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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 9-10 JUNE 2015

Chairperson: Ambassador Al-Otaibi (Kingdom of Saudi Arabia)

Addendum

The present document contains statements made during the Council for TRIPS meeting held on 9-10 June 2015.

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Subjects discussed

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* A record of statements as delivered. Some statements have been lightly edited as appropriate to ensure the consistency of presentation.

AGENDA ITEM 1: NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

1.1 Canada

1. Canada was pleased to notify a number of changes to its domestic IP regime to the WTO earlier this year. The majority of the changes are found in two bills that received royal assent in 2014. Bill C-8, also known as the Combating Counterfeit Products Act amends the Trademarks Act and the Copyright Act. The bill aims to reduce trade in counterfeit and pirated goods sold to Canadian consumers and businesses by providing new enforcement tools. The amendments made by the bill enact new border enforcement measures and create civil causes of action and criminal offences. Bill C-43, known as the Budget Implementation Act 2, amends the Industrial Design Act and Patent Act.

2. These amendments allow Canada to come into compliance with two intellectual property treaties, The Hague Agreement and the Patent Law Treaty. The Patent Law Treaty aims to simplify and harmonize administrative practices among national patent offices with respect to the patent application process and the Hague Agreement allows for protection of industrial designs in a number of countries through a single international application filed with the international bureau of WIPO. The coming into force date of the changes will be established in the new industrial design regulations and the patent rules which are currently being drafted.

3. Finally, Canada's Copyright Modernization Act, which implemented the changes needed to bring Canada in line with the WIPO Internet Treaties, was notified last year under document IP/N/1/CAN/6. The WCT and the WPPT entered into force with respect to Canada on 13 August 2014. On 14 July 2014 the Minister of Industry Canada issued a statement limiting the right to equitable remuneration in relating to sound recordings of certain Rome Convention or WPPT countries, which we also included in our notifications.

1.2 Russian Federation

4. The Russian Federation would like to present its Federal Law No.364-FZ of 24 November 2014, which has been notified. This federal law has introduced significant changes to the current anti-piracy laws. The list of objects of copyright and related rights in respect of which a procedure for limiting internet access can be applicable was expanded. The judicial procedure restricting access to illegal content stipulated by Article 15.2 of the Federal Law of 27 July 2006 No. 149-FZ on information technologies and protection of information is now applicable not only to the movies but for all objects of copyright and related rights which can be distributed by information and telecommunication networks except for photographic works and works obtained by processes similar to photography.

5. The law specifies the possibility of out-of-court settlement of copyright holders' claims. Thus the right holder has the right to send the website owner a notification about violation of its copyright and/or related rights on the internet which shall meet the statutory requirements. Within one day from date of receipt of the right holder's notification, the website owner shall remove illegal content. In addition, the law provides possibility to block the access to the website without the right for restitution in case when this website repeatedly and illegally distributed information containing copyright and/or related rights objects or information needed to obtain such kind of information using the internet.

1.3 Japan

6. This delegation is pleased to inform the TRIPS Council that Japan recently amended some of its Acts pertaining to intellectual property, namely, the Patent Act, the Design Act and the Trademark Act, which have been notified to the Secretariat and will be available on the WTO document website before long.

7. These amendments were made in order to make our domestic intellectual property system more user-friendly for applicants and more closely harmonized with intellectual property systems around the world, taking into account international developments in the relevant areas. We would like to touch upon major points of the amendments.

8. First, the Patent Act was revised in order to establish relief measures for applicants in respect of time limits. Specifically, the amendment enables applicants for patents, utility models, industrial designs and trademarks, to extend deadlines for filing, examination, and other procedures due to compelling circumstances such as natural disasters. This amendment also establishes a new post-grant opposition system that accepts oppositions from any third party within 6 months after patent grants, in order to attain the stability of patent rights in an earlier stage.

9. The Design Act was revised in order to enable Japan to accede to the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs. Finally, the Trademark Act was amended to provide protection for some non-traditional trademarks such as motion marks and sound marks.

10. To conclude, the Government of Japan will continuously fulfil its obligation to ensure accessibility to and the transparency of the Japanese intellectual property system.

