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The US and EU must waive the patents

Big Pharma claims that a lack of manufacturing capacity, not patents, are thwarting more vaccine production. That's a lie. We need a TRIPS waiver now

As we see infection rates in India and other parts of the world skyrocketing, European Union (EU) and US government officials regularly declare that the Covid-19 public health disaster and resulting economic crises will not end anywhere unless people everywhere are vaccinated. Yet the two World Trade Organization (WTO) heavyweights are blocking an initiative now supported by 100 nations that could boost access to Covid-19 vaccines, treatments and diagnostic tests worldwide. On 5 May the issue will again come to a head at the WTO. The US and EU must join the rest of the world.

At issue is a temporary waiver of WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPS) rules on industrial designs, undisclosed data, copyrights and patents to the extent that they undermine the 'prevention, containment or treatment of Covid-19.' The TRIPS agreement requires WTO member nations to guarantee pharmaceutical corporations expansive monopoly controls.

In the fall of 2020, the Trump administration recruited a handful of WTO members, including the EU, to join it in blocking even the start of negotiations about a waiver. The Biden administration has not yet reversed Trump's position.

The pharmaceutical corporations that hold patents, copyrights and industrial design and trade secrets exclusivities control if, how much and where vaccines, tests and treatments are made and where they can be made available and at what price. Especially after governments invested our tax dollars far more than pharmaceutical corporations used their funds to develop the Covid-19 vaccines, and by one estimate gave the firms more than $112bn, temporarily waiving the firms' control seems fair.

It also is proving to be necessary. The TRIPS-required monopoly rights have become a key obstacle now thwarting worldwide access to the

formulas and technology to make more vaccines and treatments. Under current projections, few people in developing countries will have access to vaccines in 2021. Poor nations will only reach herd immunity vaccination levels in 2024, if ever.

That means the pandemic will continue to burn through a large share of the world's population, resulting in hundreds of thousands of avoidable deaths and growing risk that a vaccine-resistant variant could slam the world back into broad shutdowns.

To make vaccines more available in developing nations, the World Health Organization (WHO), the Global Vaccines Alliance (Gavi), and the Coalition for Epidemic Preparedness Innovations (CEPI) jointly launched the COVAX initiative. But so far COVAX has had limited success in obtaining and distributing vaccines, even as the Biden administration contributed $2bn and promised $2bn more to match other donors. COVAX has delivered 40.2 million or 21 per cent of the 187 million doses it planned to have out by May 2021 with some large developing nations, including Pakistan and Mexico, not yet received any COVAX doses.

A major cause of the shortage is vaccine originators refusal to work with qualified manufacturers in Africa, Latin America, and Asia so more vaccines can be made around the world.

Moreover, COVAX has as its goal only providing vaccines for the 20% of countries' populations at highest risk, such as healthcare workers and people over 65. Even if it meets its full ambition of delivering 1.3 billion doses in 2021, this would not provide vaccines for the vast majority of people and not enough to establish herd immunity.

Therefore, while programs like COVAX are important, unless production is quickly ramped up around the world to meet global demand, there simply will not be enough supply for COVAX, let alone for conferring global herd immunity. Global production in 2021 pumped out one billion doses as of April 13, weeks into the second quarter.

Yet 10-15 billion annual doses are necessary for global herd immunity. And now we are learning that vaccines will require regular boosters, meaning the world may well need 10-15 billion does production capacity year on year.

Blocking needed supply by excluding manufacturers from the South

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. They are focused not on global access, but on profitable markets.

Pfizer and Moderna recently revealed Covid-19 vaccine expected revenue of $15bn and $18.4bn respectively in 2021 alone. In mid-March 2021, Pfizer's senior VP of investor relations described how the firm planned to raise prices and profit richly in 2022 by selling vaccines annually to rich countries that can pay.

There is no alternative to increasing vaccine production capacity to meet Covid-19 needs. Some of this capacity must be in the Global South, including to ensure speedy response to regional vaccine-resistant, more lethal or infectious variants before they become global.

A major cause of the shortage is vaccine originators refusal to work with qualified manufacturers in Africa, Latin America, and Asia so more vaccines can be made around the world. The vaccine monopoly holders have fuelled the wave of support for the waiver by more than 100 countries by effectively blocking production for markets they have no interest in supplying.

That has been hard to decipher because pharmaceutical interests in Washington, Brussels, and Geneva are pushing a 'big lie' strategy. Their claim is that a lack of manufacturing capacity, not pharmaceutical corporations' monopoly intellectual property (IP) protections, are thwarting greater production of Covid-19 vaccines and treatments.

