Lessons learned from the HIV/AIDS pandemic and access to medicines for COVID-19 treatment

Thalia Le
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Lessons learned from the HIV/AIDS pandemic and access to medicines for COVID-19 treatment.

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School of International Training
Global Health and Development Policy
Local Case Research Study

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Abstract

There is an imminent need to address the healthcare disparities in accessing all COVID-19 medicinal products in developing countries. While logistical issues like inadequate production facilities such as the lack of vaccines administration capacity, storage issues, gap between supply and demand as well as vaccine hesitancy can certainly play a part in impeding COVID19 medicines distribution, patent monopolies and intellectual property protection laws further exacerbated the problem, especially when vaccines were at its early stages of authorization. Historical and contemporary case studies of efforts to challenge patents on HIV AVRs treatment provide a useful lens through which we may glean insights into potential actions for challenging current and future patents on emergency and essential medicines for COVID. Currently, there is limited literature available that pinpoints the lessons learned regarding intellectual property between the HIV and COVID-19 pandemic, and they also include analysis that is out of date due to the quickly evolving situation of the availability of COVID-19 medicines. Therefore, the literature will focus on providing the background information on existing solutions to improve access to the HIV pandemic and applications of these strategies to the COVID-19 treatments by analyzing the feasibility of legal mechanisms including TRIPS flexibilities, TRIPS waiver, march-in-rights, and competing government patents. New global health initiatives brought up during the COVID-19 pandemic such as Medicine patent pool to transfer technology and know-how and COVAX and CTAP will also be discussed.
2. Preface

My upbringing in Vietnam—a developing country whose medical system falls short due to overpopulation, the lack of government findings, and lack of technologically advanced medical equipment—has motivated me to learn about global health and access to treatment equity. During the COVID-19 pandemic, as I have the privilege to access first-hand the available vaccines and therapeutics living in a developed country like the United States, I realized that many vulnerable populations, especially those in low and middle-income countries like Vietnam were struggling to acquire vaccines and treatments to COVID-19 infections. It has been rather disheartening that as the pandemic prolongs, the gap in healthcare inequities widens, disproportionally worsening the situations in these under-privileged areas. Furthermore, the COVID-19 pandemic is not the first pandemic that exemplifies the disparities in global access to medicines. Upon further research in the topic, I learned that there are many lessons from previous pandemics with regards to access to medicines: most notably and relevantly is the HIV pandemic. I have chosen to pursue this research proposal on the topic of “lessons learned from the HIV/AIDS pandemic and access to medicines for COVID-19 treatment” to analyze existing challenges and solutions to improve access to medicines during the HIV pandemic and their relevance to COVID-19.

3. Acknowledgements

I would like to extend many thanks to the people who have assisted in my research project and made this final paper possible. First, I would like to thank the SIT administration including Dr. Alexandre Lambert, Ms. Francoise Flourens, Dr. Elisabeth Meur, and Dr. Anne Golaz for their guidance, support, and advice throughout my research period. I am also grateful for the experts from various non-governmental organizations, intergovernmental organizations, and
governmental offices for setting aside their time and allowed me the opportunity to interview them and for all the knowledge they have given me. Finally, I would like to thank my parents any friends who have always supported my academic endeavors.
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4. Introduction

a. Access to medicines and challenges of intellectual property rights protection

Access to medicines is intrinsically linked to the fundamental rights of health, and thus states are obliged to strengthen their national health legislations to provide available, affordable, accessible, and quality medicinal products. That is why the topic of pharmaceuticals development, distribution, and availability regulations is important to realize the “the right to the highest attainable standard of health” ¹. With regards to SARS-CoV-2, ensuring access to the most effective prophylactic and therapeutic treatments is integral to control the global socioeconomical burden of COVID-19 and minimize fatalities. However, many low- and middle-income countries encounter a range of obstacles in achieving this due to the underdeveloped infrastructures to manufacture and store medicines, uncompetitive financial offers for essential medicines leading to national shortages of therapeutics especially during health emergencies like pandemics, as well as the growing problem of infringing intellectual property patents and legal sanctions.

b) Access to medicines during the HIV and COVID-19 pandemic

The COVID-19 pandemic, like many of the previous health pandemics, has once again renewed attention to the long-standing issues of intellectual property rights protection for pharmaceutical monopolies on the manufacture of treatments and access to medicines. Luckily, the 40-year-old HIV pandemic that has taken away more than 37 million lives globally since the 1980s has taught us many important lessons to respond to health emergencies, to enhance our healthcare

systems and infrastructure capacity, and to improve equity in global access to medicines\(^1\). This research project will attempt to analyze the existing solutions to improve access to medicines during the HIV pandemic and their relevance to the COVID-19 pandemic as well as the persisting limitations and new challenges that impede on the equitable global access to COVID-19 treatment. It is worth mentioning that the project will not take a comparative approach of the similarities and differences between the HIV and COVID-19 pandemic with regards to access to medicines, but rather a selective analysis of lessons learned from the HIV pandemic to discuss their applications to COVID-19 treatment. The paper will provide background information about the current state of global access to medicines during the HIV and COVID-19 pandemics and the impact of patents and intellectual property rights law-through the discussion on TRIPS, TRIPS flexibilities, and TRIPS waiver. The literature review will then examine three legal pathways for overriding and seizing patents on medicines employed during the HIV pandemic and could be relevant to the COVID-19 pandemic. Following this section will be a description of the methods used for the study. Next, the analysis section will further the investigation on the feasibility and challenges of employing those strategies along with new mechanisms to improve access to COVID-19 medicines. Finally, the paper will conclude with findings and implications of these strategies in both short-term vs long-term consequences