1.4 WTO Secretariat

11. The Council has directed the Secretariat, under this item, to keep it up to date on the various practical steps that are underway to improve the service provided to Members by creating a more user-friendly, accessible and efficient system for capturing, handling and disseminating the information contained in the notifications made under the TRIPS Agreement. This statement supplements successive past reports, in anticipation of a full report and associated technical presentation at the time of the next meeting of the Council, scheduled for October. As ever, we stress that the steps being taken are practical and technical in character, so as to improve and facilitate the provision, handling and dissemination of this information; this work remains squarely within the requirements established by the Agreement itself and by the guidelines already agreed by the Council.

12. We have already briefed the Council on the work in progress to create an information management system that will enable streamlined and more efficient handling of the large volumes of data that have been collected and will continue to flow into this system in the context of notification and review. This information management system or 'IMS' will form the basis of a more workable and user friendly system for Members to submit notifications.

13. A specific feature of the recent pattern of notifications, and one that is increasingly coming into focus, is the tendency for notifications to comprise amendments, revisions or consolidated texts of intellectual property laws and regulations that have already been notified in previous versions. In other words, almost all Members have already notified their basic IP legislation – in some cases, principally developed country Members, almost 20 years ago. However, it is not uncommon in many jurisdictions for there to be a regular process of reviewing and updating IP legislation, and this explains the trend we see today of notifications largely consisting of amendments and updates to past notifications: indeed, that comprises the bulk of notifications that have just been announced in this meeting. This means that, in order to be workable and user-friendly, the notification system has to provide links and references referring back to the previous notifications. As these legacy data, comprising some 4500 document symbols, are in the process of digitisation and transformation into a more user-friendly format and structure, there is a significant challenge in ensuring that new notifications refer in a practically useful way to the previous notifications.

14. We are working to improve the clarity and utility of the Council documents that report on new notifications, and these cross-references to previous notifications concerning the same law or regulations are now systematically included in these documents. Another very useful feature is the brief description of the law or regulation that many Members are now making in the course of their notifications. As has been discussed before, such a brief description is actually even more useful when it concerns an amendment or revision of an existing law than for an original notification. In effect, the general contours and content of, for instance, a patent law when first notified would be well-known. However, it can be difficult for one not well versed in the jurisdiction in question to grasp the significance of a detailed amendment to that law when it is subsequently notified. We therefore thank the Members concerned for improving the quality and utility of the notification system by furnishing these brief descriptions – an option that has for a long time been part of the practice of this Council, but one that perhaps is more helpful than ever today. If I may add, this is

exactly the kind of useful information that the delegations of Canada, the Russian Federation and Japan have shared with the Council today.

15. The pattern of notifications varies significantly between Members. At last count, 132 Members have notified laws, regulations or enforcement measures. The most recent notification filed by individual Members ranges in date from those filed in 1997 in some cases, to those filed earlier this month in other cases. Some Members have notified a series of amendments and revisions of their IP laws, and others have only notified the law once in an original notification. More details will be available during an informal briefing and demonstration that we propose to offer Delegations in an informal setting at 10am tomorrow. At that time, too, we will seek to illustrate the steps being taken to facilitate notification and use of these materials., and will be at the disposal of delegates, as ever, to respond to any more detailed questions as well as gaining the guidance of Members on how best to fine tune and adapt the system so as to make it more useful and efficient for your purposes. We look forward to reaching out to Members and consulting with delegates in the course of the next six months as we move towards implementation of the revised and updated system, with a view as ever to provide a better service for Members.

AGENDA ITEM 3: REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B

AGENDA ITEM 4: RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY

AGENDA ITEM 5: PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

5.1 Bangladesh, on behalf of the LDC Group

16. I am taking the floor on behalf of the LDC Group to address these issues which embody the unjust and unfair existing structure of international trade under the existing intellectual property regime. Our Group is happy to see you as Chair of this very important committee, and we are hopeful that under your leadership we will have consensus on all the issues before us and our Members are at your disposal to assist you. We also commend the Secretariat for their hard work in arranging this session and for all the relevant documents.

