



## 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) has submitted a communication ([IP/C/W/680](#)) to the World Trade Organization (WTO) Council for Trade-related Aspects of Intellectual Property Rights (TRIPS Council), which outlines a **counter-proposal to the proposal for a temporary TRIPS waiver** on intellectual property (IP) on COVID-19 medical tools, led South Africa and India with 63 co-sponsoring WTO members ([IP/C/W/669/Rev.1](#)). The next the formal session of TRIPS Council meeting will be held 8-9 June 2021.

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 proposals are weak and distracting, which brings nothing significantly new to the table.

Here are three reasons why the proposals do 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 proposal only applies to patent barriers and does not address other IP barriers**

The EU proposal 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 proposal 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: The proposed EU action points on compulsory licensing are redundant, confusing or too limited to make a difference

The EU proposal 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 type of IP barriers in a public health emergency. CL provisions, after all, were not drafted with the notion of a global pandemic.

Below are the comments on the three points on CLs contained in the EU proposal ([IP/C/W/680](#)):

- i. *"The EU proposes to clarify that the circumstances of a pandemic fulfil the requirement of a national emergency," and therefore, the requirement for prior negotiations with the patent holder can be waived.*

EU proposes nothing that is not already established and widely known here.

Article 31 (b) and (g) of 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 Article 31 (b) and (g).

Countries do not need to seek an agreement with other WTO members when determining any grounds to issue a CL, as reaffirmed by the Doha Declaration of TRIPS and Public Health.

Since 2020, more than 100 countries have declared the COVID-19 pandemic as a state of emergency.<sup>2</sup> Several WTO members have revised relevant provisions in their national laws to be able to use CLs quickly.<sup>3</sup>

Asking WTO members to agree on something that already exists and is exquisitely clear is redundant.

- ii. *"To support manufacturers ready to produce vaccines or therapeutics at affordable prices, especially for low- and middle-income countries, based on a compulsory license, the remuneration for patent holders should reflect such affordable prices."*

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

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

<sup>3</sup> <https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies>

remuneration.<sup>4</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>5</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>6</sup>

The EU remuneration proposal does not substantially offer anything 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. *“The compulsory licence could cover any exports destined to countries that lack manufacturing capacity, including via the COVAX facility,” and under Article 31bis of TRIPS agreement, “The EU proposes that in the circumstances of a pandemic, the WTO Members agree 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.”*

This is another redundant point and missed the key problems with CLs for exportation especially under Article 31bis of TRIPS agreement.

Under the current provision of TRIPS Agreement, an exporting member that uses Article 31bis can already make a single notification listing multiple countries, licensees and products covered. The Annex to Article 31bis 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>7</sup> There are no restrictions on the number of licensees and countries that can be notified at once by an exporting member.

However, the EU missed the most problematic aspects of using CLs for exportation under Article 31bis. As well documented, Article 31bis, 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>8</sup> These complex and unnecessary steps make the whole mechanism impractical in an emergency.<sup>9</sup>

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<sup>4</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>5</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>6</sup> <https://www.twn.my/title2/books/pdf/CompulsoryLicense.pdf>, page 33

<sup>7</sup> Annex to TRIPS Agreement, on Article 31bis 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.<sup>(9)</sup> 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. ’ Available from:

[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>8</sup> <https://msfaccess.org/sites/default/files/2021-03/COVID-IP-TRIPSMsf%20Canada%20Briefing%20on%20TRIPS%20Waiver-Feb%202021-ENG.pdf>

<sup>9</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 EU proposal does not touch these most problematic aspects of Article 31*bis* CL for exportation, and hence misses the target.

### **3. Ignore 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 remain in 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 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>10</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 counter-proposal 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

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<sup>10</sup> <https://covid19.who.int/>

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 counter-proposal, 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. 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.

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

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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](#)