

Compulsory licensing vs. the IP waiver: what is the best way to end the COVID-19 pandemic?

By Olga Gurgula*

Introduction

As of 8 October 2021, there have been 236,599,025 confirmed cases of COVID-19, including 4,831,486 deaths worldwide.¹ These numbers have been increasing every day as the virus is spreading and mutating rapidly. One of the most effective ways of stopping the virus is by achieving immunity at a global level, which could be done by swiftly vaccinating a large proportion of the

world population.² However, this has proven to be a significant challenge. The current set up of vaccine production cannot ensure sufficient doses of vaccines for everyone.³ By October 2021, more than 6 billion doses had been administered globally.⁴ However, more than 80% of these doses were administered in high-income and upper-middle-income countries,⁵ and only 2.5% of people in low-income countries received at least one dose.⁶ This

Abstract

This policy brief examines the currently discussed proposals at the World Trade Organization (WTO) that aim to resolve the problem of the production shortages of COVID-19 vaccines. This includes the two key submissions, i.e. the proposal by South Africa and India on the Intellectual Property (IP) waiver, partially supported by the United States (US), and the European Union (EU) proposal to clarify the use of compulsory licensing. While each of these mechanisms may help to improve the production of COVID-19 vaccines to various degrees, there is intense debate about which of these proposals is the most effective. This policy brief outlines the strengths and weaknesses of each of them with a view to informing the policy decisions by WTO Members on the best way to promptly accelerate the vaccine production that is urgently needed today. It concludes that the proposed IP waiver is a more effective solution for addressing the current emergency.

Ce rapport sur les politiques examine les propositions actuellement discutées à l'Organisation mondiale du commerce (OMC) qui visent à résoudre le problème des pénuries de production de vaccins COVID-19. Le rapport abordera les deux propositions clés présentées, à savoir celle de l'Afrique du Sud et de l'Inde sur une dérogation temporaire en matière de propriété intellectuelle (PI), partiellement soutenue par les États-Unis (États-Unis), et celle de l'Union européenne (UE) visant à clarifier l'utilisation des licences obligatoires. Bien que chacun de ces mécanismes puisse contribuer à améliorer la production de vaccins COVID-19 à des degrés divers, il existe un débat intense sur laquelle de ces propositions est la plus efficace. Ce rapport sur les politiques décrit les forces et les faiblesses de chacune d'entre elles en vue d'éclairer les décisions politiques des Membres de l'OMC sur la meilleure façon d'accélérer rapidement la production de vaccins dont nous avons un besoin urgent aujourd'hui. Il conclut que la dérogation en matière de propriété intellectuelle proposée est la solution la plus efficace pour faire face à l'urgence actuelle.

Este informe sobre políticas examina las propuestas que actualmente se están debatiendo en la Organización Mundial del Comercio (OMC) con el objetivo de solucionar el problema de la escasez de producción de vacunas COVID-19. El informe discutirá las dos principales propuestas presentadas, a saber, la de Sudáfrica e India sobre una exención temporal en materia de propiedad intelectual (PI), parcialmente apoyada por los Estados Unidos (EE. UU.), y la de la Unión Europea (UE) para aclarar el uso de licencias obligatorias. Si bien cada uno de estos mecanismos puede ayudar a mejorar la producción de vacunas COVID-19 en varios grados, existe un intenso debate sobre cuál de estas propuestas es la más efectiva. Este informe sobre políticas describe los puntos fuertes y débiles de cada una de ellas con miras a informar las decisiones políticas de los Miembros de la OMC sobre la mejor manera de acelerar rápidamente la producción de vacunas, que se necesita con urgencia en la actualidad. Se concluye que la exención propuesta en materia de propiedad intelectual es la solución más eficaz para hacer frente a la emergencia actual.

