

Covid-19: Should intellectual property rights be challenged ?

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This policy brief highlights the value of intellectual property pooling instruments such as the Medicines Patent Pool for the management of the Covid-19 health crisis by the international community. As an alternative between the suspension of intellectual property and bilateral cooperation agreements between firms, patent pools present advantages for both public health and the pharmaceutical industry alike.

The speed with which diagnostics, vaccines and treatments have been developed by the pharmaceutical industry in response to Covid-19 is remarkable. The magnitude of the pandemic, as well as the dramatic economic and social costs of measures taken to curb the spread of the disease, have led to a global mobilization that has resulted in new diagnostic tools, several effective vaccines and promising treatments that significantly limit the danger of the virus¹, all in less than a year. The international community is now facing a major challenge, which is to ensure that everyone is protected from the spread of the virus. The world will only emerge from this health crisis and its economic and social repercussions once the virus has stopped actively circulating on the planet. The scientific challenge of discovering vaccines and treatments is followed by an industrial, logistical and geopolitical challenge to ensure that these pharmaceuticals are rapidly manufactured in sufficient quantities and distributed to vulnerable populations throughout the world.

► Intellectual property as a core issue

Intellectual property rights, particularly patents, are a core issue in this new phase of the fight against the pandemic ([5]). Granting a monopoly -of limited duration- to a patent holder, rewards the inventor for the research and development (R&D) efforts she has undertaken and for the risk and costs she has borne, thus encouraging innovation. However, such a monopoly leads to higher prices and more limited product quantities than would be obtained if innovations were freely available. As a result, there is a current debate between advocates of strict enforcement of intellectual property rights on diagnostics, vaccines and treatments mobilized in

the fight against Covid-19, and proponents of measures to waive these rights in response to the global health emergency. Thus, South Africa and India officially filed a request with the World Trade Organization (WTO) on October 16, 2020 for a temporary suspension of intellectual property rights related to remedies in the fight against Covid-19 ([14]). This request, relayed by various stakeholders², has met with opposition from the pharmaceutical industry and many developed countries, including the United States, the European Union, the United Kingdom, Norway, and Canada.

► The case

Defenders of intellectual property rights point to the business model of the pharmaceutical industry, which is based on lengthy, costly, and risky investments in R&D ([16]), with invested funds being recouped only if some projects are eventually successful. It is the high profits obtained from these projects via intellectual property rights, they argue, that enable the industry to commit the investments and bear the risk necessary for the discovery and clinical testing of new pharmaceuticals ([15]). Lifting these rights would result in socialising the gains from successful projects, but not the losses incurred by firms because of failed projects. In the context of the Covid-19 health crisis, the efficiency of this business model has been demonstrated, according to its advocates, by the recent successes in developing vaccines and, to a lesser extent, by the number of new treatments developed in a very short time. Using the health emergency as a lever to question this economic model, they maintain, would threaten to reduce incentives for further investments in biopharmaceutical research and development, both in the current crisis, and in the event of a future pandemic.

Proponents of a suspension of intellectual

1. Outside of the pandemic context, the observed duration of discovery and clinical development of pharmaceutical products is particularly long. According to IQVIA (www.iqvia.com/insights/the-iqvia-institute/reports/global-oncology-trends-2019), the time from first patent application to market authorisation for drugs approved in the US in 2018 was on average 15 years (excluding oncology).

2. <https://msfaccess.org/open-letter-governments-blocking-proposal-remove-monopolies-covid-19-medical-tools-during-pandemic>

property rights, on the other hand, emphasize the inadequacy of the patent system in such an exceptional situation. Intellectual property rights significantly increase the price of medicines, often making them inaccessible to poor people in developing countries. The rationing effect brought about by high prices made possible by the monopoly power of patent holders, results in a disproportionate cost paid by the international community in such an acute public health crisis. This disproportionate cost, they argue, would justify any measure to speed up and increase the production of vaccines and treatments. Abandoning intellectual property rights would bring down prices and alleviate the injustice of poor people being denied access to pharmaceuticals. Added to these arguments is the fact that in high-income countries, industry has benefited massively from public spending on basic research as well as the co-development of vaccines and treatments with public laboratories, and public funding of clinical development projects initiated by pharmaceutical companies.³ The taxpayer may thus feel that she or he is paying twice for innovation when marketed products are protected by industry-held patents.