5. Background information:

a. Current infection rate of COVID-19 and the global distribution of vaccines

The SARS-Cov2 virus has infected more than 265 million people and killed more than 5.2

million people globally since January 2020. Thanks to the unprecedentedly efficient speed of vaccines research and development as well as the increasing global demand pressure to mass-scale the production of COVID19 vaccines, vaccination against COVID-19 has become one of the biggest campaigns in the history of global vaccination. Yet, it is undeniable that many countries, especially low- and middle-income countries have been grappling to gain access to COVID-19 medicines. In fact, even before vaccines and therapeutics against COVID-19 became available, some of the world’s richest countries have reserved enough doses to immunize their national population multiple times over. According to a New York Times analysis of data on vaccine contracts collected by Duke University, Unicef and Airfinity - a science analytics company-, “European Union could inoculate its residents twice, Britain and the United States could do so four times over, and Canada six times over” in 2020, with no guarantee that any particular vaccine would succeed. As of March, 2021 few African nations had received a single shipment of shots while at the time, 145 doses were administered for every 100 people in the U.S. As of December 11th, 2021, “more than 8.37 billion doses have been administered across 184 countries” with roughly 38.7 million doses a day. Yet, the poorest 20% of the world population only has a vaccination rate of roughly 5%, one tenth slower than that of the richest countries. Thus, delivering billions of vaccines worldwide to halt COVID19 infection and fast emergence of mutate variants remains a big logistical challenge. At this pace, it is estimated that it will take approximately “another 4 months before 75% of the world population has received at least one dose”. According to infectious disease experts, the COVID-19 vaccination rate needs to be

Figure 1: Unequitable global distribution of COVID-19 vaccines

reached at 70% to 85% of population before herd immunity is achieved, but boosters may be required to keep up with the mutation variants\(^1\). Campaigns for booster shots has already begun in many developed countries like the United States and Europe. Unsurprisingly, they have and will continue to worsen vaccines hoarding, aggravating global vaccine distribution inequity.

b. **Trade-Related Aspects of Intellectual Property Rights and Public Health Agreement (TRIPS) overview**

Before the adoption of the Trade-Related Aspects of Intellectual Property Rights and Public Health Agreement (TRIPS) culminated in 1994 by the World Trade Organization, there was no intellectual property law in the multilateral trading system that ensures protection of intellectual property rights to promote technological innovation and knowledge\(^1\). Thus, pharmaceutical

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products were excluded from national patent legislation and protection¹. Under the intense lobbying pressure by the United States, the International Intellectual Property Alliance, supported by the European Union, Japan and many other developed nations, TRIPS was negotiated during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) and adopted by the WTO². TRIPS provides an overarching global framework of patent issues, establishing the “minimum standards on property rights for all member states” for 20 years and mandated the granting of patents in all fields of technology, not excluding drugs, vaccines and diagnostics from patenting². TRIPS do allow individual nations to decide on the exact parameters of their domestic laws. Following the adoption of TRIPS, TRIPS plus were concluded to include other forms of market exclusivity and supplementary protection certificates (SPCs) to increase the level of protection for patent holders beyond the levels prescribed by the original TRIPS Agreement². However, to enforce appropriate public health response measures under national health emergencies, which are self-defined by national authorities, the TRIPS Agreement incorporates certain "flexibilities," which are legal mechanisms that allow member states to circumvent patent protection barriers ². These flexibilities consist mainly of (1) compulsory licenses, which allow a state to “authorize use a patented invention without the consent of the patent holder but with remuneration,” (2) parallel imports, which allows “goods legitimately sold more cheaply on another market may be imported without permission of the rights holder,” and (3) transition period extension of the TRIPS Agreement for Least Developed

Countries to exempt these countries from implementing TRIPS to issue patents on medicines and thus give them more time to create a viable technological base.

b) Access to medicines during the HIV pandemic

At the beginning of the HIV pandemics in the 1980s-1990s, antiretroviral (ARV) drugs were largely available only to patent-holders and was extremely costly at around US$10,000 to $15,000 per patient per year. Thus, as ARVs were becoming available in the industrialized countries, “they remained far out of reach of most South Africans and others living in developing countries”. South Africa was the first country to take advantage of the TRIPS flexibilities to increase access to AIDS treatment. Furthermore, the famous Big Pharma vs Nelson Mandela case between the South African Pharmaceutical Manufacturers Association along with 39 mostly multinational pharmaceutical companies and the South Africa government over the legality of compulsory licenses use “was particularly significant because it showed the need for clarifications on the flexibilities contained in the TRIPS to improve access to medicines”.

Particularly, following South Africa, pressure against the monopoly of medicines of the pharmaceutical industry power from other low-income countries like Brazil, Thailand, non-governmental organizations (NGO) and governments in low and middle-income countries, advocacy groups, and healthcare professionals was critical in making ARVs more accessible.

