

IP/C/W/669/Rev.1

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(21-4307)

Original: English

Council for Trade-Related Aspects of Intellectual Property Rights

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

REVISED DECISION TEXT

COMMUNICATION FROM THE AFRICAN GROUP, THE PLURINATIONAL STATE OF BOLIVIA, EGYPT, ESWATINI, FIJI, INDIA, INDONESIA, KENYA, THE LDC GROUP, MALDIVES, MOZAMBIQUE, MONGOLIA, NAMIBIA, PAKISTAN, SOUTH AFRICA, VANUATU, THE BOLIVARIAN REPUBLIC OF VENEZUELA AND ZIMBABWE

By means of a communication dated 21 May 2021, the following document is circulated at the request of the delegations of the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe.

1. On 2 October 2020 India and South Africa submitted to the Council for TRIPS communication IP/C/W/669 containing a proposal for a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 and a proposed draft decision text. The Council for TRIPS has had extensive discussions on the proposal and received comments on the proposed draft decision text.

2. With the aim to progress to text-based discussions, taking into account the discussions and feedback received, the co-sponsors are hereby submitting a revised draft decision text for the consideration of the Council for TRIPS.

3. The preambular text has been revised to reflect the concern of continuous mutations and the emergence of new variants and consequently the many unknowns with respect to SARS-COV-2 and its variants and the global need for access as well as the importance of diversifying production and supply. These issues and concerns have become even more acute and critical since submission of the proposal in October 2020.

4. The operative paragraph (1) has been revised to add specificity to the decision text following concern that the original decision text was too broad. Hence the revised text addresses this concern by focusing the text on "health products and technologies" as the prevention, treatment or containment of COVID-19 involves a range of products and technologies and intellectual property issues may arise with respect to the products and technologies, their materials or components, as well as their methods and means of manufacture. The co-sponsors stress that the proposed waiver is limited in scope to COVID-19 prevention, treatment and containment.

5. The revised text also adds a paragraph on the proposed duration. The international community is dealing with a novel pathogen, with many uncertainties. For instance, investigation is still underway for effective therapeutics, and there are still many unknowns with respect to vaccines which will have a bearing on the scale manufacturing and supply that will be needed to control the pandemic such as the duration of immunity conferred, effectiveness of vaccines against new variants, and the effect of vaccines on children. In addition, the duration has to be practical for manufacturing to be feasible and viable. These complexities suggest the need for a practical and

flexible duration. Hence it is proposed that the General Council assesses the existence of the exceptional circumstances justifying the waiver after a minimum period to determine the date of termination. The proposed language is based on Article IX (4) of the WTO Agreement.

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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

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 11/03/2020, 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;

Noting with great concern the continuous mutations and emergence of new variants of SARS-COV-2, which also highlights the significant uncertainties and complexities of controlling SARS-COV-2;

Recognising the global need for unimpeded, timely and secure access to quality, safe, efficacious and affordable health products and technologies for all, for a rapid and effective response to the COVID-19 pandemic and consequently the urgent need to diversify and scale-up production to meet global needs and promote economic recovery;

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

Recognizing the importance of preserving incentives for research and innovation, and that these should be balanced with the public health interest;

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 health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19.

2. This waiver shall be in force for at least 3 years from the date of this decision. The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver.

3. 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.

4. This decision is without prejudice to the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement.

5. 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.

6. 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.