17. The review of Article 27.3(b) has been a long-standing item on the agenda of this Council, unfortunately without any substantial progress. Due to the importance and magnitude, even our Ministers, as early as in the fourth WTO Ministerial Conference held in Doha in 2001 emphasized these particular issues. The members of the LDC Group consider that the review of Article 27.3(b) is an important aspect of the work of this Council. Based on standards of morality and ethics, we cannot support patentability of life forms for trade and trade-related gains, and these unethical provisions should not be subject to any kind of protection, either by granting patent or otherwise. In the same vein, it is important to maintain the flexibility in the form of *sui generis* regime developed especially for the protection of plant varieties based on individual countries' systems and requirements. This, we believe, will contribute towards improving the food security situation of indigenous people by ensuring that their inventions are protected and access to seed is guaranteed. In this respect, we note that the TRIPS Council has an in-built mandate to review the provisions of the Agreement, which had been reinforced by the Doha Ministerial Declaration paragraph 19 in line with TRIPS Article 71.

18. Regarding the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the LDCs appreciate the work that has gone into these discussions, including the efforts undertaken by the Office of the Director-General to narrow the differences among Members. Our Group considers that by harmonizing the benefits of both agreements, all of our just interests will be served. Mutually supportive and harmonious implementation of the two agreements will ensure fulfilment of our objectives.

19. For LDCs, biodiversity is a core issue and important source of livelihood for the majority of populations living in most LDCs. Yet they have been denied their due right to the benefit sharing. We also believe that genetic resources, traditional knowledge and folklore are absolutely autonomous issues of the state. The benefits derived from the appropriation of the biological resources by external entities are almost never shared with the common entities concerns. This continues to be a matter of great concern for the LDCs. We maintain that inserting a mandatory

requirement in the TRIPS Agreement on disclosure of country of origin of the genetic resources and the associated traditional knowledge used in the invention is the only effective way forward to ensure proper benefit sharing. In addition patent applicants should also mention whether they have obtained prior informed consent from competent authorities in the country of origin of the genetic resources. This will ensure the mechanism to facilitate the sharing of benefits arising out of appropriation of such resources and traditional knowledge.

20. We need to streamline the work on these issues and we further need to get assistance from the CBD Secretariat at the WTO in the TRIPS Council which would close the remaining gaps which, in our view, can be achievable with political will.

5.2 Brazil

21. Brazil has a well-known position regarding the importance of promoting the mutual support between the TRIPS agreement and the Convention on Biological Diversity. For us, enhancing the transparency in the utilization of genetic resources and associated traditional knowledge, through the introduction in the TRIPS Agreement of a mandatory requirement for the disclosure of the origin of these resources in patent applications, is a priority. All of us gathered here in the TRIPS Council to protect intellectual property should also protect the intellectual property of traditional communities.

22. In this regard, I would like to restate here the terms of the proposal detailed in document TN/C/W/59, particularly regarding its foreseen mechanism to prevent the misappropriation of genetic resources and traditional knowledge and the grant of erroneous patents, reiterating the understanding that the patent offices would not be overloaded with extra work, since they would be just checking-points in the new system.

5.3 South Africa

23. South Africa would like to associate itself with the statement made by Brazil, and further supports the inclusion of the W/59 proposal in the TRIPS Agreement. South Africa believes that there is a fundamental conflict between the spirits and objectives of the CBD and the TRIPS Agreement. We believe that there are three areas of conflict that are identifiable based on the objectives of the two agreements. First, Article 3 of the CBD provides that states have sovereign rights over their biological resources and the TRIPS Agreement overlooks states sovereignty as it recognizes private intellectual property rights over biological resources.

24. Secondly, the CBD provides states with an opportunity to demand benefit-sharing from commercial use of biological resources and the TRIPS Agreement negates that legal authority.

25. Thirdly, the CBD is aimed at reducing cases of biopiracy by requiring prior informed consent whereas TRIPS does not. This means that patent applications can be submitted over biological resources or knowledge of certain local community in any country. This is because TRIPS recognizes rights on the basis of novelty which does not take into account traditional knowledge and cultural practices. South Africa also believes that there is a need to avoid erroneous application of patents or inventions that involve the use of genetic resources and related traditional knowledge. There is also a need to secure compliance with national access benefit sharing regimes.

