

## PROPOSAL BY INDIA AND SOUTH AFRICA TO WAIVE CERTAIN PROVISIONS OF THE WTO TRIPS AGREEMENT TO SUPPORT THE GLOBAL COVID-19 PANDEMIC RESPONSE

### 6 October 2020

The prolongation of the coronavirus COVID-19 pandemic threatens developing countries disproportionately, deepening the catastrophic social and economic crisis and reversing the gains made to date to eradicate extreme poverty and meet the Sustainable Development Goals (SDGs). In this situation, ensuring timely access to essential commodities by overcoming acute shortages faced by countries due to high demand and disruptions in the supply chain is critical. There is also an urgent need to speed up development of new vaccines, treatments and diagnostics, at scale, and make these widely available.

As reaffirmed by many delegations in the-special session of the WHO Executive Board, transfer of technology and know-how is fundamental for scaling up manufacturing of medical products and equipment. In this regard, India and South Africa have made a joint proposal to the World Trade Organization (WTO) 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.

The South Centre strongly supports the proposal and strongly urges other G77 countries that are WTO members to extend their support and co-sponsorship in the upcoming TRIPS Council meeting on 15-16 October 2020 to forward a request to the General Council for the adoption of the proposed decision (see below).

The intellectual property system is meant to provide a balance between providing incentives for bringing about innovation and rewarding creativity, and promoting the broader public interest. At the same time, the intellectual property system also interacts with other legal systems. In the area of public health, intellectual property objectives must also be balanced against realising the right to health, of which access to medicines and other health products is a central part.

Accelerating the rate of innovation for medical products to address Covid-19 is a priority that all governments recognize. Direct public financing is enabling rapid research and development, as well as the good will to increase collaboration. Pooling financial and scientific resources is the only option for accelerating progress towards new vaccines, treatments and diagnostics. 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. Allowing legal monopolies may delay vaccines and treatments 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 may act as barriers to the rapid scale up for timely supply at affordable prices in all countries. To date, right holders have not shown willingness to

provide voluntary licenses to pool protected technology and knowledge as part of the access to COVID-19 Tools Accelerator (ACT-Accelerator). Developing countries cannot afford an extended time lag for vaccines and treatments to reach their populations. Scaling up manufacturing capacity to enable timely access, including in developing countries, must happen now.<sup>1</sup> As many products are currently in various stages of development, there is uncertainty about the type of IP rights such products might entail. This can create uncertainty for scaling up local manufacturing in developing countries.

The WTO TRIPS Agreement establishes international obligations on the protection and enforcement of intellectual property rights. It allows limited policy measures to be adopted to protect public health, as reaffirmed by the Doha Declaration on TRIPS and Public Health, which includes compulsory licenses.<sup>2</sup> However, these must be deployed on a case by case basis, and must be enabled in national legal framework and regulations, which currently may not be the case with many countries. Invoking compulsory licensing on product specific basis across a wide range of health products may be cumbersome. Many countries are reviewing their legislations to enable their use.<sup>3</sup> Countries may also invoke security exceptions of Article 73 of the TRIPS Agreement as a legal basis to suspend intellectual property rights, which would be subject to the unilateral actions of countries.<sup>4</sup>

Moreover, as pointed out in the previous session of the TRIPS Council, in addition to patents, other forms of IP rights such as copyrights, industrial designs, and trade secrets can also apply to products and technologies required for responding to COVID-19.<sup>5</sup> This necessitates enabling a broader application of flexibilities beyond patents to such other forms of IP rights.

India and South Africa are calling for the WTO Members to agree to waive some of the obligations under the TRIPS Agreement on protection and enforcement of patents, copyright and related rights, industrial designs and protection of undisclosed information during the Covid-19 pandemic. The waiver would absolve all countries from implementing the referred obligations for a limited time period, extending policy space for governments and extending freedom to operate to parties without risk of infringing such intellectual property rights, while ensuring legal certainty that actions are compliant with WTO international rules on trade related aspects of intellectual property rights. This is essential for WTO members to be able to comply with their human rights obligations. The adoption of this proposal will overcome potential obstacles that some categories of intellectual property rights may create to get timely and unfettered access to technologies and products needed to address the pandemic. It will not affect, however, the enforcement of other categories of rights covered by the TRIPS Agreement, nor its full implementation in relation to matters unrelated to the prevention, containment or treatment of COVID-19. Therefore, the adoption of this proposal is critical to

<sup>2</sup> See South Centre's Policy Brief 73, available at <u>https://www.southcentre.int/wp-</u> <u>content/uploads/2020/04/PB73\_The-COVID-19-Pandemic-RD-and-Intellectual-Property-Management-for-</u> Access-to-Diagnostics-Medicines-and-Vaccines\_EN-3.pdf

<sup>&</sup>lt;sup>1</sup>see South Centre's Research Paper 118, available at https://www.southcentre.int/wp-content/uploads/2020/09/RP\_118\_reduced-1.pdf

<sup>&</sup>lt;sup>3</sup> See South Centre's Policy Brief 80, available at https://www.southcentre.int/wp-content/uploads/2020/06/PB-80.pdf

<sup>&</sup>lt;sup>4</sup> See South Centre's Research Paper 116, available at https://www.southcentre.int/wp-content/uploads/2020/08/RP-116.pdf

<sup>&</sup>lt;sup>5</sup> See South Centre's SouthNews report, "WTO TRIPS Council discusses national IP measures and TRIPS flexibilities in the context of COVID-19", available at https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=184960e08b

ensure availability of medical products at affordable price for the prevention, containment and treatment of COVID 19.

