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Overriding drug and medical technology patents for pandemic recovery: a legitimate move for high-income countries, too

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INTRODUCTION

Scaling up access to new COVID-19 vaccines and therapies ('medicines') and medical technologies is essential to move from pandemic response to recovery. One of the key conditions for governments to produce and/or procure a sufficient supply of COVID-19 medicines is access to their intellectual property (IP). Although the research and development (R&D) of many vaccine and therapeutic candidates has been partially or entirely publicly funded, the resulting products will be owned by the companies that bring them to market. Therefore, intellectual property rights will be a significant determinant of global access to COVID-19 medicines.

Intellectual property rules aim to compensate inventors for their investments in R&D, while also making innovations available for use by the public. The underlying premises of this system have been called into question for, among other reasons, the disconnect between growing public-funding for drug R&D resulting in privately-owned medicines. In 1995, a set of global trade rules in the World Trade Organization (WTO) Agreement on the Trade-Related Aspects of Intellectual Property (TRIPS Agreement) established the minimum standards for protecting intellectual property worldwide (see [box 1](#)). These trade rules drastically impacted human health: introduced near to the 2000s HIV/AIDS global epidemic, owners of patents and other forms of intellectual property hampered access to lifesaving antiretrovirals to people infected with HIV through excessive monopolistic prices.¹

Nearly two decades later, the global community faces the all-too-familiar challenge of maximising the supply of affordable, new medicines needed to stave off a pandemic. Generally, there are two courses of action to

Summary box

- ▶ Compulsory licenses are legal tools to override patent-protection on medicines and medical technologies. Compulsory licenses can help scale up the production and lower prices of patent-protected medicines while still accounting for the patent holder's interests.
- ▶ Compulsory licensing is making a comeback in high-income countries as a negotiation strategy and a legal tool to remedy high prices and/or supply shortages of medicines and medical technologies.
- ▶ High-income countries that face potential legal hurdles (in world trade law and/or in the regulation of test data and market exclusivity) to effectively use compulsory licensing in the COVID-19 pandemic should consider taking measures now.

ensure intellectual property protection does not restrict access to potential pandemic medicines and medical technologies (eg, diagnostics and personal protective equipment). One avenue is for intellectual property owners (eg, companies) to offer affordable prices and adequate supply, to voluntarily license their COVID-19 medicines and share other forms of IP related to these products or to refrain from enforcing their intellectual property rights on their COVID-19 medicines worldwide. Although some companies have taken these steps in response to the COVID-19 pandemic, these decisions remain the exception, not the rule.² Only relying on voluntary measures by companies leaves the private sector—and by extension, their shareholders—to decide when and how COVID-19 medicines become widely available and affordable.

The second course of action is for national governments to use the legal tools—compulsory licenses and public non-commercial use (called 'government use')—in their national law to override excessive monopolistic prices

Box 1 How patents influence access to new medicines

Patents on pharmaceuticals and medical technologies are an important aspect of intellectual property. The Trade-Related Aspects of Intellectual Property Agreement requires the 164 countries that are members of the World Trade Organization, with the exception of Least Developed Countries, to make 20-year patents available for inventions in all fields of technology. These patent rules aim to compensate inventors (ie, patent holders) for their innovative processes and products. During this period of time, the patent holder has the sole right to produce, import, offer to sell and sell the medicine, unless the patent holder or the government chooses otherwise (see two approaches below). This arrangement often gives the patent holder a market monopoly and the power to ask any price it chooses. Voluntary licensing and compulsory licensing/government use are two approaches to increase competition in the pharmaceutical market while a patent is still valid.

while still accounting for the patent holder's interests. These legal tools allow governments to make and/or import the necessary ingredients or the medicines themselves, in generic form. In return, the patent holder receives a royalty payment for the use of its invention. Their use has been widely promoted in low-income and middle-income countries, often as a means to increase the supply and decrease the prices of HIV-related medicines.^{3–5} Even before the COVID-19 pandemic struck, all of the wealthiest countries already had legislation for compulsory licenses and/or government use on their books.⁶ International trade law (the WTO TRIPS Agreement and the Doha Declaration), international human rights law and the 2030 Agenda for Sustainable Development endorse using compulsory licenses and government use to increase universal access to essential medicines.⁷

Widely acknowledged as important tools for low-income and middle-income countries,^{3–5} compulsory licenses and government use are also legitimate strategies for high-income countries to secure access to new, expensive, essential medicines. In this analysis, we outline how compulsory licenses and government use can effectively be used by high-income countries when needed, some remaining challenges to their full use in the COVID-19 response, and possible action.