26. Having stated the above it is therefore clear that the application of the TRIPS Agreement may threaten the preservation of biological resources and traditional knowledge. The noted conflicts are what the CBD under Article 16.5 advised against. It is stated that intellectual property rights must not conflict with the sustainable use of biodiversity. What could aid in reconciling the two agreements is a proper legal review of both agreements with the aim of making amendments where necessary to ensure mutually supportive application. South Africa believes that under the current review of Article 27.3(b), amendments can be made to incorporate the CBD objectives under the TRIPS Agreement in order to preserve biodiversity, prevent biopiracy and include protection of local community rights in accordance with the spirit and purport of the CBD. Lastly, there has been substantial discussion over the issue of formally inviting the CBD Secretariat for a briefing on the Nagoya Protocol. We therefore support inviting the CBD Secretariat for a formal

briefing in the interest of the large majority of developing countries and urge the Members holding a different position on this issue to reconsider their position.

5.4 Egypt

27. Regarding our position, we would like to highlight that the protection of biotech resources, traditional knowledge and folklore represents an important developmental issue for Egypt. In view of this importance, we continue to support engagement in further negotiations on the relationship between the TRIPS Agreement and the CBD. We consider this relationship is a crucial part of the implementation-related issues and concerns, as contained in the Doha Work Programme. Therefore we urge other Members to engage in this issue of prime importance to developing countries as part of the conclusion of the DDA.

28. In fact the technical discussions on this issue have been ongoing for almost a decade so far, the essence of our efforts is that the TRIPS Agreement should be amended in order to provide that Members shall require an applicant for a patent relating to biological materials or associated traditional knowledge to disclose the source and country of origin of the biological resources and the traditional knowledge used in the invention. Furthermore, the applicant shall also provide evidence of prior consent and evidence of fair and equitable benefit sharing under the relevant national regime. Finally, Egypt continues to encourage the engagement of the Director-General in his mandated consultative process on the relationship between the TRIPS Agreement and CBD. We look forward to the outcome of these consultations, and we request other Members to engage constructively in these negotiations, taking into consideration that this issue is one of high priority for developing countries and LDCs.

5.5 Ecuador

29. Ecuador's position is well known and has not changed. We therefore request that the previous statements made by my delegation on these three issues be placed on record. (See previously IP/C/M/78/Add.1 paras 13-18 and para 20).

> Ecuador's position on the issues under consideration, as outlined by my delegation on numerous occasions, is well-known and does not therefore need to be restated. We do, however, wish on this occasion to express our concern over the impasse that characterizes these three issues.
>
> We have attended the consultations held by a number of TRIPS Chairs at the request of this Council, but note with regret the lack of willingness to move forward. My delegation has suggested that the Secretariat prepare a compilation of the discussions and proposals of the past nine years on these issues, with a view to finding elements that help identify approaches that open the way for constructive dialogue. The positions of certain countries are, however, impossible for us to understand and we call for flexibility to be shown in these divergent positions.
>
> Why not allow the Secretariat of the Convention on Biological Diversity (CBD) to report on the outcome of the Nagoya negotiations on the establishment of a Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization?
>
> My delegation considers that, on the basis of such information, countries could either adopt new positions or, where appropriate, endorse those already advanced, but new elements would at least be available. Ecuador believes that this information could be used to analyse the feasibility of establishing regulations governing the access to and use of genetic resources and derivatives thereof and defining aspects relating to prior informed consent, mutually agreed terms and benefit sharing.
> Furthermore, knowing the work of the CBD Secretariat would allow clear parameters to be established, thereby enabling the CBD and the TRIPS Agreement to be mutually supportive and thus fulfil their individual objectives.
>
> Lastly, Ecuador endorses the documents submitted by Bolivia in 2010 and 2011 in respect of the review of Article 27.3(b), which set out the adverse effects of the patenting of life forms and parts thereof.

Ecuador's proposal is that these three factual notes should be updated with new documents and at least my delegation has not received any update on those notes. That was my request.