► A need for governance instruments

Good global governance, in terms of both efficiency and equity issues, is necessary in order to overcome the crisis. Indeed, the success of the current phase of production and distribution of treatments and vaccines requires good coordination of several categories of actors whose interests are not aligned, including innovating firms and generic producers, governments of developing and developed countries, non-governmental organisations, health workers, and populations. Even if it is overly simplistic to reduce the controversy to binary opposition between companies and taxpayers, between

developed and developing countries, or between innovative industrialists and generic producers, just as it would be simplistic to systematically oppose short-term and long-term intellectual property issues, these multiple fault lines exist and must be taken into account in order to address the situation.

The industrial and logistical challenges are made even more difficult by the geopolitical issues at stake. Competition between countries for the supply of doses of vaccine, and possibly treatment, is not only likely to exacerbate the already glaring inequalities between regions of the world, but also to jeopardise the effectiveness of the process of overcoming the health crisis. Enabling access to medicines for the most vulnerable populations in the least prosperous regions comes up against the “vaccine nationalism” of governments under strong pressure from public opinion. In addition to competing to secure procurements, some governments also compete to increase their diplomatic influence on areas of the world in need of vaccines and treatments, possibly with the opposite effects. It is difficult to imagine that these competitive interactions will not widen the structural gaps in access to health care that already exist in the world. Competition between countries also risks diverting governments from serious thinking on how to overcome the above-mentioned opposition of views on intellectual property rights and its effects on the allocation of existing products as well as on the development of new ones.

However, various instruments that can help streamline the production and distribution of vaccines and treatments have already been put in place or reactivated by the international community. These instruments, whose potential has certainly not yet been fully exploited, are part of a governance effort to coordinate the actions of the many categories of actors involved.

3. This has been the case in the United States with Operation Warp Speed : <https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/>

► Compulsory licences

International intellectual property rules have been established within the World Trade Organisation (WTO). The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights)⁴ negotiated in 1994 harmonised the patent systems and their scope of application, including pharmaceuticals, among the 164 signatory countries. The TRIPS Agreement guarantees a certain flexibility in the implementation of intellectual property rights when they affect the public interest. In 2001, the Doha Declaration confirmed the right of each country, set out in Article 31 of the TRIPS Agreement, to impose compulsory licences which allow a third party to manufacture a patented product without the consent of the patent holder. In situations of national emergency, a country may resort to such licences without prior discussion.

Since the Doha Declaration, some 20 countries have activated or threatened to activate the compulsory licensing mechanism in the area of medicines ([1]). During the 2000s, Brazil, Ecuador, Ghana, Indonesia, Malaysia, Mozambique, Thailand, Rwanda, Zambia and Zimbabwe imposed compulsory licenses for one or more anti-retroviral medications to make them available to their HIV-infected populations. In the case of Brazil in 2005, it was the credible threat of imposing a compulsory licence on Kaletra (lopinavir/ritonavir) that led Abbott to agree to more than halve its prices ([6]). The use of compulsory licences is not confined to developing countries. Until recently, many developed countries have been more concerned about respecting intellectual property rights, but they have begun to show a growing interest in this mechanism, particularly since the start of the Covid-19 pandemic. Israel, for example, imposed a compulsory licence in March 2020, again on Kaletra, which was then announced as

a potential treatment for Covid-19 ([9]). Russia and Hungary also used compulsory licences in 2020 for the production of Remdesivir.^{5 6}

