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Council for Trade-Related Aspects of Intellectual Property Rights

ADVANCE MINUTES OF AGENDA ITEM 15

OF THE MEETING HELD IN THE CENTRE WILLIAM RAPPARD ON 15-16 OCTOBER 2020

As Members will recall, agenda item 15 was suspended at the Council's meeting held on 15-16 October 2020. In order to facilitate the continuing consideration of this agenda item by Members and preparations for resuming the meeting on this item, the present document contains an advance copy of the statements made under this agenda item. The final version will be included in the record of that meeting which will be circulated in documents IP/C/M/96 and Add.1.

AGENDA ITEM 15: PROPOSAL FOR A WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19

15.1 South Africa

1. I have the honour to introduce this proposal on behalf of the delegations of Eswatini, India, Kenya and South Africa.

2. The COVID-19 pandemic is a clarion call for us to answer to the better angels of our nature. High-minded language on solidarity and global public goods, however, has not been matched by tangible steps to share know-how and intellectual property rights to facilitate deep technology transfer in the COVID-19 response. Business as usual approaches will not bring back the countless lives that were lost, neither will it ensure that IP barriers to the prevention, containment and treatment of COVID-19 will be addressed effectively.

3. We have seen this before. At the height of the HIV crisis, prices set for ARVs to treat HIV were simply too high and out of reach for many developing countries. As death rates due to aids plunged in rich countries, infected people across the developing world were left to die.

4. Our leaders vowed that is would never happen again, the Doha Declaration on TRIPS and Public Health reaffirmed flexibilities to accommodate access to medicines. Even in light of this political undertaking and its translation into the Paragraph 6 System, prices of many life-saving diagnostics, therapeutics, vaccines and other medical products remain out of reach of most governments and its people.

5. In 2004 the highly pathogenic avian influenza H5N1 re-emerged, developed countries had priority access, while affected developing countries did not. Within five years another pandemic flu (H1N1) emerged and once again rich countries placed large pre-orders of a vaccine buying almost all doses that could possibly be produced. Many countries promised to donate vaccines, most of them reneged and moved to secure their own supplies. With COVID-19 history is repeating itself.

6. Several months into this pandemic there are no meaningful global policy solutions to ensure access. 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 and/or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19.

7. 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 affected.

8. 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. 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. 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. 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. The emerging second wave of the disease underscores the importance to finding global solutions that ensure equitable access.

9. There are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients. 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, as evidenced by the updated Secretariat report on national measures taken by WTO Members. 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.

10. 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. Our joint proposal requests a waiver to be granted to all WTO Members so that they do not have to implement, apply or enforce certain obligations related to COVID-19 products and technologies under Section 1 (copyrights and related rights), 4 (industrial design), 5 (patents) and 7 (protection of undisclosed information) of Part II of the TRIPS Agreement. Let me stress that the proposed waiver would be applicable only to COVID-19. The waiver is limited and does not suggest a waiver from all possible TRIPS obligations, nor does it suggest a waiver beyond what is needed for COVID-19 prevention, containment and treatment.

11. 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.

15.2 India

12. We thank South Africa for its detailed and comprehensive statement.

13. We also thank UNAIDS, UNITAID, MSF, other academics, researchers as well as numerous civil society organisations who have expressed widespread support for our proposal.

14. Let me also take this opportunity to thank the Secretariat for its report on the TRIPS Agreement and COVID-19. We believe that it is not merely coincidental that this report came out the day before, more than six months into the COVID-19 pandemic. At least our proposal could generate enough interest for action now. However, in our view, the measures listed in the report are not sufficient for an effective COVID-19 response, which necessitates the need for our waiver proposal.

15. At the outset we would like to emphasize that this proposal is, particularly important to cater for those who have insufficient or no manufacturing capacities in the health products required to combat the COVID crisis. In the past few months, India has supplied medical products and equipment needed in fighting the pandemic to more than 150 countries and resisted the attempts to corner the supplies by a few countries. We would like to remind the Members that in a global pandemic where every country is affected, we need a global solution**.** And our waiver proposal represents an open and expedited global solution to allow uninterrupted collaboration in development, production and supply of health products and technologies required for an effective COVID-19 response.

16. South Africa has very clearly explained the purpose and objective of our proposal. In this regard, we want to highlight following points:

17. First, there can be no denying the fact that the development of and equitable access to the tools – such as diagnostics, therapeutics, treatments, vaccines etc.– required to fight the COVID-19 pandemic are limited by IP barriers. It is quite evident from an array of lawsuits filed by private companies in different parts of the world for IP infringement on COVID-19 products. In the past few months, we have also seen that IPRs do come in the way of scaling up production of test kit reagents, ventilator valves, N95 respirators, therapeutics, fluorescent proteins and other technologies used in development of vaccines etc.

18. Second, governments across the globe are supporting development of new health technologies, in particular vaccines by pouring billions of USD of public funds into research and development. The EU tracker of pledged resources for access to tests, treatments and vaccines[1] stands at EUR 16 billion. Therefore, the often-repeated argument that monopoly rights are needed to allow the inventors to recoup their investment does not seem to apply in case of development of health products and technologies required for handling the ongoing COVID-19 crisis.

19. Third, we have heard from some Members in the previous meetings that voluntary licenses are the most appropriate solution to scale up manufacturing in response to COVID-19. However, the fact remains that not a single IP holder has shown willingness to commit to the COVID-19 Technology Access Pool (C-TAP) and the ACT-Accelerator voluntary initiatives launched under the aegis of WHO. In fact, the representative from WHO in the Council admitted in response to a question that no pharmaceutical company has committed to sharing its IP and technologies in the C-TAP pool since its launch more than five months ago. Given the refusal by pharmaceutical industry to routinely offer nonexclusive licenses with worldwide coverage to facilitate global access, clearly the solution to ending the pandemic does not lie in voluntary licenses.

20. Fourth, with regard to existing flexibilities under the TRIPS Agreement, the same are not adequate to address the fast-changing landscape of COVID-19. Of particular concern for countries with insufficient or no manufacturing capacity is Article 31*bis*, which is limited to pharmaceutical products, and was not designed to address challenges arising from pandemics of this scale and magnitude. Medical devices like ventilators, dialysis machines etc. that are crucial for combating the ongoing pandemic, may not be covered under the scope of Article 31*bis*. There is a reason why the Special Compulsory Licensing system has been used only once. Requirements under this System that exporters and importers have to comply with, are extremely onerous and time-consuming, thereby rendering it of no practical utility towards handling the ongoing pandemic.

21. Fifth, we have included four sections of TRIPS Agreement namely patents, copyrights, industrial designs and undisclosed information or trade secrets, in our proposal. This is because the health products and technologies like test kits, masks, medicines, vaccines, components of ventilators like valves, control mechanisms and the algorithms and CAD files used in their manufacturing are protected by these four types of IPRs. This ensures that our waiver proposal does not suggest a waiver from all TRIPS obligations, but only from these specific sections and that too only to the extent the same are essential for effective handling of the COVID-19 crisis.

[1] https://global-response.europa.eu/index_en

22. Sixth, it may be noted that the waivers granted to LDC Members with respect to obligations in Article 70.8 and 70.9 and their rights under Article 66.1 of the TRIPS Agreement are in no way impacted by this proposal.

23. Lastly, we want to clarify that the time period of 'X' years does not signify that we are seeking a waiver for an indefinite duration. The actual waiver duration will be negotiated and be limited to a period that this Council finds necessary to effectively handle the COVID crisis. Furthermore, the waiver will be reviewed annually by the General Council in accordance with the provisions of Article IX (4) of the WTO Agreement. We are flexible with regard to the scope and duration of the waiver. We look forward to constructively engage with Members having any questions or concerns regarding our proposal.

24. We believe that now is the time for WTO as an organization to rise up to the collective call for defeating the pandemic. It will not succeed in its efforts in rebuilding the COVID affected economies unless it acts now to first save those lives that are going to build these economies. It's time for Members to take collective responsibility and put people's lives before anything else. History will not judge us kindly if we do not act immediately to save large scale loss of human life and health and allow global dysfunction to prevail over global cooperation. We hope that Members will support our proposal that will ensure that vaccines and treatments become truly global public goods.

15.3 Kenya

25. Kenya welcomes the proposal from India and South Africa in document IP/C/W/669, titled Proposal for a Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, and aligns with the statement that was delivered by Tanzania on behalf of the African Group in support of the proposal.

26. The COVID-19 pandemic has had a debilitating effect on the global economy, trade, investment, and the social well-being. It has caused a dramatic decline in foreign direct investment globally, and the resultant unilateral restrictions on exports and imports have drastically affected many countries' ability to participate in international trade. The pandemic has also slowed down the pace by many countries to realize their development agenda, particularly the Sustainable Development Goals.

27. In their efforts to contain and manage the pandemic, many developing countries are facing public health challenges, due to restrictions brought about by intellectual property protection. It is noteworthy that intellectual property is at the core of the fight against the pandemic and as the TRIPS Agreement provides, protection and enforcement of intellectual property should be to the mutual advantage of both the producers and users, in a manner that is conducive to social and economic welfare, and that ensures the balancing of rights and obligations.

28. The prospects of economic recovery from the pandemic, for most countries largely depend on the duration of the health crisis, as well as the effectiveness of the policy interventions that they deploy. Countries will therefore have to constantly adjust their interventions as the health situation unfolds. Currently, access to the technological innovation and production required to respond to the pandemic is curtailed by IP protection and this extends beyond patents, to copyright, industrial designs and trade secrets, which also apply to products and technologies that are urgently needed to address the effects of COVID-19.

29. Kenya therefore welcomes the proposal by India and South Africa for the TRIPS waiver and indeed happy to be a co-sponsor and looks forward to further in-depth discussion by the Council on this submission. Kenya believes that more should be done within the context of the TRIPS Agreement to ensure that developing countries of the WTO are able to promptly respond to the COVID-19 pandemic through access to vaccines, diagnostics, personal protective equipment and other medical technologies.

15.4 Nigeria

30. We commend the delegation of South Africa and India for their joint submission. In the context of COVID-19 pandemic, we believe the paper has come at the right time.

31. My delegation would like to underscore the importance for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright and trade secrets do not create barriers to the scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19 while preserving intellectual property rights of Members.

32. Finally, while we are still awaiting instructions from capital in this regard, we welcome constructive discussions regarding this proposal.

15.5 Bangladesh

33. The delegation of Bangladesh thanks the delegation of India and South Africa for this submission (IP/C/W/669). My delegation also supports the statement delivered by Chad on behalf of the LDC group.

34. The submission presents an extremely urgent call during this time of global crisis caused by COVID-19 pandemic. The issues of public health should not be seen from a narrow perspective. We live in an interdependent and interconnected world. Therefore, a threat to public health in one society is a threat to humanity everywhere. Moreover, the pandemic may be primarily a health issue, but in the long run this is destroying our employment, investment, mobility, creativity, social relations and overall economic development. The whole world is suffering. The developing countries, particularly the LDCs, are severely and disproportionately affected by the COVID-19 pandemic. Members must act collectively to save societies and economies from the devastating impacts of the pandemic.

35. The delegation of Bangladesh requests a favourable consideration of the proposal.

15.6 Sri Lanka

36. First take this opportunity to commend you in the effective manner in which you are steering this very import Council's preceding since assumption of your role recently.

37. Also let me thank and appreciate immensely India, South Africa, Kenya and other newly joined co-sponsors for presenting their extremely relevant and timely proposal for a Waiver from certain provisions of TRIPS Agreement for Prevention, Containment and Treatment of COVID-19.

38. At the outset, let me notify Sri Lanka's strong and unequivocal support for the proposal circulated as document IP/C/W/669 and presented by the co-sponsors.

39. The COVID-19 was declared a pandemic by the WHO on 11 March 2020. It is widespread, affecting almost all WTO Members. After experiencing a very brief initial period of COVID pandemic, Sri Lanka is now experiencing a second waive, where the epidemiologists and virologists have detected the COVID-19 virus, which is more severe in affect than what we experienced before and able to spread among large sets of community groups vigorously in a given period. This has necessitated the authorities to double their efforts in containing the virus to minimize the health and socio-economic impact on our poor population.

40. 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 no vaccine or medicine yet to prevent or treat COVID-19. Hence, there is an urgent need to speed up development of new vaccines, treatments and diagnostics, at scale, and make these widely available.