5.6 Colombia

30. Our statement will focus on Agenda Item 4 "Relationship between the TRIPS Agreement and the Convention on Biological Diversity".

31. Colombia wishes to reiterate its interest in the issue of misappropriation, notably the misappropriation of components of biological diversity through product or process patents, where access to biological or genetic resources or products derived therefrom and/or the corresponding traditional knowledge has not been legally obtained. Our interest is that such access is on the basis of prior informed consent and terms mutually agreed with the country of origin of the material, as agreed under the Convention on Biological Diversity (CBD).

32. We therefore believe it is necessary to revise intellectual property systems and incorporate mechanisms that would help to address the monitoring and follow-up difficulties highlighted by mega-diverse countries dealing with biopiracy, by identifying points of convergence between the rules on intellectual property protection and those relating to the conservation of biological diversity and the use of its components, including genetic resources. The regime covering access to genetic resources and benefit-sharing would therefore be consistent with the objectives of both protection systems and these would thus be mutually supportive, pursuant to Article 16.5 of the CBD and Article 4 of the Nagoya Protocol. This, in turn, would make it possible to address the mandate provided for in paragraph 19 of the Doha Declaration in a constructive manner.

5.7 Peru

33. We would like to add a couple of additional comments – we are working on a Bali work programme in accordance with the General Council decision contained in WT/L/141. For Peru, a balanced programme must necessarily include intellectual property. In particular in connection with an amendment to the TRIPS Agreement which would make it possible to include the requirement for disclosure. Also, in line with the Doha work programme there is a need to review two aspects that is TRIPS and the CBD and the protection of traditional knowledge and folklore. Peru considers that including this item on the agenda is not enough in order effectively to comply with the mandate given to the Council. Of course there should be a greater commitment on the part of Members towards these issues, all the more so since for my delegation, it is quite clear that faced with the impossibility of people agreeing on a mandate in WIPO, we have to continue with work in this forum as well. Today the WTO is the only forum where these issues can be discussed. For this reason the Council must think about the best way of tackling these problems so that we can cover the concerns of Members, and in particular developing country Members.

5.8 China

34. The relationship between TRIPS and CBD has been an important outstanding issue at the TRIPS Council. China believes that it requires effective joint efforts of Members to find a solution for this matter.

35. China considers it is necessary to amend the TRIPS Agreement with the purpose of introducing a mandatory disclosure requirement of the origin of genetic resources and/or traditional knowledge into patent applications, as co-held by the majority of Members and can be found in documents TN/C/W/52 and TN/C/W/59. The proposed solution can contribute to prevent the misappropriation of genetic resources and the grant of erroneous patents due to lack of information, to improve the transparency of the utilization of genetic resources, and to enhance legal certainty.

36. Considering the legitimate objective pursued by the system, China does not think it would be burdensome for the patent applicant to provide the information concerning prior informed consent and access and benefit sharing.

37. China also notices the contractual arrangements or database solution proposed by some Members. However, those solutions are still far from enough for the protection of genetic resources.

5.9 Indonesia

38. Indonesia believes it is imperative that the Members of this Council place sufficient focus on this issue. The relationship between the TRIPS Agreement and the CBD requires cohesion, coherence and consistency. This would only be realized should both international instruments be implemented in a manner that is mutually supportive and does not run counter to their respective objectives.

39. It is therefore paramount that we peruse the objectives, definitions and principles of the TRIPS Agreement, the CBD, and the Nagoya Protocol. My delegation would like to place particular focus on the provisions of prior informed consent for access and fair and equitable benefit sharing enshrined within the CBD and the Nagoya Protocol. These principles are the foundation for the protection of genetic resources and associated traditional knowledge. Article 27.3(b) of the TRIPS Agreement does not oblige Members to take necessary measures for fair and equitable sharing of benefits as required by the CBD and the Nagoya Protocol. This leaves room for misappropriation and the grant of erroneous patents which would defeat the purpose of the CBD and the Nagoya Protocol.

