Getting WTO Intellectual Property Barriers Out of the Way of Access to COVID-19 Vaccines, Treatments and Diagnostic Tests

How to Transform the WTO Secretariat's May 3 Counterproposal into the Actual Waiver for COVID-19 Vaccines that President Biden Promised

In May 2021, President Biden announced support for a temporary waiver of World Trade Organization (WTO) intellectual property barriers limiting access to COVID-19 vaccines. In October 2020, South Africa and India had tabled a broader waiver text to suspend pharmaceutical corporation monopolies over vaccines as well as other COVID-19 health products and technologies, including treatments and tests. Today more than 100 countries support a waiver, but the European Union, UK and Switzerland have blocked it. In May 2022, the WTO Director General submitted a counter proposal that European officials described as similar to their non-waiver approach of relying on existing WTO "flexibilities" that have proved ineffective in the COVID-19 pandemic context.

Prominent academic experts, public health advocates and generic manufacturers from South Africa, India and the rest of the world have made clear that the Secretariat's text will not result in greater global access to vaccines, tests and treatments. Former Secretary-General of the United Nations Ban Ki-Moon and Dr. Tedros Adhanom Ghebreyesus, head of the World Health Organization, have stressed the importance of achieving a full waiver of intellectual property rules on COVID-related technologies.

Indeed, the Secretariat's text would likewise fail to fulfill President Biden's narrower ambition of waiving Trade-Related Aspects of Intellectual Property (TRIPS) Agreement barriers only for COVID-19 vaccines. For the United States to deliver on its stated objective and achieve a waiver of WTO barriers for COVID-19 vaccines to help end the pandemic, U.S. trade negotiators must fight for these baseline changes to the Secretariat's May 2 text:

Changes Needed to the WTO Secretariat Text – TRIPS COVID-19 – 03 May 2022 (IP/C/W/688)

To be effective, a waiver must cover products for which there are pending patent applications, which is the status of most COVID-19 vaccines, and not only products that have been granted a patent.

An actual waiver of IP barriers would not reference TRIPS Art. 31. Art. 31 pertains to the most well-known *existing* TRIPS flexibility, which includes compulsory licensing. This flexibility has proved to be woefully insufficient to provide countries the ability to expand access to COVID-19 vaccines, which not only have scores of patents that would require compulsory licensing but other forms of IP to which these flexibilities may not apply at all. A core flaw of the proposed text is that it doesn't waive the underlying obligations nor do paragraphs 2-6 provide new flexibilities.

1. Notwithstanding the provision of patent rights under its domestic legislation, ***[the obligation of]*** an eligible Member[1] ~~may limit the rights provided for~~ under Article 28.1 of the TRIPS Agreement (hereinafter "the Agreement") ***[shall be waived in relation to]*** ~~by authorizing~~ the use of ***the*** ~~patented~~ subject matter ***of a patent or a patent application***[2] required for the production and supply of COVID-19 vaccines ~~without the consent of the rights holder to the extent necessary to address the COVID-19 pandemic, in accordance with the provisions of Article 31 of the Agreement, as clarified and waived in paragraphs 2 to 6 below.~~

These are eligibility criteria that limit which countries may use this waiver. This provision reflects political pressures to exclude certain WTO Member countries, particularly China and Russia.

The changes reflect what is necessary to get WTO patent barriers out of the way. TRIPS Art. 28.1 imposes an obligation on WTO Members to grant a monopoly over patented products and/or processes to the right-holder. This obligation needs to be waived, not partially limited, for countries to have the "freedom to operate" necessary to produce vaccines.

This clause must go. No "necessity" tests can be required because they limit the application of a waiver. Language such as "to the extent necessary" in the context of the WTO opens government actions up to second guessing, intrusive scrutiny and subjective decisions about a policy's degree of "trade restrictiveness" and thus whether it is allowed.

[1] [For the purpose of this Decision, all developing country Members are eligible Members. Developing country Members with capacity to export vaccines are encouraged to opt out from this Decision.] [For the purpose of this Decision, developing country Members who exported more than 10 percent of world exports of COVID-19 vaccine doses in 2021 are not eligible Members.].