The full proposal text, WTO document <u>IP/C/W/669</u>, follows below.

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# WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19

### COMMUNICATION FROM INDIA AND SOUTH AFRICA

- 1. On 11 March 2020, the World Health Organization (WHO) declared the coronavirus disease 2019 (COVID-19) to be a global pandemic, after having announced a related public health emergency of international concern (PHEIC) on 30 January 2020.
- 2. The World Trade Organization (WTO) has cautioned that the "pandemic represents an unprecedented disruption to the global economy and world trade, as production and consumption are scaled back across the globe".[1] We have witnessed a break down in global supply chains coupled with growing supply-demand gaps.
- 3. Given this present context of global emergency, it is important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19.
- 4. The COVID-19 pandemic is now widespread, affecting most WTO Members. As at 1 October 2020, there were about 333,722,075 confirmed cases globally with 1,009,270 confirmed deaths.[2] To date, there is no vaccine or medicine to effectively prevent or treat COVID-19. All WTO Members are struggling to contain the spread of the pandemic and provide health care services to those affected. Many developed, developing and least developed countries have declared a national emergency with the aim to curb the growing outbreak, and as advised by the WHO implemented social distancing measures with significant consequences for society and the economy. Notably, developing countries and least developed countries are especially disproportionately impacted.
- 5. An effective response to COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.
- 6. The outbreak has led to a swift increase in global demand with many countries facing acute shortages, constraining the ability to effectively respond to the outbreak. Shortages of these products has put the lives of health and other essential workers at risk and led to many avoidable deaths. It is also threatening to prolong the COVID-19 pandemic. The longer the current global crisis persist, the greater the socio-economic fallout, making it imperative and urgent to collaborate internationally to rapidly contain the outbreak.
- 7. As new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities

and at affordable price to meet global demand. Critical shortages in medical products have also put at grave risk patients suffering from other communicable and non-communicable diseases.

- 8. To meet the growing supply-demand gap, several countries have initiated domestic production of medical products and/or are modifying existing medical products for the treatment of COVID-19 patients. The rapid scaling up of manufacturing globally is an obvious crucial solution to address the timely availability and affordability of medical products to all countries in need.
- 9. There are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients.[3] It is also reported that some WTO Members have carried out urgent legal amendments to their national patent laws to expedite the process of issuing compulsory/government use licenses.
- 10. Beyond patents, other intellectual property rights may also pose a barrier, with limited options to overcome those barriers. In addition, many countries especially developing countries may face institutional and legal difficulties when using flexibilities available in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). A particular concern for countries with insufficient or no manufacturing capacity are the requirements of Article 31*bis* and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products.
- 11. Internationally, there is an urgent call for global solidarity, and the unhindered global sharing of technology and know-how in order that rapid responses for the handling of COVID-19 can be put in place on a real time basis.
- 12. In these exceptional circumstances, we request that the Council for TRIPS recommends, as early as possible, to the General Council a waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19.
- 13. The waiver should continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity hence we propose an initial duration of [x] years from the date of the adoption of the waiver.
- 14. We request that the Council for TRIPS urgently recommends to the General Council adoption of the annexed decision text.

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ANNEX

### DRAFT DECISION TEXT

WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19

<sup>&</sup>lt;sup>[1]</sup> <u>https://www.wto.org/english/tratop\_e/covid19\_e/covid19\_e.htm.</u>

<sup>&</sup>lt;sup>[2]</sup> <u>https://covid19.who.int.</u>

<sup>&</sup>lt;sup>[3]</sup>See e.g. <u>https://www.bloomberg.com/news/articles/2020-03-20/world-war-ii-style-production-may-carry-legal-risks-for-patriots; https://eu.courier-journal.com/story/news/2020/04/03/beshear-calls-3-m-release-patent-n-95-respirator-amid-pandemic/5112729002/</u>

The General Council

*Having regard* to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

*Conducting* the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

*Noting* that the coronavirus disease 2019 (COVID-19) is a new infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);

*Recalling* that on 11 March 2020, the World Health Organization (WHO) declared the 2019–20 coronavirus outbreak to be a pandemic, and it continues to be a very high risk across the globe in all WTO Members;

*Noting with concern* the threat to human health, safety and well-being caused by the COVID-19 pandemic, which has spread all around the globe, as well as the unprecedented and multifaceted effects of the pandemic, including the severe disruption to societies, economies, global trade and travel and the devastating impact on the livelihoods of people;

*Recognising* the need for unimpeded and timely access to affordable medical products including diagnostic kits, vaccines, medicines, personal protective equipment and ventilators for a rapid and effective response to the COVID-19 pandemic;

*Recognizing* also that the COVID-19 global pandemic requires a global response based on unity, solidarity and multilateral cooperation;

*Noting* that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement);

Decides as follows:

- 1. The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to prevention, containment or treatment of COVID-19, for [X] years from the decision of the General Council.
- 2. The waiver in paragraph 1 shall not apply to the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement.
- 3. This decision is without prejudice to the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement.
- 4. This waiver shall be reviewed by the General Council not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement.
- 5. Members shall not challenge any measures taken in conformity with the provision of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO's Dispute Settlement Mechanism.