41. An effective response to COVID-19 pandemic not only requires timely access to affordable medical products, but access to diagnostic kits, medical masks, other personal protective equipment and ventilators is also vital. However, as the crises persist, there has been a rapid increase in demand with many countries facing acute shortages, constraining the ability to effectively respond to the outbreak. Importantly, timely access to affordable vaccines and medicines for the prevention and treatment of patients in dire need is another major concern, as the COVID-19 global crisis deepens. Given the disruptions in supply chains and severe shortages, local/regional production is a critical solution, may be the only solution for small economies such as mine.

42. Efforts to contain the COVID-19 spread has led to serious concerns about the impact of IPRs, such as patents, industrial designs, copyright and trade secrets on the availability and affordability of medical products. Global demand for medical products can only be met with global production of products needed to contain, treat and prevent COVID-19. Apart from availability, affordability is another concern that needs to be addressed, an aspect of which is very important and relevant for Sri Lanka.

43. In view of the above reasons, Sri Lanka considers that the Proposal is timely and importantly necessitated in the current context:

44. In the proposal, the co-sponsors are calling for the WTO Members to agree to temporarily waive certain provisions of the WTO TRIPS Agreement related to the obligations on protection and enforcement of patents and other intellectual property rights to support the global COVID-19 pandemic response.

45. 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. This necessitates enabling a broader application of flexibilities beyond patents to such other forms of IP rights. Accordingly, the proposal requests wavering of specific obligations of the TRIPS Agreement on protection and enforcement, namely, (1) patents, (2) copyright and related rights, (3) industrial designs and (4) protection of undisclosed information during the COVID-19 pandemic.

46. As elaborated in the proposal, 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 TRIPS rules.

47. As argued in the proposal, the adoption of this proposal will overcome potential obstacles that above 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 ensure availability of medical products at affordable price for the prevention, containment and treatment of COVID-19.

48. Why Sri Lanka supports the proposal:

49. Sri Lanka's government total expenditure on health sector is around USD 1.32 Billion, which is a share of 1.7% of the total GDP of Sri Lanka in 2019. Total bill on import of medical and pharmaceuticals is USD 552.6 million, which is a share of 2.8% of total imports in 2019 and is now on the rise due to the current crisis. At present, 80% of the country's drug requirement is met through imports. At present, Sri Lanka is the largest importer of drugs in the Asian region and it is high time that Sri Lanka turns the tables in its favour.

50. Sri Lanka is a country which is proud of having a universal free medical access programme securing free access to health facilities & Treatment for its population, which is also enshrined in its Constitution as a fundamental right of its citizens. When the country is inundated with balance of payment difficulties exacerbated by the COVID Pandemic, the government is seeking to reduce import bills including the expenditure on medical and pharmaceutical products through other means.

51. A disturbing development witnessed by Sri Lanka during the current pandemic is the gradual increase of domestic prices of essential medicines sold in the market by the Pharma Companies when our regulatory authorities' attention has been drawn in containing the spread of pandemic. There are investigations going on to these alleged anti-competitive practices by the regulatory authorities.

52. Recently, Government informed that its plans to increase production with a view to meeting the country's total drug requirement and to ensure the supply of high quality drugs at affordable low prices and to enhance the export production capacity of nascent items in COVID-19 product range. Sri Lanka has also decided to establish a free trade zone to accommodate such investments in the pharmaceutical sector. Through this, the Government is intending to meet at least 50% of country's

current pharmaceutical requirements. In terms of the plan, 25 medium and small scale companies are prepared to invest USD 300 million to meet the local demand.

53. This proposal is, therefore, in line with Sri Lanka's policy goal for exploring avenues for increasing domestic value addition in productive sectors, particularly by building production capacity of Domestic Pharmaceutical and Medical Devices sector.

54. Unless there is an unambiguous clarity that any domestic production of COVID-related patented drugs and medical devices, PPE products etc can be carried out in Sri Lanka for meeting the domestic demand and with plans to export to third countries, without any IPRs related legal impediment, it is highly risky to invest in new ventures if it is otherwise.

55. A research institute in Sri Lanka, namely, Sri Lanka Institute of Technology (SLINTEC), has ventured in to innovate and commercialize two new products with high export potential in the USA and the EU. These products are SLINTEC Swabs and SLINTEC Sterile. The SLINTEC has reverse engineered COVID-19 testing swabs and has been producing them in-collaboration with the Medical Research Institute of Sri Lanka, the Lady Ridgeway Hospital, and Hi-Fashion Holdings Pvt limited.

56. It indicates that these items are already under patents and though they are now made in Sri Lanka in generic form and intended to be exported under Sri Lanka brand name, there is a likelihood of overriding the patent holders' rights in the importing countries. Sri Lanka has found such new product lines and intends to capitalize on the export potentials, so that in addition to catering to our local demand, Sri Lanka can supply to those countries, who require them to deal with the current pandemic, which is going to stay in the world for many years. But, Sri Lanka may not be able to export them to those countries due to the possible IPRs infringements. If so, it not only deprives Sri Lanka generating most vital foreign exchange, but also deprives the countries which require them desperately.

57. The WTO waiver proposed in the proposal will, therefore, provide the required legal certainty to Sri Lanka in the interim period, until it is able to address those IPRs related legal impediments in the long run.

58. Currently, Sri Lanka has few provisions in Sri Lanka's National Intellectual Property Act, No. 36 of 2003 that provide such exceptions, particularly Section 86 of the Act, which unfortunately bundles the important exceptions provided under 'exhaustion of rights (parallel imports) and Compulsory Licenses (CL) and offers less clarity in their application.

59. Further, Sri Lanka is yet to amend its National Intellectual Property Legislation to introduce the complaint provisions necessitated by the Amendment to the TRIPS Agreement (under Article 31*bis* of the TRIPS Agreement), which is overdue. This amendment is particularly important to Sri Lanka, as it lacks domestic manufacturing capacity and would, therefore, be dependent on imports to meet its medical needs.

60. Many developing countries, including Sri Lanka may also face legal, technical and institutional challenges in using TRIPS flexibilities due to the lack of ambiguity in the existing legal provisions. This is especially true for countries, such as Sri Lanka that have never utilised flexibilities such as compulsory licenses (CL). National patent laws may not even have the necessary provisions to issue compulsory licenses in the public interest or government use licenses.

61. In some countries, including Sri Lanka the issuance of compulsory license may not be possible until the expiration of three-four years following the grant of patent. Sometimes, provisions on compulsory licensing in national legislation are subject to specific processes and as such the issuance of compulsory license may involve lengthy processes that are time-consuming.

62. As explained above, a few countries have introduced or are in the process of introducing simplified procedures for issuing compulsory licenses in times of a public health crisis. This however may not be an option for Sri Lanka, where legal and technical capacity maybe lacking and the passing of national legislation is often a very long process.

63. In order to support these efforts, Sri Lanka is in the process of carrying out a gap analysis on the Sri Lanka's existing National IPRs Legislation to ascertain the areas where further improvements

are necessary to ensure that the production can commence on those products protected under IPRs enabling the long-term survival of those investments and projects.

64. While the process of amendments will be time consuming on a variety of IP rights that are relevant in the fight against COVID-19, Sri Lanka along with other like-minded countries have been working on a joint proposal, initiated by India and South Africa, which has now been submitted to the WTO TRIPS and the General Council seeking a more integrated approach to address the public health concerns/challenges of COVID-19 pandemic, through TRIPS flexibilities that include other various types of intellectual property (IP) rights including copyrights, industrial designs and trade secrets.

65. The use of TRIPS flexibilities in other areas of intellectual property, beyond patents, is less understood at the national level. In fact, in other fields of IP, National IP laws may not even provide for sufficient flexibilities to address issues of access.

66. In view of the above forgone and justifiable reasons, Sri Lanka calls for support for the multilateral solutions, more particularly this joint proposal which is before us in assuring and delivering fair access to COVID-19 treatments for all those in need in the developing countries and the LDCs.

15.7 Pakistan

67. Pakistan welcomes the proposal on 'a waiver from certain provisions of the TRIPS Agreement for the Prevention, Containment and treatment of COVID-19' contained in document IP/C/W/669, and we thank the co-sponsors for this very important contribution. It is high time that WTO stood up and made itself counted in the global fight against the pandemic.

68. It is proven that the COVID-19 pandemic presents in every way, a global health emergency. This is coupled with a resultant economic crisis. The effects on livelihoods and general health of the populations in developing countries in particular, are devastating while health budgets of many countries find it difficult to sustain availability of highly priced COVID-19 related medical products and limited access to diagnostic testing.

69. In order to combat the COVID-19 pandemic, we require 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. At the same time, it is feared that, the development, dissemination and public availability of medicines including vaccines can become subject to monopolistic behaviour of large pharmaceutical firms and the global political economy of price premiums.

70. In wake of this challenge, there is an urgent call by many for global solidarity for unhindered global sharing of technology and know-how; cheap and easy access to medicines and medical equipment, and the enhancement of local production capacities of these products for developing countries.

71. While the TRIPS Agreement contains some flexibilities, many WTO Members face challenges in using them effectively. The flexibilities are selective, limiting in their scope and application and virtually impossible to implement. For instance, Pakistan finds it difficult to implement the compulsory licensing provisions due to various limitations of time, price, quantity, region of production.

72. The current pandemic requires collective global action to tackle IP barriers at a more comprehensive level. Acknowledging that we are passing through this unprecedented global medical emergency, we wish to echo the concerns raised in the subject proposal and support the waiver. We feel that this will ensure adequate and affordable supply of medical products including vaccines and medicines, allow scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19 and have an overall positive effect on the ability of developing countries to tackle the mounting challenges posed by the pandemic.

15.8 The Bolivarian Republic of Venezuela

73. The Bolivarian Republic of Venezuela would like to thank India and South Africa for such a necessary proposal at this time and fully supports it.

74. Extraordinary situations, such as those resulting from the COVID-19 pandemic, call for equally extraordinary decisions. Article IX of the Marrakesh Agreement provides us with the legal basis for this.

75. The epidemiological report by WHO issued this week states that, from 30 December 2019 to 11 October 2020, more than 37 million cases of COVID-19 and more than a million deaths were reported worldwide. But what is most alarming is that, despite all of the collective efforts to try to reduce the effects of this pandemic, last week saw the highest number of cases reported in a single week to date.

76. No one has been spared by this pandemic. All governments are dealing with the challenges of ensuring timely, adequate and affordable access to medicines, vaccines, diagnostic kits and other essential medical supplies. This is particularly challenging for many developing countries that are dealing with limitations on the development and expansion of production capacity due to intellectual property barriers.

77. In the context of this universal emergency and while the pandemic lasts, this waiver is required for the benefit of all humanity, since no one can be safe in this world until we all are.

15.9 Nepal

78. My delegation would like to extend sincere appreciation to the delegation of India and South Africa for their submission.

79. While going through the proposal, it seems an appropriate and timely initiative in the context of current COVID-19 pandemic.

80. The COVID-19 pandemic has severely devastated the global economy where developing especially, least developed countries are suffering most because of their limited capacity to cope with the impact of the pandemic.

81. In this context, sufficient policy space as per the need of country's context is essential to overcome the difficulties faced as indicated in the submission.

15.10 Philippines

82. The Philippines thanks India and South Africa, Kenya and Eswatini for their proposal document IP/C/W/669, on an issue of profound importance not just for TRIPS Council Members but also for all participants of the multilateral trading system.

83. The Philippines has elevated concerns over the COVID-19 global pandemic to the highest levels, and has made the effort to eradicate the novel coronavirus one of its highest priorities. No less than our Head-of-State, President Rodrigo Duterte, declared at the recent 75th Session of the U.N. General Assembly last September that "ensuring universal access to anti-COVID-19 technologies and products is pivotal in the global pandemic recovery."

84. During the Special ASEAN Summit, our Leaders committed to intensify cooperation to ensure adequate provision of medicines, essential medical supplies and equipment, including, but not limited to diagnostic tools, personal protective equipment.

85. At the recent APEC Ministers Responsible for Trade Virtual Meeting, our Trade Minister Mr Ramon Lopez called for closer cooperation in data gathering and R&D, particularly to strengthen health systems and provide access to affordable, high-quality health products, treatments and services.

86. The WTO has a positive role to play in promoting trade in medical goods and in ensuring balance of trade and intellectual property and public health interests. At the height of the HIV/AIDS pandemic, WTO Members responded by adopting the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which eventually led to a Decision of the General Council on 30 August 2003 amending the TRIPS Agreement on the Special Compulsory Licensing mechanism. Like other WTO Members, the Philippines would later incorporate this mechanism as part of our national law as the Universally Accessible Cheaper and Quality Medicines Act of 2008.

15.11 Nicaragua

87. We thank the proponent delegations for including this agenda item on the proposal for a temporary waiver from certain provisions of the TRIPS Agreement.