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inequitable distribution of vaccines has enabled the virus to continue spreading and mutating, putting millions of lives at risk.⁷

To accelerate the production and equitable distribution of COVID-19 vaccines, two proposals were put forward at the World Trade Organization (WTO) Council for the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). One of them was suggested in October 2020 by South Africa and India.⁸ As revised in May 2021, this proposal requests that the WTO waive certain provisions of the TRIPS Agreement⁹ for the prevention, treatment or containment of COVID-19, including copyright, designs, patents, and undisclosed information regarding vaccines and other necessary health technologies; such a waiver is proposed to be in force for at least three years from the date of the decision.¹⁰ This proposal has been widely supported,¹¹ including by the United States (albeit for COVID-19 vaccines only).¹² Several WTO Members, including the European Union, Norway, the United Kingdom and Switzerland, however, oppose the IP waiver, claiming, among other things, that the current TRIPS flexibilities, such as compulsory licensing, are sufficient and could be used to deal with intellectual property (IP)-related barriers concerning vaccines and other medical products.¹³ In line with this argument, in its submission to the WTO Council for TRIPS on 4 June 2021, the EU proposed to clarify the use of compulsory licensing, notably in the context of Article 31*bis* of the TRIPS Agreement.¹⁴

While each of these mechanisms may help to improve the production of COVID-19 vaccines to various degrees, they both have their strengths and weaknesses. This policy brief will, therefore, examine these two proposals to inform the policy decisions by WTO Members on the rapid increase of vaccine production and distribution to combat the global pandemic.

1. Compulsory licensing of patents

One of the important mechanisms to improve access to pharmaceuticals is compulsory licensing.¹⁵ Pharmaceutical companies have been actively patenting the results of their research into COVID-19 medical products.¹⁶ Owning these exclusive rights allows them to control the distribution and prices of such products, which may restrict or even block access. However, the TRIPS Agreement contains a specific mechanism in the form of compulsory licensing which allows a limit to be placed on the exercise of exclusive rights under a patent.¹⁷ A compulsory license is the permission granted by a state authority that authorizes a third party to use a patented invention without the patent holder's consent. In 2001, the Doha Declaration on the TRIPS Agreement and Public Health¹⁸ confirmed that compulsory licensing is one of the flexibilities under the TRIPS Agreement and that all WTO Members have the right to grant such licenses.¹⁹ This mechanism has been implemented in the majority of jurisdictions worldwide and may be relied upon to address public health

needs.²⁰

A specific type of compulsory license is 'government use' or, to use the wording of TRIPS, a 'public non-commercial use';²¹ this allows a government to grant the authorisation for its own use, including production, importation and distribution of the protected products.²² In the matters of public health, government use may be an effective tool as governments can act upon their own initiative by authorising the use of patented pharmaceuticals and, thus, facilitate access to more affordable drugs.²³ Moreover, under Article 31(b) of the TRIPS Agreement, in the case of 'public non-commercial use', the requirement for prior negotiations with the patent holder may be waived. Similarly, under the same provision, there is no need to conduct prior negotiations in the case of compulsory licenses granted to third parties to address a national emergency or other circumstances of extreme urgency.

Therefore, in the context of this pandemic governments have the right to grant compulsory licenses/government use of patents related to COVID-19 medical products without negotiating with the patent holders. This is because the COVID-19 pandemic clearly falls within the bounds of Article 31(b): e.g., the pandemic may qualify as a 'national emergency' and such licenses can be granted for public non-commercial use to protect public health. While Article 31 does not limit the grounds for the grant of a compulsory license/government use, it does subject it to several conditions. Article 31(h), in particular, requires that the right holder must be paid adequate remuneration.²⁴

There is no doubt that compulsory licensing can be an effective tool in facilitating access to affordable medicines, as can be evidenced by its use in relation to life-saving drugs by several countries in the past.²⁵ Therefore, the use of this mechanism should be encouraged and can be effectively applied to certain COVID-19 medicines, vaccines, diagnostics and personal protective equipment at a country level. Where possible, countries should utilize this mechanism to the fullest extent, as well as revise their laws to avoid lengthy bureaucratic delays, making this tool more efficient.²⁶

During this pandemic, several countries have already issued COVID-19-related compulsory licenses/ government use, in particular, Hungary and Russia for Remdesivir, and Israel for Lopinavir/Ritonavir,²⁷ as well as revised their laws related to compulsory licensing, including Australia, Brazil, Canada, Germany, Indonesia and Russia.²⁸

As was noted, in its proposal the EU has suggested relying on compulsory licensing "to ensure a rapid and equitable roll-out of vaccines and therapeutics globally".²⁹ To improve the operation of this mechanism, it has proposed that certain provisions be clarified, in particular:

[to] provide more legal certainty and enhance the effectiveness of the [compulsory licensing] system, the EU considers that all WTO Members should be ready to agree on the following:

(a) The pandemic is a circumstance of national emergency and, therefore, the requirement to negotiate with the right holder may be waived;

(b) To support manufacturers ready to produce vaccines or therapeutics at affordable prices, especially for low- and middle-income countries, on the basis of a compulsory license, the remuneration for patent holders should reflect such affordable prices; and

(c) The compulsory license could cover any exports destined to countries that lack manufacturing capacity, including via the COVID-19 Global Access (COVAX) facility.