“First, civil society had to put access to treatment for HIV on the global political agenda; second,

effective and thus feasible in resource-poor settings; and third, the price of medicines had to come down. Once these ingredients were in place and increased funding for ARVs followed, investment in strengthening health systems to deliver treatment and care for was made possible."

c. Access to medicines during the COVID-19 pandemic

Similar to the HIV pandemic, since the beginning of the SARS-CoV-2 pandemic, pharmaceutical companies have been quick to apply for patent protection for any therapeutics with possible efficacy. For instance, Gilead Sciences applied for patent protection for Remdesivir—a drug that showed promise for treating SARS-CoV-2 in early clinical trials but was later found to have negligible effects on COVID19 treatment outcomes—and was granted ‘orphan rights’ by the U.S. Food and Drug Administration. The company holds “exclusive rights to manufacture Remdesivir in most high-, middle- and low-income countries” while “limiting the sale of generic formulation to just 127 LMICs.” This strategy made it difficult to mass produce the generic version of Remdesivir, skyrocketing the drug price to $3,120 per treatment course and thus not very accessible to many socioeconomically underprivileged populations. Many pharmaceutical companies with therapeutics development currently in clinical trials follow the same pathway. However, as of December 2021, only MSD’s molnupiravir and Pfizer’s PF-07321332 show promising results against COVID19 infections. Take the recently approved COVID-19 therapeutic Molnupiravir-licensed by Merck—that has been showed in clinical trials to halve the

mortality and hospitalization risk measures as an illustration\textsuperscript{1}. The company has been publicly praised for its agreement with the Medicines Patent Pool to issue voluntary licenses and allow companies in 105 low- and middle income countries, mostly in Africa and Asia, to manufacture the antiviral pill\textsuperscript{1}. Unlike Pfizer and Moderna, vaccine patent holders that have refused to issue abroad manufacturers license agreements and sharing their know how of vaccine technology development, Merck is not only pending the issues of licensing eight large Indian companies to increase the production of Molnupiravir generics, but it also has promised assistance with technology transfer to many generic licensees to boost the pill production in developing countries \textsuperscript{1}. These generic versions will significantly drive down the cost of a 5-day course treatment, from $712 per course that the U.S. government has agreed to pay for its initial purchase to approximately $20 per treatment\textsuperscript{1}. Yet, according to Mr. Patrick Durisch during the interview: “the practice of giving voluntary licenses to nations who cannot afford to pay high prices for the drug while excluding high income countries or those with large pharmaceutical industries is a standard practice adopted by pharmaceutical companies since the HIV pandemic”\textsuperscript{3}. “This is how pharmaceutical companies select their partners, deceive the public notions of their commitment to access to medicines, and determine the rule of the game”\textsuperscript{3}. “It’s not a coincidence that Merck has experience from H.I.V., internally, with their leadership and culture, they know that if they don’t address the access challenges, they will be slammed.”

\begin{itemize}
\item[3.] Durisch, Patrick. Personal interview. 24 November 2021
\end{itemize}
Secondly, under this agreement, Merck is able to make profits of molnupiravir in wealthy nations at significantly higher prices. Furthermore, like Gilead, the license restricts sales and contains exclusion to most middle-income countries such as China, Russia, Chile or Colombia, Thailand or Mexico as well as most nations in Latin America, predisposing citizens of these countries to limited access to COVID-19 treatment.¹

6. Research Methodology

a) Literature review: analysis of primary and secondary sources

In order to conduct a comprehensive analysis of access to medicines during the HIV and COVID-19 pandemics, the method employed for this project was qualitative consisting primarily of a literature review process and formal interviews with experts in the field of health care policies and intellectual property rights protection. Information collected from both the review and interviews will be integrated to investigate the efficiency of policies that promoted HIV antiviral therapies accessibility in low and middle-income countries in the 1990s-2010s and their application to the COVID treatments and vaccines distribution currently.

With regards to the literature review procedures, both primary and secondary sources were included. Primary sources such as vaccines and therapeutics roll-out tracker websites, - pharmaceutical companies agreements, monthly/annual reports from credible organizations like the WHO, UNAIDS, non-governmental organizations such as the South Centre and Public Eye were included. Secondary sources through searches on Google Scholar, Pub Med, and other

peer-reviewed articles on the topic of intellectual property rights, access to COVID-19 vaccines and therapeutics, access to HIV antivirals, as well as TRIPS agreement, TRIPS flexibilities, and TRIPS waiver proposal were included.

b) Interview procedures and analysis

With regards to the interviews, the data was collected through formal, semi-structured, virtual or in-person, question-answer formatted meetings with professionals with expertise and knowledge in the topics of intellectual property rights for pharmaceuticals, patents protection, and advocacy activities for access to medicines during the HIV and COVID-19 pandemic. They were also chosen from different advocacy backgrounds to diversify the perspectives on solutions to increase access to medicines for COVID19 infections treatment. Expert informants were contacted via email or were referred by personal and professional contacts. The literature review was also used to provide contextual information to prepare for the interview discussions.

The first interview conducted was with Dr. Marcela Cristina Fogaca Vieira, Project Coordinator of the Knowledge Network for Innovation and Access to Medicines, Global Health Centre. Dr. Vieira has an educational background in Law and Social Sciences, with a concentration in Intellectual Property Law and New Technologies of Information. She was also selected as an informant for the research project as she had experience working as the coordinator of the Brazilian civil society Working Group on Intellectual Property (GTPI) and legal consultant and researcher at Access IBSA: Innovation & Access to Medicines in India, Brazil and South Africa prior to joining the Global Health Centre. Her knowledge on access to medicines and intellectual
property issues from a former civil society organization member and an academic expert now at the Global Health Centre was conducted first to help contextualize and direct my project in the beginning. The second interview conducted was with Dr. Nirmalya Syam, a senior program officer at the South Centre, Geneva. It is without doubt that the advocacy roles of non-governmental organizations like the South Centre played a significant part in improving access to medicines in developing countries, especially during the pandemic periods. With his educational background in intellectual property law negotiations, Dr. Syam has provided the project much insight into the importance of TRIPS waiver during the COVID19 pandemic as well as the lessons learned from the HIV pandemic from an NGO perspective. The third interview was conducted with Mr. Patrick Durisch, a famous public figure and advocate for equitable access to medicines and a leader in health policy at the Swiss NGO Public Eye. This interview was not only to diversify the different roles taken by various civil societies and non-governmental organizations in improving access to medicines but also to diversify the academic backgrounds of interviewees. Specifically, Mr. Patrick Durisch’s perspective strictly as an public health advocate to break pharmaceutical monopolies and barriers to medicine availability will be different from lawyers and academic professionals like Dr. Marcela Cristina Fogaca Vieira and Dr. Nirmalya Syam. Last but not least, the fourth interview was conducted with an anonymous expert who works as an advisor on Innovation, IP & Public Health at Swiss Federal Institute of Intellectual Property. This expert has experience with international trade relations and Switzerland’s intellectual property policies as well as European Economic Law. This interview offered a unique perspective on the topic of access to COVID-19 medicines and intellectual property laws because Switzerland, along with many other European countries, opposed the
suspension of TRIPS. Thus, many of the points discussed were completely contradicting with previous interviewees.

