

GLOBAL ECONOMIC GOVERNANCE INITIATIVE

Vaccinating the World

Waiving Intellectual Property Rules on COVID-19 Products

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Introduction

The development of multiple viable vaccines to eradicate the COVID-19 pandemic in less than a year was an incredible scientific achievement which is now undermined by severe vaccine inequality. An inequitable vaccination program could prolong the pandemic for many years through cycles of mutation, resistance, and reinfection and will cost the global economy an estimated USD\$9.2 trillion (Cakmaklı et al 2021). Tackling this inequality will require more effective distribution of vaccines to every region combined with a faster rate of vaccination.

At the moment, speeding up vaccination is held back by what new Director General of the WTO Dr. Ngozi Okonjo-Iweala calls "serious supply scarcity" (Okonjo-Iweala 2021). To address this, Dr. Okonjo-Iweala stated that the world needs additional vaccine manufacturing capacity at an affordable price.

A primary barrier to scaling up COVID-19 vaccine production is the collection of intellectual property (IP) rules relating to patents and technology transfers of key medical products. To this end, South Africa and India with the co-sponsorship of 56 other WTO Members have proposed a waiver from specific provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 which has the backing of the majority (around 120) of WTO Members. However, a few Members have continued to block the Waiver since its proposal last year, including the United States (US), the United Kingdom (UK), the European Union (EU), Japan and Brazil. This is despite strong public support in many of these Members' territories for such an initiative (People's Vaccine Alliance 2021).

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This briefing considers the shortcomings of the current approach to global vaccination for COVID-19, how the TRIPS waiver could overcome these challenges, and counterarguments to the Waiver. It concludes that supporting the TRIPS Waiver is the best way for WTO members to advance a global vaccination program, and would be most effective with additional financing to develop regional manufacturing facilities and incentives to ensure pharmaceutical companies share patents, industrial designs, and technology.

The Current Approach

COVAX, the vaccine pillar of the World Health Organization's (WHO) Access to COVID-19 Tools (ACT) Accelerator partnership, is aiming to have two billion vaccine doses available by the end of 2021 to vaccinate approximately 20 percent of the population of every country participating in their facility, with a priority for health personnel. Approximately 1.3 billion of these doses are to be made available to lower income countries. But there are several emerging problems with relying only on the COVAX Facility: a severe funding shortage of USD\$22.9 billion (WHO 2021), a pooling mechanism which is not being used by higher income countries who prefer to negotiate directly with pharmaceutical companies, and an opaque financing mechanism (Nature 2021). Further, a 20 percent vaccination rate is not the 60-80 percent needed to prevent transmission (Bartsch et al 2020). Some analysts say that with current projections, COVAX looks more likely to deliver only 570 million doses in 2021 (Nature 2021). While some vaccine-hoarding countries have offered to donate their excess doses to the facility (Rigby and Newey 2021), it is unlikely that they will give them up any time soon when they are in the midst of their own vaccination programs and the pandemic continues. Absent a huge shift in funding, the COVAX effort is unlikely to make a dent in vaccination needs, and has no approach to increasing vaccine manufacturing.

The Problem

Timeline

At the current rate of vaccination, it will take over five years for enough of the world to be vaccinated to avoid further transmission (Bloomberg 2021). Five years is a long time for the virus to mutate and build resistance to currently viable vaccinations—a risk recently highlighted by the emergence of new strains in different regions of the world (Centers for Disease Control and Prevention 2021). With the looming risk of reinfection with a more deadly or contagious version of the virus, it is paramount that every tool at our disposal is oriented to producing enough vaccines to eradicate it swiftly everywhere.

Fiscal Space

The pandemic is not just a public health crisis, but an economic crisis. However, the economic outlook of different countries shows North-South asymmetries in both response and recovery needs. While advanced economies have benefitted from historically low interest rates to fund their response packages, sources of income for developing countries have dried up with remittances plummeting, global supply chains collapsing and tourism halted (United Nations Conference on Trade and Development (UNCTAD) 2020). More than 60 countries were having to spend more on debt servicing than on their health budgets before the pandemic (Jubilee Debt Campaign 2020), and this debt burden has now increased by around USD\$1.9 trillion (Eurodad 2020). While the G20 postponed 1.66 percent of all debt payments due in 2020 from lower income countries (Eurodad 2020), this fell far short of the fiscal space necessary to combat the virus and protect lives. To put this in perspective, the global response stimulus has amounted to more than USD\$13 trillion, but less than 1 percent of this

has gone to lower income economies (United Nations Economic Commission for Africa (UNECA) 2020).

