SDGHI Perspectives Essay Series - **COVID-19 A Year Later**

Vaccines in Southeast Asia

Enabling equitable access to COVID-19 vaccines: the role of intellectual property

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May 2021

Introduction

The initial global euphoria of discovering multiple efficacious vaccines has been tempered with the realisation that tackling the complex issues of vaccine rollout and implementation is an evolving process with a variety of challenges. Concomitant with that realisation comes the increasingly apparent divide between vaccination access for populations in low- versus high-income countries. According to WHO estimates, as of early April 2021, approximately one in four of the population of high-income countries have been vaccinated, compared with only one in 500 in low-income countries [1].

There is a whole gamut of legal, manufacturing, distributional, financial, socio-cultural and operational issues that must be tackled to enable equitable access to COVID-19 vaccines at a global scale. This essay will outline major legal issues related to intellectual property (IP) rights for COVID-19 vaccines. It will also consider other options to enable access.

Background: What governs international IP rights?

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was established in January 1995 after extensive negotiations during the Uruguay Round of the General Agreement on Tariffs and Trade [2]. TRIPS establishes minimum standards for the protection and enforcement of IP rights that each government has to abide by in relation to intellectual property held by nationals of the World Trade Organization (WTO) member states[a]. Combined with the increased importance of IP rights due to technological and medical advances, TRIPS plays a central role in global access to medical products, therapeutics and vaccines.

To address concerns expressed by developing countries largely related to the impact of patents on access to antiretroviral HIV/AIDS medicines[b], the DOHA Declaration in 2001 clarified the scope of TRIPS and introduced a set of 'flexibilities' such that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" [3]. The declaration also highlights

[a] The World Trade Organization (WTO) is an international body that governs the rules of trade between nations. Its role is to ensure the smooth, predictable and free flow of trade. Under its aegis are international agreements that are negotiated and signed by a large majority of the world's countries. Access to the numerous international markets opened by membership in WTO incentivises countries to join the WTO.

[b] Treatment for HIV/AIDs was available but not accessible to millions in the global south. It took a concerted and combined efforts from civil society organisations, AID activists and patients, generic pharmaceutical companies (largely based in India) and national governments to break the pharmaceutical stranglehold on prices to manufacture drugs at a fraction of the cost – but this didn't happen overnight and resulted in the unnecessary tragic loss of millions of lives.

that each WTO Member state has the right to "grant compulsory licences and the freedom to determine the grounds" for such licences [4].

Current debate: IP rights in the context of COVID-19

In October 2020, the governments of India and South Africa put forward a proposal to waive IP rights of COVID-19 related products for the duration of the pandemic. The proposal assumes that such a temporary waiver will facilitate easier collaboration on manufacturing, scale-up and supply of COVID-19 medical tools amongst WTO member countries and would enable more equitable access to vaccines in low- and middle- income countries [5]. This proposal was subsequently supported by over 100 countries, Dr Tedros Adhanom (Director-General of the World Health Organization) and other prominent world leaders via several open letters and opinion pieces. Their endorsement echoes the long standing position held by civil society organisations like Médecins Sans Frontières, Oxfam, Human Rights Watch and others that have argued for the temporary suspension of IP rights in relation to COVID-19 medical tools and products [6, 7, 8].

The proposal to waive IP rights has been debated at several global meetings. WTO member states remain deadlocked on the proposal, despite a major shift in position by the United States (US) government on 5 May 2021, indicating it's support for the waiver of protections for COVID-19 vaccines (though not for all COVID-19 treatments and diagnostics). However, the required consensus has not been reached with richer countries and blocs, like the European Union, United Kingdom, Canada and Switzerland, remaining opposed to the waiver - citing issues related to manufacturing capabilities, export restrictions and required technical know-how as bigger obstacles to increased vaccine production [9].

Not surprisingly, the major pharmaceutical companies who enjoy monopoly rights and stand to gain large profits from COVID-19 vaccines and other products argue against the waiver of IP rights. The Pharmaceutical Research and Manufacturers of America rely on the standard argument that waiving IP rights would inhibit future innovations by dis-incentivising pharmaceutical companies to undertake innovative research and that their return on investments in R&D needs to be protected [10].

Upholding IP rights versus waiving IP rights is often portrayed as a balance between ensuring continued innovations in science and global access to life-saving medicines. While the rationale to uphold IP rights may seem a plausible argument when taken at face value, it stands on less firm ground when taking into account the support received through public funding and non-profit organisations. In the context of COVID-19 vaccines in particular, governments have contributed over $12 billion to support vaccine discovery and expand manufacturing capabilities. In addition, governments have also committed over $24 billion in advance purchase agreements [11, 12]. Public benefits from public funds should be prioritised[c].

