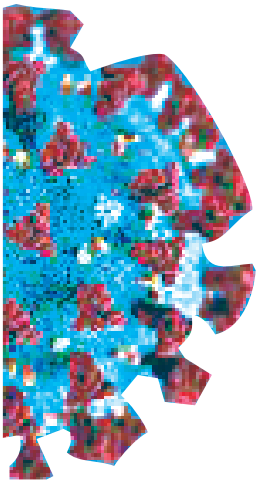
A PATENT WAIVER THAT NEVER WAS:

Where Do We Go From Here?



Summary

After nearly two years of intense negotiations, member states of the World Trade Organization (WTO) have finally agreed a deal that waives patents and other intellectual property rights (IPRs) on Covid-19 vaccines. However, the highly restrictive deal – "at best, a distant cousin of the original proposal"[1] that sought a full waiver of protections on patents, trade secrets, copyrights and industrial designs on not only vaccines, but also on diagnostics and therapeutics – is unlikely to boost global vaccine production and equity. This brief argues that while Low- and Middle-Income Countries (LMICs) should endeavor to utilize the WTO's tockenish waiver, the campaign continues for a meaningful pathway to global equity in access to COVID-19 vaccines and other pandemic response tools.

1 https://www.devex.com/news/devex-newswire-how-wto-got-its-trips-waiver-compromise-103477

Covid-19 vaccine inequity

Vaccines are currently the most promising tool to save lives and end the Covid-19 pandemic.[1] However, as observed by the UN Secretary-General, access to Covid-19 vaccines has been wildly uneven and unfair.[2]

For instance, in the first six months of vaccine roll-out, 80% of the vaccines went to wealthy countries, as low-income countries shared a paltry 0.3%.[3] Fast forward to February 2022, high-income countries had on average, administered about 183 vaccine doses per 100 of their people, compared to just 14 doses per 100 people in LMICs.[4]

High-income countries started vaccinations on average two months earlier than low-income countries, and 39 of them had already achieved the 70% target by January 2022.[5] In sharp contrast, only four countries in Africa were on track to achieve that target by mid-2022; the rest of the 50 countries – Uganda inclusive – are off-track.[6]

The ugly head of 'vaccine nationalism'

As of 25 March 2022, WHO had approved eight vaccines for emergency use, from a handful of countries.[7] These are: Covishield from Oxford University and pharmaceutical multinational AstraZeneca, both from UK; Comirnaty from US pharmaceutical multinational Pfizer and Germany's BioNTech; Spikevax from US pharmaceutical novice Moderna; BBIBP-CorV from China's state-owned Sinopharm BIBP; CoronaVac from China's vaccine specialist Sinovac Biotech; Janssen from US-based drug multinational Johnson & Johnson; Covaxin from India's Bharat Biotech; and Nuvaxovid from US biotechnology company Novavax.

1 WHO Afro. Covid-19 vaccines. https://www.afro.who.int/health-topics/coronavirus-covid-19/vaccines
2 UN News (17 February 2021). Covid-19 vaccination 'wildly uneven and unfair': UN Secretary-General. https://news.un.org/en/story/2021/02/1084962
3 Harman S, Erfani P, Goronga T, *et al.* (2021). Global vaccine equity demands reparative justice – not charity. *BMJ Global Health* 2021;6:e006504.
4 The PLOS Medicine Editors (2022). Vaccine equity: A fundamental imperative in the fight against COVID-19. PLoS Med 19(2): e1003948. https://doi.org/10.1371/journal.pmed.1003948
5 UNDP. Global Dashboard for Vaccine Equity. https://data.undp.org/vaccine-equity/
6 UNDP. Global Dashboard for Vaccine Equity. https://data.undp.org/vaccine-equity/vaccine-equity-and-speed/
7 WHO. Covid-19 vaccines. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines

Even before any of these vaccines reached the market, wealthy western countries scrambled to place advance orders with pharmaceutical companies directly, to secure supplies for their own populations – often beyond need – potentially limiting the stock available to poor countries.[8] The term "vaccine nationalism" has been coined to describe this selfish tendency.[9]

The global response to potential vaccine inequity – Covid-19 Vaccines Global Access (COVAX) – came early in the response, in April 2020. From the outset, well before any vaccine was on the horizon, COVAX was handed the mandate to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for all countries.[10] But after COVAX began to deliver vaccines to LMICs in February 2021, it was starved of supplies[11] [12] as wealthy nations hoarded and stockpiled vaccines beyond their need[13] and was unable to secure any production licence from vaccine manufacturers.

The role of intellectual property rights

Intellectual property rights (IPRs) are rights that give the creator of a novel idea the exclusive usage of their creation over a specified period of time.[14] The main objective of IPRs is to encourage innovation by providing the incentive of protection, to inventors to allow them time to recover research and development (R&D) investments.[15]

The Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPs agreement) of the World Trade Organization (WTO) is currently the most comprehensive multilateral agreement on intellectual property setting out the minimum protection standards for many forms of intellectual property rights (IPRs), including copyrights, trademarks, patents, undisclosed information (trade secrets, test data, etc).

