

## **STATEMENT**

## TRIPS WAIVER: AN INSUFFICIENT MULTILATERAL RESPONSE. TRIPS-CONSISTENT NATIONAL ACTIONS ARE CALLED FOR

After almost 20 months from the submission of a "TRIPS waiver" request by India and South Africa, co-sponsored by 65 WTO member States (and supported by more than 100 WTO Members), a "Ministerial Decision on the TRIPS Agreement" (WT/MIN(22)/W/15/Rev.2) ('the Decision') was belatedly adopted by the 12<sup>th</sup> Ministerial Conference of the World Trade Organization on 17 June 2022.

This Decision does recognize that, as argued by developing countries and a large number of organizations and academics, intellectual property (IP) poses obstacles for the expansion of manufacturing capacity and timely access to health products and technologies to respond to COVID-19. The response to the pandemic required a rapid increase in the supply of countermeasures, while technology holders refused to share their technologies.

However, despite the efforts by the proponents and sponsors of the TRIPS waiver, WTO developed country members aligned with the narrative of the pharmaceutical industry (which benefitted from massive public investment to develop COVID-19 vaccines) and the unproven argument that a TRIPS waiver, even if temporary and limited to address the current pandemic, would irreparably jeopardize innovation.

The original TRIPS waiver proposal aimed at waiving the application of sections 1,4,5 and 7 of part II and their related enforcement obligations under part III of the TRIPS Agreement, in relation to health products and technologies for the prevention, treatment or containment of COVID-19. The covered health products and technologies included vaccines, diagnostics, therapeutics, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture.

The Decision, however, only waives certain provisions relating to the grant of compulsory licenses under article 31 of the TRIPS Agreement, and provides some clarifications in relation to that article and article 39.3 (regarding test data protection). The Decision is limited to patents over vaccines to address COVID-19; negotiations need to continue to extend it to therapeutics and diagnostics.

The adopted provisions and clarifications may, as such, facilitate the grant of compulsory licenses at the national level. In practical terms, however, given the Decision's limited reach and the conditionalities imposed for their potential use, it does not represent a genuine response to the TRIPS waiver request. In a 'Statement following the conclusion of the WTO Ministerial Conference', the United Kingdom has stressed that "this is not

about waiving IP rights. This decision should make it easier for developing countries to export the vaccines they produce within existing flexibilities". 1

Not only developed countries successfully deviated the negotiations towards an outcome different from what was pursued by developing countries' diplomats; the process for its adoption did not allow for the full and informed participation of the latter. Like in other negotiating areas, the methodology of arbitrarily constituted small negotiating groups, including 'green rooms', made a strong come back to the WTO. Although the WTO Rules of Procedure require texts to be submitted 12 hours before the meeting for their adoption, the Decision was presented at the Conference's plenary for its immediate adoption.

The multilateral negotiating process has, in summary, been too slow and unbalanced to respond to the urgent needs of the largest part of the world population. WTO Members can and should consider other options consistent with their international obligations and national contexts to respond to the current (and future) pandemic(s). In particular, they can:

- i) use the compulsory license system in conformity with article 31 of the TRIPS Agreement,<sup>2</sup> without being subject to limitations regarding products, duration of the authorization and re-exportation/ importation as established in the Decision;
- ii) invoke the national security exception contained in article 73 of the TRIPS Agreement and suspend the substantive and enforcement obligations in relation to any COVID-19 related products;<sup>3</sup>
- iii) interpret article 30 of the TRIPS Agreement, consistently with the rules of interpretation of customary international law, to allow for the manufacture and export of such products;<sup>4</sup>
- iv) allow for the parallel importation of products manufactured under a compulsory license, in accordance with the freedom to regulate on this matter recognized under article 6 of the TRIPS Agreement.<sup>5</sup>

The process leading to the Decision confirms the need to fully use the TRIPS flexibilities to address emergency and other situations where public health and other public interests are at stake, and to review the current international IP regime (including article 31bis of the TRIPS Agreement) to accelerate the sharing of technology, including know-how. The South Centre remains ready to support national and regional efforts to this end.

<sup>&</sup>lt;sup>1</sup> See <a href="https://www.gov.uk/government/news/uk-statement-following-the-conclusion-of-the-wto-ministerial-conference">https://www.gov.uk/government/news/uk-statement-following-the-conclusion-of-the-wto-ministerial-conference</a> (emphasis added).

<sup>&</sup>lt;sup>2</sup> The national compulsory licensing system may need to be reviewed/improved and regulations adopted to streamline the grant of such licenses.

<sup>&</sup>lt;sup>3</sup> See Frederick Abbott, "The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic", Research Paper 116 (Geneva, South Centre, August 2020). Available from https://www.southcentre.int/wp-content/uploads/2020/08/RP-116-reduced 1.pdf.

<sup>&</sup>lt;sup>4</sup> See Carlos M. Correa and Juan I. Correa, "Manufacturing for Export: A TRIPS-Consistent Pro-Competitive Exception", Research Paper 155 (Geneva, South Centre, May 2022). Available from <a href="https://www.southcentre.int/wp-content/uploads/2022/05/RP155">https://www.southcentre.int/wp-content/uploads/2022/05/RP155</a> Manufacturing-for-Export-A-TRIPS-Consistent-Pro-Competitive-Exception EN.pdf.

<sup>&</sup>lt;sup>5</sup> If the relevant products were patented in the eligible importing country and parallel imports were not allowed, a compulsory license may also need to be granted in the importing country.