88. We consider that this proposal is of great importance amid the current difficulties, since it is a measure that would offer developing countries like Nicaragua timely and affordable access to the medical products, medicines, vaccines, inputs and medical equipment necessary for detecting and treating COVID-19. It would also provide fair access to medical technologies, which are essential for the proper handling of the fight against COVID-19.

89. Our Government wishes to take this opportunity to express its support for this proposed waiver, based on the content of document IP/C/W/669.

15.12 Chile

90. Our delegation would like to thank the proponents of document IP/C/W/669 in which a waiver to the implementation of the main obligations contained in the TRIPS Agreement is proposed.

91. Firstly, I would like to state that as a country, and since the beginning of this Organization, we have maintained that the objective of intellectual property (IP) is to be a tool for stimulating technological innovation, and the transfer and dissemination of technology to the mutual advantage of producers and users, in a manner conducive to the economic and social welfare of countries, as stated in Article 7 of the TRIPS Agreement. In this respect, our country has vigorously defended and promoted balanced IP systems which both foster innovation and meet the needs of society as a whole.

92. This is why we share the premise that IP should not hinder or impact access to medicines, but we understand that the same IP system contains the tools to prevent this situation from happening and that there are flexibilities in the system which allow Members to strike the necessary balance appropriate to their own socio-economic reality. Also, and like other Members we are open to analysing which types of conduct may constitute an abuse of IP rights, as well as exploring the mechanisms that the Agreement establishes to rectify such types of situation.

93. Specifically, we can announce that, at local level, our country has managed to use the flexibilities contained in the TRIPS Agreement, which has resulted in suitable production of generic medicines, as well as being an attractive market for marketing latest generation medicines. Instances of this include the establishment of an international IP rights exhaustion system, which along with our network of free trade agreements, allow us to seek the best prices for a specific medicine on the world market. As regards our IP legislation, it has maintained the exclusions from patentability stipulated in Article 27 of the TRIPS Agreement, as well as introducing a strict and thorough examination of patent applications. Additionally, this year has seen reforms to the Law on Industrial Property with the aim of facilitating the use of the flexibilities contained in Article 31 and 31 *bis* of the TRIPS Agreement, which are currently before our National Congress.

94. At international level, our country was one of the first to support the creation of the Medicines Patent Pool and to collaborate on the database that today provides a means of clearly identifying when a patent has entered the public domain in such a way as to generate access to the medicines listed therein. Chile, for its part, promoted the recommendations of the World Intellectual Property Organization Development Agenda and particularly those listed under Cluster B on the use of flexibilities and the public domain, among others.

95. Like all WTO Members, Chile has been severely impacted by the pandemic, and to date, my country finds itself in an extraordinary constitutional situation with, among other measures, restrictions on the movement of people, quarantines and social distancing. The priority is to not only ensure that there are beds and medical supplies, including mechanical ventilators, but also that a vaccine against COVID-19 is now made available.

96. This is why we are working on two fronts. Firstly, in the field of clinical research and trials, we have forged partnerships with universities and laboratories so as to foster timely access to vaccines and upscale scientific capabilities. Secondly, we have increased contact through meetings and discussions with the main laboratories which are developing the most promising vaccines and, in particular, have reached an agreement with COVAX, a global initiative led by the WHO, the EU and associations such as the Bill & Melinda Gates Foundation.

97. All the above, despite the repercussions of the pandemic, has enabled a developing country such as Chile to show that it is able to seek solutions to current and future problems, and notably we have seen a spirit of collaboration emerge between all actors of the health system and of innovation given the nature of the pandemic. We believe that in recent months we have witnessed how the most brilliant of minds in the world have searched for solutions to the pandemic. The response to the pandemic has involved collaboration between innovative enterprises, universities, research centres, SMEs and even independent inventors on a global scale.

98. That said, and given the importance of the proposal set forth in document IP/C/W/669, we would like its proponents to provide some clarification on its potential impacts and implementation. In this regard, and to evaluate the proposal, we would like for them to clarify the following:

a. Firstly, we would be grateful if the proponents could provide us with more information on specific cases where, in the context of the COVID-19 pandemic, IP has hindered access to the vaccines currently being developed.

b. Secondly, we would appreciate some clarity on the economic impact that the proposal would have, as well as whether they may have *a prior*i identified any type of impact on innovation in the medical field.

c. Lastly, we believe it is important that we better understand how the proponents would implement this waiver at local level. Specifically, we would be interested in understanding how this waiver would be implemented as regards the domestic laws of the proponent Members, what would the implications be for IP rights already preliminarily granted and whether it might impact most favoured nation and national treatment commitments.

99. The proposal before us is unprecedented in this Council and in that light, we believe it is crucial that the above issues be clarified so that we can evaluate what effects the proposal may have, who it would benefit and the way in which it could be implemented, if approved.

15.13 Turkey

100. At the outset we would like to thank India and South Africa for the proposal regarding a waiver from certain provisions under the TRIPS Agreement concerning the need for prevention, containment and treatment of COVID-19.

101. While we note the comprehensive and in-depth nature of the proposal, we would like to make preliminary comments without prejudice to later interventions of our delegation with regard to the way forward.

102. Turkey has always put not only the health of her citizens but also other countries medical needs, at the top of her policy agenda. We attach great importance to provide affordable health care and ensure an equitable access to medicines for everyone.

103. COVID-19 pandemic poses a widespread and major threat to the world. And there is not yet a vaccine or scientifically proven treatment although there are many important studies which are ongoing. We have seen that medical equipment, such as ventilators, personal protective equipment and medical supplies have been very critical to combat the pandemic.

104. In that sense, Turkey values close collaboration among the members during such difficult times. We were in solidarity with many countries in their struggle with COVID-19. Turkey supplied medical and personal protective equipment as well as ventilators to over 150 countries and six international organizations since the beginning of the outbreak.

105. As this proposal requires close and thorough coordination among relevant national authorities, we need further consultations in Turkey. However, we are ready to engage constructively to achieve a global strategy so that everyone can better cope with this global health crisis.

15.14 Egypt

106. Egypt aligns itself with the statement to be made by Tanzania on behalf of the African Group, and we would to thank India and South Africa for this timely proposal.

107. It is now evident after the difficult times we have been through since the beginning of the pandemic, that there are limitations on relying on a "case by case" approach when using the TRIPS flexibilities to address IP barriers in confronting this crisis. We believe that Responding to COVID-19 effectively requires a collective and global solution that overcomes the restrictions of addressing IP barriers on a national level so that countries can collaborate and freely share manufacturing and supply capacities.

108. In this context, we believe that this proposal can provide a very good base for discussions in this Council on the role our organization has to play in the current unprecedented global crisis during which all governments are facing challenges ensuring timely, sufficient and affordable access to effective medicines, vaccines, diagnostics and other essential medical tools.

15.15 Indonesia

109. We thank the delegation of India and South Africa for their proposal for a Waiver from certain provision of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 as circulated in the document IP/C/W/669.

110. This proposal is timely to open the discussion on our and WTO role in ensuring global solidarity through effort in ensuring equal, affordable, and timely access to PPE, medical equipment, diagnostic test, drugs and vaccines for the prevention, containment and treatment of COVID-19.

111. This COVID-19 pandemic has become a global threat, not only for global trade and economy, but also to humanity. Global solidarity in combatting this pandemic should materialize in concreate action. International organizations should also contribute in a meaningful way toward this effort.

112. Fortunately or unfortunately (as we could decide later), the TRIPS Agreement as one of the most important agreement during global public health crisis, is under our auspices. It is well recorded, both in public health papers, journals or writing by United Nations Bodies or Special Rapporteur under the UN Human Rights Council, that Intellectual Properties could become a serious barriers for combatting public health crisis.

113. While the TRIPS Agreement has governed the flexibilities under the patent protection, we have been taught that the barrier for prevention, containment and treatment of COVID-19 pandemic is not only posed by patent protection. We share the view that beyond patent, there are lack of flexibilities offered, or even known, to ensure those IP protection not become barriers to combat global health crisis.

114. This proposal, we believe, will open positive discussion on the limitation and possible solution for the TRIPS Agreement in assisting Members to deal with global health crisis. This proposal would also provide assurances for Members in taking legitimate immediate measures for protection of the public health in the time of crisis, as granted under the Article IX:3 of Marrakesh Agreement.

115. The fact that there will be no immediate and adequate of therapeutics and vaccines to deal with the COVID-19, has become serious issue that we need to deal. The possible limited manufacturing of vaccines from private pharmacy companies, as we learned, has been secured by

several members under private contracts which would create imbalance access to the products for others.

116. The waiver, as proposed, hopefully could boost cooperation in research and development and scale-up manufacturing of necessary medicines and vaccines to ensure that no Member is left behind.

117. As the number of infection is keep rising in every part of the world, we shall all agree that there is no global recovery, both in global public health and economy, if some Member are left behind in the recovery process.

15.16 Argentina

118. We thank South Africa and India for submitting document IP/C/W/669.

119. We see that the world is facing an extraordinary situation due to the pandemic, which requires extraordinary solutions to ensure affordable access to medical products needed for the prevention and treatment of COVID-19, within the multilateral regulatory framework.

120. The challenges linked to accessing health products to combat COVID-19 are at the core of the multilateral trading system. The matter has permeated the discussions of many forums and was also touched upon in the communiqué issued by the G20 Trade and Investment Ministers, which stressed the need to ensure that all countries have access to essential medical supplies and pharmaceuticals, including vaccines, at an affordable price.

121. In light of the above, my delegation supports the proposal contained in document IP/C/W/669.

15.17 Chad on behalf of the LDC Group

122. The LDC Group thanks South Africa and all the co-authors for the communication on the prevention, containment and treatment of COVID-19 through the proposed measures in the framework of the TRIPS Agreement. We believe that this proposal is a step in the right direction given the extraordinary situation in which we find ourselves, which calls for equally extraordinary measures.

123. It is clear, as we have already mentioned in our committee, that we must be able to quickly and effectively secure the means to tackle and defeat the pandemic, which poses a considerable threat to the lives of millions of people worldwide. It is well known in our countries and in many developing countries that we lack sufficient technology and equipment to produce protective equipment, treatments and even vaccines.

124. We are therefore totally dependent on exports from equipped countries to our countries. In the current situation, we are obviously trying to figure out how to obtain masks, hydro-alcoholic gel, ventilators, medicines and eventually vaccines as quickly as possible. In the current context, everything must be streamlined as much as possible in order to save lives. We need solidarity now more than ever.

125. The following fact was highlighted in the preamble of the draft decision: the pandemic poses a threat not only to human health, safety and well-being, but also has unprecedented and multifaceted effects, including the severe disruption to society currently being witnessed, disruption to economies, disruption to global trade, disruption to travel, and the devastating impact on the livelihoods of people. Moreover, the statistics from international agencies, whether it be the WHO, FAO or the World Food Programme, in terms of the impact on human lives are getting worse and worse.

126. The LDC Group considers it appropriate to take a new initiative in terms of flexibility in the provisions of the WTO Agreements. With regard to the TRIPS Agreement, flexibility is needed to simplify and speed up the provision of medical products accessible to all, in terms of both cost and supply, in order to effectively tackle the pandemic. Every country in the world without exception -

developed countries, developing countries and least developed countries - is affected by the pandemic.

127. Stopping the growing and alarming surge in the pandemic is therefore a matter of global urgency. We must ensure that intellectual property rights do not become barriers to the provision of affordable medical products for all and, in particular, for those who need them most and/or are ill.

128. In conclusion, the LDC Group believes that the intention of the proposal before us is good. We would simply like to be able to further discuss the proposal with its co-author at a meeting with our Group in order to have some clarification in the coming days and weeks. We are also awaiting feedback from the capitals, as the communication has been forwarded to the LDC capitals, where the proposal is still being analysed. All the LDC Group wishes to say about this communication for now is that we are open and flexible to discussing the proposal with the co-author.

15.18 China

129. We thank India, South Africa and co-sponsors for presenting this proposal. COVID-19 has severely threatened human life, security and health, disturbed the function of global supply chain and brought great challenges for the normal supply of treatment medicines and relevant medical equipment. The joint proposal emphasizes the difficulties faced by developing countries and LDCs and seeks to ensure Members' timely, equitable and affordable access to commodities in relation to the prevention, containment and treatment of COVID-19, especially COVID medicines and vaccines. We would lend our support to exploring this issue at the TRIPS Council.

