Technical Press Briefing

Patents, profits & monopolies: The case for the TRIPS waiver

Introduction

The global health crisis generated by Covid-19 has exposed the broken system of Intellectual Property Rights (IPR) that regulates the production and distribution of treatments and drugs. Under the pretense of creating incentives for Research and Development (R&D), the patent system has created a set of monopolies, resulting in whopping profits for Big Pharma. This is poignantly evident in the rollout of Covid-19 vaccines: on one hand, billions of people in Asia, Africa and Latin America remain unvaccinated. Crucially, many of them have no hope of receiving a vaccine in 2021, 2022, or even 2023. On the other hand, the broken system of patents and monopolies has created nine new billionaires with a combined net wealth of €15.8 billion, enough to fully vaccinate the entire population of all low-income countries 1.3 times.[1]

The patent system created

9 new Billionaires

€15.8 billion

#VACCINE EQUALITY

GUE/NGL THE LEFT IN THE EUROPEAN PARLIAMENT

1 https://www.euronews.com/2021/05/20/nine-billionaires-created-by-discovery-of-covid-19-vaccines-say-ngos

Since the beginning of the pandemic, The Left in the European Parliament has been active in denouncing the monopoly rights granted to pharmaceutical corporations that are impeding the timely and sufficient accessibility of life saving medicines and vaccines. The Left has systematically called upon European institutions and member states to support the proposal put forward by India and South Africa in the WTO for a waiver of the agreement on Trade Related aspects of Intellectual Property Rights (TRIPS).

Thanks to a trailblazing mobilisation of citizens across Europe, the European Parliament is finally ready to vote on a resolution on the TRIPS waiver. This long-awaited resolution comes after Parliament's key vote last month in support of a Left amendment calling on the European Commision to support the TRIPS waiver proposal. The real question now is what are the Commission and member states waiting for?

This briefing aims to shed light on the current IPR architecture, the flexibilities contained in the TRIPS Agreement and its related structural issues, providing an overview on how the current legal landscape impacts public health objectives. The document also offers an outline of The Left's demands and its work for #VaccineEquality.

1. Why waiving TRIPS is the only option

Covid-19 vaccines were developed largely with public subsidies. In January 2021, it was reported that the global public sector had spent at least €93 billion on the development of Covid-19 vaccines and therapeutics.[2] Yet, profits flow exclusively into the pockets of the very pharmaceutical companies that refuse to share the patents, knowledge and technology to allow greater production and distribution.

Patent owners have the power to artificially restrict the production of a good and to exercise unfettered pricing power within a market. This is possible because a patent creates a legal monopoly right over the use of the patented invention for 20 years. It is a restrictive right by definition. It is designed to bestow upon the holder an exclusive right to an invention's commodification. Health is not a commodity, it is a right. This was a painful lesson learnt during years of HIV/AIDS campaigning which led to the revision of some of the provisions of the WTO's TRIPS Agreement , introducing flexibility with regards to IPR and public health that are enshrined in the Doha Declaration.

2 Thambisetty, Siva and McMahon, Aisling and McDonagh, Luke and Kang, Hyo Yoon and Dutfield, Graham, The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic (May 24, 2021). LSE Legal Studies Working Paper (2021, Forthcoming), Available at SSRN: https://ssrn.com/abstract=3851737 or http://dx.doi.org/10.2139/ssrn.3851737

Nonetheless, existing flexibilities are not enough. The patent system is set up in such a way that there is a constant race to patent the same invention with small modifications. Multiple patent applications with minor modifications from an original application grow into patent families - or thickets - with dozens and even hundreds of patents existing over the same product. These overlapping rights can result in a de facto extension of patent protection beyond the initial 20 years, making it difficult for competitors to identify whether or not the technology is still protected.

Among these flexibilities the most cited one is Compulsory Licensing (CL). A compulsory licence is a permit granted by the government to allow alternative production or importation of a generic version of a patented medical product, without the prior consent of the patent holder. Nonetheless, the practical application of CL is fraught with difficulties, especially in the context of a pandemic when a fast and extensive solution is needed. Key drawbacks flagged by researchers and organisations include:

1. Compulsory licensing can only be applied for on a product-by-product, and country-by-country basis. A blanket compulsory licence in all states for, say, Covid-19 vaccines is not possible under TRIPS.[3]

2. The WTO system sets down minimum criteria for a compulsory licence to be used in Art. 31 of the TRIPS Agreement, but countries can impose additional requirements for a compulsory licence, meaning the procedures for obtaining it at the national level are often bureaucratic, uncertain and time consuming.[4]

3. While CL is a flexibility allowed for by TRIPS, some states have traditionally been reluctant to invoke the process for issuing a compulsory licence, often due to fears of lawsuits and/or of trade sanctions being imposed on them (this has happened in the past).[5] In April 2021, for example, Gilead launched a lawsuit before the Supreme Court of Russia, challenging the compulsory licence granted on remdesivir by the Russian government.