40. Indonesia would also like to address the issue of Article 29 of the TRIPS Agreement with regard to its disclosure requirement. We are of the view that this provision is incomplete without the inclusion of a disclosure of origin of genetic resources and associated traditional knowledge. Including such a provision would enhance transparency in the utilization of genetic resources and associated traditional knowledge. In this regard, Indonesia would like to align itself with document W/59 and maintains its view on the urgency of the mandatory disclosure requirement to be included in the TRIPS Agreement to prevent both misappropriation of genetic resources and the grant of erroneous patents.

41. It is also important to take into account the current deliberation of the Post 2015 Development Agenda in the United Nations. These deliberations urge to ensure fair and equitable benefit sharing arising from the utilization of genetic resources as one of its targets in order to achieve one of the goals of the future agenda of global development that would replace the Millennium Development Goals. In line with this, Indonesia believes that it is timely for the Council to give simultaneous and adequate attention to address issue towards common efforts to ensure that genetic resources and associated traditional knowledge are utilized in an appropriate manner in accordance with the objectives of the CBD, the Nagoya Protocol and future development agenda.

42. In addition, as a country with immense biodiversity, Indonesia reaffirms its support for the protection of traditional knowledge and folklore. It is worthy to note that misappropriation of traditional knowledge and folklore remain rampant as indigenous and local communities continue to face claims from other parties utilizing the existing IP system to obtain rights over these traditional knowledge and folklore.

43. It is to this end that Indonesia has consistently been in favor of establishing a *sui generis* regime in the protection of genetic resources, traditional knowledge and folklore, specifically through the Intergovernmental Committee on GRTKF in WIPO. Efforts being made by countries in WIPO could be put at risk should the existing TRIPS Agreement not be amended. Therefore, in line with our views on Agenda item 4, Indonesia emphasizes the need to ensure that the Council takes into account discussions carried out in other fora, such as WIPO, as reflected in the preamble of the TRIPS Agreement.

5.10 India

44. India would like to associate with the statements made by Brazil, South Africa, Egypt, Peru, China, Indonesia and other like-minded countries. We have been extensively discussing these agenda items for many years. During the course of the discussions, many Members have not only highlighted the misappropriation of genetic resources and traditional knowledge but have also

proved beyond doubt that such misappropriation and granting of wrongful patents is possible because of the inadequacy of the TRIPS Agreement to address these issues.

45. India has been a major victim of biopiracy. Pursuant to the ratification of the Convention on Biological Diversity (CBD), India developed a comprehensive legislation on biodiversity, enacted Biological Diversity Act in 2002 and notified Biological Diversity Rules in 2004. In 2003 the National Biodiversity Authority (NBA) was set up. All matters relating to requests for access by foreign individuals, institutions or companies, and all matters relating to transfer of results of research to any foreigner are dealt with by the National Biodiversity Authority.

46. The Government of India has also developed a Traditional Knowledge Digital Library (TKDL) database to prevent misappropriation of traditional knowledge at international patent offices so that cases of biopiracy can be prevented. India has signed TKDL Access Agreement with nine International Patent Offices. So far about 211 patent applications of pharmaceutical companies from the United States, Great Britain, Spain etc. have either been set aside/withdrawn/amended, based on the Prior art evidences present in the TKDL database. While India has pioneered the Traditional Knowledge Digital Library (TKDL) to overcome language and format barriers, the results could only be limited. Improving prior art searches through the TKDL was only one part of the solution. Further, the TKDL represented a subset of the universe of available traditional knowledge. The realm of traditional knowledge in areas other than herbal cures and genetic resources was not covered by the TKDL.

47. While India is undertaking a number of measures at the national level in order to prevent misappropriation of genetic resources and/or associated traditional knowledge, the problem has an obvious international dimension and needs an international solution in order to be addressed effectively. The TRIPS Agreement continues to ignore the numerous IPR-related obligations in the CBD which are of interest to the developing countries. The disclosure proposal (IP/C/W/474) which was submitted in 2006 was followed up by the submission TN/C/W/52 in June 2008 with the support of 108 countries. The latest submission on this issue TN/C/W/59 "Enhancing mutual supportiveness between TRIPS and CBD" has been proposed by a vast majority of the WTO membership. A mandatory disclosure requirement in patent applications to include disclosure of origin and evidence of prior informed consent and access and benefit sharing, would, in addition to combating biopiracy, further strengthen the credibility of the patent system by facilitating assessment of the novelty and inventiveness criteria.