130. China has taken good note of the capacity constraints that developing countries encounter in using TRIPS flexibilities such as compulsory licensing, as pointed out by the proposal. China has made serious commitment that COVID-19 vaccine development and deployment in China, when available, will be made a global public good and developing countries will be our priorities. Earlier this month, China joins the COVID-19 Vaccines Global Access Facility, or the COVAX Facility, and will take concrete measures to promote the fair distribution of COVID vaccines, especially among developing countries.

131. China is willing to discuss access to commodities in relation to the prevention and control of COVID-19, including medicines and vaccines under the framework of the TRIPS Agreement, and supports the discussions on possible waiver or other emergency measures to respond to the pandemic, which are "targeted, proportional, transparent and temporary", and which do not create unnecessary barriers to trade or disruption to global supply chains.

15.19 Thailand

132. Thailand would like to thank India and South Africa and co-sponsors for submitting the proposal and providing a comprehensive introduction.

133. Like others, we witness the impacts of the COVID-19 crisis on societies, economies, and vulnerable groups in developing and least developed countries in the present year and for years to come. And we note the importance of strengthening cooperation among countries in multilateral level to maintain socio-economic stability for sustainable development and to protect public health and promote access to medicines for all.

134. With respect to the intellectual property measures in the context of COVID-19, Thailand always recognizes that intellectual property protection is important for the development of new medicines and vaccines while understands that the prompt policy responses to utilizing the flexibilities available in the TRIPS Agreement for public health at this challenging stage is also needed to mitigate the impact of the pandemic.

135. Thailand has always supported a right balance between IP protection and public interest. However, since the proposal presents the broader dimensions on the waiver from the TRIPS Agreement, we, therefore, currently are studying the proposal prudently and may seek further clarification from the proponents in the future.

15.20 Tunisia

136. Tunisia thanks India and South Africa for their joint communication in document IP/C/W/669 and supports their initiative, which aims to provide equitable and affordable access to medical products needed for the prevention, containment and treatment of COVID-19.

137. Tunisia, which urgently called for international solidarity and secured by unanimous consent the adoption, on 1 July 2020, by the UN Security Council of a Resolution on combating the COVID-19 pandemic, would like to underline the need for exceptional measures to deal with an equally exceptional health, economic and social global situation; as well as the WTO's decisive role to play in promoting such multilateral cooperation to protect international public health at this critical juncture.

138. My country, like all countries, has undergone disruptions to its production and trade cycles for medical products needed to combat the pandemic and has suffered the consequences, which may worsen with this second wave of the virus.

139. Tunisia would therefore be open to the proposal for a "Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19", and in this regard would like to highlight the following:

a. The TRIPS Agreement provides for the use of waivers in cases of approved exceptional situations and this is case of COVID-19, which was declared a global pandemic by WHO.

b. This waiver is limited to medical products needed for the prevention, containment and treatment of COVID-19, and should be time-bound until a vaccine is available worldwide, thereby mitigating its adverse effect on intellectual property rights.

c. Ten months into the pandemic, a meaningful solution to the health crisis is still not within reach, along with persisting inequality in access to the technologies required to deal with the pandemic. The solution to dealing with this pandemic, therefore, must be global and shared by all.

15.21 Tanzania on behalf of the African Group

140. The African Group welcomes the joint submission by the delegations of India and South Africa contained in document IP/C/W/669 titled Proposal for a Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19. The African Group is consulting internally and with Capitals on this joint submission.

141. As we have previously expressed at the Informal HOD and General Council meetings, the African Group holds the view that the WTO has an instrumental role to play in fostering multilateral cooperation that will promote equitable and affordable access to key products necessary for the prevention, containment and treatment of COVID-19. In this connection, and in accordance with the Doha Declaration on TRIPS Agreement and public health, solidarity and close cooperation among Members is necessary to ensure that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health, an important aspect at this critical time.

15.22 Ecuador

142. We thank India and South Africa for introducing this proposal, on which we wish to make a few comments.

143. With regard to the first Article of the proposal, in which it is proposed to waive Members' obligation to implement or apply sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19, we are of the view that is approach is, in principle, a positive one.

144. The global health crisis has had a severe impact on countries and may require decisions to help them tackle the pandemic, in accordance with international law and following the relevant multilateral processes.

145. However, Ecuador considers that the proposal needs to offer clearer guidance on, *inter alia*, what are intellectual property developments, the possibility of second uses, and research related information.

146. It is vital to avoid uncertainties over what would be covered by a waiver.

147. This would prevent any adverse effects on the development of a solution to COVID-19 and avoid setting inappropriate precedents.

148. Likewise, in our view, the idea of non-compliance with Part III of the Agreement on the enforcement of intellectual property rights is ambiguous. More clarification is needed on the matter to ensure consistency with the principle of protection.

149. In this respect, although Ecuador agrees with the urgency and humanitarian aims behind the proposal from India and South Africa, we are of the view that the initiative needs to be reworked in order to address the above-mentioned concerns.

15.23 Senegal

150. My delegation thanks South Africa, India, Kenya and Eswatini for the proposal for a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19.

151. Our delegation understands the grounds for this proposal as reflected in the statements made by South Africa and India. We strongly believe that, pursuant to the Doha Declaration on intellectual property and public health, the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.

152. The ongoing and profound health, economic and social crisis around the world, which impacts developing countries and LDCs in particular, is an opportunity for Members to strengthen cooperation and international solidarity to ensure universal access to affordable medicines, equipment and vaccines needed for COVID-19 prevention and treatment.

153. The document IP/C/W/669 is being reviewed in my capital, and my delegation welcomes constructive discussions on this item on our agenda for this meeting and at the next meeting of the Council.

15.24 Costa Rica

154. At the outset, Costa Rica wishes to thank India and South Africa for their proposal, which enables us to resume an important discussion.

155. Humankind is currently facing a number of challenges without precedent in recent history. Tackling these challenges requires a response that is, above all, solidarity-based, joint, and respectful of the law. As societies, our commitment to innovation must be focused on promoting scientific research, technological development and the widest possible dissemination of the scientific advances drawn from COVID-19.

156. As we face this pandemic, we cannot lose sight of the fact that human health is fundamental and that our actions must be based on cooperation and solidarity. There can be no doubt that our success in these uncertain times will lie in our ability to tackle the current situation collectively, as well as in the acceptance that individual actions will be decisive and impact collective actions.

157. The generation of knowledge on COVID-19 has increased over the past few months. It is crucial that these findings are shared as much as possible so that they benefit everyone, everywhere, at the same time.

158. Our country remains firmly committed to the protection and enforcement of intellectual property rights, and will continue to promote innovation by recognizing and enforcing the rights of creators and innovators.

159. Based on this belief, Costa Rica asked the WHO to establish a health technology pool for vaccines, medicines, diagnostic methods and any other tools useful in the fight against COVID-19. On 29 May, Costa Rica, the WHO and other WHO Members launched a "Solidarity Call for Action". This initiative led to the establishment of the C-TAP platform for the open, voluntary and collaborative exchange of knowledge, information and intellectual property relating to existing and new health technologies for combating COVID-19. Costa Rica has already shared advances made by its own scientists, such as the equine serum protocol, which is currently in the clinical trial phase. We strongly but respectfully encourage WTO Members to voluntarily share their knowledge through this platform.

160. Within this Organization, the proper management of intellectual property rights has, in the past, enabled us to promote and foster research and development, which are two key elements for promoting innovation in the fight against the current pandemic.

15.25 Mauritius

161. Would like to thank the delegation of South Africa and India for introducing this proposal which from our perspective aims at buttressing Public Health.

162. As my delegation indicated at the General Council meeting a few days ago, Mauritius will support initiatives that go in the direction of upholding Public Health.

163. COVID-19 has severely impacted on the National Budget as we seek to preserve Public Health whilst at the same time economic growth has come to a standstill. Our trajectory towards the achievement of the Sustainable Development Goals has been challenged as funds are diverted towards efforts aimed at fighting the pandemic.

164. I am sure many countries have been through similar experiences and in particular Small Island developing countries which have felt their vulnerability further exacerbated.

165. One aspect which came to the fore for us during this time was the issue of Remoteness, distance from our export destinations and our supply chains.

166. Two words will guide us in future when looking at Public Health Initiatives: Affordability and Accessibility.

167. It is from this Perspective that Mauritius supports the Initiative put forward by India and South Africa.

168. It is not that we do not understand the value of Innovation or indeed the efforts we need to make to preserve Innovation. But in a situation of war, one needs exceptional measures.

169. We fully support this initiative.

15.26 Colombia

170. Colombia wishes to thank the delegations of South Africa and India for submitting the communication on the waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19. We have always expressed our interest in making the most of the TRIPS Council as a forum for coordination and constructive discussion among WTO Members.

171. We note that there are interesting aspects that may be useful. I should also point out that the document is still being reviewed by the relevant authorities in my capital, for which reason we will refrain from addressing the content of the proposal. Nevertheless, as we have stated previously, I wish to stress that this is a significant discussion, because we consider the interaction between the protection of intellectual property rights and public health to be of great importance.

15.27 El Salvador

172. As is the case worldwide, the Covid-19 pandemic has been a tough and unexpected blow to our country. The Government of El Salvador has stepped up its efforts to support affected sectors of the population. Despite intensive and early efforts to prevent the virus's entry into national territory, we were ultimately unable to contain its entry and spread. In addition to the loss of human life and the health crisis, the economy has been hard hit and the Government is therefore implementing an economic recovery plan.

173. In light of this, we wish to stress the importance that we as a country attach to the comprehensive handling and management of the Covid-19 health crisis and of any tool that may serve such purposes. We are currently considering the proposal internally.

174. During this analysis, a need for greater clarity on some aspects of the proposed decision has arisen. We are therefore seeking to meet bilaterally with the proponent delegations in the coming days, so that we are able to continue our internal analysis and consultation process.

15.28 Mali

175. The sudden emergence of coronavirus has brought out humans' most basic survival instincts. Many Members have taken protectionist measures that, although temporary, may have dramatic consequences:

a. - Export restrictions on basic foodstuffs, medical products, pharmaceuticals and medical equipment;

b. - The imposition of compulsory licences, which, despite the WHO's alarming projections, deprives the poorest of adequate care and the means to protect themselves from the virus.

176. These restrictive measures, combined with the border closures imposed across the world, have exacerbated the damaging effects of the pandemic in LDCs and small, vulnerable economies, pushing tens, if not hundreds, of millions of people into insecurity and extreme poverty.

177. Landlocked LDCs, such as Mali, have been particularly hard hit.

178. Access to affordable medicines and vaccines should be a right for all, yet it represents an immeasurable challenge for our low-income countries. For LDCs and even certain developing countries, it is vital for Article 66.2 of the TRIPS Agreement to be effectively applied and implemented so that we can benefit from the transfer of technology needed to manufacture medicines and vaccines.

179. In the 21st century, no country should be left unable to care for its citizens. No human being should be forced to make the impossible choice between feeding their family members or securing medical care for them. Unfortunately, this is very often the case in our countries.

180. The virus has shown that it can hit anywhere, regardless of level of development. It has shown that it cannot be stopped by border closures and does not require an entry visa to travel. Help us, the most vulnerable, to fight it with the right weapons, by redressing the grievances expressed in this meeting.

181. In conclusion, Mali fully endorses and supports the communications from India and South Africa, as well as the one submitted by Chad on behalf of the LDC Group. The waiver under Article 66.1 of the TRIPS Agreement should be extended for as long as LDCs exist.

15.29 Jamaica

182. Jamaica wishes to join other delegations in thanking the co-sponsors of this proposal. It is being studied in Capital and we will revert with more detailed comments at a later date.

183. Jamaica has not been speared the impact of the COVID-19 pandemic. With an infection rate of close to 8000 and 151 deaths, Jamaica sees the discussion of TRIPS and public health as taking on an added level of significance.

184. We have long advocated for the WTO to play a critical role in balancing the protection of intellectual property rights on the one hand with affordable and equitable access to medicine and other protected health products, especially for developing countries.

185. We do welcome the discussion at this important juncture. We do listen to the views expressed and remain of the view that we can find convergence on these issues in a manner that balances the interests of access, affordability and the encouragement of innovation.

186. Jamaica stands ready to contribute to this discussion as we seek to manage this global challenge.

15.30 European Union

187. The European Union fully shares concerns expressed by various Members about pandemic caused by COVID-19 and its devastating impact on people's health and wellbeing as well as on economic prosperity.

188. Safe and effective diagnostics, treatments and vaccines are crucial in the fight against COVID-19. In a global pandemic only broad and equitable access to vaccines across the globe will ensure that the public health crisis can be tackled effectively, including in developing countries that have no production capacities or more limited financial resources.

