

Submission by the South Centre to the USITC hearing on Covid-19 diagnostics and therapeutics

17 March 2023

The South Centre is an intergovernmental organization of 55 developing countries, see www.southcentre.int

We fully supported the proposal submitted by India, South Africa and other co-sponsors in March 2020 to temporarily waive certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to support the global Covid-19 pandemic response. See <https://www.southcentre.int/statement-october-2020/>

Two years later, it is evident that the waiver, as originally proposed, would have helped to overcome intellectual property barriers to accelerate the manufacturing across regions of medical countermeasures for Covid-19, increasing the global production and lowering the cost for these. The waiver was meant to be a rapid, emergency measure to respond to the Covid-19 pandemic. Rapid, scaled up production of diagnostics, free from intellectual property barriers, would have helped with the early identification of cases, helping to avoid the spread of Covid-19. Instead, lengthy discussions based on theoretical, unproved arguments of potential disincentive to innovation disarrayed effective action by WTO members. The WTO failed to provide an adequate response to pandemic. The United States had since March 2020 to consider the proposal, and it is baffling that it has taken the initiative only in 2022 to commence this process, further delaying any action at the WTO.

Intellectual property, in the pandemic context, is not the main enabling factor for mobilizing investments and broadening collaborations to deliver and accelerate the necessary innovation. Public sector financing and research capacity together with other support measures were at the core of the success in the discovery of Covid-19 vaccines, and likewise for treatments and diagnostics. Allowing legal monopolies proved to delay vaccine rollout and treatments from becoming available, as evidenced by rising disputes on infringement of intellectual property rights. Moreover, as new diagnostics, therapeutics and vaccines are developed, intellectual property rights and reluctance to share related know-how were barriers to the rapid scale up for timely supply at affordable prices in all countries. This situation was evident in the set up and functioning, to date, of the mRNA hub supported by the WHO and based in South Africa. Right holders did not show willingness to voluntarily licence IP and transfer technology and know-how when it was most crucial to do so – from the outset of the Covid-19 pandemic.

The TRIPS waiver for Covid-19 vaccines should be extended to diagnostics and therapeutics, with the aim to promote increased affordability and local manufacturing in developing countries. The control of production of these essential products by a limited number of manufacturers is a global health risk. Current voluntary licences under the Medicines Patent Pool (MPP) and bilateral voluntary licences do not cover all geographical territories, for example for Paxlovid the license with the MPP only covers 95 countries. The demand for

diagnostics and therapeutics is variable, given that new waves of infection can happen at any time.

The South Centre considers that as part of pandemic preparedness, there is need for multilateral agreement to ensure timely production and distribution of medical countermeasures. This agreement should include commitment for governments, particularly from developed countries, to temporarily waive the provisions for the protection and enforcement of intellectual property rights in the TRIPS Agreement, and restrain from pressuring developing countries, including through mechanisms such as the USTR Special 301 report, to refrain from the use of the TRIPS flexibilities to protect public health, which is contrary to the Doha Declaration on TRIPS and Public Health.

For further views by the South Centre, please see:

- South Centre Statement on the extension of the TRIPS waiver for diagnostics and therapeutics for COVID-19, January 2023, <https://www.southcentre.int/statement-on-extension-of-trips-waiver-for-covid-19-diagnostics-therapeutics-9-january-2023/>
- South Centre Statement, TRIPS WAIVER: AN INSUFFICIENT MULTILATERAL RESPONSE. TRIPS-CONSISTENT NATIONAL ACTIONS ARE CALLED FOR, June 2022, <https://www.southcentre.int/sc-statement-trips-waiver-21-june-2022/>
- Carlos M. Correa and Nirmalya Syam, Analysis of the Outcome Text of the Informal Quadrilateral Discussions on the TRIPS COVID-19 Waiver, Policy Brief 110, May 2022, <https://www.southcentre.int/policy-brief-110-5-may-2022/>
- Carlos M. Correa and Nirmalya Syam, The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement it?, Research Paper 169, November 2022, <https://www.southcentre.int/research-paper-169-8-november-2022/>