



WORLD TRADE ORGANISATION (WTO)
Council for Trade-Related Aspects of
Intellectual Property Rights (TRIPS Council)

**AIPPI's position paper on the Ministerial Decision on the TRIPS Agreement
adopted on 17 June 2022**

12 September 2022

This position paper is submitted in relation to the Ministerial Decision on the TRIPS Agreement adopted on 17 June 2022 within the WTO. AIPPI has not yet officially adopted a resolution on the matter, but it has had two of its standing committees study the matter and present their views with the belief that they are both useful and likely to represent the views of the Association as a whole. Accordingly, this position paper has been prepared by AIPPI's Standing Committees on TRIPS and Pharma, been approved by the AIPPI Bureau and constitutes a follow up to that published last year on 12 May 2021¹ on the proposal for a waiver for certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19. We attach hereto said position document as Annex A for easier reference.

A. INTRODUCTION TO AIPPI

Please refer to the corresponding passage in page 1 of Annex A.

B. BACKGROUND

The result of discussions within the WTO TRIPS Council on the waiver proposal resulted in document WT/MIN(22)/30 WT/L/1141² under the title "Ministerial Decision on the TRIPS Agreement" adopted by the 12th Ministerial Conference of the WTO on 17 June 2022 (hereinafter the Decision). While the Decision is limited in scope with respect to the original waiver proposal, it raises serious concerns regarding its possible implications as we detail below.

C. POSITION POINTS

1. AIPPI recalls the statements made at points B.4 – B.9 of our position paper dated 12 May 2021. Consequently, AIPPI does not endorse law changes, statements or suggestions addressing Intellectual Property (IP) Rights as actual or potential barriers to access to products or services of any kind, specifically in this case vaccines covered by patent rights, without a clear and predictable legal framework. In our view, the Decision implies unjustified and incorrect assumptions.
2. As stated, AIPPI has supported the right of the WTO members to use the flexibilities already provided by the TRIPS agreement to protect public health, including those established in Articles 8, 31, 31bis and the Doha Declaration of the TRIPS Agreement and Public Health³, and encouraged members to implement functional domestic legal frameworks enabling them swiftly to do so. At the same time, we called for appropriate

¹ https://aippi.org/wp-content/uploads/2021/05/AIPPI-Position-Paper-on-WTO-Waiver_12May2021.pdf

² <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:WT/MIN22/30.pdf&Open=True>

³ https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

assessment of the execution, implementation and effects of changes in legal systems before any such a change is effected, as provided in points 8 and 9 of Annex A.

3. The Decision fails to safeguard the incentives that allowed multiple innovators to develop, produce and deploy globally in record time effective vaccines that have helped reducing the COVID-19 pandemic threat. It fails to analyse and address the reasons that prevented effective vaccine delivery, as it is broadly known that trade barriers and logistic inefficiencies have severely undermined efforts to deliver vaccines^{4,5}. Instead, without tackling such trade and logistic inefficiencies, diminishing IP rights has been assumed to resolve insufficient access to vaccines.
4. We note that our call for appropriate assessment of legal predictability as well as of the effectiveness of changes to legal systems before said changes take place does not seem to have been taken into account by the Decision, as it is evidenced by a plurality of aspects in the Decision requiring clarification such as:
 - a. The definition of “developing country” in footnote 1, and therefore “eligible Member” in the whole Decision, since to our knowledge WTO does not provide a list of countries complying with such qualification as in the case of least developed countries⁶.
 - b. The broadness of “subject matter of a patent” which is defined by a nonlimiting language in footnote 2. We would note additionally that identifying the patents even potentially implicated by a particular vaccine is a non-trivial exercise and there is no certainty that a single, agreed view could be reached. One country may consider a certain patent to be implicated, and another may not. This uncertainty would create an unpredictable system for licensing and could even incentivise countries to insist on a compulsory licence to *all* of the patents of certain vaccine developers, which is clearly disproportionate and unjustified.
 - c. The vague boundaries of the language “to the extent *necessary* to *address* the COVID-19 pandemic” in point 1, which requires the assessment of a “necessity” without further guidance to do so provided by the Decision.
 - d. The extensive discretion provided for by the language “law of the Member” in point 2 allowing governments to invoke any instrument including those not currently existing but expressly enacted to authorize the use of patented subject matter without the rights holder’s consent and the inexplicable entitlement given to developing countries that have enacted compulsory license mechanisms to be able to directly make use of the Decision without previously deploying efforts to trigger said mechanisms (which already provide for licensing under reasonable conditions) or adjust the same to face the COVID-19 pandemic if proven deficient or mendable.
 - e. The incomplete clarification at 3(c) intended to prevent the re-exportation of *products* manufactured under the authorization *in accordance with the Decision* that have been imported into a territory, in conjunction with the broad discretion to define “exceptional circumstances” for an eligible Member to be able to re-export COVID-19 vaccines to another eligible Member, which do not seem to avoid the exportation of vaccines manufactured from ingredients (products) imported by the another eligible Member since strictly said vaccines would not be the same as the products imported in accordance with the Decision.
 - f. The silence in the Decision on the issue of parallel imports, which is relevant to countries in which exhaustion of rights requires putting products in their markets

