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Page: 1/3

Council for Trade-Related Aspects of Intellectual Property Rights

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

COMMUNICATION FROM INDIA, MOZAMBIQUE, PAKISTAN AND SOUTH AFRICA

The following communication, dated 14 January 2021, is circulated at the request of the delegations of India, Mozambique, Pakistan and South Africa**.**

This document contains the questions by proponents raised on the waiver proposal IP/C/W/669 in the TRIPS Council meetings on 3 and 10 December 2020.

1 INFORMAL TRIPS COUNCIL MEETING- 3 DECEMBER 2020

1.1 Question raised by Mozambique

1. After years of discouraging WTO Members especially developing countries to take steps to improve their patent law so that compulsory licenses may be issued in the interest of public health, how does the European Union expect all WTO Members to be ready to use compulsory licenses should the need arise?

1.2 Questions raised by South Africa

2. We would like to ask Canada, Germany and Hungary, when they decided to swiftly amend national laws to enable quicker use of compulsory license, what kind of data was relied upon at that time - demonstrating the necessity of revising the laws? [We refer to the Secretariat note and compilation of COVID-19 measures.]

3. The European Union (EU) and Switzerland both highlight the flexibilities as the key measures for Members to use, does it mean the EU and Switzerland will from now on commit not to pressure developing countries when they improve their laws on compulsory license and other TRIPS flexibilities or make use of compulsory license? Would the European Commission from now on exclude compulsory license and other TRIPS flexibilities from its IP enforcement report? Would the United States Trade Representative (USTR) do the same to its Special 301 report?

4. If voluntary licensing (VL) mechanisms work, why do various license agreements concluded by companies exclude half of the world's population from supply and only license to a few very specific manufacturers. Why is it that no one knows the full terms of the license?

5. If VL works then why are there geographical restrictions in the VL to limit supply to only to low- and middle-income countries (LMICs) under the agreements, excluding supply to other developing countries? Taking note that the issue of classification of countries based on singular criteria such as per capita GDP ignores the deep and persistent structural deficits between developed and developing countries.

6. The European Union IP Action Plan, released on 25 November 2020, reiterates the exigent need to deploy COVID-19 technologies, "not only in Europe but also on a global basis. "To this end, the EU IP plan calls for "voluntary pooling and licensing of intellectual property related to COVID-19 therapeutics and vaccines, in line with the recent resolution of the World Health Assembly to promote equitable global access as well as a fair return on investment." Can the European Union elucidate further on how they intend to transform this lofty rhetoric into concrete action? The EU IP Action Plan notes that the Commission is "working on mechanisms that would enable and incentivise the rapid pooling of critical IP in times of crisis". **Could the European Union please explicate on these mechanisms that would enable the "rapid pooling of critical IP in times of crisis."**

7. Following on from President Ursula von der Leyen's State of the Union call for the establishment of an EU BARDA, the EU's IP action calls for the development of an "effective framework for march-in rights that should guarantee that publicly funded IP is available in case of critical shortages". **Could the European Union please provide details on the design of these march-in rights?**

8. We would counter the EU's assertion, repeated once again today, that compulsory licensing should be used as "means of last resort and a safety net when all other efforts to make IP available have failed." Nonetheless, **could the European Union please provide further details on the EU IP Action Plan's recommendation that EU Member States "establish fast-track procedures to issue compulsory licenses in emergency situations"?**

9. The Commission will explore with Member States the possibility of creating an emergency co-ordination mechanism, to be triggered at short notice when Member States consider issuing a compulsory license. **What is the rationale behind this policy decision?**

10. In the European Union, data exclusivity and on certain products market exclusivity are granted. **How does the EC want to make effective use of CL in this pandemic with these non-patent barriers in place?**

11. As the European Union has opted out of Article 31*bis* of the TRIPS Agreement, how would EU Member States with no or insufficient manufacturing capacities make effective use of the compulsory licensing provisions of the TRIPS Agreement, especially in light of the IP Action Plan's emphasis on establishing "fast-track procedures to issue compulsory licenses in emergency situations"?

1.3 Questions raised by India

12. Do the opponents have any data regarding how the waiver would demonstrably have negative impact on Members' economies, if any?

13. Public funding has been driving COVID-R&D. In addition, billions of dollars are spent on purchasing the vaccine. Given the demand volumes, pharma companies will anyway make profits. So why is there a need for IP as an incentive, in a global pandemic situation?

14. Can the opponents provide data as to how voluntary licensing approaches and existing global cooperation mechanisms, including ACT Accelerator, the COVAX facility and COVAX AMC, would be sufficient to address the vaccine requirements of 7.8 billion people in the world?

15. If voluntary mechanisms work, why has the pharmaceutical industry collectively rejected participation in the World Health Organization (WHO) COVID-19 Technology Access Pool (C-TAP), an initiative that encourages voluntary contribution of IP, technology and data to support global sharing and scale-up of manufacturing and supply of COVID- 19 medical and pharmaceutical products?

2 FORMAL TRIPS COUNCIL MEETING- 10 DECEMBER 2020

2.1 Questions raised by South Africa

16. In launching the Pharmaceutical Strategy for Europe, Vice President Schinas underscored the importance that the transparency of R&D costs plays in ensuring access to affordable medicines.[1] In

[1] https://ec.europa.eu/commission/presscorner/detail/en/speech_20_2212

his remarks to the press on 25 November 2020, Vice-president Schinas said, "Equally important, ensuring affordability of medicines will be guaranteed through bolstering transparency on R&D costs and expenditure on medicines in healthcare systems, finding a consensus on costing principles and addressing aspects that impede the competitive functioning of the markets impacting on affordability." **Could the European Union provide more details on how it intends to ensure the "affordability of medicines" through the "bolstering of R&D costs"?**

2.2 Questions raised by Pakistan

17. How would countries that argue for such licensing arrangements (voluntary licensing), address companies' conduct and ensure the availability of non-exclusive, global, open licenses on reasonable terms and conditions, where all manufacturers globally may be engaged; and all countries may benefit from supply without any restrictions?

18. Also, what steps are those countries taking to ensure full transparency and accountability in the cost of R&D and in licensing agreements?

2.3 Question raised by India

19. We would like to know how European Union plans to persuade pharma companies to enter into transparent, non-exclusive global open licenses, where all manufacturers can be engaged without any restrictions, and what steps EU is taking to ensure full transparency and accountability in the cost of R&D and in licensing agreements.