189. We need to find solutions for everyone, whether in the developed or developing countries, because it is a challenge we face together and because no one is safe until everyone is safe. The European Union stands committed to work with all Members on this global challenge.

190. Researchers and pharmaceutical industry, supported by public funding, have put extraordinary efforts into the development of future treatments and vaccines against COVID-19. A well-functioning intellectual property rights system is crucial to ensure that these efforts are adequately incentivised and rewarded.

191. There is no indication that IPRs issues have been a genuine barrier in relation to COVID-19-related medicines and technologies. While we agree that maintaining continued supply of such medicines and technologies is a difficult task we all face, non-efficient and underfunded healthcare and procurement systems, spike in demand and lack of manufacturing capacity or materials are much more likely to have an impact on the access to those medicines and technologies.

192. A well-functioning IPRs system, including its wide range of exceptions and flexibilities, is part of the solution rather than an obstacle. It is our view that we should concentrate on the key current challenges:

a. rapidly developing safe and effective treatment or vaccine against COVID-19;

b. increasing manufacturing capacity;

c. keeping global supply chains open; and

d. ensuring broad and equitable global distribution of treatments and vaccines once they become available.

193. We would like to present in more detail how the European Union tackles these challenges.

194. The absolute priority and a major challenge at the moment is the rapid development and rolling out of safe and effective treatments and vaccines against COVID-19. Vaccine development is a complex and lengthy process, which normally takes around ten years. The public funding and support is contributing significantly to the development of the future vaccines, potentially within a timeframe between 12 and 18 months. However, it is the researchers and the industry with their know-how, previous and current investment that will be delivering these new vaccines, including the running of

clinical trials in parallel with investing in production capacity to be able to produce millions, or even billions, of doses of a successful vaccine. This work must be incentivised and adequately rewarded and the IPRs system is one the main economic incentives.

195. We note that public financing of research and development of the innovative treatments and vaccines can be subject to certain conditions. For example, the European Commission has published a Manifesto for EU COVID-19 research to encourage recipients of EU funding to make research results accessible to all. Recent Horizon 2020 COVID-19 calls have also included a temporary obligation to license results on a non-exclusive basis and at fair and reasonable conditions.

196. Once the treatment or the vaccine is available, the manufacturing of these treatments and vaccines at such an unprecedented scale and within an unprecedented timeline is likely to be the most problematic issue to be tackled. We should collaborate and assist the pharmaceutical sector in ramping up the manufacturing capacity. To tackle current and future supply side shortages, the European Commission signed and continues discussing further pre-purchase agreements that incentivise and enable the pharmaceutical sector to build and prepare large-scale production facilities once effective treatments and vaccines become available.

197. Being aware of the importance of the global supply chains in the pharmaceutical sector, the EU is discussing with some WTO partners a possible WTO 'trade and health' initiative with the aim to facilitate global access to affordable healthcare products, including for vulnerable countries without appropriate manufacturing capacities. The goal is to make supply chains more resilient and diversified and to support efforts to build strategic reserves of critical equipment. This initiative would cover issues such as establishing a scheme of global cooperation in times of health crisis in order to remove unnecessary barriers to trade, abolishing tariffs on pharmaceutical and medical goods, enhanced transparency and trade facilitating measures.

198. Finally, global collaboration is the only way to overcome a global pandemic. At present, international efforts are being made to ensure equitable distribution of affordable vaccines, in particular to the most vulnerable populations. To enable broad and equitable global distribution of treatments and vaccines, the EU has taken a leading role in the Global Coronavirus Response where so far nearly EUR 16 billion have been pledged for universal access to tests, treatments and vaccines against COVID-19 for the global recovery.

199. In collaboration with the WHO, the European Commission is actively supporting the Access to COVID-19 Tools Accelerator (ACT-A) and its vaccine pillar – the COVAX Facility. In September, the European Commission announced that it would fully participate in the COVAX Facility for equitable access to affordable COVID-19 vaccines everywhere, for everyone who needs them. As part of a Team Europe effort, the Commission contributes EUR 400 million in guarantees to support COVAX and its objectives in the context of the Coronavirus Global Response.

200. The EU considers that on the basis of the global innovation system, with the necessary IP tools such as patent pools and procurement arrangements as the COVAX Facility in place, existing and new treatments, and ultimately vaccines, can be made available and effectively deployed rapidly across the globe.

201. The TRIPS Agreement together with the principles endorsed in the Doha Declaration, is fit for purpose and allows for the necessary flexibilities in relation to IPRs protection, including in the case of a health emergency, such as the COVID-19 pandemic.

202. If all voluntary solutions failed and IP became a barrier to treatments or vaccines against COVID-19, mechanisms to overcome it are already available. The EU has consistently supported the use, where necessary and justified, of the flexibilities provided under the TRIPS Agreement and the Doha Declaration with the objective of ensuring effective access to medicines.

203. In particular, the TRIPS Agreement provides for the possibility, under certain conditions, of issuing a compulsory licence for local consumption of medicines and provides for fast-track procedures in health emergencies. The TRIPS Council Secretariat has, regularly and consistently, offered its services to any WTO Member that sees itself in the need of getting help to manage the process of Article 31*bis*. This was confirmed in the presentation we saw the previous day.

204. This system is accompanied by other inbuilt TRIPS flexibilities, applying to the various IP rights. In addition, we note that the least developed countries are exempt from the application of the TRIPS Agreement and, in particular, its pharmaceutical-related provisions.

205. Public health in light of the pandemic is a clear and undisputed priority. No effort must be spared to obtain safe, effective and affordable treatments, vaccines, tests and medical devices necessary to fight this pandemic and to ensure that these products are equitably distributed on a global scale. However, all these efforts must be geared towards addressing genuine challenges in this pandemic with appropriate solutions.

15.31 United States of America

206. The United States is committed to working with international partners in identifying practical ways both to increase access to safe, effective, affordable and lifesaving medicines around the world and to support policies that drive the development of new medicines.

207. Intellectual property encourages innovation, incentivizes research and development, and can facilitate manufacturing and distribution, thus helping to expand access to medicines around the world. These core features of intellectual property are necessary for the global community to find and develop treatments and cures for this deadly pandemic and to support economic recovery.

208. IP plays a key role in facilitating access to today's medicines and enables investments in R&D that lead to tomorrow's cures. IP promotes collaboration that is essential for the rapid development of new treatments and cures, particularly during crises like COVID-19.

209. We have the shared objective of helping to ensure the swift delivery of potential COVID-19 therapeutics and vaccines around the globe. We believe that facilitating incentives for innovation and competition to develop, test, and produce safe and effective therapeutics and vaccines for the COVID-19 response, including by respecting intellectual property rights, and supporting industry-led collaboration and voluntary knowledge sharing, will best achieve our shared objective.

210. As we have stated in past discussions, IP is an important piece, but ultimately only one piece of addressing the issue of access to any potential therapy. We believe that IP has not been an obstacle in addressing the pandemic but rather has motivated global efforts to find treatments and cures. Limits to manufacturing capacities and supply chain issues, for example, are of much greater concern, especially for vaccines, given the need to provide access to the entire global population. We also must be concerned about the pandemic creating the opportunity for the increase of counterfeit COVID-19 pharmaceuticals, which are in and of themselves a threat to health and safety. In fact, the perspective that IP is a barrier to access to medicines is often voiced by governments that have significant barriers like taxes and tariffs in places that affect access.

211. Where intellectual property rights exist, they can be licensed to companies around the world to scale up manufacturing. But if the time needed to get the required regulatory approvals is too long, and other barriers make the cost of products too high, the raw materials or labour needed are unavailable, or the market is flooded with counterfeit goods, then safe and effective access to needed treatments and equipment would be affected.

212. The United States does not support the waiver proposal of India and South Africa. Weakening IP protection and enforcement would be counterproductive to our global fight against COVID through the creation of needed medical technologies and would not address the current, main challenges to access concerning manufacturing and raw material resources.

15.32 Switzerland

213. The COVID-19 Pandemic poses an enormous challenge to the global community. The urgent need for a new vaccine and effective medical products to combat the novel coronavirus is out of question.

214. Switzerland fully acknowledges the challenges that come with the current pandemic. In these trying times, it is imperative for WTO Members and all stakeholders, whether public or private, non-governmental, scientists and researchers, to collaborate in close partnership to ensure rapid,

affordable and equitable access to medical products. So how can we best ensure access at a global scale?

215. Under the heading of COVID-19, the authors of document IP/C/W/669 propose a sweeping waiver from the implementation, application and enforcement of most of the intellectual property protection that the TRIPS Agreement provides for.

216. Switzerland shares the concern that individual Members and the international community must now do everything that is necessary to ensure affordable and equitable access to COVID-related medical products globally.

217. However, Switzerland does not believe that a TRIPS waiver is the right way forward to achieve this goal. On the contrary, we are convinced that such a move would have the opposite effects from those looked for.

218. The intellectual property system has been and continues to be a pivotal factor ensuring a pipeline of innovative pharmaceutical products, including vaccines to work. It is the reliable legal framework which provides the foundation for stakeholders, for the public and private actors, to invest, work and innovate together.

219. IP rights, and in particular patents, spur stakeholders' interaction, and enable them to share information, knowledge and data, to aliment the global databases, license in and out technology, and to do what is necessary to eventually scale up capacity.

220. Declaring a TRIPS waiver for COVID-19 would mean to put into question the foundation of a large part of the investments and efforts currently undertaken to research and develop a vaccine and medical products against the novel coronavirus. It would risk to undermine the partnerships that bring about first results in the fight against the global pandemic.

221. Rather, we need to ensure that the unprecedented collaboration between all relevant actors, who have come together over the past few months to do everything possible to contain the crisis, continues without disruption.

222. This being said, as soon as Research & Development for a new vaccine and medicines against the novel coronavirus will succeed, equitable and affordable access to these innovative products must be ensured. To meet this challenge, all relevant factors need to be taken into account that determine access.

223. It is important that we continue to address the challenges ahead in a holistic and sustainable manner, and within the rules-based multilateral trading system.

224. The TRIPS Agreement, strikes the right balance, provides for the necessary means and remedies to allow the use of protected content and products, should voluntary mechanisms fail. In such an instance, a country may make use of the flexibilities which WTO Members confirmed in the Doha Declaration on TRIPS and public health.

225. We should avoid sweeping measures resulting in a comprehensive revocation of rights for the time of the pandemic which would disincentivize efforts underway.

226. Rather, the collaborations and partnerships currently engaged in the search of a new vaccine and medicines against the virus must be deployed to work for broad and equitable.

227. We need to continue working at the multilateral level and supporting global initiatives. Several mechanisms, which facilitate access to medicines and other health technologies to fight diseases other than COVID-19 for the poorest countries, already exist. These are voluntary collaborations between the private and public sectors and international initiatives. For COVID-19, we should build on the ample experience that is already there.

228. Among the many initiatives under way, I would like to highlight the COVID-19 Vaccine Global Access facility (COVAX) and the Gavi COVAX Advance Market Commitment (AMC). These and others

take IP as an important basis for the cooperation of the participating stakeholders and their joint endeavour.

229. Switzerland has released CHF 400 million in support of international action in response to COVID-19. Working together with partners and the relevant international organizations to find global solutions for access and an equitable distribution of COVID-19 medical products for all countries, Switzerland supports all three pillars of the Access to COVID-19 Tools (ACT) Accelerator. This to ensure global collaboration to accelerate and scale up development, production and equitable access to diagnostics, treatments as well as a future COVID-19 vaccine.

230. Switzerland further supports international partnership organizations such as Coalition for Epidemic Preparedness Innovations (CEPI) or the vaccines alliance GAVI. They have a leading role together with the ACT Accelerator in the process, covering the four pillars of access in the response to the pandemic.

231. As part of the holistic response to the challenges we face, we also welcome the recent initiatives aiming at facilitating international trade in essential goods in order to promote more resilient and diversified supply chains.

232. To sum up, partnerships, multilateralism, a sound and reliable legal framework and IP protection as provided by the TRIPS Agreement are essential for the collaboration that we see now engage in the process of innovative research and development for a vaccine and effective treatments against the novel coronavirus. Switzerland calls on Members to engage in and contribute to those international initiatives and partnerships, which in that collaborative spirit prepare and work towards ensuring equitable access.

233. Let's hope for the best, that we will soon have such a new vaccine and safe, medical products at our disposal against the novel coronavirus, to fight the pandemic effectively together.

15.33 Japan

234. Japan recognizes the need for all Members to have unhindered timely access to quality, safe, efficacious and affordable diagnostic kits, medicines, vaccines, and essential medical technologies for the COVID-19 response.