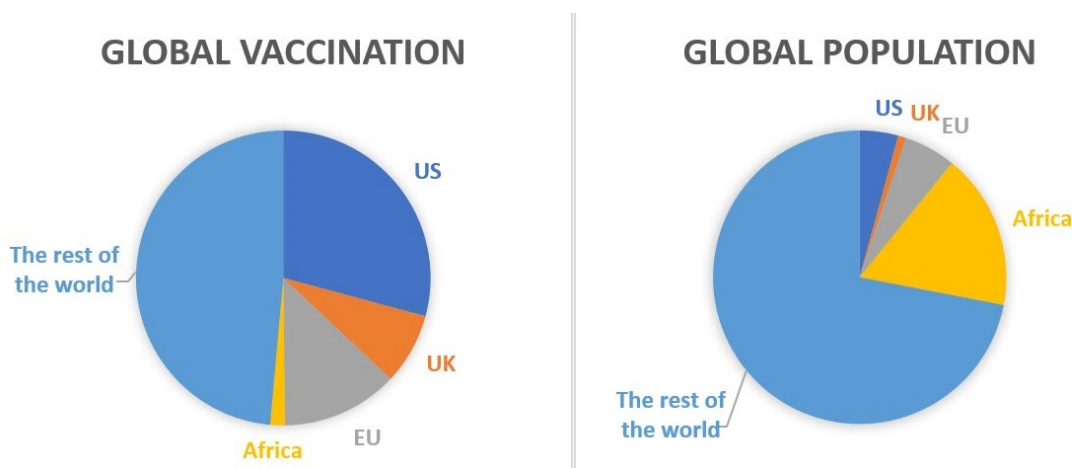
As long as the pandemic goes on, it will be impossible for economies and international trade in particular to recover. New US Secretary to the Treasury Janet Yellen stated in a letter to fellow finance ministers that “a rapid and truly global vaccination program is the strongest stimulus we can provide to the global economy” (United States Department of the Treasury 2021). Affordable vaccines are therefore vital to support countries to overcome the pandemic’s fiscal pressures and evade dangerous economic scarring.

Production Bottlenecks

There are a number of different limiting factors that affect rapid rollouts including available health personnel, logistics and transport limitations during the pandemic, availability of storage facilities for different vaccines, and productive capacity (Wouters et al 2021). At the moment, the world is not producing sufficient vaccines to stem transmission enough to end the pandemic, despite the existence of several approved candidates. The concentration of production in the US and Europe also means that vaccine products are fairly straightforward to distribute in the North, but less so in the South. On top of this, several countries have reserved far more supplies than they need: wealthy countries representing just 13 percent of the global population have reserved over 50 percent of expected COVID-19 vaccine supplies through the end of 2021 (Oxfam 2020). Switzerland - with a population of 8.5 million - has reserved 27.5 million doses (United Nations International Children’s Emergency Fund (UNICEF) 2021). The US, EU and UK have delivered 50 percent of total global vaccinations so far despite making up only 10.8 percent of the global population, while African countries make up only 1.5 percent of vaccinations so far with 17.2 percent of global population (Our World in Data 2021).

Without seeking new avenues for regional production of vaccines that suit the transport and storage facilities in developing countries, it is unlikely that enough people will be vaccinated to prevent cycles of mutation, resistance and reinfection.

Figure 1: Comparing the Composition of Global Vaccination Rates with Population, as of 4 March 2021



Source: Coronavirus (COVID-19) Vaccinations, Our World in Data, 2021. Available at: <https://ourworldindata.org/covid-vaccinations>.

The TRIPS Waiver

The international community has recognized that nobody will fully recover until everybody recovers (Conte et al 2020). In addressing the G20 Finance Ministers and Central Bank Governors' meeting in February 2021, International Monetary Fund Managing Director Kristalina Georgieva stated that the first priority in the year ahead should be 'to accelerate production and make vaccines available everywhere as fast as possible' (Georgieva 2021). To eradicate the virus everywhere, the world needs additional vaccine manufacturing capacity at an affordable price.

One way to encourage the adequate supply and equitable distribution of vaccines, medicines and medical technologies, is to remove some of the barriers created by intellectual property rights in the area of technology transfer and to encourage manufacturers and research groups to work together towards a common goal. If the international community cooperated to achieve this, multiple manufacturers could start producing viable vaccines simultaneously.

