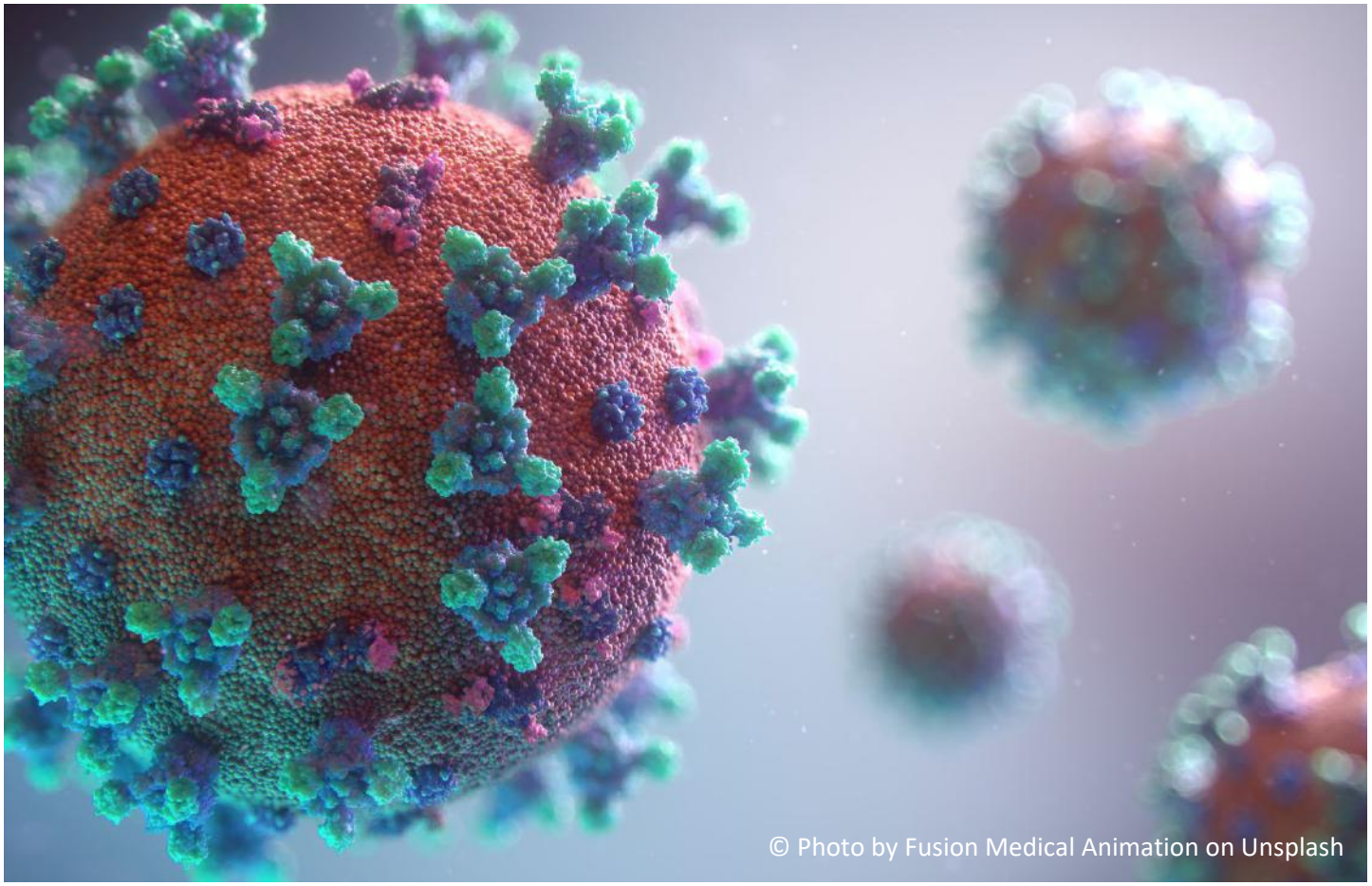

T7 Task Force Global Health

POLICY BRIEF

HOW THE G7 CAN USE PATENT BUYPUTS TO HELP THE WORLD WIN THE RACE AGAINST CORONAVIRUS MUTATIONS

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Abstract

As new variants keep the Covid-19 pandemic raging in many countries, the worldwide race between vaccinations and mutations may yet be lost: with more uncontrolled infections, further mutations are more likely to emerge, especially when unvaccinated hosts with weak immune systems allow infections to last longer. Transmission to vaccinated hosts can then facilitate the selection of mutations that "escape" the vaccine-induced immune response. To win that race, the worldwide campaign for vaccinations must be redesigned to exploit economies of scale more efficiently. But popular calls for patent waivers are misguided; they risk damaging the incentives for continued vaccine innovation efforts on which the world depends in fighting against SARS-CoV-2, other existing epidemics and future pandemics. Instead, the G7 should help convert the existing Covid-19 Vaccines Global Access initiative (COVAX) into a more generously endowed global fund that instead of – as it was de facto forced to do, against initial intentions – merely acquiring rich countries' surplus vaccines and relying heavily on unpredictable donations, acquires the most promising vaccine patents in what is known as a patent buyout, aiming to offer free production licenses to all technically qualified vaccine and generic drug manufacturers around the world. This Policy Brief spells out detailed steps the G7 must take, and the funding for COVAX they must provide, to achieve this turnaround in the worldwide fight against the pandemic. It also argues the proposed patent buyouts would be more efficient than the draft compromise on patent waivers that India, South Africa, the EU and the US have recently negotiated and that is now waiting for approval by their respective governments and EU member countries and thereafter by all member countries of the World Trade Organization (WTO).

Challenge

When SARS-CoV-2 started the ongoing pandemic, the G7 countries quickly adopted policies that supported and prioritized the development of vaccines whose effectiveness and speed to market surprised. Yet, that was only half the battle. In bringing shots into people's arms, the world as a whole has been far less successful, failing in particular to deliver for the poor – above all in Africa. This failure appears to come with huge economic costs as the IMF forecasted already in May 2021 that successful worldwide inoculation, then estimated to cost $50 billion in public investment (Agarwal and Gopinath 2021), would boost global economic growth by up to $9 trillion, 40% of which would flow to economically advanced countries and augment their tax revenues by roughly $1 trillion (Georgieva 2021). Equal access is thus not only a matter of justice, but also a precondition for efficiency in exploiting the economies of scale that vaccines afford. To maximize their value to society, high levels of population immunity must be achieved at the highest possible speed in all countries. Any delays exacerbate the risk of viral escape mutations that could undermine vaccine effectiveness and reignite the pandemic.

