



COMPULSORY LICENSES, THE TRIPS WAIVER AND ACCESS TO COVID-19 MEDICAL TECHNOLOGIES

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Introduction

Médecins Sans Frontières (MSF) has time and again witnessed how monopoly rights granted to pharmaceutical corporations have impeded the timely and sufficient accessibility of life-saving medicines, vaccines, diagnostics and other health technologies. These barriers continue to undermine healthcare providers' ability to respond to health challenges, such as HIV/AIDS, drug-resistant tuberculosis, hepatitis C, and now the COVID-19 pandemic.

To address these issues, MSF has constantly advocated for the use of flexibilities available under the World Trade Organization (WTO) Agreement for Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), including compulsory licenses and government use licenses. In response to the grave effects of the COVID-19 pandemic, we have gone even farther to advocate that the WTO and member countries adopt additional measures to suspend the application and enforcement of relevant intellectual property (IP) to enable uninterrupted production and supply of essential COVID-19 health technologies for the duration of the pandemic, until global herd immunity is achieved.¹

In October 2020, South Africa and India submitted a proposal to the WTO for a temporary waiver during the COVID-19 pandemic to allow WTO members to choose not to apply, enforce or implement certain IP rules concerning COVID-19 medicines, vaccines, diagnostics and other related technologies and materials.² To date, the proposal is widely supported by more than 100 countries and by United Nations agencies, other international organizations, civil society organizations and community leaders.³ On 5 May 2021, the US announced that it would participate in the text-based negotiations,⁴ and other high-income countries that have stalled the start of the negotiations may follow. While the waiver text is being negotiated, countries should utilise all legal flexibilities already available under TRIPS to increase access to COVID-19 medical products. These flexibilities potentially include the right to suspend enforcement of IP rights on national security grounds under TRIPS Article 73.⁵

This briefing provides an overview of one key existing TRIPS flexibility: compulsory licensing, including government use licensing. These licenses have been used in the past, especially with respect to antiretroviral medicines to treat HIV/AIDS, cancer treatments, and direct-acting antivirals to treat hepatitis C. Not surprisingly, compulsory licenses have also already been used as a public health safeguard to respond to the COVID-19 pandemic. In addition to discussing compulsory licenses as an independent flexibility, this briefing explains how the proposed TRIPS waiver could supplement compulsory licensing given the limitations of TRIPS rules in addressing IP-related pandemic challenges.

Compulsory licenses

A compulsory license 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. The Doha Declaration on the TRIPS Agreement and Public Health confirms that countries have the right to use compulsory licenses and other flexibilities to safeguard health^a and are free to determine the grounds of compulsory licenses.^b Compulsory licenses can be granted on several grounds, including, but not limited to, the following:^c

1. To remedy anti-competitive practices or failure to work the patent or insufficient working of the patent such that domestic needs are not met.
2. When the patented medicine is unaffordable or unavailable, making it inaccessible to patients.
3. For public non-commercial use.
4. When the patent-holder refuses to license the patent to other qualified producers, including domestic producers.
5. When there is a risk of stockouts.
6. When public health is at stake, including, but not limited to, public health emergencies or other circumstances of extreme urgency, and epidemics.

^a Paragraph 4, Doha Declaration on TRIPS and Public Health.

^b Paragraph 5(b), Doha Declaration on TRIPS and Public Health.

^c Article 31(b) of the TRIPS Agreement.

In some circumstances, attempting negotiations for a voluntary license on reasonable terms is required before government agencies can issue a compulsory license. However, no prior negotiation with the patent holder is required for national emergencies,^d other circumstances of extreme urgency,^e public non-commercial use,^f or as a remedy for competition violations.^g Judicial authorities can also allow previously unauthorised use of patent rights in patent infringement cases by refusing to issue injunctions and instead allow continued infringement, conditioned on the payment of royalties.^h

Compulsory licenses as a legal measure first drew attention in the context of access to medicines when governments wanted to overcome patent barriers to allow importation or production of generic antiretroviral treatments for HIV/AIDS at the beginning of this century. Over the past two decades, compulsory licenses have been considered or used by countries nearly a hundred times to address access challenges on medicines such as treatments for HIV/AIDS, hepatitis C and cancer.⁶