48. The Nagoya Protocol of the Convention on Biodiversity (CBD) entered into force on 12 October 2014. So far 60 countries have ratified the Protocol. According to the CBD website, the Access and Benefit-sharing Clearing-House (ABS-CH), which is a platform for exchanging information on access and benefit-sharing established by Article 14 of the Protocol, is a key tool for facilitating the implementation of the Nagoya Protocol, by enhancing legal certainty and transparency on procedures for access, and for monitoring the utilization of genetic resources along the value chain, including through the internationally recognized certificate of compliance. By hosting relevant information regarding access and benefit-sharing, the Clearing-House will offer opportunities for connecting users and providers of genetic resources and associated traditional knowledge.

49. In view of the entry into force of the Nagoya Protocol, there is now an urgency to request the CBD Secretariat to brief the TRIPS Council regarding the implications of the entry into force of the Nagoya Protocol. We reiterate our demand for a formal briefing by the CBD Secretariat in the interest of the large majority of developing countries. We also support Ecuador's proposal for updating the three factual briefs by the Secretariat.

50. To mark the adoption of the text of the CBD, 22 May every year is celebrated as the International Day for Biological Diversity, to increase awareness about the importance of and threats to biodiversity. The theme for this year, 'Biodiversity for Sustainable Development' is very topical, as the international community accelerates its efforts to define the post-2015 agenda including adopting a set of goals for sustainable development.

51. I conclude by stating that the TRIPS-CBD issue is one of the outstanding implementation issues and positive outcomes on outstanding implementation issues are one of the most important deliverables of the Doha Round for the developing countries.

5.11 Mali

52. My delegation takes the opportunity to insist upon respect for traditional knowledge because of its importance in developing our societies and also our economies and also in the name of preserving the biodiversity of the resources resulting from that at a precise time when the very devastating effects of climate change are increasingly weighing upon our economies and the development prospects of our countries. My delegation would like to say how very much interested it is in a thorough overview of the provisions of Article 27.3(b) in order, as advocated by others and in particular our colleague from Bangladesh who in his statement on behalf of the LDCs underscored this fully and for which we ourselves fully endorse. It is very important for us for there to be a consistent relationship between the TRIPS Agreement and the Convention on Biodiversity, so that we can limit all of the disastrous effects on our countries and in order to give a change for our traditional societies to develop and to preserve and even develop further our environment.

5.12 Tanzania

53. The relationship between the TRIPs Agreement and the Convention on Biological Diversity is critically important to be explored by Members. The genetic resources, traditional knowledge and folklore are essential resources for the livelihood for most of the populations in the LDCs. My delegation believes the benefits could be shared with the communities concerned by respective owners of inventions. This would be possible if a mandatory requirement is enshrined in the TRIPS Agreement to ensure transparency by disclosing the origin of genetic resources used in inventions. Therefore, as alluded to by the delegation of Bangladesh, the LDC Group coordinator, my delegation also supports further discussions in respect of this matter, with a view to allowing benefit-sharing between inventors and the communities endowed with the respective resources, particularly in LDCs.

5.13 Chile

54. Regarding this agenda item, it should be noted that Chile makes use of the TRIPS flexibilities on the patenting of plants and animals.

55. For Chile, this is a topic that addresses ethical principles and public health criteria. The creation of monopolies over life forms is an issue which involves interests that transcend innovation and trade, and which, we believe, should be left to the judgement of individual Members. It is therefore important to preserve the flexibility contained in the TRIPS Agreement.

5.14 Pakistan

First of all I wish to align my position with what has already been stated, and we totally echo what Brazil, China, Indonesia and other like-minded Members have stated. Let us not forget that the relationship between TRIPS and CBD is well-known to all of us, it is mandated under paragraph 19 of the Doha Ministerial Declaration. We attach significant importance to carrying the work forward and our position is well-known, we do not want to repeat what has already been stated.

