Disinformation, Diversion, and Delay:
The Real Text of the European Union's Communication to the WTO TRIPS Council – Urgent Trade Policy Responses to the COVID-19 Crisis

Professor Brook K. Baker, Senior Policy Analyst Health GAP
June 5, 2021

If the European Union's Communication to the TRIPS Council – Urgent Policy Responses to the COVID-19 Crisis has no real substance, then it is fair to conclude that its true purpose is disinformation, diversion, and delay. The Communication purports to address clarifications needed to make existing TRIPS flexibilities more operational for countries that might need to issue compulsory licenses to access COVID-19 vaccines and therapeutics. However, the proposed clarifications have no substance beyond what is already well established in the text of Articles 31 and 31bis of the TRIPS Agreement and of the Doha Declaration on the TRIPS Agreement and Public Health. When a powerful group of nations, like the E.U., offers a set of "pseudo" proposals with no substance, we can look beyond the façade to see that their real intention is to misinform decision-makers, the press, and the public and to divert attention from the proposal by India, South Africa and 61 other countries to the WTO to waive intellectual property protections on COVID-19 health products and technologies for at least three years. (Adopting this substantive waiver would mean that countries experiencing grossly inequitable access to vaccines, medicines, diagnostic, personal protective equipment, and other medical supplies could act on their own behalf to find alternative producers to ameliorate shortages, excessively high prices, and stockpiling by rich countries.) In addition to muddying the water and diverting attention, the E.U. is also hoping that its empty-package compulsory licensing proposals will delay text-based negotiations of a waiver agreement so long that implementing the waiver would be economically impractical for alternative producers and countries. Just as the existing 8-month delay in responding to the October waiver proposal has coincided with at least a million extra COVID-19 death, continued prevarication by the E.U. will leave many millions more in its former colonies waiting in line to die.

The Table below presents the relevant existing text of the TRIPS Agreement and the Doha Declaration, the pseudo-proposals on compulsory licensing clarifications put forth by the E.U. to the TRIPS Council, and critical commentary on the illusory impacts of what the E.U. has proposed.

TRIPS Agreement Article 31 and 31*bis* and Doha Declaration on the TRIPS Agreement and Public Health	**EU [Pseudo] Proposal to the TRIPS Council on Clarification of Compulsory Licensing rules**	**Critical Comments**
Doha ¶4: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be	¶10: "The discussions in the Council for TRIPS since the start of the COVID-19 pandemic have identified aspects related to the use of compulsory licensing that, in the view of a number of WTO Members, limit the use of this	• The EU underplays the concerns that waiver proponents and other expert commentators have advanced concerning the limited effectiveness of existing TRIPS flexibilities.

interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."	tool. In order to address these aspects, provide more legal certainty and enhance the effectiveness of the 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 licence, the remuneration for patent holders should reflect such affordable prices; and (c) The compulsory licence could cover any exports destined to countries that lack manufacturing capacity, including via the COVAX facility.	• Critics have pointed to the massive problems of coordination and cooperation in issuing compulsory licenses in multiple territories that must export patent protected components, intermediate products, and final formulations. • These complexities are doubled with the need to issue coordinated import licenses as well. • Moreover, the clarification will not be self-effectuating, countries, many of which have not previously adopted Article 31*bis* provisions domestically would have to do so. • Finally, TRIPS compulsory license provisions only deal with patent rights and do not address the confidential information, trade secret, regulatory data, and biologic resource protections that act as barriers to alternative producers of vaccines, biologics, and other COVID-19 health technologies, nor associated copyright and industrial design protections.
Doha ¶5(c): Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency	¶10: "The EU proposes to clarify that the circumstances of a pandemic fulfil the requirement of a national emergency and therefore the requirement to demonstrate the efforts to negotiate for a certain period of time can be waived."	EU proposes nothing that is not already exquisitely clear – countries have absolute sovereign discretion to determine what constitutes emergencies or matters of extreme urgency; epidemics are clearly intended to be covered; COVID-19 is both an emergency and global

