



## MÉDECINS SANS FRONTIÈRES (MSF) ANALYSIS OF COMMUNICATIONS FROM THE EUROPEAN UNION TO THE COUNCIL FOR TRIPS

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On behalf of the European Union (EU), on 4 June 2021, the European Commission (EC) submitted a communication ([IP/C/W/680](#)) to the World Trade Organization (WTO) Council for Trade-related Aspects of Intellectual Property Rights (TRIPS Council). This attempt was seen as countering **the proposal for a temporary TRIPS waiver** on intellectual property (IP) on COVID-19 medical tools, led by South Africa and India with 63 co-sponsoring WTO members ([IP/C/W/669/Rev.1](#)). On 18 June 2021, the EU formatted its communication into a draft WTO General Council declaration text and submitted it to the TRIPS Council ([IP/C/W/681](#)). The substance of the texts in the two EU submissions is the same.

In parallel, the EU submitted a communication to the WTO General Council ([WT/GC/231](#)) containing IP elements suggesting that governments should encourage voluntary actions of pharmaceutical corporations towards the expansion of production, and recommending reliance on 'clarified' compulsory licenses on patents.

The EU communications are weak and distracting, bringing nothing significantly new to the table and diluting some of the existing public health flexibilities enjoyed by WTO members.

Here are three reasons why the EU initiative does not add anything significantly new to address the current global inequity in production, supply and access of COVID-19 medical tools:

### **1. Limited scope: The EU initiative only applies to patent barriers and does not address other IP barriers**

The EU initiative only applies to patent barriers. It does not address IP barriers in the regulatory system and other forms of IP that should be waived when countries and alternative manufacturers seek to expand the supply of COVID-19 vaccines, medicines, and other health technologies. The EU focuses on TRIPS compulsory license (CL) provisions, which solely deal with patent barriers. They do not address the challenges with access to and the legal right to use confidential information including trade secrets and regulatory test data, which act as barriers to alternative independent producers, nor associated copyright and industrial-design barriers. Our [analysis](#) has shown that CLs alone would not be enough to achieve urgent access to lifesaving COVID-19 medical tools [even in the EU itself](#) during this pandemic.

## **2. Insufficient for impact and dilutes existing flexibilities: The EU's proposed action points on compulsory licensing are redundant, confusing, and too limited to make a difference, and undermine existing public health safeguards**

The EU communication seeks to repurpose existing CL provisions in the TRIPS agreement but ignores their limited effectiveness in responding to a pandemic. CLs under the TRIPS agreement apply to patents only. In the pandemic, when the entire supply chain needs to be monopoly-free, CLs may need to be granted in multiple exporting and importing countries supplying key patent-protected components; in countries formulating and performing final production steps; and in countries of final importation and use, making coordination difficult. The special rules relating to exportation and importation are complex, cumbersome and impractical in a pandemic. In that sense, a waiver will facilitate easier coordination and greater legal certainty and allow removal of multiple major types of IP barriers in a public health emergency. CL provisions, after all, were not drafted with the notion of a global pandemic. The EU communication also dilutes some key TRIPS flexibilities enjoyed by WTO members and may introduce a dangerous drawback from public health safeguards under the Doha Declaration.

Below are comments on the three points on CLs contained in the EU proposed draft declaration ([IP/C/W/681](#)) that the EU suggests WTO members to agree:

- i. *"A pandemic is 'a national emergency or other circumstances of extreme urgency' within the meaning of Article 31(b) of the TRIPS Agreement. For the purposes of issuing a compulsory licence pursuant to Articles 31 and 31bis of the TRIPS Agreement, a Member may waive the requirement of making efforts to obtain authorization from the right holder, provided for in Article 31(b)."*

EU proposes nothing that is not already established and widely known here, and risks diluting the existing flexibility enjoyed by WTO members.

Articles 31 (b) and (g) of the TRIPS agreement clearly exempt countries from needing to engage in prior negotiation with patent holders to address emergencies, other matters of extreme urgency, public non-commercial use or anti-competition situations for the issuing of a CL.

Even when countries use CLs under Article 31bis for exportation, according to Article 31bis.5,<sup>1</sup> countries remain holding the right under the other TRIPS provisions, and hence remain exempted from the prior-negotiation requirement under Articles 31 (b) and (g).