For example, in 2017, Malaysia issued a government use license for sofosbuvir to increase access to the treatment for more than 400,000 people living with hepatitis C in Malaysia.⁷ The decision was made after the Ministry of Health's efforts to be included in the voluntary license and price negotiations with the patent holder were unsuccessful.⁸ The compulsory license eliminated the patent barrier. The price of sofosbuvir dropped by 99.7%, from RM360,000 for an entire course of treatment with the patented medicine to RM1,248 for the generic version, improving the availability of hepatitis C treatment in public hospitals throughout the country.⁹

Updates to national laws to enable and improve compulsory licensing for COVID-19

Compulsory licensing is now becoming an important tool for access to COVID-19 medical products and technologies.¹⁰ Several countries have amended their laws to facilitate easier and quicker processes for compulsory licenses or government use licenses in the pandemic.

Australia: In February 2020, Australia amended its Patents Act to make changes to the rules for Crown use (government use) of patents.¹¹ The amendment clarifies the circumstances in which Crown use can be invoked, including emergencies and when an invention is not available to the public on reasonable terms.

Brazil: In April 2021, the Federal Senate of Brazil approved a bill to facilitate compulsory licensing in health emergencies.¹² The bill includes patent applications in the scope of compulsory licenses and establishes a procedure to enable the simultaneous licensing of a group of technologies, defined in a list that must be issued within 30 days of the health emergency declaration and open for civil society inputs.

^d Article 31(b) of the TRIPS Agreement.

^e Article 31(b) of the TRIPS Agreement.

^f Article 31 (b) of the TRIPS Agreement.

^g Article 31 (k) of the TRIPS Agreement.

^h F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Limited, I.A 642/2008 IN CS (OS) 89/2008, Delhi High Court, Order dated 19 March 2008.

The bill also obliges patents holders to share all the necessary technical information, including biological materials, to enable the reproduction of the technology by third parties.¹³ The bill is pending consideration by the lower house of the National Congress.

Canada: In March 2020, Canada's COVID-19 Emergency Response Act amended the Canadian Patent Act to allow for a simpler and speedier process for issuing a compulsory license in the event of a public health crisis.¹⁴ The Act empowered the government and any person specified in the application made by the Minister of Health to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency. The amendment expired in September 2020.

Chile: In March 2020, Chile's Chamber of Deputies (the lower house of its congress) passed a resolution declaring that the coronavirus pandemic constitutes sufficient justification for the government to issue compulsory licenses for any patented medicines, vaccines, or diagnostics needed to respond to the pandemic.¹⁵

Colombia: In March 2020, Colombia issued a decree to allow measures to guarantee the prevention, diagnosis and treatment of COVID-19 within the framework of the State of Economic, Social and Ecological Emergency. The law grants power to the Ministry of Health and Social Protection to declare of interest the medicines, medical devices, vaccines and other health technologies needed to diagnose, prevent and treat COVID-19. Under Colombian law, the declaration of public interest can be a step towards a compulsory license.¹⁶ Once public interest is determined, the Superintendency of Industry and Commerce has the power to grant and issue compulsory licenses for the specified products.¹⁷

Ecuador: In March 2020, a committee of the National Assembly in Ecuador has passed a resolution authorizing the Minister of Health to use compulsory licenses for COVID-19-related preventative, diagnostic, and treatment technologies.¹⁸

Germany: In March 2020, Germany passed a new bill, the "Act on the Protection of the Population in the Event of an Epidemic Situation of National Significance," amending the Prevention and Control of Infectious Diseases in Humans Act. Among other measures, the bill empowers the Federal Ministry of Health to instruct a government use of patented subjects concerning "medicinal products including narcotics, the active ingredients, starting materials and excipients for these, medical devices, laboratory diagnostics, aids, as well as items of personal protective equipment and products for disinfection."¹⁹ The measures should remain in place until an epidemic situation of national significance is revoked.

Hungary: In May 2020, the government of Hungary passed an emergency measure that allowed the government to issue compulsory licenses to address domestic needs for COVID-19 related medical products.ⁱ

ⁱ See, for example, WTO TRIPS Council (October 2020): Hungary answers queries posed by South Africa regarding Hungarian compulsory licensing provisions ([KEI](#)); see also Hungary: Government Decree 212/2020 on public health compulsory license ([WIPO](#)).