235. In this regard, research and development (R&D) activities for medicines and vaccines, which would be effective for COVID-19, have been intensively progressing thus far. Each Member needs to do their utmost to support research institutes and pharmaceutical companies for development of such medicines and vaccines and provide them incentives for such development. In addition, it is essential to support the initiatives which allow all Members, including developing countries, to be able to readily access these medicines and vaccines.

236. We understand that intellectual properties play a central role in providing incentives for developing such medicines and vaccines, and relevant medical technologies. If the obligations of protection and enforcement of IP rights under the TRIPS Agreement were waived, incentives for the development would be undermined. As a result, this would not only hinder the development of medicines and vaccines effective for COVID-19, but also diminish incentive to invest substantial time and money in developing treatments of infective disease and for the next global health crisis as well.

237. Furthermore, in the midst of this COVID-19 crisis, it should be noted that many companies and researchers are working to ensure access to effective medical products and useful information for combatting COVID-19 through voluntary efforts including licensing IPs, waiving their IP rights enforcement, publishing scientific data, and providing copyrighted works.

238. Japan is of the view that this proposal does not indicate sufficient grounds that the existing framework is not working well. Furthermore, the proposal does not fully explain the necessity for waiving any sections of the TRIPS Agreement.

239. Therefore, even though Japan recognizes the need for unhindered timely access to essential medical products, Japan is not in the position to support this proposal.

15.34 Norway

240. We would like to thank Eswatini, India, Kenya and South Africa for their proposal. Norway attaches great importance to tackling the global health challenges in the context of COVID-19, including providing access to the necessary medical products for all. To develop and produce, in sufficient amount, all necessary products, whether protected by patents or not, international cooperation is crucial and there are many strategies being employed by governments to achieve the best possible outcome.

241. Norway believes that the availability of medicines and other medical products in the context of COVID-19 is a very important and multifaceted issue which needs a balanced and coherent approach. There is a range of factors weighing in with respect to these issues, at both the international, regional and national levels. All aspects should be considered together, not only the aspects related to intellectual property.

242. The COVID-19 pandemic is one of the worst health crises that the world has ever faced. Everyone is affected, but yet again we see that the most vulnerable and marginalized are disproportionately impacted. Testing, treatment and vaccines for COVID-19 should be accessible for everyone as they become available.

243. To achieve this objective of equitable access, Norway is heavily engaged in the ACT-Accelerator – or ACT-A. Through this partnership between governments, scientists, businesses, civil society, and philanthropists and global health organizations Norway is a member of COVAX where we have pledged approximately USD 25 million (NOK 230 million) to the COVAX AMC to secure fair access to vaccines for low income countries. Together with President Ramaphosa of South-Africa, our Prime Minister Solberg is co-chairing the ACT-A Facilitation Council where we are working to raise the necessary political awareness and finances for ACT-A. Equitable access is a top political priority for us and we hope to partner with all of you to make it a reality.

244. Likewise, the COVID-19 Technology Access Pool (C-TAP) will compile, in one place, pledges of commitment made under the Solidarity Call to Action to voluntarily share COVID-19 health technology related knowledge, intellectual property and data. Norway supports voluntary mechanisms for sharing of patents and we would like to encourage private companies to share COVID-19 related knowledge and patents during the pandemic. Some companies have come forward with voluntary licenses or pledged not to invoke their patent rights during the pandemic.

245. The TRIPS Agreement provides for minimum standards of IPRs protection, while at the same time providing for the possibility of compulsory licensing of patents under the conditions set out in the agreement, which particularly aim at providing flexibility in situations of national emergencies and extreme urgency such as the COVID-19 pandemic. Thus, this is already catered for by the TRIPS Agreement.

246. A balanced and coherent approach requires that both the incentives for the development of new medicines and medical products to tackle COVID-19 provided by the availability of intellectual property rights protection – as well as the need for national flexibilities to make exceptions in extreme situations, must be taken into account. The WTO system is in our view already reflecting the required balance in this respect.

247. To introduce even further and very broad exceptions related specifically to COVID-19 as proposed, seemingly opening for providing no IPRs protection at all for COVID-19 related products under the discretion of national authorities, would mean a setback for the incentives for innovation in the field of medicines and medical products related to COVID-19, as well as it would provide legal uncertainty with respect to what the relationship would be between such derogation provisions and the already existing provisions on compulsory licensing in TRIPS.

248. Against this background, Norway believes that the already existing flexibilities of the TRIPS Agreement are sufficient, and cannot support the current proposal.

15.35 United Kingdom

249. The United Kingdom would like to thank Eswatini, Kenya, India and South Africa for introducing this agenda item and giving the Council an opportunity to discuss this very important issue.

250. The UK has long supported affordable and equitable access to essential medicines, including in low and middle-income countries. In this vein, intellectual property rights provide incentives to create new inventions, such as life-changing vaccines, treatments, and technologies.

251. The UK believes that a robust and fair intellectual property system is a key part of the innovation framework that allows economies to grow, while enabling society to benefit from knowledge and ideas.

252. In the current pandemic, we must acknowledge the IP system is not just made up of rights, but it also contains built-in mechanisms to support the sharing and dissemination of innovation and creativity. Flexibilities such as limitations and exceptions to IP rights have already proved invaluable to the development of digital solutions to support diagnostics and treatment. Text and data mining exceptions have been used in initial research into COVID-19, including for tracking and predicting its spread and are being used in the search for treatments.

253. Beyond hypotheticals, we have not identified clear ways in which IP has acted as a barrier to accessing vaccines, treatments, or technologies in the global response to COVID-19.

254. A waiver to the IP rights set out in the TRIPS Agreement is an extreme measure to address an unproven problem. The UK is of the view that pursuing the proposed path would be counterproductive and would undermine a regime that offers solutions to the issues at hand. Rather, we should consider how to meet the objectives of prevention, containment and treatment of COVID-19 as set out in the communication.

255. Multiple factors need to be considered to ensure equitable access for all to COVID-19 vaccines. These include increasing manufacturing and distribution capacity, measures to support or incentivise technology transfer, ensuring global supply chains remain open, and ensuring that effective platforms are utilised to voluntarily share IP and know how.

256. There are existing mechanisms that facilitate the sharing of IP through voluntary licensing of intellectual property. Organisations like the WHO are developing initiatives by learning lessons from these mechanisms. For example, expanding the mandate of an existing organisation such as the Medicines Patent Pool to address needs emerging from COVID-19.

257. The world urgently needs access for all to safe, effective, quality, and affordable vaccines, diagnostics, medicines, and other health technologies to enable an effective response to the COVID-19 pandemic, which is why a strong and robust multilateral IP system that can meet this challenge is vital.

258. The UK has played a leading role in financing the global effort and working with our international and national partners, to identify end-to-end solutions that ensure affordable access for all and ensuring no-one is left behind, including the poorest and most vulnerable.

259. For example, the UK has been leading the way in delivering a multilateral solution to COVID-19 vaccines, therapeutics, and diagnostics such as by committing GBP 298 million to the COVAX Advance Market Commitment (AMC), with GBP 250 million more available as "matched funding" if others commit USD 1 billion by December. We urge other Members to join the COVAX AMC in order to secure manufacturing capacity for 92 low and middle-income countries. This will support equitable access and will demonstrate that a multilateral response can rise to global challenges.

260. We are also committed to collaborating with public and private partners in the UK and internationally, including exploring voluntary arrangements and approaches such as non-exclusive voluntary licensing which promote affordable access for all while also providing incentives to create new inventions, to accelerate development and equitable access in all countries to affordable health technologies for responding to COVID-19.

261. We would like to encourage active dialogue between industry and governments to explore how best to work together to prevent, contain and treat COVID-19, including by using TRIPS-compliant licensing models in developing countries. While we welcome discussion of this issue and acknowledge the concerns of the co-sponsors as set out in their communication, we do not consider a waiver of the TRIPS Agreement to be an effective way to achieve the objectives outlined in the communication.

262. As we said in the informal consultation on standing TRIPS Council matters, we would be happy to participate in a workshop or other event that can support understanding how best the IP system can meet the objectives of Members in relation to COVID-19.

15.36 Brazil

263. The COVID-19 pandemic is an unprecedented human tragedy, with severe economic implications.

264. The Brazilian Government has been working to mitigate the health and economic impacts of the crisis domestically and has strengthened scientific collaboration with international partners in the search of possible solutions, such as a vaccine.

265. It is in the interest of all Members to guarantee adequate access to medicines and therapeutics for the disease.

266. The intellectual property system has been envisaged to strike a balance between access and protection, between public and private interest.

267. And it is our job to make sure that the appropriate balance is attained. This is not always an easy task. We have crafted a system that allows for some carve-outs, for limitations and exceptions, to tackle situations as the one we are living.

268. We believe that the TRIPS Agreement provides us with tools and policy space for Members to take measures to protect public health.

269. Brazil has been an historic promoter of TRIPS flexibilities and of the right of WTO Members to use, to full extent, the provisions in the TRIPS Agreement.

270. We therefore believe that solutions can be legitimately sought within the system.

271. This does not mean that the system is not amenable to improvement, as we have done in 2003 with the inclusion of the Article 31*bis* Amendment to the TRIPS Agreement.

272. The COVID-19 crisis is a textbook example of the balance we should strike with the intellectual property system. On the one side, we want innovation systems (public and private) to be fully mobilized in the search for solutions to the pandemic. On the other, it is necessary that any solution produced be widely available.

273. At this point in time, we are not convinced that a waiver to the TRIPS Agreement would guarantee us meaningful improvement of access, while it might give the wrong signs to innovators and potentially hinder efforts to produce the solutions we need.

274. We should use this opportunity to exchange among ourselves any concrete difficulties faced in implementing TRIPS flexibilities for the purpose of prevention, containment and treatment of COVID-19, further enhancing our understanding of how limitations and exceptions could serve those purposes.

275. We must also be honest in recognizing that not all difficulties encountered are attributable to the agreement itself. They may relate to limitations in national legislation or pertain to a larger range of issues that fall outside the scope of the agreement and may impact access to COVID-related therapeutics and technologies.

276. Brazil remains open, as usual, to discussing any proposals that aim at improving the intellectual property system and its balance of interests in line with the legitimate aspirations of Members.

15.37 Mozambique

277. The delegation of Mozambique would like to welcome and commend the delegations of South Africa and India as well as the co-sponsors for the proposal put forward (document IP/C/W/669), in view for a waiver from certain provisions of the TRIPS Agreement, for prevention, containment, and Treatment of COVID-19 .

278. COVID-19 is an unprecedented pandemic disease, facing the global community for long, and, it continues to challenge the world. It is a fact that it has been disproportionately affecting the countries and, due to diversity on the country's economic and development levels, the responses vary from one to another, being more critical in developing and least developed countries due to limited capacity to cope with the pandemic.

279. The calls for solidarity, cooperation and collaborative efforts have been continuously put forward in view to help countries to contain, reduce and even eliminate the transmission of COVID-19 including its elimination as such. A lot has been done in view to respond to the above appeals but, as it can be seen, given the nature of the COVID-19 pandemic disease; it seems factual that the global community is still very far from reaching a stage in which no more lives could be lost as well as infections not occurring.

280. This facts show clearly that all that has been done so far is still insufficient to solve the problem, and , thus, meaning that a massive involvement is required so as to produce the necessary testing materials, vaccines, medicines, medical equipment and all needed tools and other elements.

281. For our delegation, the proposal in debate is of utmost importance and very timely due to the current situation and, it would bring flexibility that would extensively help to update the current status of availability and access to the needed medical and technological goods.

282. According to the proposal, the request is objectively addressed, as it foresees a limited duration, thus, envisaging to be lasting solely while COVID-19 Pandemic disease continue to face the humanity. Till now, there is no certainty as to when will the vaccines and or certain medical drugs be encountered and or approved to be efficient to eradicate COVID-19.

283. Along with the above reality, even if vaccines and or other medicines are approved, there is no certainty if they are going to be accessible, rapidly available and even affordable to all.

284. We totally support the proposal. If accepted and operationalized, it can enable countries to substantially contribute to respond to internal needs, and help to address the needs that are so far not sufficiently responding to the huge, not only current but near future challenging demands.

285. We associate ourselves to the statement made by the Africa Group and others who positively appreciates the proposal.

286. To conclude, our delegation expresses support to the above-mentioned proposal.

15.38 Canada

287. Canada's longstanding view is that IP rights can serve as an important incentive to innovation, while ensuring that there is an appropriate balance between protecting IP rights and promoting access to medicines and other health care technologies. Canada remains supportive of the existing multilateral legal framework under the TRIPS Agreement, which already establishes an important balance among these areas.