► The ACT accelerator

In order to accelerate access to health technologies related to the pandemic, the Access to COVID-19 Tools Accelerator (ACT) was launched in April 2020 by the World Health Organization (WHO), the Bill & Melinda Gates Foundation, the European Commission and France. The ACT accelerator is an international solidarity mechanism, financed mainly by government grants. It is organised into three pillars relating to diagnostic products, immunisation products, and treatments, plus a cross-cutting initiative to strengthen national health systems.⁷ The mechanism has already provided low-cost diagnostic products adapted to different low-income country settings and contributed to clinical trials that identified dexamethasone as the first treatment to reduce mortality in the most severely affected Covid-19 patients. For vaccines, a scheme called COVAX⁸ (COVID-19 Vaccines Global Access), led by GAVI, the Vaccine Alliance, and CEPI (Coalition for Epidemic Preparedness Innovations), is implementing pooled procurement for equitable vaccine distribution in participating countries, particularly those with low and middle per capita income. The first allocation of vaccines was announced on March 2, 2021, and a total of 237 million doses were funded through COVAX.⁹ Ghana and Côte d'Ivoire were able to start their vaccination campaigns, with another 140 countries expected to follow in the spring.

5. <https://makemedicinesaffordable.org/russian-government-issues-its-first-ever-compulsory-license-for-covid-19-treatment/>

6. <https://www.reuters.com/article/us-health-coronavirus-remdesivir-richter-idUSKBN26S283>

7. For a presentation of the ACT accelerator, see <https://www.who.int/publications/m/item/act-a-prioritized-strategy-and-budget-for-2021>

8. <https://www.gavi.org/vaccineswork/covax-explained>

9. <https://www.france24.com/fr/afrique/20210302-covid-19-le-ghana-et-la-cote-d-ivoire-lancent-leur-campagne-de-vaccination-grace-a-covax>

4. https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm

The COVAX mechanism does not call into question intellectual property rights and only impacts the redistribution of doses received. It has no effect on the volumes produced by the companies that develop the vaccines. As a result, because of the limited production capacity of these companies, the goal of distributing at least 2 billion doses in 2021 will be difficult to achieve.¹⁰

► The C-TAP initiative

In May 2020, the C-TAP (COVID-19 Technology Access Pool) mechanism was launched by the WHO in conjunction with an initiative by the government of Costa Rica and some 40 other countries that signed a call for solidarity “to realize equitable global access to COVID-19 health technologies”.¹¹ The objective of this mechanism is to voluntarily share data, knowledge, intellectual property and know-how useful in the fight against the pandemic. Several associated organisations are taking part in the implementation of the mechanism. One of them is the Tech Access Partnership, whose mission is to support the production of various medical devices in the developing world with a focus on protective equipment (masks), medical equipment (respirators), and diagnostic tools. Another associated organisation, the Open Covid Pledge, allows any individual, company, or organisation to contribute by pledging to make their intellectual property freely available for the purpose of ending and minimising the impact of the Covid-19 pandemic.¹² The technologies involved cover a wide set of applications, ranging from cryo-electron microscopy for laboratory use to contact tracing.

The Medicines Patent Pool (MPP)¹³ is a third key instrument for the implementation of the C-TAP mechanism. The MPP solicits voluntary li-

censes for patents held by pharmaceutical and biotech companies and then acts as a one-stop shop for the dissemination of (combinations of) these licenses to generic producers who are then able to develop formulations and presentations adapted to the specific contexts of low- and middle-income countries. The pricing of sub-licenses by the MPP replaces the negotiations that each of the patent-holding companies could carry out separately, thus considerably reducing transaction costs for all stakeholders. The original mission of the MPP, founded in 2010 and supported by the United Nations, is to facilitate access to medicines for HIV, tuberculosis and hepatitis C in developing countries. As of March 31, 2020, the organisation has expanded its mandate to include Covid-19 health technologies. Eligible products include approved drugs that have been shown to be effective against the disease or are undergoing clinical trials to evaluate their repositioning for the treatment of patients infected with SARS-CoV-2 (antivirals, anti-inflammatories, monoclonal antibodies, etc). In the event of favourable results, companies holding patents on the active ingredients of the drugs or on their manufacturing processes may consider the inclusion of their intellectual property in the MPP. The expanded mandate also foresees, in principle, the possibility of including patented technologies necessary for the production of vaccines ([10]). However, to date, none of the companies that have developed any approved COVID-19 treatments or vaccines have contributed to the MPP.

► Why pool intellectual property rights ?