However, the scale and dimensions of the current pandemic pose certain limitations on the effective utilization of this mechanism; these have not been addressed in the proposal and, thus, it is hardly capable of substantially improving the production and distribution of COVID-19 vaccines, which are urgently needed today. To begin with, the first point (a) is clearly stated in TRIPS and it is unlikely that it requires clarification. In particular, as was mentioned, under Article 31(b) TRIPS, compulsory licenses may be granted in the case of a national emergency and, in such a case, the requirement to negotiate is waived.

In 2020, several countries declared a state of national emergency due to the COVID-19 pandemic, that under Article 31(b) TRIPS would allow them to grant compulsory licenses of patented medicines without the need to negotiate with the patent holders.³⁰ Other countries are encouraged to do so should they decide to rely on this mechanism. Even without declaring a state of national emergency, governments can authorize government use ('public non-commercial use') without the need for prior negotiations, as per Article 31(b) TRIPS discussed above. Both these mechanisms, however, and the conditions to use them, would need to be provided for in national patent laws. The application of the exception to prior negotiations when issuing a compulsory license in the course of the Article 31*bis* procedure, which is also proposed by the EU as part of the suggestion under (a), may indeed be useful and could be applied by analogy with Article 31(b).

In relation to point (b), while the clarification and a general agreement of WTO Members regarding the mechanism of remuneration may be useful, this issue has been extensively discussed at the international level and specific guidelines for calculating such a remuneration was published by the World Health Organization (WHO) and may be relied upon in this matter.³¹

As to point (c), the suggestion that "the exporting Member may provide in one single notification a list of all countries to which vaccines and therapeutics are to be supplied directly or through the COVAX Facility" does not add anything new in this respect. Currently, this can be made under the Article 31*bis* system, which establishes the obligation of the exporting Member to identify "the country(ies) to which the product(s) is

(are) to be supplied".³² At the same time, the proposal under point (c) does not solve the complexity of the procedure set by Article 31*bis*, and its inapplicability to certain countries due to their opting-out from this mechanism (see below).

Importantly, this proposal does not address the challenges that need to be resolved to make the compulsory licensing mechanism, including under the Article 31*bis* system, work effectively. This includes the fact that a compulsory license can usually be granted only in relation to existing patents and, thus, cannot be applied to patent applications.³³ As some of the COVID-19 technologies are new, patent applications are currently being filed and will be granted in the coming years.³⁴ Until the time when the patent is granted, the mechanism of compulsory licensing may not, therefore, be applicable. Furthermore, the information about such rights may not be known in advance. Many patent applications on COVID-19 products may have been filed but not yet published, i.e., normally, patent applications are published 18 months after the filing date, and, prior to that, they remain confidential. This may further complicate the patent search and grant of a compulsory license. Also, it is arguable whether compulsory licensing may be applied to supplementary protection certificates, in the countries where they are granted, as they create a separate, *sui generis*, form of protection different from patents.³⁵

Moreover, a compulsory license must be granted only on a product-by-product basis.³⁶ It is currently not possible to issue a general compulsory license that would relate to all or certain COVID-19 vaccines (as well as medicines, diagnostics and personal protective equipment). The need to grant such licenses for each product (which may include multiple patents covering various aspects of the product) would, therefore, significantly impede the process, which, considering the urgency to resolve the vaccine supply shortages today, is obviously unacceptable. A further complication is that patents have a territorial nature, and, thus, a compulsory license would cover only a specific territory, i.e., it must be granted on a country-by-country basis. This means that it would not be possible to issue a compulsory license that would have regional or worldwide coverage. In addition, patent landscapes that cover COVID-19 vaccines are very complex. For example, a recent study revealed that vaccines based on mRNA technology, with the frontrunner producers of such vaccines being Pfizer and Moderna, are covered by an intricate web of patents that belong to different right holders and sublicensed to a number of companies.³⁷ This means that this web of patents would pose a significant hurdle for a government that intends to issue a compulsory license on a COVID-19 related medical product as it would need to research its patent status, which may be very burdensome, costly and which may cause significant delays in issuing such a license.