Indonesia: In July 2020, the government passed Presidential Regulation No. 77 of 2020 concerning “Procedures for the Implementation of Patents” under Article 120 of the Indonesian Patent Law. The new regulation expands the scope of the government’s ability to use patents for the very urgent need in public interest. The “urgent public need” ground includes the issuance of a license on pharmaceutical and biotechnology products that are expensive and/or necessary to overcome a disease that could cause a large number of deaths or significant disabilities in the short term and constitute a global public health emergency.²⁰ The Indonesian government already has the power to issue compulsory licensing through existing patent laws and has done so for HIV medicines in the past.

Russia: In December 2020, Russia issued an ordinance adopted on the basis of Article 1360 of the Russian Civil Code, which provides for the issuance of a compulsory licence in the interests of the defence and security of the state without the consent of the patent holder, subject to payment of commensurate remuneration.²¹

Issuance of compulsory licenses on specific COVID-19 products

There are at least three instances in the pandemic where governments issued a compulsory license to enable generic production and supply of medicines.

Hungary: In late 2020, the Hungarian government granted a compulsory license on remdesivir, citing their newly promulgated law.²² The compulsory license was issued to support domestic manufacture by the Hungarian company Richter, which was approached by the government to produce the drug during the first wave of the pandemic.²³

Israel: In March 2020, Israel was the first government to issue a compulsory license on the HIV treatment lopinavir/ritonavir, which was at the time being tested and repurposed for treating COVID-19. Israel issued a compulsory license and turned to generic alternatives from India because the patent-holder, AbbVie, was unable to provide sufficient supplies of lopinavir/ritonavir at the time. Thereafter, AbbVie announced a global non-enforcement of patents on lopinavir/ritonavir for all indications, including HIV and coronavirus.

Russia: In August 2020, civil society organizations asked the Russian government to issue a compulsory license on remdesivir.²⁴ The patent-holding company, Gilead Sciences, refused to grant a voluntary license to Pharmasyntez, a Russian manufacturer that had developed a generic version of the treatment. Gilead also excluded Russia from receiving a generic version of remdesivir under the existing bilateral voluntary licensing arrangements with nine generic manufacturers in Egypt, India and Pakistan. Finally, in December 2020, a compulsory license was granted to Pharmasyntez to produce and provide the population of the Russian Federation with generic version of remdesivir without Gilead’s permission, which amounts to a compulsory license.^{25,26}

While both lopinavir/ritonavir and remdesivir were later found to be ineffective for COVID-19 by WHO,²⁷ the above compulsory licenses show that governments can encourage domestic production and importation of a more affordable generic medicine for public health.

Limitations of compulsory licenses in a pandemic

Compulsory licenses have been used by countries as an important public health safeguard. However, countries also need a temporary waiver of IP to more effectively address IP barriers in this pandemic. The current rules of compulsory licensing under the TRIPS Agreement were not designed to address some key challenges arising in a global pandemic, and some provisions also contain limiting factors in the context of a pandemic or an emergency in general. Using compulsory licensing for access to medicines has also been inappropriately politicised, and countries are discouraged from the usage for fear of trade retaliation.

1. Use of compulsory licenses may invite unwarranted pressure

Historically developing countries have been systematically discouraged from using compulsory licensing for access to medicines due to pressures from their trading partners and pharmaceutical corporations. In the COVID-19 pandemic, pharmaceutical corporations continue to pressure countries over the use of compulsory licensing.

For example, Gilead is suing the Russia government for issuing a compulsory license on remdesivir.²⁸ The Pharmaceutical Research and Manufacturers Association (PhRMA) and the Biotechnology Innovation Organization (BIO), the industry's trade association in the US annually submit complaints to the US Trade Representative (USTR) relating to compulsory license measures considered and taken by foreign governments. At the behest of pharmaceutical corporations, the annual USTR Special 301 Report on IP enforcement has over the years threatened trade sanctions against Brazil, Chile, India, Malaysia, South Africa, Thailand, and several other countries for issuing compulsory licenses to allow lower-priced versions of desperately needed medicines for HIV, cancer, viral hepatitis, and other diseases to be supplied while the medicine was still under patent. The European Commission has also been critical and issued warnings to countries on the use of compulsory licenses.²⁹