c. Ethical considerations of the methodology procedures

All interviews were conducted ethically and professionally with the permission to record and disclose information from each participants obtained verbally prior to the meetings. The project has received the IRB approval before conducting interviews. The Human Subjects policies and ethical research guidelines were strictly adhered to and request for anonymity and confidentiality of research participants were also discussed with the interviewees and accordingly reported here.

7) Literature review

The main purpose of the literature is to provide background information on access to medicines during the HIV pandemic and intellectual property rights law used in the past. The summary of this literature review will illustrate the successes and failures in making ARVs more accessible of three legal pathways to override patents on medicines namely: (1) TRIPS flexibility, (2) march-in rights, and (3) government patents along with case studies. The analysis followed the literature review will highlight the applications of these existing solutions to apply to improving access to COVID-19 treatments as well as discuss the importance and feasibility of the TRIPS waiver.

a/ TRIPS flexibilities

Prior to the HIV pandemic, TRIPS flexibilities were already used to either tighten or loosen intellectual property rights protection for pharmaceuticals. However, these early attempts by LMICs to utilize TRIPS flexibilities, by incorporating compulsory licenses and parallel imports
into their national laws “faced aggressive retaliatory threats from patent holding countries, often as a result of pressure from pharmaceutical companies and trade associations” ¹. Following the Big Pharma and Nelson Mandela case during the HIV pandemic was the birth of the Doha declaration and it had provided further protection for countries utilizing TRIPS flexibilities by “implementation challenges due to the limited manufacturing capacity of some member nations¹. On the other hand, there are many challenges when LMICs attempt to implement TRIPS flexibilities to provide affordable generic treatment during the HIV pandemic that are likely to persist during the COVID-19 pandemic, as outlined in detailed here in Table 1².

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Policy and Advocacy Suggestions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emphasis on IP over public health. Compulsory licensing and parallel importations are optional, while mandating intellectual property protections for patent holders.</td>
<td>Mandatory implementation and default issuing of compulsory licensing for member nations, based on public health need.</td>
</tr>
<tr>
<td>Bilateral and multinational trade agreements and state patent laws undermine TRIPS flexibilities and create needless complexity for states seeking to utilise flexibilities.</td>
<td>TRIPS should be made a ceiling on patent protections for essential and emergency medicines, rather than a floor. WTO members should be restricted from enforcing policies that place additional levels of protection on essential and emergency medicines.</td>
</tr>
<tr>
<td>State governments face challenges when navigating the complexities of multi-layered intellectual property rights laws, and mistakes made during the process can create delays in implementation.</td>
<td>In lieu of immediate policy change, global health organisations and policy experts should be prepared to guide local governments through instances where TRIPS requirements are made increasingly complicated due to additional intellectual property laws to avoid delays in acquiring urgently needed drugs.</td>
</tr>
<tr>
<td>Power imbalances mean that LMICs are at a disadvantage compared to high-income, patent holding countries, as well as powerful pharmaceutical companies with global economic influence.</td>
<td>TRIPS should explicitly prohibit economic and other threats by patent holding nations and firms on those attempting to import drugs or manufacturer drugs via TRIPS flexibilities.</td>
</tr>
</tbody>
</table>

**Table 1. Challenges and Suggestions, TRIPS.**

b) Case study of TRIPS flexibilities implementation and potential implications to COVID19

In 2006, during the HIV pandemic, when Rwanda used compulsory licenses to manufacture and import ARVs from Canada into Rwanda through the generic manufacturer Apotex, the use was complicated with much “redtaping” ¹. The Rwandan government was forced “to comply not only with TRIPS articles, but also with Canadian patent law,” causing constant delays from meeting

the formality of requesting imports, prolonged negotiation between Apotex-the generic manufacturer- and the patent holding companies for 30 days on royalty deal agreement before they were granted a compulsory license from the WTO1. “This entire process took thirteen months, followed by five months to manufacture the ARVs for importation”1. The legal hurdles, little financial incentives in return, and long process proved to be unexpectedly strenuous for the generic manufacturer Apotex and they proceeded to make a public announcement that ”[they will be unwilling to participate in compulsory licensing and importation following this experience” 1. Dr. Syam commented that this case has discouraged other generic manufacturers from participating in similar efforts and thus might be inefficient to use during the COVID-19 pandemic 2. Additionally, the complicating requirements of labelling and packaging of the final generic products with the compulsory licenses also add to the burden2.

b/ March-in rights

The second legislation worth highlighting to increase access to medicines during the HIV pandemic and relevant to the COVID19 pandemic is the Bayh–Dole Act adopted in 1980 in the United States. The bill addresses patent rights on inventions developed using government funding for universities, non-profit organizations and small businesses3.