Furthermore, Article 31(f) TRIPS poses a barrier for those countries that have manufacturing capacity. This provision requires that the "use must be authorised predominantly for the supply of the domestic market of the Member authorizing such use" and, thus, restricts the

quantities of medicines that can be exported to other countries in need of such a supply. It is to overcome this problem that a decision to waive the limitation in the TRIPS Agreement to predominantly supply the local market when generic medicines are produced under a compulsory license was agreed upon in 2003.³⁸ It was later incorporated as an amendment to TRIPS in the form of the already mentioned Article 31*bis* (the amendment entered into force on 23 January 2017).³⁹ This 'Special Compulsory Licensing System' essentially allows WTO Members with domestic manufacturing capacity to issue compulsory licenses for export to those countries that do not have such capacities.

However, due to its complexity and its cumbersome procedure,⁴⁰ this system has been used only once. In 2007, Rwanda informed the WTO that it intended to import 260,000 packs of the combination AIDS therapy drug, TriAvir,⁴¹ and on 4 October 2007, the WTO received notification from Canada that it had authorised a pharmaceutical company, Apotex, to make a generic version of a patented medicine for export.⁴² Despite the issued compulsory licenses and efforts by Médecins Sans Frontières and Apotex, it took five years before the export of TriAvir was initiated.⁴³ This led to a public statement by Apotex that it would not use this mechanism again unless it was reformed.⁴⁴ This is because, as Médecins Sans Frontières explained, the Article 31*bis* system "through requirements that range from adding unnecessary steps (i.e. mandatory differential packaging and colouring of products under the compulsory license), to actively impeding the flexibility needed in an evolving public health crisis (i.e. requiring importing countries to specify the quantity needed for each product in each compulsory license used under the notification made to the WTO)" considerably complicates the use of this mechanism.⁴⁵ This results in "excessive procedural requirements" that "create unnecessary barriers, particularly during the pandemic when all resources and every moment of time are precious".⁴⁶ In addition, some high-income countries opted out of this system, indicating they would not use the Paragraph 6/Article 31*bis* mechanism as an importing Member⁴⁷ including in "situations of national emergency or other circumstances of extreme urgency".⁴⁸ These challenges, therefore, may present a significant barrier for utilizing this mechanism effectively, and some countries would not be able to use it at all unless they were to opt-in again.

Moreover, patent-protected components for the production of vaccines may be procured from multiple suppliers⁴⁹ and different stages of manufacture may be conducted by different producers located in different countries.⁵⁰ In addition, the restrictions that prohibit export of vaccines and the required inputs for their manufacture (as well as other medical products) may further complicate the use of compulsory licensing. In January 2021, the European Union implemented vaccine export restrictions, which were relied upon by Italy to block the export of Oxford-AstraZeneca vaccines

to Australia.⁵¹ Also, in March 2021 the European Commission adopted a decision concerning the strengthening of controls over vaccine exports, which introduced the principles of 'reciprocity' and 'proportionality' as new criteria to be considered for authorizing exports under the transparency and authorization mechanism for COVID-19 vaccine exports.⁵² Early this year, several producers in India that manufacture AstraZeneca and Johnson & Johnson ('J&J') vaccines warned that the production of vaccines worldwide was under threat because of the US export control during the pandemic.⁵³ On 25 March 2021, India introduced a de facto ban on vaccine exports, forbidding the world's largest vaccine manufacturer, the Serum Institute of India, from exporting its vaccines, and prioritizing local vaccination due to the sharp increase of coronavirus infection in the country.⁵⁴

Some further challenges may arise when granting a compulsory license of a medicine or vaccine. One of the barriers that also needs to be overcome relates to data and marketing exclusivity that protects clinical test data submitted by the originator to the relevant regulator. Such exclusivity aims to prevent other pharmaceutical companies from relying on such data during the term of protection to obtain a marketing authorization for their generic or biosimilar version of the originator's medicine. As suggested by some authors, such data and market exclusivity should be waived to allow the licensees under compulsory licenses to obtain their marketing authorizations and launch their products before the end of exclusivity.⁵⁵