288. We note that TRIPS contains important flexibilities for various categories of IP rights under the Agreement, and that the Doha Declaration on the TRIPS Agreement and Public Health affirms the rights of WTO Members to make use of flexibilities for the purpose of protecting public health and promoting access to medicines.

289. Canada also reminds that IP rights are only one part of a broad discussion informing the availability and accessibility of medicines; indeed, as the Doha Declaration emphasizes, the TRIPS Agreement is part of the wider national and international action to address public health problems.

290. With respect to the COVID-19 pandemic, and as a complement to our own procurement efforts, Canada has made significant investments to ensure that COVID-19 vaccines, therapeutics, and diagnostics are affordable and equitably distributed globally. For instance, Canada is highly supportive of the Access to COVID-19 Tools (ACT) Accelerator, which provides a critical platform for global cooperation towards the development, production, and distribution of safe and effective COVID-19 medical interventions. On 27 June 2020, the Government of Canada committed CAD 120 million (or roughly USD 91 million) in support of the activities of the ACT Accelerator. On 25 September 2020, Canada announced a CAD 440 million (or approximately USD 335 million) contribution to the COVAX Facility and Advance Market Commitment (or COVAX AMC), to facilitate rapid, fair and equitable access to COVID-19 vaccines for all countries, regardless of income level. As part of this commitment, Canada has allocated CAD 220 million (or approximately USD 167 million) to the COVAX AMC to purchase vaccine doses for low- and middle-income countries.

291. Canada remains fully available to discuss the specific challenges faced by Members in procuring COVID-19 treatments and other related technologies, so that Members may identify what WTO and other avenues would provide the best ways forward, as appropriate and in coordination with other efforts at the WTO, WHO, and other institutions. Canada also remains fully available to discuss the specific challenges of Members in using the special compulsory licensing system under the TRIPS Agreement, and to discuss Canada's own experience with this system.

292. We are also open to hearing more from proponents of the document IP/C/W/669 proposal on the specific problems and gaps that this proposal would seek to address as well as the views of other Members.

15.39 Australia

293. Australia thanks India and South Africa for their communication.

294. Australia recognizes the communication's concern that COVID-19 represents an unprecedented disruption to the global economy and world trade, and that the world requires rapid access to affordable medical products, including vaccines and medicines.

295. As Prime Minister Morrison made clear at the UN General Assembly the previous month, there is a global and moral responsibility on all countries to share a COVID-19 vaccine far and wide:

a. Prime Minister Morrison made clear that if Australia finds a vaccine, we will share it, and the Prime Minister urged all countries to make that pledge.

296. To this end, Australia has committed USD 80 million to the Gavi COVAX Facility Advance market Commitment, which will improve access for 92 developing countries to safe, effective and affordable COVID-19 vaccines:

a. and we've committed a further USD 23.2 million for a COVID-19 Vaccine Access and Health Security Programme for the Pacific and Southeast Asia; and

b. we have also invested USD 20 million the development of COVID-19 vaccines in Australia for the greater global good and a USD 7.5 million contribution to the Coalition for Epidemic Preparedness Innovations which is supporting nine of the leading COVID-19 candidates globally.

297. Australia sees well-functioning and well-understood international trade and IP rules, including their flexibilities, as a necessary tool in delivering universal access to COVID-19 medical products and technologies, such as vaccines after all, the COVAX Facility is underpinned by international IP rules.

298. To this end, Australia cannot support the waiver of Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement

a. at a time when we must come together to address the complex and broad-ranging challenges posed by COVID-19, this waiver could upend global supply chains, spread uncertainty and undermine international rules.

299. Intellectual property plays a key role in incentivising the often costly and timely development of important health products referred to in the communication

a. the waiver may jeopardise the private investment that has been instrumental in driving a number of vaccines towards the final stages of phase III testing.

300. Australia also recognizes that beyond IP rules, other trade-related measures have an important role in helping members respond to COVID-19:

a. to this end, we underscore the importance of domestic regulations that support the free flow of technology and vital health products, and the need to resist disproportionate export restrictions.

301. But Australia acknowledges that international rules must support quick, fair, predictable and implementable access arrangements to vital health products, including vaccines:

a. consistent with the concerns raised in the communication, we recognize the need for all members to fully understand their rights and obligations under the TRIPS Agreement and its flexibilities

b. to this end, we would support the provision of further information to members regarding the application of the TRIPS Agreement and its flexibilities.

302. It is Australia's view that a harmonious, well-functioning and clearly understood international IP framework, underpinned by the rules and flexibilities set out in the TRIPS Agreement, is crucial in ensuring members can address the challenges posed by COVID-19 fairly and in a timely manner.

15.40 Honduras

303. We welcome the proposal submitted by India and South Africa.

304. Our country considers that such a proposal may be a good initiative for seeking solutions in light of the current worldwide situation due to COVID-19.

15.41 Holy See

305. Since this is the first time my delegation is taking the floor during the current session of the TRIPS Council, allow me to begin by congratulating you on your assumption of the Chairmanship and by assuring you of the full engagement of the Holy See.

306. Pope Francis has recently reminded us that "a worldwide tragedy like the COVID-19 pandemic momentarily revived the sense that we are a global community, all in the same boat, where one person's problems are the problems of all. Once more we realized that no one is saved alone; we can only be saved together". As has emerged over the last months, and has been consistently recalled by this delegation, "access to affordable medicines no longer represents a challenge just for the least developed and other developing countries; it has also become an increasingly urgent issue for developed countries". In the context of the current global emergency, it is important for the international community as a whole, and for WTO Members in particular, to work together to ensure that intellectual property rights, such as patents, industrial designs, copyrights and the 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".

307. A well-designed intellectual property system must balance the private rights of inventors with the public needs of society. International intellectual property regulations reflect the premise, as stated in the Objectives of the TRIPS Agreement, that "…the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". These rights need to be adequately recognized, insofar as they compensate investments in time and capital and encourage promising research. Furthermore, such rights promote the common good by accelerating the search for solutions that benefit all needy persons in the modern world. For example, in the pursuit of new medical treatments, special protections are needed to ensure that producers are able to recover their massive expenditures on research. These protections include the assurance of just wages for scientists and researchers, as well as measures to guarantee compliance with regulations regarding product safety. In this regard, the protection of intellectual property rights enables the search for solutions to global problems.

308. Nonetheless, it is important to note that intellectual property rights are not an end in themselves but rather a means to an end. In order to maintain their validity, they must be subordinated, therefore, to the requirements of the common good. This requires the implementation of control mechanisms to monitor and, when necessary, to correct the logic of the market. As St. John Paul II affirmed, the "law of profit alone cannot be applied to that which is essential for the fight against hunger, disease, and poverty". These words continue to ring true.

309. Policies and laws should maintain a perspective focused on the respect and the promotion of human dignity, in a spirit of solidarity within and among nations. This means that, while recognizing the importance of protecting intellectual property rights, we should focus on the purpose of such rights and strive to avoid the potential negative consequences of the current system, which can arise when the aforementioned rights are divorced from their inherent foundation in the pursuit of the common good and the dignity of the human person. When, for example, high-income countries excessively protect knowledge based on a rigid assertion of intellectual property rights, this leads to an imbalance that must be addressed. Let us not forget that health care should not be subordinate to private interests; thus, access to medicines should be guaranteed in accord with the principle of non-discrimination and in a spirit of equity, transparency, participation and accountability.

310. As Pope Francis has stated, "what is needed is sincere and open dialogue, with responsible cooperation on the part of all: political authorities, the scientific community, the business world and civil society". In order to promote constructive dialogue that might results in positive action, the principles of solidarity, subsidiarity, and concern for the common good must be applied. Solidarity would encourage us to be attentive to the needs and concerns of others as much as our own and subsidiarity would have us supply the technical expertise and manufacturing capacity to those communities that otherwise would not have access to them.

311. In the midst of this global health crisis, we are all called to bring generously the best of our abilities to tackle the challenges of the current pandemic in all of its aspects and in every part of the world and to look to the future with creativity and hope. In this way, we will succeed in giving witness to the concrete solidarity that is indispensable to address the global challenges of our times. Almost 20 years ago, WTO Members agreed to remove an important obstacle to affordable drug imports: they waived certain restrictions in the TRIPS Agreement regarding the import and export of generic medicines under compulsory license, so as to ensure ready and affordable access to these medications.

312. In a similar fashion, given these exceptional circumstances, the TRIPS Council could recommend to the General Council, as early as possible, to grant 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.

313. Policies and laws should maintain a perspective focused on the respect and promotion of human dignity, in a spirit of solidarity within and among nations. This implies, *inter alia*, that, while recognizing the value of protecting intellectual property rights, we should focus on the purpose of such rights and on the limitations and potential negative consequences of the current system. "It would be sad if, for the vaccine for COVID-19, priority were to be given to the richest. It would be sad if this vaccine were to become the property of this nation or another, rather than universal and for all".

15.42 World Health Organization (WHO)

314. The World Health Organization (WHO) welcomes the India and South Africa proposal that helps to highlight the concerns in relation to sharing knowledge, intellectual property and data to promote R&D and affordable access to treatments, diagnostics and vaccines for COVID-19. The content of the proposal has been at the forefront of the public discussion since it has been presented and received support from several stakeholders and UN Agencies, including Unitaid, UNAIDS the Joint UN Programme on HIV/AIDS.

315. WHO is hopeful that the TRIPS Council will expeditiously advance discussions toward consensus on matters that will facilitate bringing the pandemic to an end.

316. WHO is convinced that collective action and a joint response to COVID-19 is vital for ending the pandemic and to avoid further damage to life, health and the global economy. All effective mechanisms to support this cause should be explored and utilized in order to contribute to the solution.

317. As mentioned in our previous statements the WHO COVID-19 Technology Access Pool (C-TAP) is one alternative, a voluntary mechanism to facilitate sharing of patents and all other forms of intellectual property such as know-how, data, trade secrets, and copyrights, as well as to assist in technology transfer necessary to expand the development and production of existing and new technologies needed in the response to the pandemic.

318. Voluntary mechanisms like C-TAP go in parallel with other measures available in the TRIPS Agreement and highlighted by the Doha Declaration to promote public health. The success of C-TAP in helping countries respond to the pandemic, will depend on collective political support it will receive from Members, so far, 40 countries have endorsed the initiative. Governments and funders that are investing resources on the development of new treatments, diagnostics, and vaccines should support encouraging private sector to share the know-how, IP and data through WHO C-TAP to facilitate scale-up tools for prevention, detection and treatment of COVID-19.

319. WHO-WIPO-WTO recent Study states that "…each country can tailor its domestic IP system to its particular needs and circumstances, including through TRIPS flexibilities." WHO, in collaboration with other international organizations and in line with the Global Strategy on Public Health, Innovation and Intellectual Property (GSPA-PHI), provides, upon request of Members, technical support to countries that intend to make use of the provisions contained in the TRIPS Agreement, including the flexibilities recognized by the Doha Declaration.

320. WHO is closely following the discussions of the TRIPS Council regarding Members concerns to respond to the pandemic and how to enable the use of a broad range of national and multilateral strategies to promote global equitable access to COVID-19 health technologies. An unprecedented crisis needs unprecedented response.

15.43 Joint United Nations Programme on HIV/AIDS (UNAIDS)

321. The Joint United Nations Programme on HIV/AIDS (UNAIDS) takes the floor to support the proposal made by the Governments of South Africa and India for a temporary waiver of certain TRIPS obligations to facilitate an appropriate response to COVID-19, as it reflects the urgency and global health emergency that COVID-19 represents. Its implementation will enable countries to work together to establish national and multilateral strategies to promote innovation of, and access to, medicines, diagnostics, vaccines, and other health technologies, by reducing transaction costs and eliminating key barriers across the R&D cycle and the supply chain for access to health technologies to prevent, diagnose, and treat COVID-19 disease.

322. Global solidarity and shared responsibility have been recognized as fundamental principles that guide the UN system response. There is a growing consensus that universal access to health care, including COVID-19 health technologies, must be a global public good.

323. In the response to the colliding pandemics of COVID-19 and HIV, UNAIDS has adopted a multi-sectoral and people-centred approach, to protect the gains for people living with and affected by HIV and drive progress towards the Sustainable Development Goals. The AIDS community knows

that to tackle public health threats, focusing on inequality is essential – including inequalities in access to solutions, whether vaccines, diagnostics or therapeutics.

324. The international community cannot repeat the painful lessons from the early years of the AIDS epidemic, when people in wealthier countries got back to health, while millions of people in developing countries were left behind. In the current context, business as usual is the recipe to fail in delivering equitable access to COVID-19 treatments for all those in need. Access to health is the human right of everyone, no matter the colour of their skin, the money in their pocket, or the country they live in.