It “allows the government to break industry held patents on inventions that are needed by the public: a process referred to as ‘march-in rights.’” March-in rights can be used to seize patents on government funded inventions and challenge pharmaceutical patent holders to benefit the
public commercialization of essential medicines. Like the use of TRIPS flexibilities, march-in-rights are subjected to enormous opposing pressures and lobbying by pharmaceutical companies.

c/ Case study of march-in-rights:

Ritonavir is an HIV protease inhibitor funded by the US government through the ‘National Cooperative Drug Discovery Group for AIDS’ grant. In response to Abbott’s increase in ritonavir price by 400% in 2004, Essential Inventions, an organization committed to accessible distribution of essential inventions, petitioned the US government to enforce the march-in rights to overturn Abbott Laboratories’ patent on ritonavir. The proposal was supported by over 100 HIV/AIDS groups and doctors. Although NIH denied to use march-in rights in this case due to the “integral partnerships between the NIH and industry,” the public backlash of the petition was significant enough that “Abbott Laboratories agreed to waive ritonavir price increase for government insured patients.”

Until the present day, march-in rights have never been used in the United States to reclaim patents or to challenge pharmaceutical patents or the expensive setting of drug prices because the government is reluctant to challenge the pharmaceutical industry. However, as previously discussed from the literature review section, implementation of march in rights is encountered with many political partnership and economic challenges, as summarized in Table 2.

Lastly, closely linked to the march in rights, the third mechanism is to use government patents. According to the U.S. Patent and Trademark Office, “pharmaceutical advances funded by tax-payer money can lead to duplicate patents” if the government takes action to hold a competing patent 1.

e/ Case study: government patents

In early 2019, the PrEP4All Campaign conducted a careful review of the U.S. government’s PrEP patents and discovered that “the CDC held legally enforceable patents on PrEP” 1.

Eventually, with public pressure on the CDC to reclaim its patent against Gilead to drive down the cost of PrEP, “the Department of Health and Human Services (HHS), on behalf of the CDC, filed a patent infringement suit against Gilead Sciences, claiming the company infringed on four patents issued by the United States Patent and Trademark Office for PrEP” in late 2019 1.

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Although the case concluded in 01/2021 with the Government’s motion to strike and motion to dismiss denied by the court ruling, it is historically important because the United States doesn’t regularly enforce its intellectual property rights against drug manufacturers. Secondly, it paved the way for future patent claims over other government funded medicines, notably for the COVID-19 medicines, many of which are publicly funded. The challenges of employing government patents as well as suggestions to overcome them are summarized in Table 3 below.

The application of the government patents to the COVID-19 medicines will be explored further in depth in the following analysis section.

<table>
<thead>
<tr>
<th>Table 3. Challenges and Suggestions, Competing Patents.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Challenges</strong></td>
</tr>
<tr>
<td>Only a useful option for inventions for which the government holds a competing patent, limiting this pathway.</td>
</tr>
<tr>
<td>Government has been unwilling to use this path in the past, speaking to their hesitancy to challenge corporate interests.</td>
</tr>
<tr>
<td>Lack of transparency regarding competing, government held patents.</td>
</tr>
</tbody>
</table>


8. Analysis: application to the COVID-19 pandemic

The use of the TRIPS flexibilities like compulsory licenses and parallel imports was successful in increasing access to AVRs during the HIV pandemic, so many experts believed that this historical use potentially could pave the way to allow for easier use of the TRIPS flexibilities in future health emergencies like the COVID19 pandemic. In fact, in March 2020, Israel was the first country to apply for a compulsory license for lopinavir/ritonavir for the treatment of SARS-CoV-2, but the drug was later proved to be not efficacious” and many other countries have followed the move as more COVID-19 drugs emerge. However, as the pandemic prolongs, it seems like employing TRIPS flexibilities might not efficient and applicable for COVID19 vaccines. TRIPS flexibilities worked well during the HIV pandemic because the “reverse engineering” method of small molecule therapies were relatively simple to carry out by generic pharmaceutical companies. Thus, as long as legal barriers created by TRIPS are removed by using TRIPS flexibilities, mass-production of AVRs was easily obtained.

With regards to the COVID-19 pandemic, while TRIPS flexibilities like compulsory licenses can certainly still be valid to allow generic production and improve access to small molecule therapeutics like Molnupiravir in developing countries, their application will not extend to manufacturing procedures that require a more detailed and sophisticated transfer of know-how than the simple reverse engineering method. The second disadvantage of compulsory licenses is that it does not cover other forms of IP rights such as copyrights, industrial designs, and trade secrets. This data is extremely important for successful reverse engineering and surveillance of equitable distribution of medicines worldwide. Thirdly, according to Dr. Syam,
compulsory license can only be issued for a particular drug/therapeutic at a time³. “The BioNTech/Pfizer vaccine contains 280 ingredients sourced from 19 countries. Moderna’s AstraZeneca’s and Johnson & Johnson’s are similarly complex” claimed the International Federal of Pharmaceutical Manufacturers and Associations (IFRMA)¹. That is not to mention the complexity and heavily interconnected network analysis of mRNA-based vaccine candidates for COVID-19 as shown in the figure below². Given the diversity of Covid vaccines and complexities of the supply chain for messenger RNA (mRNA) and viral vector vaccines, this case-by-case approach would not be efficient due to the cumbersome and time-consuming process required to obtain the licenses for each and every patented component or process.