Therefore, to increase the effectiveness of the compulsory licensing mechanism, the clarifications suggested by the EU are insufficient. It would require further substantive revisions, including the possibility of compulsorily licensing patent applications (both published and unpublished) and supplementary protection certificates, waiving data and market exclusivity, and simplifying the procedure and conditions for compulsory licensing for export. Moreover, to avoid complex and lengthy searches of all the relevant patents that cover a vaccine (or any other COVID-19-related medical product) that delay the grant of a compulsory license, such a license may include the list of patents that have been identified and any other patents which may be asserted by the owner at a later stage. The requirement of 'prompt notification' of the patent holder with regards to the latter patents may be satisfied by the notification about the grant of a compulsory license or government use license in an official publication. The use of identified and later asserted patents would be subject to a remuneration set by the government in such a license (except by importing countries under the Article 31*bis* system).

Finally, considering the current insufficient manufacturing capacity not only in developing countries but also in developed countries, it may be necessary for countries that notified the WTO that they would not use the Article 31*bis* system to opt back in.

2. IP waiver

As mentioned, a proposal aimed at facilitating “rapid access to affordable medical products” was put forward on 2 October 2020 by South Africa and India.⁵⁶ On 21 May 2021, following extensive discussion, and to address the comments by other WTO Members, such as that the initial proposal was too broad, a revised proposal was submitted. This revised version concerns “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19.”⁵⁷ It is proposed that the waiver would be in force for at least three years from the date of the decision.⁵⁸ As was mentioned, this proposal has generated widespread support, including a partial support from the US.⁵⁹

The IP waiver has the potential to overcome some of the limitations of the compulsory licensing system. These include the product-by-product requirement of compulsory licensing that restrict the effective and speedy application of this mechanism, as well as the need to spend time on identifying the patents that cover the products in question prior to issuing a compulsory license. With the adoption of the IP waiver, these obstacles would be removed. In addition, the barrier posed by marketing authorizations would also be eliminated. Moreover, the issue of remuneration would not arise, unless there was an agreement to provide certain remuneration to the rightsholders. This is, however, undesirable, as this would complicate the process, the aim of which is to remove the complexities in the first place. Moreover, the waiver would also remove the need to comply with the cumbersome procedure of Article 31*bis* TRIPS in the case of exporting COVID-19 vaccines or medicines to other countries with no or limited manufacturing capacity.

It is important to appreciate what the IP waiver is. At the WTO level, if the waiver is agreed upon, WTO Members would not be able to sue a WTO Member for TRIPS non-compliance in the case where it waives IP rights at national level. The effect of the IP waiver at national level, in turn, is that IP rights would not be enforceable against third parties once the IP waiver is implemented into domestic IP laws. Specifically, the national adoption of the IP waiver would presuppose suspending the enforceability of IP rights, including obligations under free trade agreements, and declaring that the manufacture of the IP-protected products and other activities that fall within the exclusive rights of the IP owner by third parties without their permission would not be considered an infringement.⁶⁰ This, however, would only be applicable if the aim is to eradicate the COVID-19 pandemic, and, therefore, it is advisable to draft this provision in a manner that would avoid abuses by third parties. All other uses would be infringing on patents and other IP rights. The suspension of enforceability would also mean that injunctions could not be granted against such third parties. In addition,

such a suspension of IP rights would be temporary, e.g., while the IP waiver is in force.

Based on this IP waiver implementing legislation, some administrative acts may be issued to clarify the operation of the IP waiver. This may include guidance for the patent office on how to deal with patent applications during the waiver, e.g., to accelerate the publication of patent applications related to COVID-19 vaccines and medical products. The latter is important because, as was noted above, patent applications are generally published 18 months after the filing date and, prior to that, they remain secret. Therefore, the early publication of patent applications would provide clarity as to the developments in this area, including whether COVID-19-related inventions could be used by others or whether there is a risk of infringing a patent in the future (e.g., after the IP waiver is terminated).