The joint proposal by India and South Africa – with co-sponsorship from 56 other countries including the Least-Developed Country (LDC) and Africa Groups – urges WTO members to grant a time-limited waiver from the specific provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 (WTO 2021). These specific provisions include patents, industrial designs, copyright and protection of undisclosed information such as trade secrets. This waiver would ensure that intellectual property rights do not restrict rapid scaling up of manufacturing and do not hinder equitable and affordable access for vaccines and treatments throughout the globe.

This proposal is currently supported by around 120 countries in the WTO but is being blocked by a few members including the US, UK, EU, Switzerland, and Japan. Many of these same countries have hoarded more vaccines than they need, exacerbating vaccine inequity and hindering coordination for an efficient global vaccination program.

Counterarguments

Innovation

One of the reasons for rejecting the Waiver proposal is that it will negatively impact the incentives for private pharmaceutical companies to invest in research and development for medicines in the future. Countries blocking the proposal have argued that this will have a harmful impact in the long-run on the development of effective medicines, especially if and when the next pandemic hits.

However, it is important to point out that much of this innovation has been predicated on decades of public support for research and development (Torreele, Mazzucato and Li 2021). With respect to the COVID-19 vaccines, governments around the world have invested an estimated \$100 billion through different means in COVID-19 vaccine development so far (kENUP 2020). These vaccines would not exist without support from governments who have the resources available to contribute. Even where vaccine creators did not rely on public funds for the initial research and development stage, they had significant pre-orders and guaranteed global demand, ensuring massive profits.

The purpose of the rules in the TRIPS agreement and in domestic IP laws is to compensate innovators for the uncertainty inherent in making something entirely new. Research and development can be very costly and demand is not always what inventors hope it will be. In the context of COVID-19 vaccines, as well as treatments, diagnostics and equipment, however, all of this uncertainty was effectively removed, and the purpose of the global IP protection regime is moot. Moreover, this same scenario is likely to be the case in the next pandemic or for resistant strains of COVID-19, where

governments invest money to support multiple vaccine candidates to develop at once, thus incentivizing industry innovation.

The waiver is also narrowly targeted, only covering measures related to “prevention, containment or treatment of COVID-19” and only “until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.” This means there is very little risk of it having a detrimental impact on the standards of IP protection, generally, around the world since the vast majority of IP falls outside the scope of the waiver.

Existing Flexibilities

Another argument made against the waiver is that it is unnecessary because there are existing flexibilities in the TRIPS Agreement which countries could use. However, this route is already being challenged by the pharmaceutical industry (Fang 2021) and is likely to take much longer and be burdensome on individual national governance, rather than the multilateral measure of a Waiver.

The TRIPS flexibilities are best understood in the context of patents. Flexibilities in other categories of IP rights (for example industrial designs and trade secrets) are less well-understood and implemented. As a consequence, options available to Members are likely to be limited. Even where the flexibilities are well identified, there may be legal, technical and institutional challenges in exploiting those flexibilities.

The TRIPS agreement allows member states to authorize compulsory licenses (CLs) under their own domestic law in cases of extreme urgency, as long as the scope and duration of the license is narrowly circumscribed. In ordinary circumstances, countries can impose a CL if they are unable to negotiate a voluntary license within a reasonable period of time. Certainly, there has never been a case of extreme urgency like this one, and WTO members theoretically may have recourse to this provision.

However, the pharmaceutical industry is already lobbying for countries pursuing these measures - including Hungary, Colombia and Chile - to face punitive sanctions (Fang 2021). Indeed, previous CLs issued by member states have met with both public and private opposition. The US has repeatedly put pressure on India for its CL on an expensive cancer drug, claiming that India is ‘diluting’ IP rights and violating the TRIPS Agreement (Médecins sans frontières 2015). Private pharmaceutical companies and US lawmakers have even threatened sanctions against India through its Special 301 Report, a trade watch-list of sorts. Colombia faced similar backlash when they took the first steps toward issuing a CL for a leukemia treatment - Glivec. Both the Swiss government and Novartis, the patent holder, argued forcefully that CLs are “tantamount to expropriation” - code for exercising a sort of eminent domain through regulation (Goldman and Balasubramaniam 2015). More recently, Malaysia attempted to use a CL to increase affordability of a Hepatitis C medication and once more the US, together with its pharmaceutical industry, threatened to wield the power of sanctions through a Special 301 Report (New 2019). As a result of these and other instances, countries have, understandably, been reluctant to develop more flexible domestic CL policies and are certainly out of practice in using them. Moreover, not all Members would have the capacity to do so in times of a pandemic.