Fourthly, lessons from the HIV pandemic have shown that past uses of compulsory licenses are often challenged by “high royalties and limitations on the number of products/doses,” and that countries with historical usage of compulsory licenses are under the sociopolitical pressures of the EU and the US to forfeit other trade rights. For instance, US threatened to stop funding for Pax-
Colombia when Columbia applied for compulsory license over Glivec \(^1\). Therefore, these challenges will likely continue to be relevant to the COVID19 pandemic,

**b/ TRIPS waiver**

With all the difficulties previously discussed of using TRIPS flexibilities, the solution to improve the access to medicines without infringing on patents and intellectual property laws is a TRIPS waiver. On 2 October 2020, India and South Africa proposed to the World Trade Organization (WTO) the TRIPS waiver, with the support of 62 WTO member states\(^2\). This proposal is to “temporarily waive intellectual property rights protections for technologies needed to prevent, contain, or treat COVID-19, including vaccines and vaccine-related technologies” \(^2\). Since its proposal, more than 100 low-income countries have supported this proposal, but many high-income countries, including some European Union (EU) member states, the UK, Japan, Canada, and Australia have announced their opposition\(^2\). Surprisingly, on May 5, 2021, the US’s Biden administration announced their support for negotiating this waiver, although no legal actions of support have been carried out\(^2\). The map of countries that support and oppose the waiver is shown below\(^3\).

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On the other hand, opposition against the TRIPS waiver has also been raised by many developed countries, including Switzerland, Japan, the UK, and many other EU countries. According to the interviewed expert from the Swiss Intellectual Property Rights Office, “the problem is not protection of intellectual property but a lack of sufficiently large production facilities, supply and demand efforts such as the lack of vaccines administration capacity, storage issues, as well as vaccine hesitancy” 1. Thus, proving a blueprint of the vaccine recipe to developing countries through TRIPS waiver will not resolve the issue. This echoed the statement made in the Neue Zürcher Zeitung paper, saying that it isn’t “enough to have the recipe, you need different ingredients, a lot of know-how and infrastructure” 1.

Furthermore, “many thousands of vaccine doses have been destroyed in African countries because they've exceeded their expiry dates”. More specifically, Malawi has destroyed almost 20,000 doses of the AstraZeneca (AZ) vaccine, while South Sudan announced it would destroy 59,000 doses 2. Similarly, the Democratic Republic of Congo gave away 1.3 million out of the


1.7 million AstraZeneca doses it had received from Covax because it couldn’t administer them before they expired\(^1\). Most recently, South Africa has requested to stop receiving donated vaccines from COVAX as vaccine hesitancy and public distrust in the national public health system and government halt the vaccination rate\(^1\).

According to the interviewed representative from the Swiss IP office, clearly the problem was not the lack of vaccine availability or intellectual property rights but rather the supply and demand issues, the lack of funding in infrastructure, understaffed healthcare work force to administer the shots, as well as refrigeration and transportation network and public health education to address the community distrust\(^1,3\). Secondly, the opponents are concerned that waiving patent protection would discourage private investments, research and development of new COVID-19 medicines. “Why should you invest your money in risky research projects in the future if the patent is then revoked if it is successful? That stifles innovation,” René Buholzer, the head of the Swiss industry lobby group Interpharma\(^2\).

c/ March-in-rights and government patents:

The implications and use of march-rights might be critically relevant to improving the access to COVID19 medicines. After “the 2003 SARS outbreak, the NIH immediately spent 700 million on coronavirus research\(^4\). According to Dr. Vieira, many of the current COVID-19


\(^3\) Swiss Federal Institute of Intellectual Property. Personal interview. December 2\(^{nd}\), 2021

vaccines development were funded publicly. Preliminary findings from the Global Health Centre, Geneva showed that R&D investments for the development of COVID vaccines are “primarily generated by public sources (98.12% of the USD 5.9 billion tracked).” The Congressional Budget Office also estimated that the Biomedical Research and Development Authority (BARDA) alone has spent $19.3 billion on COVID-19 vaccine development. The United States and Germany governments are by far the largest public investors in vaccine R&D and private companies and academic groups such as Moderna, Johnson & Johnson, BioNTech/Pfizer, CureVac and the University of Oxford are the primary recipients of R&D funding. As such, the public has financially through three mechanisms. First, it supported the cost for additional preclinical and clinical studies: “Johnson and Johnson, Moderna, Sanofi, and AstraZeneca together are estimated to have received more than $2.7 billion from the federal government to cover expenses related to human clinical trials.” Secondly, the development of vaccines is usually associated with much investment risk for pharmaceutical companies as it often consists of a long study and testing process and complicated manufacturing capacity. The federal government basically insulate these companies from these commercial risks by (1) ensuring that there would be “sufficient manufacturing capacity to produce the necessary volume of vaccines” and (2) making large purchase commitments at “predetermined quantities and high prices enough to guarantee a healthy return.” Although pharmaceutical contracts on pre-order remained largely obscure, many public sources revealed that “Johnson and Johnson had a $1 billion contract for 100 million doses of their vaccine. Moderna had contracts totaling $4.95

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billion to produce 300 million doses. Pfizer, a firm that claims to not have received funding from the government, had advance purchase contracts totaling $5.97 billion for 300 million doses” ¹. Therefore, “many medicines and devices emerging from federally funded coronavirus research will be subject to the use of march-in rights.” ²