Fearing retaliation, countries may also feel reluctant to even consider compulsory license actions. The government of India recently argued before the country's supreme court that compulsory licenses would have "serious, severe and unintended adverse consequences" at global platforms.³⁰

In a more positive recent development, the USTR explicitly acknowledged the right of all countries to use compulsory license for the first time in a decade in its 2021 Special 301 Report.³¹ This is a welcome step. However, to remove political and trade pressures completely, this needs to lead to an actual end to pressuring countries for issuing compulsory licenses to support access to generic medicines, vaccines and other medical products and not just be an exception because of COVID-19.

2. Compulsory licenses require a case-by-case approach and are difficult to coordinate across jurisdictions

The TRIPS Agreement sets up some procedural and substantive conditions for using compulsory license by governments, some of which may pose limitations in a global pandemic. To begin with, TRIPS provisions require the use of compulsory licensing to be based on a country-by-country basis and individual merits,^j suggesting a case-by-case and product-by-product approach. Secondly, except in cases of emergency and other circumstances of urgency, public non-commercial use, or competition violations, prospective licensees must first attempt to secure a voluntary license on commercially reasonable terms, which can result in time delays. Finally, there must be opportunities to review the grounds for the license and the royalty rate, which have led to several legal disputes being filed against generic manufacturers that obtain a license or government agencies that issue a license.

In the situation of a global pandemic, to effectively establish patent-free supply chains for products involving a large number of components and complex background patent landscapes, such as in the case of some vaccines,³² would create a monumental coordination crisis because of the possible need to initiate and win compulsory licensing proceedings in multiple jurisdictions. Some jurisdictions also have other laws that may undermine compulsory licensing. For example, the European Union regulation on data and market exclusivity on medicinal products could hinder effective use of compulsory licenses by EU member states.³³

3. Compulsory licenses do not provide an effective remedy for emerging and evolving patent barriers

Compulsory licensing only provides a remedy after patent barriers on individual medical products have been established, blocking production and supply. The IP landscape continues to change as product development pipelines for drugs and other products are constantly evolving during the pandemic, making it inefficient to only take actions after a barrier has been established. The evolving IP landscape also suggests that new patents may remain unpublished due to the interval between application and publication, when preparation to ramp up production and supply is already required. To remove legal risk expeditiously, it is imperative to allow a quicker option in addition to compulsory licenses.

4. Compulsory licenses must be used primarily to supply a domestic market

Article 31(f) of the TRIPS Agreement requires the use of compulsory licensing to be predominantly for the supply of domestic market, unless the license is issued to remedy competition violations. This means that if countries want to export generic products produced under compulsory licensing, they may need to justify that the quantity for export is a limited percentage relative to domestic supply. In a pandemic where large-scale and rapid humanitarian assistance is required, Article 31(f) is inadequate and hugely problematic.

^j Article 31(a) of the TRIPS Agreement.

For instance, in April 2021, Russian media reported that Gilead launched a lawsuit before the Supreme Court of Russia, challenging the compulsory license granted on remdesivir by the Russian government.³⁴ Russia was willing to provide generic remdesivir produced under its compulsory license as part of the Russian humanitarian assistance package to support India who faced shortages of the drug during the recent wave of COVID-19 cases.³⁵ Yet, the final shipment to India was not sent due to concerns that Gilead's patent may be infringed.³⁶ Russia's compulsory license was issued under its national law in compliance with Article 31 of TRIPS Agreement, which means generic formulations produced under the license are meant predominantly for domestic use, limiting exports, even for humanitarian assistance. The concerns regarding patent infringement in India, risks invoked by litigation by pharmaceutical corporations against governments and the possible constraints due to the current framework of TRIPS provisions make it challenging to provide humanitarian assistance with generic medicines produced under compulsory licenses in a pandemic.

5. Compulsory licenses for export are logistically and procedurally impractical

The special compulsory license under Article 31*bis* of TRIPS Agreement allowing production, export, and importation to countries with insufficient manufacturing capacity does not provide a practical option to facilitate exportation.

