



**QUESTIONS ON INTELLECTUAL-PROPERTY CHALLENGES EXPERIENCED BY MEMBERS
IN RELATION TO COVID-19**

COMMUNICATION FROM AUSTRALIA, CANADA, CHILE AND MEXICO

1 INTRODUCTION

1. As the world continues to grapple with the profound social and economic challenges caused by COVID-19, WTO Members have engaged in constructive dialogue on how the multilateral rules-based trading system can support an inclusive, sustainable, and resilient recovery. Given the complex challenges created by the pandemic, a coordinated global response is needed to support international efforts to prevent, contain, and treat COVID-19. Through seeking multilateral solutions, including on how trade rules can be used to address these important challenges, we can be better prepared to fight both COVID-19 and future pandemics.

2. With respect to intellectual property (IP), the WTO TRIPS Council provides an important forum to discuss complex issues and concrete challenges faced by WTO Members, as well as to share Members' experiences on how incentives for innovation can be appropriately balanced with other public health policy considerations. In this regard, the co-sponsors of this communication take note of the communication by Eswatini, India, Kenya, Mozambique, Pakistan and South Africa on a proposed waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19 (document IP/C/W/669), as well as the subsequent communication from South Africa titled Examples of IP issues and barriers in COVID-19 pandemic (IP/C/W/670). The co-sponsors of the present communication also welcome the constructive exchange among Members at the recent 15-16 October and 20 November 2020 formal and informal sessions, respectively, of the TRIPS Council.

3. The co-sponsors of this communication remain of the view that these important, challenging, and complex issues merit further reflection and significant consideration, in order to identify any specific and concrete IP-related challenges faced by Members in addressing COVID-19. In addition, we take note that IP rights are one part of a broad discussion informing the availability and accessibility of treatments for COVID-19. Indeed, as the Doha Declaration on the TRIPS Agreement and Public Health emphasizes, the TRIPS Agreement itself is part of the wider national and international effort to address public health problems. With respect to COVID-19, this broader response includes significant investments through procurement mechanisms like the Access to COVID-19 Tools Accelerator and the COVAX Facility and Advance Market Commitment, as well as work within the WTO and elsewhere to safeguard and protect global supply chains.

4. The co-sponsors of this communication are actively committed to a comprehensive, global approach that leverages the entire multilateral trading system in place to supporting the research, development, manufacturing, and distribution of safe and effective COVID-19 diagnostics, equipment, therapeutics, and vaccines. The co-sponsors also reaffirm their support for the TRIPS Agreement, including the flexibilities it provides, and for the Doha Declaration on the TRIPS Agreement and Public Health. In this context, we invite consideration of how the existing legal framework under the TRIPS Agreement, including the flexibilities affirmed under the Doha Declaration on the TRIPS Agreement and Public Health, have operated thus far in the context of Members' efforts to address the COVID-19 pandemic. We are also committed to fully understanding the nature and scope of any concrete IP barriers experienced by Members related to or arising from the TRIPS Agreement, and such that would constitute impediments to the fight against COVID-19. To that end, and with a view to facilitating a consensual, evidence-based

approach, the co-sponsors of this communication therefore respectfully submit the following questions to Members for their consideration and response.

2 QUESTIONS

1. Have Members, or organizations acting on their behalf, experienced IP challenges that have impeded or prevented the timely procurement of COVID-19 diagnostics, equipment, therapeutics or vaccines? If so, can Members describe these challenges, including in relation to the TRIPS Agreement.

2. With respect to the local production or manufacture of specific COVID-19 diagnostics, equipment, therapeutics or vaccines, have Members, or organizations acting on their behalf experienced IP challenges that have impeded or prevented local production or manufacturing? If so, can Members describe these challenges, including in relation to the TRIPS Agreement?

3. Have Members formally initiated processes toward the issuance of compulsory licences under Article 31 of the TRIPS Agreement in relation to any COVID-19 diagnostics, equipment, therapeutics or vaccines, but were unable to complete these processes and issue any corresponding compulsory licence due to circumstances other than those attributable to domestic legislation, procedures, or litigation? If so, can Members identify what prevented the issuance of any such compulsory licence?

4. Have Members formally initiated processes toward the issuance of compulsory licences under Article 31*bis* in relation to COVID-19 pharmaceutical products, but were unable to complete these processes and issue any corresponding compulsory licence due to circumstances other than those attributable to domestic legislation, procedures, or litigation? If so, can Members identify what prevented the issuance of any such compulsory licence?

5. Have Members experienced copyright-related challenges in specific instances of procurement or of seeking local manufacture or production of COVID-19 diagnostics, equipment, therapeutics or vaccines? Specifically, have Members experienced any such challenges that could not be addressed through the implementation of the flexibilities contemplated in the TRIPS Agreement? If so, can Members describe these challenges, including in relation to the TRIPS Agreement?

6. Have Members experienced industrial-designs-related challenges in specific instances of procurement or of seeking local manufacture or production of COVID-19 diagnostics, equipment, therapeutics or vaccines protected by industrial-design rights? Specifically, have Members experienced any such challenges that could not be addressed through the implementation of the flexibilities contemplated in the TRIPS Agreement? If so, can Members describe these challenges, including in relation to the TRIPS Agreement?

7. Have Members experienced challenges in specific instances of procurement or of seeking local manufacture or production of COVID-19 diagnostics, equipment, therapeutics or vaccines with underlying undisclosed information? In any such instances, have Members experienced challenges with the application of the flexibilities outlined the TRIPS Agreement, due to circumstances other than those attributable to domestic legislation, procedures, or litigation? If so, can Members describe these challenges, including in relation to the TRIPS Agreement?

8. In relation to the above questions, as the TRIPS Agreement is a minimum-standards agreement that is given effect via the applicable domestic laws of its Members (per Article 1.1), how would the proponents envisage giving effect to such a waiver under Members' domestic IP legal regimes? Put another way, what specific legal amendments or actions would the proponents seek to enact for the prevention, containment, and treatment of COVID-19 that are not – or may not be – consistent with the TRIPS Agreement and its flexibilities?