⁴ <https://www.oecd.org/coronavirus/policy-responses/covid-19-and-international-trade-issues-and-actions-494da2fa/>

⁵ <https://www.ifpma.org/global-health-matters/why-we-must-remove-barriers-to-trade-to-achieve-vaccine-equity-step-3/#:~:text=Skilled%20workers%20are%20needed%20to,supply%20of%20COVID%2D19%20vaccines.>

⁶ https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf

with the authorisation of patent holders while strictly under point 2 of the Decision such an authorisation would not be obtained.

- g. The vague and incomplete language at point 4 relating to Article 39(3) TRIPS, namely data exclusivity, failing to expressly preserve non-disclosure obligations and which impact depends on regulations and procedures for marketing authorisation of eligible Members, but which might be construed to the unacceptable extent to authorise regulatory entities to disclose exclusive data or force vaccine originators to share said data. In our opinion, this is contradictory to the WTO call for sharing regulatory information on a voluntary basis to face the current COVID-19 and future pandemics as encouraged in point 11 of the “Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics”⁷ dated 22 June 2022.
 - h. The undefined deadline and kind of information to be provided by an eligible Member that has adopted a measure to comply with the transparency clause in accordance to point 5 of the Decision.
 - i. The unjustified pre-set possibility to apply the provisions of the Decision for five years at point 6 of the Decision without limitation to reaching at least certain degree of control of the COVID-19 pandemic in an eligible Member, further posing questions on the actual outcome and utility of the annual review of the operation of the Decision by the General Council.
 - j. The lack of explicit possible counteractions at point 7 available to Members enabling them to challenge measures taken by an eligible Member when such measures are not considered to be in conformity with the Decision. Point 7 seems to shield eligible Members from being questioned by simply invoking that a measure has been taken in conformity with the Decision.
5. In consequence of the above, AIPPI does not support the possible extension of the Decision to cover the production and supply of COVID-19 diagnostics and therapeutics as a probable outcome of point 8 of the Decision, and encourages WTO TRIPS Council members not to approve such an extension since it may represent a disincentive for any innovators which includes a broad range of entities (pharmaceutical companies, physicians, biotechs, researchers, public institutions, universities, students, hospitals) as well as financial institutions that operate in the health environment (banks, governments which provide grants, business angels, etc) to decide to invest in the research and development of new medicines and new uses for old medicines. Besides, there is no evidence that expanding the Decision will improve access to the targeted products.
 6. AIPPI reiterates its commitment to the improvement of IP right systems, particularly for the protection of innovation. We trust that innovation will continue to provide solutions to help our societies overcome challenges and crisis such as the current COVID-19 pandemic, and that a suitable protection system balancing the right to all to access to health is the correct approach to follow in order to face present and future adverse situations rather than simply trying to override IP rights.

Encls. Annex A. *AIPPI's position paper on the waiver for certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19 proposed by some countries within the WTO.*

⁷ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True>