Furthermore, countries do not need to seek an agreement with other WTO members when determining any grounds to issue a CL. Countries enjoy the freedom to determine any ground upon which CLs are granted, as reaffirmed by Paragraph 5(b) of the Doha Declaration of TRIPS and Public Health.<sup>2</sup>

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<sup>1</sup> Article 31bis.5, TRIPS agreement: [https://www.wto.org/english/docs\\_e/legal\\_e/trips\\_e.htm#art31\\_bis](https://www.wto.org/english/docs_e/legal_e/trips_e.htm#art31_bis)

<sup>2</sup> Paragraph 5(b) of the Doha Declaration clearly states that "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.":  
[https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)

Since 2020, more than 100 countries have declared the COVID-19 pandemic as a state of emergency.<sup>3</sup> Several WTO members have revised relevant provisions in their national laws to be able to use CLs quickly.<sup>4</sup>

Asking WTO members to agree on something that already exists and is exquisitely clear is redundant. Asking WTO members to agree on something that they already have the freedom to determine, undermines the enjoyment of the existing TRIPS flexibility.

- ii. *"In the circumstances of a pandemic and to support manufacturers ready to produce vaccines or medicines addressing the pandemic at affordable prices for low- and middle-income countries, a Member may provide, for the purposes of determining the remuneration to be paid to the right holder pursuant to Article 31(h) and paragraph 2 of Article 31bis of the TRIPS Agreement, that the remuneration reflects the price charged by the manufacturer of the vaccine or medicine produced under the compulsory licence."*

TRIPS provisions only require "adequate" remuneration be made available when issuing a CL, and that "taking into account the economic value of the authorization" is done to determine the remuneration.<sup>5</sup> The amount of adequate remuneration is subject to national discretion and can be based on remuneration guidelines established by Member States.

In the past, the World Health Organization (WHO) and UN Development Programme (UNDP) published guidelines concerning possible remuneration rate for CLs from the perspectives of public health. Those guidelines suggest the rate could vary depending on countries of concern, ranging between 0.02% and 4% of the price of the generic products.<sup>6</sup> In practice, when countries issued CLs for HIV, hepatitis C virus and cancer drugs, a range of remuneration rates have been set up and go as low as 0.5% based on the generic price of the licensed medicine.<sup>7</sup>

The EU remuneration proposal does not offer anything substantially new. The EU paper provides no concrete information on what the proposed measures looks like in minimising the impact of the remuneration to prices.

- iii. *"In the circumstances of a pandemic, for the purposes of Article 31bis and paragraph 2.c) of the Annex to the TRIPS Agreement, the exporting Member may provide in one single notification a list of all countries to which vaccines and medicines are to be supplied by the exporting Member directly or through indirect means, including international joint initiatives that aim to ensure equitable access to the vaccines or medicines covered by the compulsory licence. It shall be presumed that such joint initiatives supply those vaccines and medicines to eligible importing Members within the meaning of paragraph 1.b) of the Annex to the TRIPS Agreement."*

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<sup>3</sup> <https://www.icnl.org/covid19tracker/?location=&issue=5&date=&type=>

<sup>4</sup> <https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies>

<sup>5</sup> Article 31(h), TRIPS agreement: [https://www.wto.org/english/docs\\_e/legal\\_e/trips\\_e.htm#art31\\_bis](https://www.wto.org/english/docs_e/legal_e/trips_e.htm#art31_bis)

<sup>6</sup> [https://www.who.int/medicines/areas/technical\\_cooperation/WHOTCM2005.1\\_OMS.pdf?ua=1](https://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf?ua=1)

<sup>7</sup> <https://www.twn.my/title2/books/pdf/CompulsoryLicense.pdf>, page 33

This is another redundant point and misses the key problems with CLs for exportation, especially under Article 31*bis* of TRIPS agreement. It also limits the scope of products covered by the existing rules.

Under the current provision of TRIPS Agreement, an exporting member that uses Article 31*bis* can already make a single notification listing multiple countries, licensees and products covered. The Annex to Article 31*bis* TRIPS agreement notes that the exporting member should notify the name and address of the licensee, and “the country(ies) to which the product(s) is (are) to be supplied.”<sup>8</sup> There are no restrictions on the number and type of licensees and countries that can be notified at once by an exporting member. There are also no restrictions on the type of products upon which such notification can be made, while the EU proposal limits the scope to vaccines and medicines only.

However, the EU missed the most problematic aspects of using CLs for exportation under Article 31*bis*. As well documented, Article 31*bis*, instead of simplifying and accelerating the process, does quite the opposite, through requirements that range from adding unnecessary steps for mandatory differential packaging and colouring of products under the CL, to actively impeding the flexibility needed in an evolving public health crisis, such as requiring importing countries to specify the quantity needed for each product in each CL used under the notification made to the WTO.<sup>9</sup> These complex and unnecessary steps make the whole mechanism impractical in an emergency.<sup>10</sup>

The EU initiative does not touch these most problematic aspects of Article 31*bis* CL for exportation, and hence misses the target. The EU initiative also arbitrarily limits the scope of eligible products covered by the existing rules, which dangerously weakens this public health safeguard under the TRIPS agreement.

