time to waste. The DG's priority should be to pave a quick path to countries engaging in text-based negotiations on a waiver. If some WTO member countries have specific concerns with the waiver that South Africa and India have proposed, then the way forward is to offer changes to that proposal. Facilitating negotiations among WTO member countries to fix a problem caused by existing WTO rules, by preparing a waiver text that can be approved by all at the WTO General Council, is precisely the role of the DG and the WTO.

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