Countries with insufficient or no domestic manufacturing capacity would have to rely upon the use of provisions under Article 31*bis* of the TRIPS Agreement, which waives the condition that a CL should be used predominantly for the supply in a domestic market. However, the cumbersome and lengthy process for the import and export of pharmaceutical products under Article 31*bis* renders it meaningless and impractical to use, and has been used only once in the past (Hestermeyer 2007). It should be also noted that Article 31*bis* only applies to “pharmaceutical products,” whereas products and technologies required to prevent and contain COVID-19 may also rely on non-pharmaceutical interventions.

Lastly, some civil society organizations have proposed that WTO Members deploy unilateral invocation of the security exception under the TRIPS Agreement. Article 73 of TRIPS allows a WTO Member to take “any action which it considers necessary for the protection of its essential security interests... taken in time of war or other emergency in international relations.” Read together with the Doha Declaration on Public Health and other statements about the object and purpose of the agreement, it seems that Article 73 should give Members the flexibility to violate international patents for the protection of their citizens (Baker 2021). Like CLs, however, this approach will likely raise the ire of countries who are most protective of their companies’ IP rights. Moreover, the mechanism for invoking Article 73 would vary from country to country, it would have to be made effective through their own domestic law, and there is no precedent of such use.

Production Bottlenecks Persist

Countries blocking the waiver have also made the case that the Waiver itself would not in fact address the production bottlenecks which are holding back a wider rollout. They argue that available facilities are already in use, and that upgrading facilities with the advanced technologies necessary to make the vaccines would take too long for them to be viable.

While it is difficult to assess exactly how many more vaccines would be produced with the TRIPS waiver versus current conditions, we know there are already multiple firms in different continents who have offered to make hundreds of millions of doses but cannot without protected blueprints and know-how (Cheng and Hinnant 2021). The UNICEF COVID Vaccine Market Dashboard further reveals that there is a lot of unused manufacturing capacity for vaccines still in development (UNICEF 2021).

The “third way” suggested by Dr. Okonjo-Iweala to increase licensing agreements between manufacturers could increase production between existing facilities (WTO 2021). However, this proposal would not address the severe global asymmetry where global pharmaceutical production is concentrated in the North; a reality that must be addressed for short and long-term regional resilience to public health challenges. Though some argue that building or upgrading manufacturing facilities could take many years, timelines have been much shorter for many of the vaccine manufacturers who have entered into contract manufacturing agreements with dozens of producers in a matter of months.

One such example is the increase in domestic vaccine production that has been enabled in the UK through public investment. At the beginning of the pandemic, they had just two plants which made seasonal flu jabs and a Japanese encephalitis vaccine. This has now expanded to four plants, all of which are making COVID-19 vaccines, as well as two additional rapid response centers that can produce vaccines and will be ready by the end of 2021 (Cookson 2021).

With the help of a TRIPS Waiver and additional financing, the same increase in productive capacity could happen many times over in different countries and regions around the world. Sticking instead to keeping licenses within the current infrastructure of plants not only creates a ceiling on global production, but prevents resilient, regional public health infrastructure from being developed to guard against the next pandemic.

Who Stands to Benefit from Blocking the Waiver?

There is a moral and economic imperative to do everything in our power to increase productive capacity and vaccinate the world. If we fail to deliver an equitable rollout, it is estimated to cost the

global economy USD\$9.2 trillion (Cakmaklı et al 2021), half of which will be borne by the wealthiest economies. If we do not increase productive capacity, the pandemic will be prolonged, and the chance of deadly or more infectious mutations that are resistant to current vaccines will develop. Cycles of mutation and reinfection could persist for many years, preventing the much-needed action on sustainable development goals and devastating global trade flows.