By emphasising alternatives to the waiver, countries with vaccine shortages face a constrained set of solutions. With a view to ensuring access to COVID-19 vaccines, it is important to unpack the different options advocated.

[c] Additionally, as the need for COVID-19 booster vaccines looks like the most likely option going forward, the profit scope for pharmaceuticals does not seem to be in doubt.

Enabling equitable access to COVID-19 vaccines: existing options

Options that are currently available to enable equitable access to COVID-19 vaccines are described below.

- *Compulsory licences*

As mentioned earlier, TRIPS has enabled 'flexibilities' that allow member governments to bypass IP rights if acting to protect the health of their populations. Chief amongst these flexibilities is the use of compulsory licences, which allow member states to issue licences to safeguard the health of their nationals in emergencies. However, while applying for compulsory licences, governments must navigate onerous WTO administrative procedures and meet specific conditions. These include differing national laws, pre-existing international and bi-lateral treaties, threat of litigation and trade sanctions, regulatory obstacles and the need to pay 'adequate remuneration'. In addition, a single vaccine might involve a number of different patents and compulsory licences must be negotiated for each of them separately [3, 13]. Many countries may not have the legal expertise and administrative infrastructure required to successfully apply for these licences[d].

- *Voluntary licencing agreements or production licences*

Voluntary licences are agreements between the company holding the patent(s) and another company (usually a generic manufacturer) that allows the production of the patented product. Voluntary agreements usually mean the IP holder specifies the markets that the licensee can sell the product, sets prices, establishes quality benchmarks and receives royalties. Therefore, not only does the IP holder control the specific technologies involved, it also has significant control over governance of the outputs related to the patented technologies [3].The agreements between AstraZeneca and the Serum Institute of India and Siam Bioscience of Thailand are examples of such voluntary licences.

If used judiciously and effectively, voluntary licences can facilitate and accelerate greater access. On the flipside, such agreements are criticised for their lack of transparency, their limited applications and the level of control vested with the IP holder in relation to markets the products can be sold in.

Searching for a compromise between the advocates for and proponents against the blanket waiver of IP rights for COVID-19, Dr Okonjo-Iweala, Director-General of the WTO, advocated a 'Third Way' "through facilitating technology transfer within the framework of multilateral rules" [14]. However, this solution largely mirrors existing voluntary licencing agreements.

- *International structures to enable access*

The WHO created the COVID-19 Technology Access Pool (C-TAP), with the objective of pooling global knowledge, expertise and IP in relation to COVID-19 products. The rationale for this initiative was built on the successful Medicines Patent Pool, which played a key role in increasing the accessibility and affordability of medicines during the HIV and AIDS epidemic[e]. However, as of Feb 2021, C-TAP has not received a single patent contribution. Hence, when the UK government argues against the blanket

[d] MSF international president Christos Christou said in a release: "The waiver proposal offers all governments opportunities to take action for better collaboration in development, production and supply of Covid-19 medical tools without being restricted by private industry's interests and actions, and crucially would give governments all available tools to ensure global access".

[e] Though it came into effect only after the issue of IP rights was challenged by the Indian pharmaceutical industry.

waiver by citing the existence of structures like C-TAP to play the role of technology transfer facilitation, it is pointing to a paper tiger [15].

In collaboration with CEPI and GAVI the Vaccine Alliance, WHO also created the COVAX Facility in April 2020 as a pooled procurement initiative that aims to provide equitable access to vaccines and secure lower prices for a diverse portfolio of vaccines [16]. The figure below displays COVID-19 vaccine doses allocated for ASEAN countries though COVAX. As each country's numbers indicate, the allocated doses are not sufficient to achieve effective levels of vaccination coverage for most of the low- and middle-income ASEAN countries (self-financing countries can presumably buy the additional vaccine supplies needed for effective coverage in the free market). While a waiver of IP rights will not magically increase vaccine production, the SEA region (notably Indonesia, Singapore and Thailand) has the potential to manufacture vaccines, provided it has access to the required technologies and know-how [17].