### **3. Ignores lessons learned: Too dependent on voluntary actions of pharmaceutical corporations**

The EU proposes in the paper to WTO General Council ([WT/GC/231](#)) that countries should encourage corporations to engage in voluntary actions including voluntary licensing, contract manufacturing, tiered pricing, and sharing know-how voluntarily to expand production; and notes that voluntary licensing is the most effective way to share know-how. However, all of these measures already existed before this pandemic and have proved to be insufficient.

While tiered pricing has [not made treatments or vaccines substantially more affordable](#), voluntary licenses lack transparency and are mostly reduced to [contract manufacturing arrangements](#) and do not allow countries and companies to acquire legal rights to independently supply the concerned technologies, materials and products. Control under such voluntary-licensing agreements remains in

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<sup>8</sup> Annex to TRIPS Agreement, on Article 31*bis* 2(c) reads that: ‘the exporting Member shall notify<sup>(8)</sup> the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence.’

[https://www.wto.org/english/docs\\_e/legal\\_e/31bis\\_trips\\_annex\\_e.htm](https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm)

<sup>9</sup> <https://msfaccess.org/sites/default/files/2021-03/COVID-IP-TRIPSMSEF%20Canada%20Briefing%20on%20TRIPS%20Waiver-Feb%202021-ENG.pdf>

<sup>10</sup> [https://www.southcentre.int/wp-content/uploads/2019/01/PB57\\_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf)

the hands of the pharmaceutical rightsholders. [MSF analysis](#) of license terms and conditions reveals that pharmaceutical corporations can set limitations on where and to whom a product can be sold, control the supply of active pharmaceutical ingredients (API) and impose other restrictions on licensees. In the current practice of voluntary licenses, most high- and upper-middle-income countries are excluded, including many with a high burden of disease.

While asking governments to encourage companies to share COVID-19 medical technologies with producers in lower- and middle-income countries is fine, major multinational pharmaceutical companies that hold essential IP and technologies have repeatedly resisted such calls, and choose not to engage or show resistance to voluntary initiatives, such as the WHO COVID-19 Technology Access Pool (C-TAP) or the WHO mRNA technology transfer hub. The past year's experience has shown that lip service by governments and calls for action are not enough. Providing more financial incentives to companies without clear accountability requirements to share technologies is flawed. The EU proposal has not reflected these key lessons learned. While acknowledging the importance of transferring know-how and technologies, the EU offers no concrete information about how EU will take its responsibility to make it happen.

## Conclusion

The EU has resisted the waiver proposal for the past eight months. Since the proposal was first tabled, the pandemic has worsened and increasingly hit lower- and middle-income countries, and 3.74 million COVID-19 deaths<sup>11</sup> having been reported globally in that time period. Instead of realizing the urgency and acting with global solidarity, the EU has submitted a separate initiative that provides nothing significantly new to the worsening COVID-19 pandemic, but which could threaten to further delay rapid text negotiations and adoption of the TRIPS waiver. This demonstrates a questionable and troubling motive of the EU that risks derailing the global efforts to seek a more expeditious option to overcome IP barriers in the pandemic.

By engaging in this initiative, the EU has missed the target of addressing IP challenges as a matter of collective responsibilities of governments; ignored the key shortcomings of the existing rules that informed the need to adopt an additional legal tool in a pandemic; and missed the essence of the TRIPS waiver proposal, which demonstrates the strong demand of countries to alter decision-making power and ensure self-reliance and autonomy in the supply of lifesaving COVID-19 health technologies, especially in all low- and middle-income countries, to end the pandemic. The EU initiative also contains worrying elements that substantively dilute and diminish existing public health flexibilities enjoyed by all WTO members, including in a pandemic.

Instead of resisting an emerging global consensus on the need for joint action to overcome monopolies, the EU should join forces with other countries to advance the negotiation and adoption of the TRIPS waiver.

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<sup>11</sup> <https://covid19.who.int/>

The proposed TRIPS waiver would provide countries with an effective and expeditious way to remove key IP barriers in the pandemic. The EU should join the more than 100 countries supporting the waiver to ensure this temporary measure is adopted quickly without further delay.

*For further analysis on what the waiver could achieve, why compulsory licensing is not sufficient and why the TRIPS waiver will not block future innovation, please refer to the following MSF briefing documents:*

- [Compulsory licenses, the TRIPS waiver and access to COVID-19 medical technologies](#)
- [Analysis of EU position on compulsory licensing and TRIPS waiver in the COVID-19 pandemic](#)
- [Canada position on TRIPS waiver](#)
- [Proposal for a TRIPS waiver for COVID-19](#)
- [Myths, realities and an opportunity for governments to protect access to medical tools in a pandemic](#)