On the other hand, the five major pharmaceutical companies—Pfizer, Moderna, AstraZeneca, Novavax and Johnson & Johnson—are expected to make USD\$38.5 billion from sales of COVID-19 vaccines in 2021 (Saganowsky 2020). While some companies have claimed they will not make profit from the vaccine during the pandemic, companies have been caught charging two to three times the price for the vaccine in poorer countries compared to the cost to wealthier countries (Dyer 2021). Other companies have been accused of “bullying” governments in COVID-19 vaccine negotiations, asking some countries to put up sovereign assets, such as embassy buildings and military bases, as a guarantee against the cost of any future legal cases (Davies et al 2021). Pharmaceutical industry lobbyists are now pressuring the Biden administration to sanction countries which seek to use CLs to manufacture their own vaccines (Fang 2021). Amidst the pandemic, these companies are not acting in the public interest, yet stand to benefit most from the ongoing protection of the TRIPS agreement.

Patents and Monopoly Pricing

The elasticity of demand for important medicines is very low as there are no substitutes and the alternative to consumption may be a serious threat to life. For such medicines and related medical products creating monopoly rights through patents can have very heavy social costs. While on the one hand anti-trust laws exist that prohibit and punish monopolies, on the other hand there is legislation protecting patents that create monopolies precisely where they can be most dangerous to global public health. This was well understood in former global health challenges, for example, when universal no-cost or low-cost access to the polio vaccine was fundamental to its eradication.

However, patenting is being defended in the current global health crisis ushered in by COVID-19. Studies have found that the cost of developing a new drug is often over-estimated by drug companies. According to Gøtzsche (2018) the cost of developing a new drug was estimated as USD\$1 billion by the industry while independent analysts put the figure at around 10 percent of this. In reality the price of a patented drug does not reflect research and development costs but what the ‘markets’ are willing to pay. One example of how patents provide super profits to drug makers is the hepatitis drug. In 2015, Gilead claimed it cost USD\$84,000 to make a complete course of the hepatitis C drug but according to an investigation by the US Senate Finance Committee it was found that the price was based on “a pricing and marketing strategy designed to maximize revenue with little concern for access or affordability” (Wyden 2015). Novartis is another example of how the monopolist rights that patents infer on drug producers are abused for profit. After acquiring the exclusive marketing rights to the cancer drug Lutetium-octreotate, the company increased the price of one infusion from €4,000 to €23,000 bringing the total cost of a course of treatment to €100,000 (‘t Hoen 2019).

Financing Global Vaccination

With just the COVAX facility, governments will continue to pay the full cost of current available vaccines. With the TRIPS waiver, costs could be substantially decreased as a consequence of increased competition, and resources could be directed to building regional productive capacity for viable candidates, which will strengthen resilience to future pandemics in the long-term. In both scenarios, however, the challenge of financing a global vaccine rollout persists.

One potential source of income could be a Windfall Tax on the pharmaceutical industries' pandemic profits. In the UK, 53 percent of people supported the idea of an 'excess profit tax' on industries who have benefited from the pandemic (Pickard and Eley 2020). Such a policy tool is not a new idea, but has been used in recent history in the aftermath of major crises including World War I and II. Such a tax was as high as 80 percent in the UK during World War I, and 95 per cent in the US during World War II. A rate of around 70 per cent on the profits from the five major COVID-19 vaccine producers could raise extra resource to support global vaccination. With a TRIPS waiver scenario, this resource could substantially fund technology transfers and upgrading facilities – a productive investment, rather than routing cash back to pharmaceutical industry shareholders.

A policy such as an excess profits tax could also be used as a positive incentive for companies to maximize effectiveness of the TRIPS Waiver. A preferential rate could be agreed for companies which support increases in global productive capacity by working with the WHO to share patents, key technologies and know-how to enable other manufacturers to produce COVID-19 vaccines.

Conclusion

Without substantial government intervention, the pandemic is likely to continue in cycles of resistance and reinfection for years to come, causing devastating and irreversible damage and undermining any chance we have of achieving the Sustainable Development Goals or tackling climate change. Current approaches to vaccine equity have critical failings and fundamentally do not address global scarcity. The Waiver is a win-win for all WTO Members: it advances a faster and cheaper global vaccination, can support regional resilience in public health in preparation for the next pandemic, and will reinforce confidence and trust in multilateralism and the WTO as an institution. Blocking the Waiver only benefits pharmaceutical profits and prolongs the pandemic for everyone; an injustice when these profits have been facilitated by substantial public investment. Instead, by supporting the Waiver, WTO Members will demonstrate their commitment to putting the interests of their people first, to ending the pandemic everywhere, and to working in solidarity for the health and future of all.

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GLOBAL ECONOMIC GOVERNANCE INITIATIVE

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