However, because IPRs tend to create monopolies that naturally limit production and inflate prices, the TRIPS Agreement includes safeguards known as "flexibilities" which least developed member states can utilize to take certain measures to address public health emergencies.

The TRIPs Agreement has four key provisions (flexibilities) that Least Developed Countries (LDCs) can utilize to safeguard public health that can use to respond to COVID-19:

1) *Compulsory licenses*

   Compulsory licensing enables a third party or government agency to use a patented invention without consent from the patent-holder in order to address a national emergency – in this case, COVID-19.

2) *Parallel importation*

   The TRIPs Agreement gives members freedom to import a patented product from another country where it is marketed by the patent-holder (or with their consent) at a lower price.

8 Kai Kupferschmidt. 'Vaccine nationalism' threatens global plan to distribute COVID-19 shots fairly. *ScienceInsider*, 21 July 2020. doi: 10.1126/science.abe0601

9 Hellen Lock. Vaccine Nationalism: Everything You Need to Know. Global Citizen, 11 February 2021. https://www.globalcitizen.org/en/content/what-is-vaccine-nationalism/

10 Gavi. COVAX. https://bit.ly/3LTLbKT

11 Aljazeera, 16 March 2022. WTO chief welcomes COVID vaccine patent waiver plan https://www.aljazeera.com/news/2022/3/16/wto-chief-welcomes-covid-shot-patent-plan-drugmakers-balk

12 Aljazeera, 16 March 2022. Ibid

13 Transparency International Health Initiative. Is Covid-19 vaccine nationalism corruption? Article, 21 December 2021. https://ti-health.org/content/is-covid-19-vaccine-nationalism-corruption/

14 World Trade Organization. What are intellectual property rights? https://bit.ly/3OpmdVv

15 UNCTAD. Examining the interface between the objectives of competition policy and intellectual property. Intergovernmental Group of Experts on Competition Law and Policy Fifteenth Session, Geneva, 19-21 October 2016. https://unctad.org/system/files/official-document/ciclpd36_en.pdf

3) *LDC transition period for patents on pharmaceuticals*

   LDCs, such as Uganda, are currently not required to grant or enforce patents on pharmaceutical products until 2033. The spirit of this provision is to allow time for development of technological capacity for local pharmaceutical production in LDCs.

4) *The Bolar provision*

   The 'Bolar provision' allows generic manufacturers in LDCs to start producing test-batches of a product before a patent expires. This enables them to collect the necessary data for submission for regulatory authorization. This will reduce the delay for generic products to enter the market after the patent expires, and thereby enhance competition.

However, attempts to utilize these fliexibilities have met resistance from western pharmaceutical manufacturers and governments. For example, in 2012, India issued a compulsory licence to Natco for generic production of an expensive cancer drug Nexavar, reducing its price by up to 97%. However, although the compulsory licence was issued on condition of Natco paying royalties to Germany's Bayer, repeated pressure opposing the move came from the US.[16] Similar pressure has been put on Colombia over a compulsory licence for production of Novartis' leukemia drug Glivec; and Malaysia's attempt to use a compulsory licence to produce a Hepatitis C medication.

As a result of these and other instances, countries have been reluctant to develop flexible domestic compulsory licensing policies and are certainly out of practice in using them, according to Intellectual Property Watch.[17]

The waiver of IPRs on Covid-19 vaccines

It has been noted that Covid-19 vaccine supply could be substantially increased if manufacturers shared their technology with other pharmaceutical manufacturers.[18] This was the gist of the proposal from South Africa and India to WTO to temporarily waive IPRs for COVID-19 vaccines during the pandemic in order to boost production and address inequality in access between rich and poor nations.

The proposal, first submitted on 2 October 2020, sought a temporary waiver for Covid-19 drugs, vaccines and related equipment and technologies in four IPR categories of intellectual property under the TRIPs agreement, namely copyright, industrial designs, patents and protection of undisclosed information.