To speed up vaccination of the world's poor, both technical and economic obstacles have to be overcome. Some of the technical obstacles are well understood and already addressed by a variety of international initiatives, such as the "Access to Covid-19 Tools (ACT)-Accelerator" of the World Health Organization (WHO). The economic obstacles are less widely understood, and addressing them requires understanding the pervasive role that social and economic inequalities play in driving infections and in preventing latent demand for inoculation from being met by a sufficiently elastic supply of vaccines. In the absence of perfect price discrimination, patent-protected monopoly power – agreed to be the key incentive for innovation in the pharmaceutical space when the World Trade Organization (WTO) adopted the Trade-related Intellectual Property Rights (TRIPS) agreement in 1995 – creates both deadweight loss, frustrating many who want a shot, and large consumer surplus for many inframarginal vaccine buyers. This combination limits developers' appropriation to no more than 5% of vaccines' total value to society even under strictly enforced patents – and most likely far less – with inequality driving appropriability down (Stolpe 2021a).

Most of the G7 and other OECD countries have long understood how inequality's corrosive influence can be overcome and built potent universal health systems with equal access for their own people: a benevolent government then derives its willingness-to-pay from the value of statistical lives population-wide vaccination would save, negotiates volume rebates from vaccine makers and offers vaccinations for free. Many non-OECD countries, by contrast, have difficulties implementing population-wide free vaccinations. What happens in the absence of equal access is explained by economic models of epidemiology, such as Geoffard and Philipson (1996): the rich have private incentives to protect themselves and then often ignore the plight of the poor. The challenge now before the G7 is thus twofold: first, to find a solution for the worldwide distribution of Covid-19 vaccines that adapts and scales up the key elements of successful countries' policies for equal access, using insights from economics research that has identified and studied these elements. Second, the G7 must look beyond the coronavirus pandemic and prepare for other already raging epidemics and future pandemics in ways that promote equal access without sacrificing incentives for continued innovation. The G7 could thus help create the "weapons of mass salvation" the world so badly needs.