4. There are additional obstacles to the use of CL for vaccines, including regulatory obstacles. For instance, in some regions like the EU, there are additional protections for clinical trial data, such as information and marketing exclusivities which mean generic producers cannot use such data when seeking regulatory approval for a generic product for a certain period. This means obtaining generic approval may not be possible in a timely manner for such products - this has proven to be a stumbling block in the use of a compulsory licence in Europe.[6]

5. When a compulsory licence is issued, the rights holder must be provided with adequate remuneration, and challenges can arise around what is 'adequate' in a pandemic context.[7]

6. Initially a compulsory licence was possible only for the supply of the domestic market. Modification of Art. 31 (notably Art. 31 bis) now allows CL for export and import. Yet, there are still many obstacles as shown by the unfulfilled request made by Bolivia to Canada to import vaccines in the case of Adenovirus Vectored vaccine.[8]

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3 Ibid.

4 Technical briefing Compulsory Licenses, the TRIPS Waiver and access to Covid-19 medical technologies, Briefing Document | May 2021 https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies

5 Thambisetty, Siva and McMahon, Aisling and McDonagh, Luke and Kang, Hyo Yoon and Dutfield, Graham, The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic (May 24, 2021). LSE Legal Studies Working Paper (2021, Forthcoming), Available at SSRN: https://ssrn.com/abstract=3851737 or http://dx.doi.org/10.2139/ssrn.3851737

6 EFM 't Hoen, P Boulet, BK Baker 'Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation' J Pharm Policy Pract (2017) 10

7 The Independent Panel, 'COVID-19: Make it the Last Pandemic' (May 2021) at 14 https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

8 Technical briefing Compulsory Licenses, the TRIPS Waiver and access to Covid-19 medical technologies, Briefing Document | May 2021 https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies

The practical challenges in applying the flexibilities foreseen by TRIPS, combined with the lack of detailed knowledge about the web of patents which may be applicable to any vaccine; inadequate information about manufacturing or regulatory processes; the terms of cross-licensing[9]; and limited knowledge about the contents of the patent applications which may be relevant for a CL application, make the effective use of CL for vaccines very difficult in both the domestic and international context.

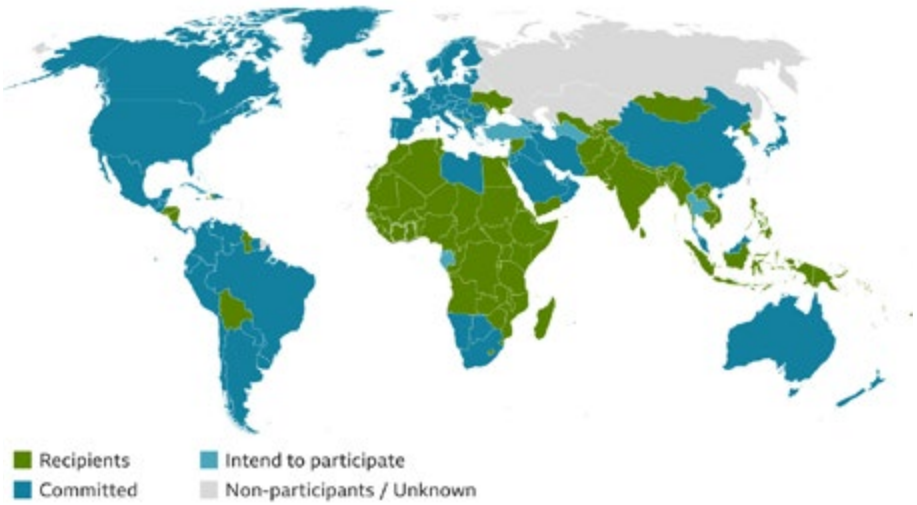
The limitations of compulsory licensing clearly make the case for additional legal options which can ensure equitable access to vaccines. This should be fully acknowledged by WTO members in the ongoing discussion on the TRIPS waiver proposal for Covid-19.