[2] For the purpose of this Decision, it is understood that ***'subject matter of a patent or patent application'*** 'patented subject matter' includes ingredients and processes necessary for the manufacture of the COVID-19 vaccine.

The first alternative is unacceptable because the very purpose of the waiver is to unleash global production capacity that can cover the health needs of every country, including those with insufficient or no pharmaceutical production capacity. Encouraging Members that can export vaccines to not do so defeats the whole endeavor.

The second option is also problematic as it doesn't define which Members ARE eligible and it seems designed to exclude China but paradoxically could leave in Russia, the United States, EU countries, etc.

2. For greater clarity, an eligible Member may authorize the use of patented subject matter under Article 31 without the right holder's consent through any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place. For the purpose of this Decision, the "law of a Member" referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders.

This is a clarification of what the text of TRIPS Art. 31 already permits, rather than a waiver of IP barriers. If a waiver is enacted, this clarification is not needed immediately. However, given some countries and many pharmaceutical firms have challenged the use of the Art. 31 flexibilities, such a clarification could be usefully included in a WTO ministerial text; however, in a form that applies generally beyond the pandemic context.

3. Members agree on the following clarifications and waivers for eligible Members to authorize the use of patented subject matter in accordance with paragraphs 1 and 2:

Again, this is not a "waiver" of IP. It is a reiteration of the existing WTO flexibilities in TRIPS Art. 31 with TRIPS-plus requirements, plus one small obligation relating to procedures for compulsorily licensed medicines' export that is actually waived. Except countries will not get to the point of exporting because none of the IP barriers that limit production are waived.

(a) [With respect to Article 31(a), an eligible Member may issue a single authorization to use the subject matter of multiple patents necessary for the production or supply of a COVID-19 vaccine. The authorization shall list all patents covered. In the determination of the relevant patents, an eligible Member may be assisted by WIPO's patent landscaping work, including on underlying technologies on COVID-19 vaccines, and by other relevant sources. An eligible Member may update the authorization to include other patents.][3]

This is already allowed under existing WTO rules – specifically TRIPS Art. 31. This language could be included in a general clarification but provides no new flexibilities.

This language imposes new obligations and limitations on countries relative to the existing TRIPS Art. 31 flexibilities. This TRIPS-plus requirement must be eliminated or it would create insurmountable hurdles for countries that might even try to use the mechanism that this text incorporates. The reference to WIPO does not fix this problem. WIPO vaccine patent landscapes are complex and rapidly outdated. It's almost impossible to know all of the patents that can be related to COVID-19 vaccines, thus this sort of listing requirement guts the use of this counterproposal. Thus, with the addition of this new requirement, countries would be better off using existing TRIPS flexibilities. Yet, these have proved ineffective for COVID-19 vaccines.

(b) An eligible Member need not require the proposed user of the patented subject matter to make efforts to obtain an authorization from the right holder for the purposes of Article 31(b).

This is already possible in emergencies, matters of extreme urgency and for public non-commercial use under TRIPS Art. 31.

(c) An eligible Member may waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market and may allow any proportion of the authorized use to be exported to eligible Members and to supply international or regional joint initiatives that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by the authorization.

This is the only 'waiver' in the Secretariat text but if Art. 28.1 barriers are removed, it wouldn't be necessary to include it for the production of COVID-19 vaccines. This provision by itself might be of some limited benefit. However, the failure to waive the IP barriers limiting production greatly diminishes the benefit of making it easier to export. Absent waivers of the IP barriers to production, this clause would mainly be useful for export of COVID treatments. (Because, in contrast to the vaccines, they are small molecule drugs with fewer IP monopolies, they would be easier to produce under a compulsory license.)

(d) Eligible Members shall undertake all reasonable efforts to prevent the re-exportation of the COVID-19 vaccine that has been imported into their territories under this Decision. All Members shall ensure the availability of effective legal remedies to prevent the importation into their territories of COVID-19 vaccines produced under, and diverted to their markets inconsistently with, this Decision.