Proposal

As a substitute for the non-existent universal global healthcare system that would pay for equal access across countries, we propose that the G7 take the lead in launching patent buyouts for the relatively narrow purpose of equal access to Covid-19 vaccines. As patents establish an intellectual property by creating a time-limited legal right to exclude others from making, using or selling the patented invention, owners also have the right to transfer or sell the patent itself – and such trade in patents and other intellectual property is common among private firms in many lines of business. In the type of patent buyouts proposed here, a government agency or an international non-profit organization would acquire the patents for the purpose of placing them in the public domain, thus making the right to produce or sell the invention non-exclusive. These patent buyouts should focus on the most promising vaccine technologies and be carefully designed to unleash worldwide competition in the production of each vaccine, thus helping to bring down their prices to the level of marginal production costs incurred by the most efficient producers – likely located in low- and middle-income countries.

This proposal, further explained in Stolpe (2021c), is meant to overcome two key problems in global vaccine supply that are intertwined: equal access exists neither within nor across countries and the G7 countries' failure to contract on production capacities has created a queue in vaccine deliveries in which the rich come first, and the poor last. The TRIPS agreement, outlawing parallel trade – i.e. the reimporting of patented goods –, was meant to enable drug and vaccine makers to supply low-income countries at lower prices without undermining their price-setting power and profits in rich countries. This form of third-degree price discrimination, reflecting countries' different average incomes, can be shown to be – in principle –compatible with global profit maximization, akin to Ramsey pricing (Ramsey 1927), but it is far from sufficient to address the large inequalities that exist within many low-income countries (Stolpe 2021a).

Sensing this, and with a non-profit commitment to worldwide equal access, the Covid-19 Vaccines Global Access initiative (COVAX) was created and initially meant to serve as a global vaccine procurement mechanism for all countries, then refocused to prioritize procurement for low- and middle-income countries. Almost from the beginning, its efforts have been undermined by G7 countries' advance purchase commitments. Intended to incentivize speedy vaccine development and preparation of mass production in 2020, they effectively created a queue and pushed COVAX to its end. Moreover, G7 countries' contracting on deliveries instead of production capacities allowed vaccine makers to underinvest in capacity and *de facto* incentivized them to delay deliveries (as predicted in Castillo at al. 2020), thus exacerbating international rivalries in procurement, driving up prices, and giving the virus more time to spread and accumulate potentially dangerous mutations. When two such mutations, Delta and Omicron, led to recommendations of booster shots, the world embarked on a replay – with booster demand for the rich again relegating the poor, and COVAX, to the end of the queue.

For worldwide vaccination to be successful, Stolpe (2021c) proposes to redesign COVAX so that instead of acquiring vaccines, COVAX buys out the patents for the most promising vaccines. COVAX can then make production licenses freely available to all technically qualified vaccine and generic drug producers anywhere, including countries of the global South. Unlike decentralized bilateral licensing, patent buyouts hosted by

COVAX will break the price setting power of private vaccine monopolies worldwide, boost global competition in the production of each vaccine and help create truly global supply chains with trade in specialized inputs, thereby accelerating the expansion of vaccine supply. To improve incentives even further, COVAX could offer countries financial rewards for successful vaccination campaigns, conditional on surpassing predetermined population-immunity targets by some set date.