Patent pools are relatively common collaborative agreements in the telecom, digital and internet sectors. They most often describe the set of technologies related to a standard, such as RFID (Radio-Frequency Identification), MPEG (Moving Pictures Experts Group), Bluetooth, or 5G. In the health care sector, the creation of pa-

10. <https://www.who.int/publications/m/item/act-a-prioritized-strategy-and-budget-for>

11. The call is available at <https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>.

12. <https://opencovidpledge.org>

13. <https://medicinespatentpool.org/fr/>

tent pools was discussed during the crises of SARS-CoV 1 in 2002-03, H5N1 in 2005, and H1N1 in 2009, but without success ([3]). In contrast to these past situations, we now have the Medicines Patent Pool, already integrated into the C-TAP initiative, providing an operational platform for technology dissemination. The MPP offers a reasonable way out of the debate on the enforcement of intellectual property rights. It offers safeguards to those who favour the status quo, for whom it would be sufficient to rely on bilateral agreements between companies holding intellectual property rights and firms holding production capacity to manufacture the required quantities. It also opens up prospects for supporters of a suspension of these rights, for whom the exceptional circumstances of the Covid-19 pandemic call for a rapid dissemination of innovations to the benefit of all populations ([2]).

The operation of a patent pool thus makes it possible to reconcile the positions defended on both sides of the debate. Beyond the reduction of transaction costs, economic reasoning shows that, even in a profit-maximising logic, the negotiation of several licenses of complementary technologies - all necessary for the formulation of a product - by a single organisation avoids the superimposition of distortions due to the monopoly power of patent holders ([11], [12], [13]). The resulting reduction in royalties, normally paid by technology users, is conducive to lower prices for licensed products on the final market. Furthermore, for companies whose investments have already resulted in products approved by regulatory authorities, for those still engaged in the discovery and clinical development of patented or patentable technologies, participation in a patent pool can generate additional revenues. These revenues, as derived from licenses that allow other companies to manufacture and market the products, do not require the use of the facilities of patent holders. Nor do they imply additional investment in production capacity on their part. From a dynamic

perspective, the possibility of participating in a patent pool can therefore increase incentives to invest in R&D and accelerate innovation ([4]).

The characteristics of the Medicines Patent Pool involved in the C-TAP mechanism distinguish it a priori from most patent pools that relate to information technologies. The MPP is not a collaborative agreement organized by drug producers but rather a foundation whose mission is to improve access to essential medicines in low- and middle-income countries. Its sub-licensing policy focuses on the geographical extension of the supplied markets and serves as a one-stop shop for generic producers who would otherwise have had to negotiate each licence on a country-by-country basis. It strives to set low royalty rates and allows for the exploitation of therapeutic complementarities that may characterise some of the active ingredients protected by its portfolio of licences. In the case of HIV, tuberculosis and hepatitis C treatments, the MPP has clearly facilitated the signing of licensing agreements with generic producers ([7]).

To date, no pharmaceutical company has joined the WHO's C-TAP initiative, which has been described as a dangerous idea by Pfizer CEO Albert Bourla¹⁴ who perceives it as a denial of property rights. However the C-TAP mechanism is based on voluntary agreements that do not challenge the intellectual property rights of firms. Moreover, the Medicines Patent Pool only covers low- and middle-income countries geographically and does not call into question the revenues generated in high-income countries. The C-TAP initiative should, therefore, from the industry's point of view, be preferred to the use of compulsory licensing, which could become widespread among both developing and developed countries.

From the point of view of governments and populations, the voluntary nature of industry participation in the MPP can be seen as an asset. Indeed, the production of prophylactic vaccines

14. <https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/>

and therapeutic biologics on a large scale by third-party companies requires a transfer of knowledge that goes far beyond the information contained in any of the patents filed ([8]). Risking open conflict with a pharmaceutical company by imposing a compulsory licence may jeopardise the transfer of know-how that is essential for production.

Finally, by aiming to reduce costs and increase production capacity, the C-TAP initiative, together with the MPP, can have a significant impact on the volume of production of vaccines and treatments. In order to achieve the objective of increasing production, these mechanisms are better equipped than the ACT accelerator and its COVAX mechanism, which aims at solidarity. While the latter is certainly essential, it is likely to prove ineffective if ambitious measures are not taken to increase production in the short run.

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