To remedy the challenges facing countries with no or insufficient manufacturing capacity to effectively use a compulsory license under Article 31(f), Paragraph 6 of Doha Declaration mandated the TRIPS Council to work out an expeditious solution to ease the use of compulsory licenses for exportation and importation. However, the resulting amendment, Article 31*bis* of the TRIPS Agreement, fails to provide an expeditious solution to the challenges identified.³⁷ Instead, Article 31*bis* introduces unnecessary and burdensome procedures for using compulsory license for exportation that are not appropriate to address health emergencies.³⁸

The provision requires a notification procedure by importing and exporting countries and requires for each compulsory license issued that only a specified quantity is allowed to be produced, and the specified products need to be coloured and packaged differently before shipment. In a pandemic while pressures to mobilise all capacities with record speed continue to mount, those requirements under Article 31*bis* are simply impractical.

For example, on 19 February 2021, Bolivia made a general notification to the WTO TRIPS Council expressing the intention to be an importing country using the Article 31*bis* procedure.³⁹ On 12 March 2021, Canadian vaccine producer, Biolyse, issued a statement revealing that it sought but failed to secure an IP licensing agreement with the vaccine developer Johnson & Johnson to produce the single-dose COVID-19 vaccine for both domestic supply and exportation. Biolyse also states that it has the capacity to produce if patent barriers are removed on the Johnson & Johnson adenovirus vectored vaccine to help meet the growing COVID-19 vaccine needs.⁴⁰ Accordingly, the company is seeking compulsory license for export under Canada's Access to Medicines Regime (CAMR) – a legal mechanism that Canada set up to

implement the Paragraph 6 mechanism (now Article 31bis of the TRIPS Agreement). In late April, a group of Canadian experts made a request to the government to add ‘COVID-19 vaccine’ to the list of Schedule 1 of the Patent Act, a step needed to initiate the process necessary to obtain a compulsory license issued under CAMR.⁴¹ On 10 May 2021, Bolivia signed an agreement with Biolyse to produce and supply 15 million doses of vaccine, should a voluntary license be obtained, or a compulsory license for exportation be issued by Canada.⁴² However nearly two months since Biolyse initiated the process necessary to obtain a compulsory license, and three months after Bolivia made a general notification, there is no progress or decision from the Canadian government. Despite these difficulties and the current and historical evidence that the procedure does not provide an adequate solution in an emergency,⁴³ Canada has continued to suggest that Article 31bis is sufficient and the country does not support negotiations on the TRIPS waiver.

In a nutshell, Article 31bis of the TRIPS Agreement and Canada's national law do not appropriately respond to the need for compulsory licenses for export to address healthcare needs, including in an unprecedented emergency pandemic situation.⁴⁴

6. Compulsory licenses cannot easily override non-patent IP barriers

Overriding patents alone is often enough to allow alternative producers to expeditiously manufacture small molecule medicines. However, to expeditiously make and gain regulatory approval for complex medical products like vaccines and monoclonal antibodies in a pandemic, alternative producers also need immediate access to other IP-protected assets. Diagnostics also involve other types of IP, such as trade secrets, copyrights on software and industry design related to equipment, in addition to patents. For these products to be expeditiously made available in the shortest timeline, producers need to be able to access confidential information and trade-secret protected knowledge, data, manufacturing, quality control know-how, regulatory data, and even cell lines and other biologic resources. Additionally, copyright protections might shield industrial blueprints, manuals, and software for production equipment, diagnostic and medical devices. In the TRIPS Agreement, compulsory licensing is only provided for under Section 5 concerning patents. To overcome non-patent IP barriers, using compulsory licensing alone is insufficient. Rapid removal of other IP barriers requires additional legal tools, such as the proposed temporary TRIPS waiver.

The need for the TRIPS waiver in the COVID-19 pandemic

The limitations of compulsory licensing suggest a practical need for additional legal options. This should be fully acknowledged by WTO members in the ongoing discussion on the TRIPS waiver proposal for COVID-19. Some countries have expressed interest in improving compulsory licensing mechanism for the future. It is a welcome suggestion to make compulsory licensing mechanisms better suited to protect public health in the long term. However, this should not be used as an excuse for countries not to support a more immediate solution in this pandemic through the TRIPS waiver proposal, which will ease the compulsory-license-related limitations of the TRIPS Agreement and ensure greater access to medical tools globally.