The efficiency of this proposal for equal access with improved incentives for continued innovation is best understood by recognizing that through patent buyouts, COVAX will help eliminate the deadweight loss from worldwide monopoly pricing power in vaccine supply in ways that are similar to the role universal national health systems have long played within many OECD countries. According to Lakdawalla and Sood (2013), insurance against healthcare expenditures resembles a two-part pricing contract where consumers pay an upfront fee (the insurance premium) in exchange for lower unit prices (the out-of-pocket co-payments) in the event of illness. Utilization of healthcare, even involving expensive medical technologies under patent protection, is thus feasible at marginal cost pricing while consumer surplus is extracted via the premiums and used to generate patent holders' monopoly rents that reward and incentivize innovation. With vaccine patent buyouts, worldwide equal access is paid for upfront and funded primarily by the rich, namely the G7. By acting as intermediary between vaccine developers and producers, COVAX ensures that voluntarily selling patents to COVAX will earn the patent holder the maximum of possible profits – exceeding those of a vaccine monopolist selling directly to consumers or countries' national health systems.

Unlike patent waivers, buyouts need not impair private incentives for continued innovation, but might even improve them – including incentives for vaccine upgrades that counter escape mutations, such as adaptations to Omicron now under development. Moreover, unlike waivers or other forms of compulsory licensing, buyouts can be designed to incentivize voluntary transfers of relevant tacit knowledge, such as technical and managerial know-how. The valuation of patents in buyouts will increase when contracts for such transfers are included. The proposed patent buyouts would therefore be more efficient, as well as more equitable, than the draft compromise on patent waivers that India, South Africa, the EU and the US have recently negotiated (Finke 2022) and that is now waiting for approval by their respective governments and EU member countries and thereafter by all member countries of the WTO. This draft compromise is to amend the TRIPs agreement by granting low- and middle-income countries that have not been major exporters of coronavirus vaccines the right to decree patent waivers for domestic use unilaterally – albeit only temporarily to facilitate recovery from the pandemic during a period of three or up to five years.

The proposed patent buyouts would also greatly facilitate the ongoing work of the *global mRNA vaccine technology transfer hub*, located at Afrigen Biologics in South Africa, that was launched with support by the WHO, the Medicines Patent Pool and the ACT-Accelerator/COVAX in the summer of 2021. Technology recipients in low- and middle-income countries selected to date include Egypt, Kenya, Nigeria, Senegal, South Africa and Tunisia in Africa as well as Bangladesh, Indonesia, Pakistan, Serbia and Viet Nam. Helpfully, Moderna Inc. whose mRNA vaccine technology has been reverse-engineered by scientists at Afrigen Biologics with WHO backing (Grimley 2022) had announced already in October 2020 that it would not enforce its COVID-19 related patents during the pandemic and made this promise *permanent* for 92 low- and middle-income countries selected by the global vaccine alliance GAVI on the basis of their GDP per capita in 2018 and 2019 (Salz 2022) – not including China, Brazil and South Africa, among others.

Implementation

Why ask the *G7* to take the lead? As patent buyouts offer the best opportunity to bring the most effective vaccines to all countries, achieve high and sustainable levels of population immunity and win the race against SARS-CoV-2 mutations, much greater financial support for COVAX and political support as well as leadership for these buyouts would be in rich countries' best interest. The G7 may be the only political entity in the world today that has the financial power, ready access to technical expertise and political credibility to turn global vaccine patent buyouts into a reality. Even if up to a further $200 billion may have to be infused to relaunch COVAX as a vehicle for patent buyouts, this investment would amount to merely around 3% of the expected global economic benefits from achieving highly effective universal worldwide inoculation coverage. At this time of pandemic crisis, no other public investments offer rates of return that come even close. All countries would enjoy approximately the same low prices for each dose of vaccines.