or other circumstances of extreme urgency.		pandemic, even worse than an epidemic; and thus the EU clarification is worthless.
TRIPS §31(b) makes it clear that the requirement that the proposed user of a compulsory license make efforts "to obtain authorization from the rightholder for a reasonable period of time on commercially reasonable terms" is waived in the case of "a national emergency or other matter of extreme urgency or in cases of public, non-commercial use." Article 31(k) states further that prior negotiations for a voluntary license are not required for compulsory licenses addressing competition abuses.	¶10: "Therefore, the EU proposes to clarify that the waiving of the requirement to negotiate with the right holder applies also in the circumstances of Article 31bis."	The waiver of requirements to negotiate before issuing a compulsory license found in Article 31(b) and (f) already fully apply to Article 31 bis licenses. No one has ever suggested that Article 31 bis licenses addressing emergencies or government use needs would require prior negotiation. Once again, the EU clarification is worthless.
TRIPS §31(h): "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; ..."	¶12: The EU proposes to clarify that in the circumstances of a pandemic, WTO Members can set the remuneration to the right holder at a level that reflects the price charged by the manufacturer of the vaccine or therapeutic under a compulsory licence. This would support production and supplies of vaccines and therapeutics at affordable prices to low and middle-income countries.	The TRIPS Agreement already only requires adequate remuneration appropriate to the circumstances taking into account the economic value of the authorized CL. Adequate remuneration for issued compulsory licenses in the past have always been single digit royalties based on the generic price of the licensed medicine. Actual rates have varied from a fraction of 1% to 7.5%. The EU remuneration proposal offers nothing of value.
TRIPS §31*bis*2(c) the exporting Member shall notify[8] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[9] 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)**	¶12: "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."	Article 31bis already allows notification relating to multiple products and multiple countries. Nothing in the existing text suggests that exporting countries cannot already rely on a single notification document. Note, however, that the EU has not proposed a waiver of the requirement to specify

to which the product**(s)** is (are) to be supplied and the duration of the licence.		quantities, which means, new needs would still require new notices. As with all its other CL clarifications, the EU's third clarification is worthless.

Conclusion:

The E.U. proposal is meaningless and insulting. Its true purpose is obscuration and postponement of the proposed TRIPS waiver. The best evidence of this intention is found in the E.U.'s *Questions and Answers: EU Communications to the WTO – EU proposes a strong multilateral trade response to the COVID-19 pandemic*:

> [W]e want to maintain the levels of [IP] protection required for investment in innovation, so we can fight against new strains of COVID-19 and any future disease. **The EU does not consider that the broad waiver proposed by a number of WTO members is the right response to the pandemic. We are arguing for a different and more targeted approach**. …

Once again, even in describing the waiver, the E.U. misinterprets its probable impacts:

> **Waiving IP rights: All relevant rights are waived, i.e. the protection granted by patents, copyright or other IP rights ceases to exist for the duration of the waiver. The vaccine developer is not remunerated and has no role or information on the product. The absence of interaction between the vaccine developer and the producers makes the transfer of know-how unlikely**.

The revised waiver test does not discount remuneration and in fact says that incentives for innovation are important. Countries would clearly be free to provide remuneration after taking into account past public and charitable investments in the subject product. If the IP rightholders were truly interested in having some role with respect to out-licenses, they could join the WHO COVID-19 Technology Access Pool, which will only grant out-licenses to qualified licensees who can meet stringent quality and equitable distribution requirements. Likewise, the suggestion that transfer of know-how would be unlikely is directly contrary to what the waiver would permit. It would permit countries to require rightholders to transfer their confidential information, trade-secrets, and manufacturing know-how, as is routinely done is the industry's regular co-manufacturing and contract manufacturing agreements.

The best response would be to ignore it so that countries could move on to the serious task of adopting an effective waiver of IP rules at the WTO, implementing them domestically, and forcing Pharma to the bargaining table to extract new open licenses and technology transfer to speed access to lifesaving COVID-19 vaccines, therapies, tests, and personal equipment. The E.U. needs a rap on the knuckles to get back to the real business of addressing the abomination of vaccine apartheid.