The waiver proposal, led by India and South Africa, offers an option 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 settle body for not fully implementing the TRIPS Agreement in a pandemic. The waiver, when implemented at the national level, could immediately mitigate the limitations in the current rules of compulsory licenses, and offers an expeditious approach to export and import products produced by generic companies. It could also offer a guidance to IP offices and courts regarding IP disputes over COVID-19 medical tools to provide a greater legal certainty and maximum freedom to operate for alternative producers and suppliers. Health authorities and public procurement agencies would not have to exhaust the full IP landscape analysis to ensure their activities would not infringe anyone's IP rights in the pandemic.

Thus, the proposal for a waiver on specific IP provisions offers an expedited global solution that allows governments to have new legal options to address the legal uncertainties and barriers that may impede production and supply of COVID-19 medical technologies in advance, rather than waiting for barriers to hit and then scramble for actions. While the TRIPS waiver negotiations are underway, governments should continue to use TRIPS flexibilities to safeguard public health, including issuing compulsory licenses as they deem appropriate for COVID-19.

Conclusion

The TRIPS waiver and the existing provisions of compulsory licenses are not mutually exclusive. All countries have the right to determine the grounds to issue a compulsory license and in non-emergency contexts, a compulsory license can be a powerful and potentially sufficient tool. The patent office, ministry of health or competition authorities should be able to issue a compulsory license according to the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property.^k But countries should do more to ensure that the IP barriers do not hinder access to COVID-19 related medical tools.

Facing a global health crisis such as the COVID-19 pandemic in which pharmaceutical corporations refuse to enter into worldwide, non-exclusive licenses, countries should collectively explore automatic and expedited measures to overcome IP challenges. This should include the suspension of certain obligations under the TRIPS Agreement and trade agreements concerning granting and enforcement of IP on essential health technologies, materials and products to enable open sharing of health technologies for all.⁴⁵ 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 in addressing IP monopolies in a pandemic. Yet seven months since the proposal was first introduced, a small group of countries continue to engage in delay tactics to block the proposal. As the COVID-19 pandemic continues to rage in the world, all governments should stand behind this critical proposal and support its adoption.

^k Article 5 of the Paris Convention for the Protection of Industrial Property allows countries to issue a compulsory license to address abuse, including failure to work patents. The provisions under the Paris Convention are in full alignment with the TRIPS Agreement, according to Article 2 of the TRIPS Agreement.



ANNEX: Access scenarios in the COVID-19 pandemic using compulsory licenses and the TRIPS waiver

Acknowledgement: The scenario analysis herein is developed jointly with Professor Brook Baker from Health GAP and Sangeeta Shashikant and Gopa Kumar from Third World Network.

Scenario 1 (from the perspective of a country with manufacturing capacity): In this scenario it is assumed that Country A has manufacturing capacity while Country B is able to manufacture the active pharmaceutical ingredient (API). It is also assumed that there are many patents over the COVID-19 product X, including on the compound, its different formulations and on the key active ingredient. If Product X is a vaccine, this would include patents on the starting materials, vaccine compositions, process technologies and even methods of use. Developers of product A have no plans to license the manufacturing of product X on a global basis to all competent manufacturers to supply all countries. The table below shows legal options available to Country A and Country B to override the patent barrier. This scenario shows the complexity involved when manufacturing and supply is conducted under Article 31 and Article 31*bis*. The situation becomes even more untenable if patented starting materials, including active ingredients are sourced from multiple countries.

Countries	Activate the waiver with respect to COVID-19 patents in Country A & B	Compulsory licenses under Art. 31	Compulsory licenses under Art. 31 <i>bis</i>
	One-time implementation (no further action required for duration of waiver)	Compulsory licenses (CLs) must be issued in the country of API production and export (B) and in the country of API import, finished formulation, and use (A). Issuance of CL based on national law, regulations and practice. Art. 31 allows compulsory license to be issued in situations of emergency without prior negotiations with the patent holder, subject to payment of adequate remuneration. However, use of CL depends on the provisions of national law and practice. Some countries may not have included this	Art.31 <i>bis</i> procedures to be followed: -notification to WTO by importing country ^l -CL by importing country (if patents exist) for specific quantity -CL by exporting country for specific quantity ^m -notification to WTO by exporting country ⁿ -product differentiation In addition to Art.31 <i>bis</i> procedures, the national law/regulations of the exporting and importing country may have additional requirements.