Use a carefully designed *auction* process for COVAX to price vaccine patent buyouts. A key issue is how to ensure vaccine patent buyouts are priced efficiently. Stolpe (2021c) argues that to be sustainable, patent buyouts must offer a price that induces patent holders to sell voluntarily, but not so high a price that COVAX stakeholders could perceive it as wasteful. To reward and incentivize the right kind of innovation, the price should be linked to the social value of vaccinations, for example by way of regular payments in proportion to average consumer surplus multiplied by the number of doses administered worldwide after the buyout. In Germany, the social value of mRNA vaccines providing immunity with 95% effectiveness has been estimated at €6.431 per person (Gandjour 2022). Values for other countries may differ, but should be similar at comparable levels of per capita income. However, as argued in Stolpe (2021c), for identifying and selecting the most promising types of vaccines, and for dealing efficiently with substitute product patents for alternative vaccine technologies, it would be important to make efficient use of decentralized information on their scalability in manufacturing, ease of distribution in resource-poor settings, and duration of induced immunity. COVAX should therefore host auctions for a range of vaccines preselected to meet certain obvious quality standards, such as minimum effectiveness in preventing hospitalizations and death, and maximum risk of adverse side-effects. A sealed-bid second-price auction, described in Kremer (1998) and Stolpe (2003), could then be used to elicit private bids for vaccine patents, say from competing pharmaceutical companies, on which COVAX would offer to pay a mark-up just high enough to ensure patent holders sell voluntarily.

Design *contracts* to include incentives for voluntary transfers of technical and managerial know-how. In addition to combining the relevant product and process patents for each vaccine, the auction should also be designed to include contracts for the transfer of technical and managerial know-how required to quickly set up vaccine production at an efficient scale. In this context, collaboration with the WHO-backed *global mRNA vaccine technology transfer hub* based in South Africa would enhance the value of patent buyouts, but direct technology transfers from vaccine developers to new producers should not be ruled out.

Acquire limited-use licenses instead of full *process* patents to minimize vaccine developers' opportunity costs of participating. The auction scheme must be adapted to deal with complementary patents for production processes that need to be bought out jointly with the chosen product patent, as explained in Kremer (1998). This raises the issue of patent holders' potentially high opportunity costs of selling patents

for processes that may be needed to make the vaccine, but also for other – perhaps even more profitable – products, such as the expected breakthrough cancer treatments for which mRNA technologies were first developed (Stolpe 2021c). Given the potential of mRNA to become a new kind of general-purpose technology for the pharmaceutical industry, with beneficial applications across a wide range of diseases, the owners of these process patents might be reluctant to sell them at prices COVAX derives solely from the valuation of vaccines against Covid-19 when much larger profits loom elsewhere. These opportunity costs might drive up the prices COVAX would have to pay in patent buyouts. To limit them, the packages put up for auction should not include the process patents as a whole, but only licenses that limit permissible use to vaccine production. This would leave untouched developers' patented rights to other uses of the process technology. These rights might subsequently be included in separate buyout schemes not financed by COVAX.

Aim for dynamic efficiency in *vaccine effectiveness*. To incentivize further vaccine innovations that may be required against escape mutations, Stolpe (2021c) proposes that COVAX commits itself to maintaining target levels of vaccine effectiveness over time, hosting auctions for new vaccines that offer the required effectiveness against mutations should they push the potency of existing vaccines below a preannounced threshold. In addition, COVAX should promise to use future auctions for new vaccines that demonstrate substantial predefined improvements in other relevant criteria, such as the duration of vaccine-induced immunity.

Address obstacles on the *demand side* for vaccines. Beyond strengthening vaccine supply, COVAX should also address obstacles on the demand side that resource-poor countries may find difficult to overcome on their own. Once competition in the production of each vaccine has relaxed existing capacity constraints and established the maximally elastic supply, COVAX should offer to provide national vaccination campaigns with any additional managerial, technical and logistical support they may seek. In many resource-poor countries, additional investments in the infrastructure for vaccine delivery may be required, including reliable cold chains for storage and transport and pharmacovigilance for preventing counterfeit vaccines from entering distribution channels. Further financial support may also be warranted for the kind of community engagement the WHO advocates to educate and enable the unvaccinated to give informed consent. COVAX might also provide financial incentives for achieving high immunization rates in resource-poor countries where healthcare is vulnerable to corruption and the effectiveness of public health programs may be compromised. Countries with these kinds of difficulties might find it helpful if COVAX promised to reward them financially – perhaps to the tune of up to 1% of their GDP – for reaching a preannounced target rate of vaccinations, such as 95% of the adult population, that experts deem to significantly slow down viral transmissions, within a predetermined period of time. Needless to say, this would have to be monitored and verified by independent experts, such as observers from the WHO.

Disclaimer:

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