A related argument, with decidedly racist overtones, is that Covid-19 vaccines are too complicated for producers in developing countries. 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.

More production capacity must be created in the Global South and in

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-

developed nations. A TRIPS waiver's quickest gains would be more production of and access to treatments and diagnostic tests.

production experts in a recent Foreign Policy article. The Serum Institute in India already is producing the Johnson & Johnson vaccine, but on its own cannot make enough to stop India's expanding outbreak. Meanwhile, Moderna declined to partner with a qualified Bangladeshi vaccine maker Incepta, claiming its engineers were too busy to focus beyond US and EU production and Pfizer never responded to Incepta's inquiries. Major Pakistani vaccine maker Getz never received responses to its requests. In Latin America, existing facilities in countries like Chile and Colombia have expressed interest in kickstarting vaccine production, but like qualified manufacturers in other countries have gotten no response from the vaccine originators.

Existing and planned contract manufacturing arrangements prove facilities in developing countries certainly can produce Covid-19 vaccines. For instance, for many months, one of the few contract manufacturing partners of the vaccine originators, South African firm Aspen, was ordered by Johnson & Johnson to export 91 per cent of the vaccines it made to Europe for sale. Only 9 per cent could be used in South Africa.

Gains from a TRIPS Waiver

More production capacity must be created in the Global South and in developed nations. A TRIPS waiver's quickest gains would be more production of and access to treatments and diagnostic tests. A TRIPS waiver now also will facilitate greater supplies of vaccines in several ways.

First, it would immediately increase government leverage on originators that have refused to share vaccine technology on a more open basis. That is because it would end vaccine originators' ability to block production.

Rather, firms would have two choices, both of which expand access. They could choose to expand production via prompt negotiations with governments, alternative suppliers, and global initiatives like the Covid-19 Technology Pool (C-TAP), which was launched in May 2020 by the WHO in partnership with the Government of Costa Rica and 40 Member State co-sponsors.

Or they could risk governments simply going around them and forcing

technology transfers. In many nations, the regulatory authorities that approved domestic use and/or patent offices have significant information on manufacturing process and have test data that they could share with skilled teams from government agencies, local universities and pharmaceutical producers — if freed from WTO obligations to protect monopoly control of it.

Supporting a waiver is the right thing to do in and of itself. But doing so would not just be altruistic.

As well, waiving IP barriers would provide the legal certainty for governments and investors in developing nations to start repurposing existing pharmaceutical manufacturing and building new facilities. Already, developing country producers in every region have unused capacity to make vaccines. And new production, especially of mRNA vaccines, could be brought online relatively quickly. Because the mRNA platform does not use live cell lines, it does not require construction of new bioreactors. Lines can be set up in any 'clean manufacturing' venue. A former Moderna chemistry chief said with technology transfer and know-how-sharing, any modern factory should be able to get mRNA vaccine production online in three to four months.

Public investment for private profits or public health?

In response to growing demand around the world for the TRIPS waiver, pharmaceutical interests have made the usual arguments. First, that monopoly rights and high prices are necessary to support innovation. And second, that if there is TRIPS waiver, somehow this will undermine their ability to help provide medicines for the next global health emergency.

However, every leading Covid-19 vaccine, on the market or in final clinical trials, has benefited from substantial public investment. The miracle of speedy Covid-19 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. And, before that, the US National Institutes of Health (NIH), military and other agencies invested in coronavirus research for decades.

Indeed, the Covid-19 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: Severe acute respiratory syndrome (SARS) coronavirus in 2002, Middle East Respiratory Syndrome (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.' 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.

And no, a TRIPS waiver will not shipwreck Big Pharma. The market for Covid-19 vaccines is the entire world. Whether or not there is technology transfer, firms that originate a Covid-19 vaccine will make a lot of money. To start with, 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.

In the United States, hundreds of organisations that represent the Democratic Party's base and many Democratic senators and House members have called for the Biden administration to reverse Trump's blockage of the emergency WTO Covid-19 TRIPS waiver. They are calling on the new administration to engage immediately with the rest of the world to finalise a waiver text. According to a recent poll, 60 per cent of US voters support the waiver, as do 170+ former heads of state and Nobel laureates from across the political spectrum. 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 prioritising saving lives over pharma corporation profits. Similarly in Europe, Amnesty International called on the EU to back the proposal to temporarily lift patent protections for Covid-19 vaccines.

Supporting a waiver is the right thing to do in and of itself. But doing so would not just be altruistic. Ending the Covid-19 pandemic as quickly as possible is also necessary to protect the health of US and European residents and reboot the global economy on which so much of the US and EU economies rely.

This is a slightly abrigded version of a blog post by FES New York.



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