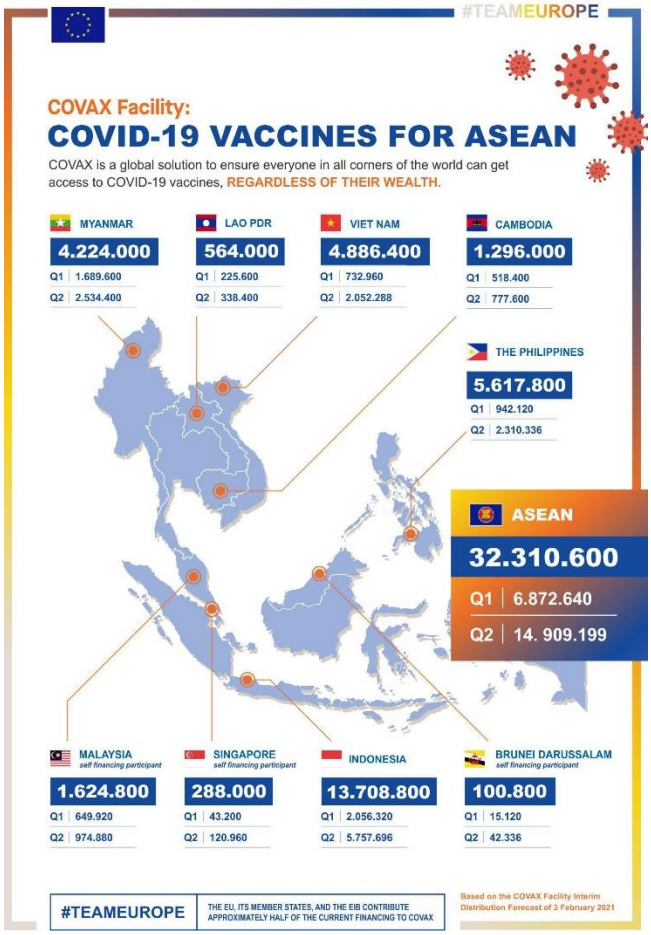

Figure 1: EEAS, COVAX Facility: COVID-19 Vaccines for ASEAN

While COVAX has certainly contributed to the goal of enabling adequate access to vaccines across the spectrum of countries, it cannot be relied on to reach that goal by itself. In the first instance, it is committed to covering only 20% of all countries' populations. To combat the continued spread of COVID-19, a much higher percentage of populations must be vaccinated. In addition, supply of vaccines through COVAX is limited by the global availability of vaccines and the fact that many of the approved vaccine manufacturers have pre-existing bilateral agreements with countries and must satisfy these obligations prior to contributing to COVAX. It is then left to individual governments to either donate their supplies to COVAX or directly to countries in need (as the US recently did to India).

Beyond IP: Other arguments against the waiver

Another rationale for not supporting the proposed waiver of IP rights purported by high-income countries is the lack of manufacturing capabilities in low-and middle-income countries; citing these limited capabilities as the bigger hurdle to improving access to vaccines, rather than IP rights. This argument can be turned on its head by noting that the historic (and ongoing) concentration of IP rights and vaccine development has led to this uneven distribution of technical know-how and manufacturing capabilities across the world. This fault line is exposed in times of crises. Even when manufacturing capabilities in developing countries are utilised, they are often decoupled from the IP. This imbalanced relationship should be re-examined to serve global populations more efficiently and more equitably.

In fact, for global access to expand, it is increasingly evident that manufacturing capabilities across the globe should be bolstered and nascent capabilities in low-and middle-income countries should be developed to overcome the production bottleneck faced globally [18, 19].

In response to the US support of the waiver, the French government has expressed its frustration with US export restrictions on essential ingredients required to manufacture COVID-19 vaccines. President Emmanuel Macron has cited these restrictions as bigger stumbling blocks than IP rights. While, the need for greater availability of these essential ingredients is not in question, it should not distract from removing other obstacles in the path to achieving more equitable access to COVID-9 vaccines by increasing opportunities for supply. Waiving IP rights is only one piece of the puzzle.

Conclusion

The overarching question to address is: why are we concerned with equitable access to vaccines? There are economic, public health and equity considerations.

From a global economic perspective, the longer the world's population takes to become vaccinated, the longer the lock downs, travel restrictions and other preventive measures will remain in place. This contributes significantly to economic repercussions across the globe.

From a public health position, experts have warned that the longer the virus circulates globally among unvaccinated populations, the greater chance there is of more easily transmissible variants and Variants of Concern developing. The current situation in India is a grim reality check.

Finally, and most importantly, from an equity lens, the fundamental consideration is that equitable access to vaccines should be built on by opening up as many roads to enable that end as possible. Advocating and implementing the waiver of IP rights is one milestone to enabling greater access. While acknowledging that the waiver of IP rights for COVID-19 medical products is not a panacea for equitable access, it is one signpost along the path of equitable access and one that is relatively easier to embrace.

About the author

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Amina Mahmood Islam is the Deputy Director for Programme Development and Business Administration at SDGHI. Amina has expertise in implementation of national level health programmes, global health strategies and multi-country collaborations. Her research interests are in health system strengthening through development of primary care capabilities. Her current responsibilities lie in bringing together the multiple parties involved in research, education, policy development and capacity building across the SingHealth Duke-NUS Academic Medical Centre and regional collaborators in a way that builds synergies. Previously, she was Deputy Director of the Signature Programme in Health Services and Systems Research, Duke-NUS Medical School. Prior to working with Duke-NUS, Amina was the Deputy Representative for the United Nations Population Fund Country Offices in Addis Ababa, Ethiopia and Dhaka, Bangladesh.

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