As was mentioned, several WTO Members oppose the IP waiver claiming, among other things, that there is a risk of low quality COVID-19 medicinal products if produced by other manufacturers, that there is no evidence that IP is a barrier, and that the implementation of the IP waiver would affect innovation.⁶¹ These arguments, however, are weak and contradictory. The argument related to the quality of COVID-19 products cannot be sustained as rigorous pharmaceutical regulations would apply to all new producers, as they currently apply to original manufacturers. With respect to the argument that IP is not a barrier, as was mentioned above, COVID-19 vaccines and medicines are covered by extensive patent portfolios and other types of IP (e.g. the mRNA and other technologies used in COVID-19 vaccines by several manufacturers are protected by numerous patents that belong to different companies;⁶² a similar situation exists with regard to COVID-19 diagnostics, medical equipment and treatment⁶³). This naturally empowers their owners to fully control these technologies, preventing others from manufacturing COVID-19 related therapeutics without their permission. This can be illustrated by the fact that pharmaceutical companies have refused to share their vaccine technologies with the WHO COVID-19 Technology Access Pool (‘C-TAP’),⁶⁴ as well as rejected requests to license these technologies for use by other pharmaceutical manufacturers that have the capacity to produce such products.⁶⁵ This ‘business-as-usual’ strategies are employed by the holders of COVID-19 technologies despite the need to swiftly increase the production of vaccines by utilizing all available manufacturing facilities worldwide in order to contain the spread and mutation of the COVID-19 virus.⁶⁶

As to the negative effect of the IP waiver on pharmaceutical innovation, several points need to be made. The waiver would concern only the COVID-19-related medical products and, thus, would not affect medical innovation in other healthcare areas. It would also be temporary. Furthermore, this argument is based on a traditional utilitarian justification for granting an exclusive IP right that presupposes that the availability of such a monopoly right incentivises pharmaceutical innovation, as well as allows companies to recoup their investments in research and development (R&D).⁶⁷ However, this justification, which

has traditionally been relied upon by pharmaceutical companies to protect their high profitability and preserve an unbalanced system of medical innovation and insufficient access to medicines,⁶⁸ is even more ill-suited today. In these extraordinary circumstances of the global pandemic, “there is no market failure that inhibits return from innovation”.⁶⁹ There is a demand that significantly exceeds the supply, i.e., governments around the world compete with each other for the limited supply of vaccines and other COVID-19 medical products.⁷⁰ Moreover, the research into COVID-19 vaccines has been heavily funded by public money,⁷¹ and large advance orders had been placed by some countries even before the vaccines were developed. Therefore, this traditional justification is difficult to sustain in these circumstances as, on the one hand, the public funding and advance orders have reduced the financial risks for the manufacturers⁷² while, on the other hand, the global need for supply of COVID-19 vaccines is likely to be long-term, providing ample incentives for innovation and reward.⁷³ Finally, it is disheartening to hear the argument that without the promise of IP exclusivities and the possibility to charge high monopoly prices for life-saving medications, scientists would not have incentive to engage in pharmaceutical innovation.⁷⁴ This line of arguments, as well as our overwhelming dependence upon the private pharmaceutical business, stems from the current design of the system of medical innovation and access to medicines. To remove this dependency, it is imperative to reconsider this system, prioritizing public interests over private, especially with respect to the drugs developed with public funds, making the pharmaceutical business part of the solution, rather than the only solution.⁷⁵

3. The importance of technology transfer

This policy brief examined the main strengths and weaknesses of the proposals that are currently discussed at the WTO concerning IP, i.e., compulsory licensing of patents and the IP waiver. However, there is an additional problem that deserves attention: it is necessary to have access to knowledge and know-how to rapidly accelerate the production of COVID-19 vaccines. Such information is typically confidential and protected by trade secrets, and it is currently owned by several pharmaceutical companies. Unfortunately, as was mentioned above, pharmaceutical companies are not willing to share their technology voluntarily and there are no mechanisms in IP laws that would force them to provide access to such information. Without that knowledge, other potential manufacturers need to develop their own manufacturing processes and know-how necessary to manufacture vaccines, which may take a lot of additional time and effort, and, thus, may significantly reduce our chances to end the pandemic in the near future. Therefore, to accelerate the production of vaccines an additional mechanism in the form of compulsory licensing of trade secrets is necessary.⁷⁶ Such a mechanism would allow governments to force pharmaceutical companies to share their technologies

with other manufacturers and thus rapidly increase the production of COVID-19 vaccines.