**d/ Sharing of know-how: the Medicines Patent Pool**

In May, 2020, before the success of any COVID-19 medicines was achieved, the President Alvarado of Costa Rica has called on the need for solidarity to create a technology pooling initiative and ensure access to COVID-19 health products for all: “It’s a Solidarity call to action to Member States, to academia, to companies, research institutions and cooperation agencies, based on global social responsibility, on a voluntary basis, promoting more global nonexclusive voluntary licensing³. The platform will “pool data, knowledge and intellectual property for existing or new COVID-19 health products to deliver ‘global public goods’ for all people and all countries. Through the open sharing of science and data, numerous companies will be able to access the information they need to produce the technologies, thereby scaling up availability worldwide, lowering costs and increasing access.” ³ Since then, the Medicines Patent Pool has expanded its mandate to also include “any health technology that could contribute to the global response to COVID-19.” ³ Agreements to share the know-how of therapeutics development by

3. Daniela Bagozz. "WHO and Costa Rica preview technology pooling initiative to ensure access to COVID-19 health products for all". WHO. 2020
Merck and Pfizer were promising in ensuring increased availability to COVID-19 medicines. However, it is concerning that up to the present, Moderna and Pfizer have not shown willingness to share their vaccine development technology, arguing that the developing countries lack necessary resources and capacity to manufacture the vaccines even with the shared technology. e/ COVAX and GAVI

To ensure equitable distribution of vaccines and therapeutics and increase the solidarity by several governments or other agencies, the COVID-19 Vaccines Global Access (COVAX) initiative- supported by the Global Alliance for Vaccines and Immunization (GAVI), Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization (WHO)- was established. Its primary goal is to provide vaccines to 92 lower-income countries, financed by cash donations by governments and organizations. For instance, the United States has donated $2.5 billion and Germany has donated $1.1 billion to COVAX. Besides from precuring vaccine shots and redistribute them to low- and middle-income countries, the initiative also acted as “an intermediary between those countries and drug companies” to ensure that countries can buy doses without jumping ahead in line regardless of the difference in their financial offers. Although COVAX has made substantial contribution to providing vaccines to low- and middle-income countries with 610 million doses delivered as of December, 2021, it has encountered many criticisms. Firstly, donation promises by wealthy nations have very time frames of their donations: some countries “specify that doses will arrive in early 2021, while others are more vague, indicating by the end of next year.”  

1. Daniela Bagozz. "WHO and Costa Rica preview technology pooling initiative to ensure access to COVID-19 health products for all". WHO. 2020
2. Times, T. N. Y. "With First Dibs on Vaccines, Rich Countries Have 'Cleared the Shelves'."
doesn’t mean you’ll get 100 million doses in December,” said Kendall Hoyt, an assistant professor of medicine at Dartmouth.¹ This makes it difficult to set up expectations and gauge the severity of vaccines deficiency, especially when considering the importance of early vaccination against the fast mutation rate of SARS-CoV2. Furthermore, although these movements have provided millions of COVID vaccine shots to developing countries, they have not done much to fight for the transfer of technology and know-how to develop and scale up vaccines and therapeutics production¹.

9) Findings and Interpretation

Interpreting the validity and implications of the discussed intellectual property protection laws and mechanisms to increase access to COVID19 medicines is a challenging task as (1) the situation is quickly evolving with new emergence of new therapeutics and vaccines and (2) these mechanisms are subjected to continuous and on-going debates on both sides.

a) A comprehensive approach is needed to improve access to COVID-19 medicines

According to Mr. Patrick Durisch, he believes that although IP laws have always created big barriers to access, their consequences and negative influence on access to medicines during the HIV and COVID-19 pandemic are different².

With regards to the HIV pandemic, “the main obstacle was that patents led to highly-priced AVRs, so it was more an issue of affordability than and less an issue of availability”¹. Indeed,


2. Durisch, Patrick. Personal interview. 24 November 2021
although “the annual price of first-line antiretroviral drugs has tremendously decreased from over US $ 10 000 per person in 2000 to less than US $ 116 for the cheapest WHO-recommended first-line antiretroviral regimen in the first quarter of 2010, a reduction of nearly 99%,” the cost of the therapeutics still remained one of the biggest barriers to increasing access to treatment and care services2. With regards to the COVID19 pandemic, the issues are more complicated. “There are issues of affordability but also insufficient productions as there was a sudden huge global demand, lack of know-how sharing, etc” said Mr. Patrick Durisch3. Thus, with herd-immunity achievement as the public health priority, the solution needs to be comprehensive to address a range of problems including “a massive drive of technology transfer, capacity expansion, and supply line coordination to bring vaccine supply in line with global demand”4. This cannot be simply achieved by employing thecumbersome TRIPS flexibilities nor just distributed donated vaccine shots through COVAX while many wealthy countries continue to hoard vaccines for booster shots despite WHO strong recommendation against it.

b/ Implications of implementing the TRIPS waiver: short-term vs long-term expectations

In the discussion of the TRIPS waiver, we need to be reminded that the COVID-19 pandemic is far from over and solutions to increase access to medicines should be considered from a long-term perspective over short-term. Obvious advantages of adopting the TRIPS waiver would allow generic manufactures to access the know-how of vaccines development and manufacture

3. Durisch, Patrick. Personal interview. 24 November 2021
cheaper vaccines and drugs to meet the surging needs as soon as possible without the fear of infringing on patents and intellectual property rights ¹.

Furthermore, the TRIPS waiver can potentially be extended to allow all countries to choose to neither grant nor enforce patents and other intellectual property (IP) related to COVID-19 drugs, vaccines, diagnostics and other technologies for the duration of the pandemic, until global herd immunity is achieved, with a possible termination period set at no more than three years ¹. This is a critical difference to compulsory licenses which only allow state to circumvent patentee’s rights to access to one particular drug or therapeutic ¹.