CHALLENGES OF LICENSING COVID-19 MEDICINES

Remdesivir was the first therapy authorised for emergency use in patients with COVID-19, opening a window of hope for treating COVID-19 infections. Although subsequent studies revealed that remdesivir has no significant impact on important clinical outcomes of COVID-19,⁸ it is an example of the challenges of licensing new pandemic medicines.

Patented by the company Gilead in the USA and other high-income nations, remdesivir is expensive, priced at US\$3120 for a 5-day COVID-19 treatment in these countries. By contrast, remdesivir sells for much cheaper in 127 low-income and lower-middle income countries as a

result of Gilead's voluntary licenses to generic producers. This deal excludes wealthier nations such as the USA, Canada, European countries and several higher-middle income countries. Consequently, in these countries, prices are high and supplies are limited by Gilead's exclusive patent rights and its finite capacity to manufacture the medicine.

In July 2020, the impact of such patent rights was palpable when the USA purchased nearly 3 months of Gilead's world supply of remdesivir. This move left few alternatives for other high-income countries that were also dependent on Gilead's remdesivir stock. In December 2020, the Russian authorities issued a compulsory license, allowing a local generic company to produce Gilead's remdesivir at a competitive price of US\$100 per vial (US\$600–US\$1100 per treatment course, depending on the number of vials needed).⁹ The generic company also pledged to supply 1.2 million vials to the Russian market in the first half of 2021, illustrating how a compulsory license has the potential to address both affordability issues and supply shortages.⁹ Compulsory licenses/government use is one legal option governments may use to license the production of medical products after attempts to negotiate with the patent holder have failed.

REDUCING MEDICINES PRICES AND INCREASING SUPPLY IN HIGH-INCOME COUNTRIES

Using compulsory licenses and government use to increase access to medicines in high-income countries has declined since the adoption of the 1995 TRIPS Agreement that tightened intellectual property laws and practices in many countries. But in recent years, compulsory licensing is making a comeback as a negotiation strategy and a legal tool.

In some cases, governments making a credible threat with a compulsory license/government use achieved their desired result: a secured supply of medicines and/or a lower price. For example, in 2017 the US state of Louisiana explored its options to leverage a government use provision in state law to lower the price of the expensive hepatitis C treatments sofosbuvir and ledipasvir/sofosbuvir.¹⁰ Although the government use provision was not invoked in the end, it was an effective negotiation strategy with the pharmaceutical manufacturer that eventually led to a more affordable 'netflix' (or subscription-based payment) model for buying these hepatitis C drugs.¹¹

Recently, government use licensing in the UK (called 'Crown use') has garnered much political and public attention following the rationing of lifesaving medicines due to their escalating prices. In 2019, the UK Parliament debated issuing a compulsory license in order to buy lower-priced generic versions of lumacaftor/ivacaftor (Orkambi) to treat cystic fibrosis. Lumacaftor/ivacaftor is patented in the UK and priced by Vertex, the rights holder, at £104 000 per patient per year. While patients awaited a solution from the government, some people

have formed ‘buyers clubs’, which link interested buyers directly with the medicines producer and possibly pool demand to negotiate a discounted price.¹² Through buyers clubs UK patients have imported generic versions of the medicine from Argentina (where it is not patented) for about £20 000 per patient per year.

COMPULSORY LICENSING IN THE COVID-19 PANDEMIC RESPONSE

Since the COVID-19 pandemic started some high-income countries have strengthened their laws permitting compulsory licensing/government use. Canada’s COVID-19 Emergency Response Act, adopted in March 2020, permits the government to issue a compulsory license immediately in response to the public health emergency.¹³ Australia, Chile, Germany and Hungary have taken similar steps to re-enforce compulsory licensing/government use provisions in their pandemic response toolboxes. Some countries, such as Belgium, are still reviewing whether their intellectual property legislation must be revised to support the nation’s pandemic response.

The COVID-19 outbreak illustrated that issuing a compulsory license in one country can have a global impact on access to that medicine. On 19 March 2020, Israel issued a compulsory license to import generic versions of the experimental COVID-19 treatment lopinavir/ritonavir (brand name Kaletra) and an essential medicine for the treatment of HIV. Days later the ripple effect of this decision was felt worldwide when the patent holder, AbbVie, announced it would no longer enforce its patents on lopinavir/ritonavir for any indication in any country. The COVID-19 crisis spurred the change in the company’s policy that global HIV/AIDS advocates had sought for years: access to lower-priced, generic versions of lopinavir/ritonavir.