^l Annex to TRIPS Agreement, para 2(a), 3 (WTO)

^m Annex to TRIPS Agreement, para 2(b) (WTO).

ⁿ Annex to TRIPS Agreement, para 2(c) (WTO).

				flexibility or may subject its use to additional procedures.			These complex and time-consuming processes pose hurdles in timely supply and distribution of medical products.	
	<i>For Domestic Use</i>	<i>Export of finished product</i>	<i>Import of patented API from Country B</i>	<i>For Domestic Use</i>	<i>Export finished product under CL</i>	<i>Import of patented API from Country B</i>	<i>Export finished product under CL</i>	<i>Import patented API</i>
Country A with manufacturing capacity	Yes	Yes, without any limitation or additional procedure.	Yes, without any limitation or additional procedure from Country B, if waiver is implemented by Countries A & B	Subject to issuance of CL as per national law, regulations and practice. CL issued on a case- by- case basis.	Limited quantities as CL is limited by condition: predominantly for the supply of the domestic market.	Very limited quantities as CL in Country B is limited by condition: predominantly for the supply of the domestic market.	Subject to complying Art. 31 <i>bis</i> procedures and other requirements in Country A and importing countries.	Subject to complying Art. 31 <i>bis</i> procedures and other requirements in Country A & Country B.
	<i>For Domestic Use</i>	<i>Export of patented API</i>	<i>Import of finished product from Country X</i>	<i>For Domestic Use</i>	<i>Export of patented API</i>	<i>Import finished product from Country X</i>	<i>Export of patented API</i>	<i>Import finished product from Country X</i>
Country B (producing patented API)	Yes	Yes, without any limitation or additional procedure.	Yes, without any limitation from Country A which implements waiver.	Subject to issuance of CL as per national law, regulations and practice. CL issued on a case- by- case basis.	Limited quantities as CL is limited by condition: predominantly for the supply of the domestic market.	Very limited as CL in Country A is limited by condition: predominantly for the supply of the domestic market	Subject to complying Art. 31 <i>bis</i> procedures and other requirements in Country B and importing countries.	Subject to complying Art. 31 <i>bis</i> procedures and other requirements in Country A & Country B.

Scenario 2 (from the perspective of a country lacking manufacturing capacity): In this scenario, the patent holder is uninterested in supplying, refused to issue a voluntary license, or is unable to supply as its supply has been reserved for a few wealthy countries. It may also be the case that Country C is excluded from being supplied by a voluntary licensee. The scenario then shows the options available if the product is patented in Country C and Country D. In this scenario, it is assumed that Country D has the manufacturing capacity and Country C lacks manufacturing capacity. Country D may be able to produce and export to Country C.

	Patent holder	Activate the waiver with respect to COVID-19 patents	Compulsory licenses under Art. 31	Compulsory licenses under Art. 31bis
			Compulsory licenses (CLs) must be issued in the country of API production, formulation, and export (Country D) and in the country of import, and use (Country C). Issuance of CLs based on national law, regulations and practice. Art. 31 allows CLs to be issued in situations of emergency without prior negotiations with the patent holder, subject to payment of adequate remuneration. However, use of CL depends on the provisions of national law and practice. Some countries may not have included this flexibility or may subject its use to additional procedures. In any case, to date countries issuing CLs have faced significant pressures from developed countries and the pharmaceutical industry.	Art.31bis procedures to be followed: -notification to WTO by importing country* -CL by importing country (if patents exist) for specific quantity -CL by exporting country for specific quantity** -notification to WTO by exporting country*** -product differentiation In addition to Art.31bis procedures, the national law/regulations of the exporting and importing country may have additional requirements. These complex and time-consuming processes pose hurdles in timely supply and distribution of medical products.
Country C (lacks manufacturing capacity)	Patent holder unable to supply/refused to issue voluntary license or Country C is excluded from the list of territories included in voluntary license. No access.	Able to import without any limitation or additional procedure from Country D or any other source able to supply.	Able to import limited quantities as CL in Country D is limited by the condition the CL is predominantly for the supply of the domestic market.	Subject to complying Art. 31bis procedures and other requirements in Country D & Country C.