Secondly, in response to the concern of TRIPS waiver opponent that even with blueprints of vaccine recipe of the waiver of patents on vaccines, low- and middle-income countries would not have the capacity to manufacture them due to inadequate technical advances, Dr. Syam called it a rather “colonial thinking” and condescending approach from wealthy patent holders².

According to him, the sharing of vaccines know-how is complicated as far as technology is concerned but it is not impossible to be done². He argued that developing countries have manufacturing experience with vaccines. For instance, nucleic acid vaccines have been studied in India for a long time and the country has successfully developed and approved (for emergency use) a new DNA COVID19 vaccines in September, 2021³. Indeed, these breakthroughs in vaccine research and developments are proof that many generic companies in low- and middle-income countries are capable of vaccines production scale-up if proper transfer of know-how and

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technology is executed. The bottom line is there are usually ways to turn around with and without the know-how. India, for instance, might not necessarily have the resources and it might some time to set up the infrastructures. Yet, again the scientific capacity is there and will be more efficient with free access to the know-how transfer, especially when considering that the fighting the pandemic is a long-term effort and not a short-term battle.

Thirdly, in response to the belief that the TRIPS waiver would discourage research and vaccine development and that it is not justifiable for pharmaceutical companies to invest in high-risk vaccine development only to receive patents protection suspension, it is important to reevaluate the risk taken by private pharmaceutical companies over the course of vaccines and therapeutics developments. Patent laws work on the idea that the incentives for pharmaceutical industries to take on risks to develop new inventions in the long run are offset by financial gains at the expense of slower distribution of medicines in a short run1. However, as previously explained, since much of the research and development of COVID-19 medicines are publicly funded, and the commercial risks absorbed by large contracts of preorders by federal governments, pharmaceutical companies cannot claim the same bargain from the 20-year monopoly like usual. Additionally, during pandemics and other public health emergencies, measures should be taken to speed up distribution not to slower the diffusion of therapeutics.

10. Strengths and limitations of the methodology

A strength of this methodology is that it allows for an analysis of diverse perspectives on the challenges and solutions to improve access to COVID19 medicines. Yet, there are a few limitations associated with the qualitative nature of the methodology. Firstly, due to the small

sample size of representatives from each organization that were interviewed, the analysis drawn from their statements remained subjective and does not necessarily reflect the organization’s mandates. Furthermore, due to limited research time to one-month span and geographic limitations, initially planned interviews with experts from many important organizations and initiatives such as the WHO, UN, and GAVI were not conducted. Future projects with interviews with these organizations can further the insights on health policies relevant to COVID10 treatment availability.

It is also important, however, to note that the knowledge of COVID-19 and availability of medicines both with regards to research and distribution equity continue to rapidly evolve globally. Therefore, certain interpretations of the discussed legal mechanisms may no longer be relevant in the future.

11. Conclusions

In this article, we have explored multiple strategies by which governments, ideally in partnership with civil society groups, can learn from previous healthcare emergencies like the HIV pandemic to improve access to COVID-19 medicines. Due to the quickly changing situation of COVID-19 infections and medicines availability, these include but not limited to TRIPS flexibilities, TRIPS waiver, march-in-rights, competing government patents, Medicine patent pool to transfer technology and know-how, as well as global health initiatives like COVAX and CTAP. The first lesson learned from the HIV pandemic was that we needed a stronger and more collaborative coalition between the government, private sector such as pharmaceutical companies, non-governmental organizations, and civil societies to accelerate the research and development of as well as distribution of medicines.” For instance, through the Medicines Patent
Pool, technology transfer agreements can be made, and they might be a good solution to encourage collaboration for scientific findings and knowledge between research institutions and universities, or business labs, to public and private users to protect public health. Secondly, the importance of advocacy groups as presented through the analysis of case studies from the literature review was clearly illustrated during national health emergencies as they created pressure on both pharmaceutical industries and the government to take actions to prioritize accessibility and affordability of medicines over financial gains. Furthermore, before the HIV pandemic, “civil societies were usually taken for granted,” said Dr. Vieira from the Graduate Institute. It is usually the WHO and UN that attract the most attention and praised for the state of global health. However, after the HIV pandemic, greater attention, responsibility, and expectations to the importance of civil societies, advocacy groups, and non-governmental organizations were gained to improve access to medicines during pandemics like the COVID-19. Thirdly, while the TRIPS flexibilities including compulsory licenses and parallel imports worked well to improve the manufacturing scale-up of HIV antiviral generics and might potentially extend to improving access to COVID19 small molecule therapeutics, they offer little values to improve access to COVID-19 vaccines. Thus, the TRIPS waiver as an alternative strategy for making COVID-19 medicines, medical devices and knowledge more easily accessible must be taken seriously. This should take priority over financial benefits gained by private sectors like pharmaceutical companies, especially when considering the fact that most COVID19 medicines development were funded by the public and pharmaceutical companies insulated from commercials risks thanks to huge preorder commitments from the governments. Fourthly, the HIV pandemic has also demonstrated that there many under-utilized mechanisms to challenging patents on medicines in the United States such as the Bayh Dole Act’s march-in rights and
competing government patents, first used during the HIV pandemic and could be used for COVID-19 medicines. All in all, with a comprehensive, integrative, and collaborative approach of these strategies as well as the pending outcome of the TRIPS waiver implementation, past inequitable access to COVID-19 medicines could be better tackled.
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