This is a TRIPS-plus requirement that is aimed at addressing a diversion problem that has never materialized in the past and would add enforcement burdens to countries wanting to use the decision.

(e) Determination of adequate remuneration under Article 31(h) may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members. In setting the adequate renumeration in these cases, eligible Members may take into consideration existing good practices in

Nothing new here. WTO Members are already free under TRIPS Art. 31 to determine what's adequate remuneration.

[3] This paragraph is under further consideration as to whether to keep or delete.

~~instances of national emergencies, pandemics, or similar circumstances.~~[4]

4. *[The obligations of (eligible?) Members to implement or apply]* ~~Nothing~~ in Article 39.~~3~~ of the Agreement shall *[be waived to guarantee that nothing]* prevent*[s]* a Member from taking measures necessary to enable the effectiveness of any authorization issued as per this Decision.

5. For purposes of transparency, as soon as possible after the adoption of the measure, an eligible Member shall communicate to the Council for TRIPS any measure related to the implementation of this Decision, including the granting of an authorization.[5]

6. An eligible Member may apply the provisions of this Decision until ~~[3]~~[5] years from the date of this Decision. The General Council may extend such a period taking into consideration the exceptional circumstances of the COVID-19 pandemic. The General Council will review annually the operation of this Decision.

7. Members shall not challenge any measures taken in conformity with this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of the GATT 1994 *[or through the WTO's Dispute Settlement Mechanism.]*

8. No later than six months from the date of this Decision, Members will decide on its extension to cover the production and distribution of COVID-19 diagnostics and therapeutics.

~~[4] This includes the Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO (WHO/TCM/2005.1)~~

~~[5] The information provided shall include the name and address of the authorized entity, the product(s) for which the authorization has been granted and the duration of the authorization. The quantity(ies) for which the authorization has been granted and the country(ies) to which the product(s) is(are) to be supplied shall be notified as soon as possible after the information is available~~

The Secretariat proposal is framed as a clarification of a TRIPS obligation that requires countries to protect undisclosed test and other data submitted to obtain marketing approval of a pharmaceutical product and provides for exceptions to that rule. However, the actual text simply states that one part of the obligation (Art 39.3) is not a problem without waiving the obligation. Moreover, it limits the existing exception with a "necessary test" and application only in the context of a compulsory license issued using the mechanism of the Secretariat text. To meet Pres. Biden's goal of great vaccine production, all of Art. 39 must be waived. That provision requires "undisclosed information" related to a pharmaceutical product be kept secret. Drug manufacturing information is often classified as "trade secrets" or "undisclosed information" by companies. A full Art. 39 waiver is needed so that countries are able to share information about how a vaccine is made and related test data with capable manufacturers so they can get production started promptly rather than having to reverse engineer a vaccine and do new clinical trials.

The waiver duration must be long enough to create incentives for countries and manufactures to invest in developing sustainable production capacity.

The Secretariat's text allows countries to challenge another country's efforts to use of this mechanism with a WTO tribunal empowered to decide if a country's action is allowed. (The reference to GATT Art. XXIII excludes only two specific bases for a challenge.) In contrast, the waiver text explicitly forbids any and all challenges of countries' actions taken according to its terms. The added clause comes from the original waiver text.

These notification requirements are unnecessary and burdensome. The existing flexibilities don't require sharing this extensive list of information.

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The redlined version above proposes the baseline changes needed to deliver on the explicit promise President Biden made – to "waive IP barriers" for COVID-19 vaccines.

However, since May 5, 2021 when President Biden made that commitment, new effective COVID-19 treatments have been developed. Broad, global access to these lifesaving medicines is essential to saving lives, avoiding economic disruption and getting the pandemic under control. And, to effectively use these treatments, and to detect new outbreaks, broad global access to diagnostic testing tools is also critical. Indeed, rich countries are moving towards a test-and-treat strategy to deal with COVID-19. There is no economic, political or moral reason to prevent low- and middle-income countries from taking the same steps. Thus, the Biden administration should advocate for diagnostics and treatments to be included in a waiver from the outset.