Compulsory licenses can be a persuasive tool for national authorities to negotiate lower prices for medical technologies if governments back up their price demands with a credible threat of a compulsory license. This is one of the reasons why in 2020 the chairman of the Dutch Compulsory Licensing Commission proposed an assessment framework to determine whether an individual medicine warrants a compulsory license and whether such a license can be effectively executed. He recommended that the government issue a compulsory license following a positive assessment, otherwise the effect of a credible threat will be lost.¹⁴ In the midst of a health crisis, the outcome of such an assessment is self evident and would warrant government action.

REMAINING CHALLENGES

While members of WTO are entitled to use compulsory licenses to manufacture or import generics under conditions defined by the TRIPS Agreement, two potential roadblocks remain. The first challenge is the opt-out, by several high-income countries, of a special compulsory licensing provision for export (TRIPS article 31bis). These countries are:

Australia, Canada, the European Communities and their Member States, Iceland, Japan, New Zealand, Norway, Switzerland, the UK and the USA. In 2003, this group opted out of a system in international trade law that allows import of medicines produced under a specific compulsory license in other countries.¹⁵ Today most countries are dependent on imported medicines and raw materials, in particular from India and China. To effectively use compulsory licensing for COVID-19-related medicines patents this group of high-income countries should reverse their opt-out of the use of this provision in world trade rules.

A second hurdle to the effective use of compulsory licensing by high-income countries is found in the medicines regulatory system. Data and market exclusivity rules are in place in European and other countries as an extra compensation for manufacturers who have invested in clinical studies to generate the data necessary for regulatory approval. These rules prevent the registration and marketing of a generic or biosimilar product that relies on the same data for a certain period of time (in the European Union, this period is between 8 and 10 years after market approval). EU countries should adopt a data and market exclusivity waiver to enable the registration of products that are manufactured or imported under a compulsory license.¹⁶

ALTERNATIVE APPROACHES

Non-voluntary measures that force the hand of the patent holder (eg, compulsory licenses) are only relevant in situations where voluntary mechanisms do not exist or have failed to yield affordable and available medicines. An important voluntary mechanism was established by the WHO in May 2020: the COVID-19 Technology Access Pool (C-TAP), modelled after the Medicines Patent Pool. This pool aims not only to provide access to patents but also to other forms of intellectual property such as know-how and data, including cell lines and registration data needed to make and market COVID-19 technologies such as vaccines. The challenge of C-TAP is that it depends on voluntary collaboration by those who hold the intellectual property and such collaboration has so far not been forthcoming.²

This may explain why on 2 October 2020, India and South Africa sent a proposal to the WTO, asking that it allows countries to suspend their obligations to protect patents and certain kinds of intellectual property related to the prevention, containment and treatment of COVID-19. The two countries, later joined by Kenya, Eswatini, Pakistan, Mozambique, Bolivia, Venezuela, Mongolia, Zimbabwe, Egypt, the African Group and the Least Developed Countries Group, propose this waiver last until widespread COVID-19 vaccination is in place globally, and when the world’s population has developed immunity to the virus. The proposal, currently under discussion at the WTO, is broader than what compulsory license/government use allows for. If approved, the waiver could address the challenges presented above to importing and licensing COVID-19 medical products.

Some experts have also proposed that certain ‘security exceptions’ in international trade law (TRIPS article 73) may be used to overcome the IP hurdles facing COVID-19 medical products that are not resolved by compulsory licensing/government use alone.¹⁷ These security exceptions in global trade law have not yet been used in relation to pandemics.

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Contributors KP is a health scientist and legal scholar with a focus on international and European law related to global health and pharmaceuticals. EtH is a lawyer and public health advocate with a focus on pharmaceutical and intellectual property policies. She was the founding Executive Director of the Medicines Patent Pool. PB is a lawyer and an expert in intellectual property policies to promote public health focus. The authors, a team of emerging (KP) and established (EtH, PB) researchers, are experienced at advising governments, NGOs and international organisations on pharmaceutical issues. This article is rooted in literature and policy developments on intellectual property and trade law as they relate to pharmaceutical supply and pricing in a globalised context. KP is the guarantor of the article.

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