The waiver proposal led by India and South Africa offers options for countries to choose to temporarily not apply, implement and/or enforce patents, protection of undisclosed information, industrial design and copyrights related to medicines, vaccines, diagnostics and other related Covid-19 health technologies and materials. If adopted, countries can be exempted from being sued before the WTO dispute settlement body for not fully implementing the TRIPS Agreement in a pandemic. The proposed waiver would be in force for three years and when implemented at the national level, could immediately mitigate the limitations in the current rules of compulsory licences and offer an expeditious approach to export and import products made by generic companies. This is the only way to ramp up the production of Covid-19 vaccines and put an end to the pandemic.

2. Why is Covax not working?

Covid-19 Vaccines Global Access (COVAX) is a global initiative set up to ensure that the poorest of countries also have access to the vaccine. Almost a year and a half into the pandemic, it has not succeeded in this purpose. The initiative, led by the WHO, Gavi, the Vaccine Alliance and the Coalition for Epidemic Preparedness Innovations, along with Unicef as the implementing partner, is struggling to meet its targets.

The prime reason for this has been its over-dependence on a limited number of vaccine manufacturers. COVAX aims to provide around two billion doses by the end of 2021 so that each country can immunise at least 20 percent of their populations. The vaccines are distributed among the 180 participating countries. While the rich countries pay for the vaccines, the 92 low- and middle-income countries are subsidised by aid and the private sector. But vaccines are in short supply due to the monopolies granted to Big Pharma.



Countries that participate in the COVID-19 vaccine WHO-backed COVAX Alliance.

Source: BBC

9 Licence agreements are not disclosed to the public

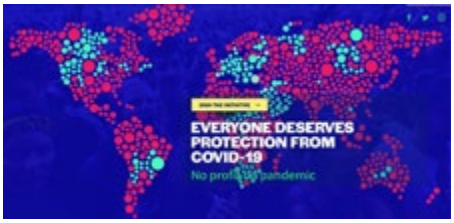
From the beginning, COVAX struggled to enter into firm purchase agreements with vaccine manufacturers. Companies' slow or piecemeal submission of clinical trial data to the WHO for emergency use listing posed delays, while individual governments secured vaccine doses via bilateral deals that increasingly ate up the global vaccine supply, limited by production capacity problems. To date, COVAX has only managed to purchase 1.1 billion doses of vaccine, compared to the 4.6 billion doses bought by high-income countries.[10]

Unfortunately, the Covid-19 Technology Access Pool (C-TAP) - a WHO program for pharmaceutical companies to voluntarily share Covid-19 related knowledge, treatments and technology - has had a similar experience to COVAX. C-TAP has yet to attract any participants because, companies want to hold on to monopolies and see sharing as a threat to profits.

The COVAX initiative, together with C-TAP and the latest 50 billion program put forward by the WHO, IMF and WTO, will not be able to tackle the scarcity of vaccines, because they rely on the good will of Big Pharma and rich countries.

3. The Left's demands

The Left in the European Parliament has been at the forefront of the fight for a socially equitable and sustainable Europe based on international solidarity. The crisis we are suffering today is the result of years of austerity and neoliberal restructuring of our public health systems which has left us completely unprepared for a pandemic. The fight for accessible vaccines for all, procured with transparency and accountability, is the battle of our time and will shape the future of health and healthcare in Europe for years to come.



This is why the Left launched a campaign on #VaccineEquality (find here the campaign manifesto and a Q&A , as well as our selection of weekly must reads) and fully supports the European Citizen Initiative 'No Profit On Pandemic', which has now collected over 200,000 signatures.

The temporary TRIPS waiver proposal for Covid-19 led by South Africa and India offers an opportunity for countries to unite and provide a critical legal option for addressing IP monopolies in a pandemic. Yet seven months since the proposal was first introduced, the EU - increasingly isolated - continues to engage in delaying tactics to block the proposal. As the pandemic continues to rage, causing immeasurable death and suffering, all political leaders should stand behind this critical proposal and support its adoption.

What are they waiting for?

10 https://www.devex.com/news/is-covax-part-of-the-problem-or-the-solution-99334

#VACCINE EQUALITY

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