In the final decision, largely based on proposals from the European Union, eventually adopted at the WTO's 12th Ministerial Conference held 12-17 June 2022, is highly restrictive: it provides a temporary waiver of patents on Covid-19 vaccines exception to a restriction on the quantities that may be exported under a compulsory licence; such compulsory licences may be granted only for vaccines, not diagnostics or treatments; it can be used only to respond to the Covid-19 pandemic and not to other health crises; and it will apply for only five years.[19]

Implications for Uganda

Local pharmaceutical firms in Uganda, as is the case in the rest of the region, mainly produce simple dosage forms, such as plain tablets, hard capsules, lotions and suspensions.[20] Local production does not include advanced formulations, such as sustained release, layered tablets and immune sera, and highly regulated product lines, such as sterile products, vaccines, and diagnostics.[21] Imports provide up to 90% of the country's essential and medicines and health supplies (EMHS) – and 90% of the imported EMHS are from India and China.[22]

16 Medicins Sans Frontieres, 2015. A rimeline of US attacks on India's Patent Law and generic competition. Access Campaign, January 2015. https://msfaccess.org/sites/default/files/2018-10/IP_Timeline_US%20pressure%20on%20India_Sep%202014_0.pdf

17 www.ip-watch.org

18 The Business Standard (2021). Globe biotech gets BMRC nod for human trials. https://www.tbsnews.net/coronavirus-chronicle/covid-19-bangladesh/globe-bio-tech-gets-bmrc-nod-human-trials-333622.

19 Yousuf Vawda, Fatima Hassan & Tian Johnson (2022). New WTO deal is a slap in the face for poorer countries. News24, Opinion, 18 June 2022. https://www.news24.com/fin24/opinion/opinion-new-wto-deal-is-a-slap-in-the-face-for-poorer-countries-20220618

20 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017-2027

21 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017-2027

22 Ministry of Health. Health Sector Strategic and Invest-

Given the country's lack of capacity in biotechnology to produce vaccines locally and the exclusion of China, from the final decision on the TRIPs waiver, Uganda's only window is cooperate with other LMICs that have vaccine production capacity, such as South Africa and India that can produce and export to other LMICs over the limited period of the waiver.

The current predicament highlights the need to invest in R&D going forward. One success story has been Bangladesh.[23] The country's leading biotech company Incepta Vaccine Limited (IVL) has secured contract license for domestic manufacture of BBIBP vaccine from China's Sinopharm.[24] IVL is also in the race to develop its COVID-19 vaccine in collaboration with international partners.[25] Bangladesh is participating in a clinical trial for a novel nasal-route Covid-19 vaccine developed by Sweden's Karolinska Institute.[26] In addition, Globe Biotech has completed non-human primate trials of its own mRNA-based vaccine and received approval for human trials.[27] Bangladesh's generic company Beximco started distributing its version of Paxlovid, an antiretroviral pill that has proven effective against COVID-19.[28]

There needs to be a similar determination on part of the Government of Uganda to invest in R&D capacities, but also to negotiate mutually beneficial partnerships. Ugandan researchers have participated in Covid-19 vaccine research led by France's Sanofi and British GlaxoSmithKline (GSK), but their role is limited to provision of blood samples.

The major concern is that it is not clear whether Ugandan researchers have any guarantee of access to the Sanofi-GSK vaccine for Ugandans for a candidate vaccine that has proven 100% efficacy against severe COVID-19 disease and hospitalizations; 75% efficacy against moderate or severe COVID-19 disease; 57.9% efficacy against any symptomatic COVID-19 disease, and for which regulatory approval is already being sought.[29]

The researchers may not have the capacity to negotiate with Big Pharma, but the National Drug Authority (NDA), Uganda National Health Research Organization (UNHRO), Uganda National Council for Science and Technology (UNCST) and the President's Office which approve research in Uganda should demand Uganda preferential access to Sanofi's final product.

Conclusion

Given the challenges of imposing compulsory licenses under the TRIPs Flexibilities, and the limits of voluntary licences, the TRIPS waiver offers another way for vaccine producers around the world to ramp up global production without the risks of facing domestic and international IP disputes. However, the restrictions of the waiver means that the campaign for a more meaningful option continues, including campaigning for the expansion of the scope and duration of the waiver. In the meantime, Government of Uganda and other LMICs should explore mutually beneficial collaborations not only in exploiting the current waiver, but in global advocacy and in R&D investments.

ment Plan (HSSIP).

23 The Business Standard (2021). Globe biotech gets BMRC nod for human trials. https://www.tbsnews.net/coronavirus-chronicle/covid-19-bangladesh/globe-biotech-gets-bmrc-nod-human-trials-333622.

24 Mahmud-Al-Rafat A, et. al (2022). Ibid

25 Mahmud-Al-Rafat A, et. al (2022). Ibid

26 Mahmud-Al-Rafat A, et. al (2022). Ibid

27 Mahmud-Al-Rafat A, et. al (2022). Ibid

28 Kerry Cullinan (2022). Bangladesh Produces First Generic of Pfizer's Antiviral But Indian Company Hits Snag with its Merck Generic. *Global Health Policy Watch,* 11 January 2022. https://healthpolicy-watch.news/bangladesh-produces-first-generic/

29 Sanofi. Sanofi and GSK to seek regulatory authorization for COVID-19 vaccine. Press release, 23 February 2022. https://www.sanofi.com/en/media-room/press-releases/2022/2022-02-23-11-15-00-2390091