325. A range of solutions will be needed in order to ensure equal access and to unlock supply.

326. UNAIDS calls for support for the multilateral solutions that are on the table and for collaboration through fostering transfer of technology and mass-production of COVID-19 tools, using a public health lens. This is the basis of the current proposal before this Council.

15.44 South Africa

327. It has been exactly three hours since the last time I took the floor, good evening colleagues. It has been a marathon session with many interventions and discussion.

328. The co-sponsors would like to thank all Members and observers that had intervened. We have heard many concerns raised by Members that intervened. Given the time constraints, the co-sponsors would like to respond to some of the general elements that have emerged out of the discussion. There are more direct questions posed by delegation that could be answered at a later stage and we will reach out to delegations concerned.

329. We want to stress that the protection and enforcement of intellectual property are not absolute, Article 8 of the TRIPS Agreement recognizes that countries may adopt necessary measures to protect public health. COVID-19 constitutes an unimaginable global pandemic which requires swift and bold action. COVID-19 is far from over and there is no certainty as to when effective vaccines will be available in sufficient quantities to ensure equitable access. COVID-19 is here to stay, as the EU pointed out in their intervention, vaccines take up to ten year to develop.

330. We explained the rationale for our proposal and believe that our proposal demonstrates the existence of exceptional circumstance that justifies our request for a waiver decision, clear terms and conditions governing the application of the waiver.

331. The waiver does not imply any change of the substantive treaty obligations; it only temporarily suspends their operation of certain provisions for a period to be agreed by Members and thus will be time-bound. It has a clearly defined scope related to the implementation, application and enforcement of Sections 1 (Copyright), 4 (Industrial Designs), 5 (Patents), and 7 (Protection of Undisclosed Information) of Part II of the TRIPS Agreement which are aspects critical to the diagnosis, prevention, containment and treatment of COVID-19.

332. We further clarified that the date on which the waiver will continue to apply 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. This period can be negotiated.

333. We heard the refrain from the EU and others that the TRIPS Agreement is fit for purpose and its flexibilities are usable without limitation or any problem? We once again contest this this notion.

334. Delegations that have taken the floor to condemn this waiver proposal claim that that TRIPs flexibilities already include the option to issue compulsory licenses where necessary.

335. The proposal for a waiver on certain IP provisions offers an expedited, open and automatic global solution that allows for uninterrupted collaboration in development and scale up of production and supply and that collectively addresses the global challenge facing all countries. Countries should continue to use TRIPS flexibilities to safeguard public health, including issuing compulsory licenses and placing limitations on or making exceptions to exclusive rights.

336. However, the "case by case" or "product by product" approach required when using flexibilities to address IP barriers at the national level could be limiting during the pandemic. Some countries also face limitations with respect to their national laws, pressures from their trading partners, or lack the practical and institutional capacity required to exercise TRIPS flexibilities during the pandemic quickly and effectively. The existing mechanisms for compulsory licenses under Article31 and Article 31*bis* of the TRIPS Agreement contain territorial and procedural restrictions that make the practice of issuing product-by-product compulsory licenses a complex process, making it difficult for countries to collaborate. Article 31 requires that compulsory licenses are issued on a case-by-case basis and used predominantly to supply domestic markets, thereby limiting the ability of manufacturing countries to export to countries in need.

337. Article 31*bis* requires that any product produced and exported under a compulsory license be identified with specific packaging and quantities, which can lead to unnecessary delays in the context of COVID-19 where countries need urgent access to medical tools. There is even less experience in areas such as industrial designs, trade secrets, algorithms and copyright, applying compulsory licenses to such areas may be legally complicated and novel.

338. Political pressure from two delegations that oppose the waiver proposal have taken action to ensure that countries do not use compulsory licenses, for example:

a. EU IP enforcement report 2020, issued right before the COVID-19 pandemic, put a number of developing countries, including India, Indonesia, Turkey, Ecuador, under the spotlight of criticism for their laws allowing the use of compulsory license if patent holding companies do not fulfil the obligation of supporting production of medicines locally;

b. USTR 2020 Special 301 report, issued right in the middle of the COVID-19 pandemic, continue to condemn countries who improve their laws on compulsory license or make use of compulsory license – countries specifically pressured for their law or their use of compulsory license include Chile, Indonesia, Colombia, Egypt, India, Malaysia, Russia, Turkey, Ukraine, El Salvador.

339. Voluntary Licenses are somehow touted as the solution for COVID-19.

340. IP rights can be exercised by their owners to decide on whether to grant a license or withhold from licensing the technology, designs and knowhow required for manufacturing or for further developing the products required for COVID-19. By enforcing exclusive rights backed by IP, such as patents, pharmaceutical companies slow down research and innovation. The use of restrictive voluntary license terms limits the catching up and innovation made by generic competitors.

341. Nine months into the pandemic voluntary approaches have proven to be insufficient. For instance, despite receiving significant public funding of at least USD 70.5 million, Gilead has signed secretive bilateral licenses for Remdesivir (a therapeutic for COVID-19 treatment) with a few generic companies of it choosing that excludes nearly half of the world's population from its licensed territories. Much of Gilead's supply has also been reserved for very rich nations. As a result, to date, most developing countries have barely received any supply of Remdesivir. The prices of Remdesivir are also prohibitively high.

342. On the other hand, to date not a single company has committed to the voluntary COVID-19 Technology Access Pool of WHO.

343. In cases where companies have made such commitments to issue voluntary licenses, the lack of transparency of license agreements for products to treat COVID-19 is substantial. These initiatives are *ad hoc* and are not a sustainable way of addressing IP barriers.

344. While such companies can limit the production, quantity and export of products produced under license to certain geographical areas thereby excluding large parts of the world population. Non-profit undertakings are time bound, while such companies will decide when they think the pandemic is over.

345. If we are serious to address access issues, production cannot be concentrated in the hands of only a few manufacturers, in order to scale up production, governments have a critical role to play.

346. Various Members have asserted that the waiver proposal will impede innovation and that it is improper and ill-conceived on the side of the co-sponsor to bring a waiver proposal at this critical time.

347. Never has there been a weaker case for the granting of monopolies. Governments have been funding the development of COVID drugs and vaccines, and no company is able to meet the global demand. In the context of COVID-19, despite the billions of taxpayer dollars invested in R&D, and announcements that COVID-19 vaccines should be considered a public good, no government has openly stated committed to this undertaking.

348. Monopoly-based and market-driven R&D in biomedical sector ignores unmet health needs - no new medicine was developed for more than 40 years on TB; no effective R&D in addressing antimicrobial resistance (AMR) despite of the constant increasing of number of IP – patents granted in pharmaceutical sector globally for zero value add.

349. The R&D of drugs is often a joint multi-stakeholder effort, benefitting from significant amounts of public taxpayer money. For COVID-19, the search for an effective treatment or vaccine is a global effort involving by multiple actors – it is not the result of the pharmaceutical industry's efforts alone. Governments and public funding agencies around the world have poured billions of US dollars of public money to support COVID-19 R&D, especially for drugs and vaccines. However, by and large no conditions for access or affordability have been included as a precondition to any of that funding. Governments must attach strings to any public money given for COVID-19 medical tools to guarantee that, if they prove safe and effective, they are available to everyone. Some Members have admitted that some conditions had been set on companies, but none of it goes far enough to ensure that IP rights assigned to companies benefiting from taxpayer money do not abuse such rights down the line.

350. It was professed by Members that voluntary cooperative approaches will solve the COVID-19 crisis through generous pledges to multi-stakeholder collaborative platforms. We thank the EU and other delegations for their generous support for these initiatives, including the donation of vaccines and access to COVAX-facility to cooperate in the purchase of future vaccines for the benefit of vulnerable countries.

a. The co-sponsors agree that global cooperation and collaboration is key to addressing the COVID-19 pandemic, initiatives such as the COVAX facility are helpful but insufficient. Our waiver proposal is designed to work synergistically with such initiatives by enabling the rapid scaling of production by multiple producers across many countries, enabling the sharing of knowledge and transfer of technology with the aim of addressing the pandemic;

b. COVAX at best provides very short-term, limited access to vaccines. Its approach is not sustainable in the medium and long term. The global needs are massive and can only be addressed with global sharing of technology, knowledge and related IP. Not by artificially limiting competition and supply which in turn only results in high prices in the medium and long term; and

c. Notably wealthy nations representing just 13% of the world's population have already cornered more than half (51%) of the promised doses of leading COVID-19 vaccine candidates[2]. This creates significant uncertainty for universal access.

    i. The EU together with some other wealthier nations and regions, have already pre-booked more than 51% of the global supply capacity of the potential future COVID-19 vaccines – leaving limited share for developing countries and least developed countries to share. It is this conduct that has created huge uncertainty to the guarantee of universal access to COVID-19 medical tools and products.

d. Global equitable allocation and donation are separate issues from the waiver proposal that we put on the table.

[2] https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19

e. While some initiatives such as COVAX is aiming to address the initial shortage of supply of medical tools for COVID-19 treatment and prevention, its effects can be limited due largely to the following factors:

   i. The model and the conducts reinforce the deep inequality in the global health architecture and do not provide a sustainable solution;

   ii. Both the investment to COVAX and donation commitment cannot solve the issue of the need to diversify, to the maximum level the global capacity of development, manufacturing and supplying COVID-19 medical tools; and

   iii. COVID-19 reveals the deep structural inequality in access to medicines globally, and one of the root causes is that IP sustains dominating industry's interests at the cost of lives.

351. We heard some Members saying that intellectual property is not a hindrance but a help to end COVID-19; Suspending key protections of the TRIPS Agreement would send the wrong message to industry investors.

a. Huge public funding has been poured into R&D for COVID-19 – more than USD 70 billion mostly from governments including many developing countries governments; it is taxpayers in different countries who have invested the COVID-19 R&D;

b. People around the world who are taking huge risk of joining in and supporting the unprecedented R&D process and clinical trials;

c. The incentive for people to take substantial risks in supporting and joining clinical trials has nothing to do with IP, but the conscience and common sense of contributing to the finding of a cure for all; and

d. Industry has asked governments to take over their liability and request for indemnity so that industry does not have to bear the risk but can make all the profit without much value add.

352. We also heard that intellectual property has enabled collaboration between bio-pharmaceutical innovators and governments, universities and other research partners to speed up progress on our most pressing unmet medical needs, however the co-sponsors strongly contest this notion.

a. It is the pandemic – not IP – that has mobilized collaboration of multiple stakeholders;

b. It is knowledge and skills held by scientists, researchers, public health experts and universities that have enabled the cross-country collaborations – not IP; and

c. It is public funding, again, facilitated these collaborations – not IP.

353. I will leave it here in the interest of time and as we indicated at the start of this intervention the co-sponsors will reach out to other delegations to address more specific issues and questions that may have been raised.

354. It is clear that Member have different opinions regarding the waiver proposal introduced at the TRIPS Council meeting, there is a need to discuss this proposal further. According to Article IX.3(b) a request for a waiver shall be submitted to the relevant Council for consideration during a period which shall not exceed 90 days. We request that this item remain open for discussion for the intervening period. This can be done on the basis suspending this item and reconvening the TRIPS Council formally or informally or through consultations that may be convened by you or a combination of both modalities.

15.45 WTO Secretariat

355. As regards the procedure for waivers, as the delegation of South Africa just mentioned, Article IX.3 of the Marrakesh Agreement provides that in exceptional circumstances the Ministerial

Conference may decide to waive an obligation imposed on a Member by the Marrakesh Agreement or any of the multilateral trade agreements.

356. Article IX.3(b) of the Marrakesh Agreement then provides that requests for waivers concerning the multilateral trade agreements in Annexes 1.A, 1.B or 1.C – i.e. the TRIPS Agreement – shall be submitted initially to the relevant Council, in this case the TRIPS Council, for consideration during a time period which shall not exceed 90 days. At the end of the time period the relevant Council shall submit a report to the Ministerial Conference.

357. The practice – most of the practice of waivers comes from the Goods Council – has been that after the expiry of 90 days the Chair of the relevant Council takes the floor in the General Council under the waiver item to report that the 90-day period has expired. In some cases, there is a recommendation to the General Council, for instance to adopt the waiver. In cases where there is no such recommendation, the Chair of the CTG has often informed the General Council that the Council for Trade in Goods will continue its consideration.

15.46 United States of America

358. The decision-making process for the TRIPS Council is by consensus and we request that this agenda item be suspended for further consultations.