Conclusions

While the deadly coronavirus has been ravaging the world for more than a year and a half now, legal battles around IP that protect life-saving COVID-19 vaccines and medicines continue. This has stalled the rapid response to the global pandemic by governments worldwide, resulting in the loss of thousands of lives that could have been saved otherwise. It is, therefore, paramount that the global community agrees on the most effective solution without further delays removing all the barriers to the swift increase of vaccine production and distribution, as well as other medical products necessary to fight the pandemic. This policy brief has demonstrated that both proposals that are currently discussed at the WTO, i.e., compulsory licensing of patents and the IP waiver, have their strengths and weaknesses. At the same time, the IP waiver has the potential to overcome many of the difficulties that the current mechanism of compulsory licensing of patents is fraught with. It would, however, need to be supplemented with an additional mechanism that would allow involuntary technology transfer in the form of compulsory licensing of trade secrets. Moreover, while the debates at the WTO continue, governments are advised to revise their national IP laws, including making the currently available mechanism of compulsory licensing of patents more efficient by removing all the bureaucratic hurdles and enabling a swift and timely grant of such licenses when necessary.

Endnotes:

¹ World Health Organization (WHO) Coronavirus (COVID-19) Dashboard. Available from <https://covid19.who.int/>.

² Our World in Data, Coronavirus (COVID-19) Vaccinations. Available from <https://ourworldindata.org/covid-vaccinations>.

³ Olga Gurgula and Wen Hwa Lee, “How can governments end the COVID-19 pandemic?”, Oxford Martin School blog, 28 May 2021. Available from <https://www.oxfordmartin.ox.ac.uk/blog/how-can-governments-end-the-covid-19-pandemic/>.

⁴ Our World in Data, Coronavirus (COVID-19) Vaccinations.

⁵ T. V. Padma, “COVID vaccines to reach poorest countries in 2023 – despite recent pledges”, Nature, 09 July 2021. Available from <https://www.nature.com/articles/d41586-021-01762-w>.

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⁷ Padma, “COVID vaccines to reach poorest countries in 2023 – despite recent pledges”.

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⁹ World Trade Organization Agreement on Trade-Related Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 15 April 1994, in World Trade Organization, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 321 (1999), as amended on 23 January 2017 (hereinafter ‘TRIPS Agreement’).

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- ¹² Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver, Office of the United States Trade Representative Press Release, 5 May 2021. Available from <https://ustr.gov/node/10649> (accessed 21 May 2021).
- ¹³ MSF Access Campaign, “Opposing countries must stop filibustering negotiations on ‘TRIPS Waiver’ at WTO”, Press Release, 26 July 2021. Available from <https://msfaccess.org/opposing-countries-must-stop-filibustering-negotiations-trips-waiver-wto>; Nature, “A patent waiver on COVID vaccines is right and fair”, 25 May 2021. Available from <https://www.nature.com/articles/d41586-021-01242-1> (accessed 23 June 2021).
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- ¹⁵ For an extensive literature review related to compulsory licensing, see Danielle Navarro and Marcela Vieira, “Research Synthesis: Compulsory Licensing”, Graduate Institute, February 2021. Available from <https://www.knowledgeportalia.org/compulsory-licensing>; Olga Gurgula and Wen Hwa Lee, “COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?” *Journal of Generic Medicines*, vol. 17, no. 2 (2021). Available from <https://journals.sagepub.com/doi/pdf/10.1177/1741134321993182> (accessed 29 August 2021).
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- ¹⁷ TRIPS Agreement, Article 31.
- ¹⁸ WTO, document WT/MIN(O1)/DEC/2.
- ¹⁹ Ibid., Sub-paragraph 5 (b): “Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: ... b. Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”
- ²⁰ Carlos M. Correa, *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents*, Research Paper, no. 107 (Geneva, South Centre, 2020), p. 13; European Patent Academy, “Compulsory licensing in Europe: a country-by-country overview (2018). Available from <https://www.epo.org/learning/materials/compulsory-licensing-in-europe.html>.
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- ²² Medicines Law & Policy, Tools. Available from <https://medicineslawandpolicy.org/tools/>.
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- ²⁴ This payment is waived, however, for the importing country in the context of Article 31bis TRIPS.
- ²⁵ Examples of compulsory licensing, including public non-commercial use, can be found in the TRIPS Flexibilities Database that provides worldwide information on the instances when authorities have invoked, planned to invoke, or have been asked to invoke a TRIPS flexibility for public health reasons, in particular, to assure access to medicines. See Medicines Law & Policy, The TRIPS Flexibilities Database. Available from <http://tripsflexibilities.medicineslawandpolicy.org>.
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³⁵ Ibid.

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