Scenario 3: This scenario shows that when importing and exporting countries implement the waiver, with greater freedom to operate, global supply by non-originator manufacturers is possible. In the case of voluntary licenses access is likely to be limited or in some cases there may not be access. In situations, where neither a voluntary license nor a waiver exists, supply and access depends on the use of Art. 31 and Art. 31bis and supply by non-originators is uncertain. In this scenario, multiple countries might be involved, including Countries E and F (which have manufacturing capacity), Country G (a Least-Developed Country (LDC) with limited manufacturing capacity), Country H (not an LDC and lacks manufacturing capacity).

	Activate the waiver with respect to COVID-19 patents	Voluntary license situation	No voluntary license & no waiver
Country E with manufacturing capacity	Full freedom for all manufacturers with capacity to manufacture for domestic use and export. Impact: global supply by non-originators available.	Voluntary license (VL) limited to specific manufacturers in a few selected countries. Restricts countries to be supplied. May restrict quantities to be manufactured under license. Subject to terms and conditions of the license. Terms and conditions of license, including countries and quantities to be supplied unknown. <i>Example 1:</i> Gilead’s VL to 5 manufacturers for remdesivir but excludes other competent manufacturers globally. Terms of VL unknown. ⁴⁶ <i>Example 2:</i> AstraZeneca’s exclusive VL to Serum Institute (1 billion vaccine doses). Terms of VL unknown. Impact: supply by non-originators limited to terms of VL (geographic coverage and other supply limitations).	Subject to Art. 31 and 31bis procedures. Manufacturing may not be attractive option if there are no economies of scale, if active pharmaceutical ingredients or other components are patented and the exporting country unwilling to use Art. 31/Art. 31bis. Impact: supply by non-originators uncertain.
Country F with manufacturing capacity	Full freedom for all manufacturers with capacity to manufacture for domestic use and export. Impact: global supply by non-originators available.	VL not granted to any developing country manufacturers <i>Example 1:</i> Regeneron’s casirivimab and imdevimab to be administered together for the treatment of mild to moderate COVID-19. Received emergency use authorization in US. <i>Example 2:</i> Pfizer/BioNTech vaccine. Impact: limited supply by patent holder. If patent holder is unable to supply, there is no access.	Subject to Art. 31 and 31bis procedures. Manufacturing may not be possible if there are no economies of scale, or if active pharmaceutical ingredients or other components are patented and the exporting country unwilling to use Art. 31/Art. 31bis. Impact: supply by non-originators uncertain.
Country G (LMIC) lacking manufacturing capacity. Included in VL allowing	Full freedom to import from voluntary licensee or from any other manufacturer with capacity to manufacture. Impact: global supply by non-originators available. More suppliers, lower prices.	Some VLs may allow supply to a list of low- and middle-income countries (LMIC) as defined by the World Bank. But such VLs exclude other developing and developed countries. <i>Example 1:</i> Gilead’s VL to 5 manufacturers for remdesivir but excludes other competent manufacturers globally. Excludes supply to more than half of the world population. Terms of VL unknown.	Subject to Art. 31 and 31bis procedures. Access is dependent on a country with manufacturing capacity to use Art. 31/Art. 31bis to manufacture and export. Impact: supply by non-originators is uncertain, hence access is uncertain.

supply to some LMICs.		Impact: supply by non-originators limited to terms of VL. Country G may be supplied but countries excluded from VL may not be supplied. Limited competition, prices may remain high.	
Country H (non-LMIC) lacking manufacturing capacity. VL exists but licensee not allowed to supply Country H.	Full freedom to import from any manufacturer with capacity to manufacture. Impact: global supply by non-originators available. More suppliers, lower prices.	VL does not allow supply to Country H Impact: limited supply by patent holder, high prices. If patent holder is unable to supply, there is no access.	Subject to Art. 31 and 31bis procedures. Access is dependent on a country with manufacturing capacity to use Art. 31/Art. 31bis to manufacture and export. Impact: supply by non-originators uncertain, hence access is uncertain.



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