5.15 Switzerland

56. Switzerland is a member of the so-called W/52-Coalition of 108 WTO Members which in document TN/C/W/52 have proposed modalities language for the 3 TRIPS issues under discussion in the Doha-Round. Next to the multilateral GI-register and the so-called GI-extension proposal, it also covers the disclosure of source requirement for patent applications for inventions based on genetic resources and traditional knowledge.

57. Switzerland is of the view that a non-burdensome disclosure requirement in the TRIPS Agreement for patent applications relating to the source of a genetic resource or traditional knowledge on which the invention is based will enhance transparent use of GR and TK in inventions and corresponding patent applications. Such transparency is crucial to help access and benefit sharing systems put in place by Members at their national level to work properly.

58. Such transparency is ultimately in the interest of those in favour of the patentability of biotechnological inventions. Switzerland is convinced of the eminent role that this field of technology plays today and will play in the future for the benefit of mankind.

59. My delegation associates itself with the intervention made earlier by China as regards the work to be undertaken on these three issues by the end of this year. The three TRIPS issues need to be taken appropriately into account in the current Doha Work Programme process. Accordingly, my delegation joins others in calling upon the Director-General to resume the relevant consultations under his mandate from the Hong Kong Ministerial Conference.

5.16 Cuba

60. Cuba does consider that this debate should take place in the TRIPS Council so as to proceed to the review of the relationship between the TRIPS Agreement and the CBD and the extension of traditional knowledge and folklore. This is indeed of great importance, and as Members have already said, this is still pending application, despite the fact that there is an explicit mandate expressed in paragraph 19 of the Doha Ministerial Declaration. Cuba would like to repeat once again that we have to move this pending work forward, and one of the ways of doing so would be to apply the request which has been submitted for the update of the three elements, so that consultations take place with the Secretariat of the CBD so that we have the information that so many Members have requested.

61. We would also like to highlight an aspect which was raised by India and that is the proposal that are contained in IP/C/W/474 and document TN/C/W/59, subscribed by a large number of countries as far back as 2006 and 2008 respectively. These documents serve as a very good basis so as to be able to move forward in our work. We do indeed regret to hear year after year, Council after Council, a great number of Members expressing their positions on the need of progress to be made in this work, but unfortunately no progress is being made. We do hope that under your leadership, Chairman, we will be able to move forward markedly and we do hope that we will have some positive signals on these issues which I say once again are issues which have pending application, and which do, however, have a specific mandate contained in the Ministerial Declaration of Doha.

5.17 United States of America

62. In February 2014, we noted "the inherent tension between those Members intervening under item 3 on Article 27.3(b) of the TRIPS Agreement regarding prohibiting patents in certain areas, and those intervening under items 4 and 5 on the relationship between the TRIPS Agreement and the CBD, who are seeking to use the patent system to do this very thing.

63. We also noted that the "statement that life forms such as plants and animals should belong to the whole of mankind…is inconsistent with the position that States have sovereignty over plants and animals and can exercise exclusive rights and insist upon prior informed consent and mutually agreed terms for others to use those plants and animals."

64. We asked "[w]hy is it that a country can have a perpetual right to insist upon benefit sharing under the CBD, but an inventor of a new plant cannot be given a 20-year term for the plant they invented?" We continue to look forward to a response to these questions.

65. Regarding genetic resources, traditional knowledge and folklore, we continue to believe that WIPO serves as the best forum to address these issues.

66. As to the relationship between the TRIPS Agreement and the CBD, some delegations have noted that they believe that there is a need to avoid erroneous patents that involve the use of genetic resources and related traditional knowledge. We agree that there is a need to avoid erroneous patents, but disagree that a disclosure of origin requirement would help improve the quality of patents as we have explained extensively in past meetings of the TRIPS Council.

67. Finally, we are not in a position to support decisions on this issue by this Council at this meeting, including with respect to an update of the three factual notes or a briefing by the CBD Secretariat.

5.18 Japan

68. These three issues have been discussed for a long time at a series of meetings of the TRIPS Council. This delegation, therefore, believes that our position is well-recognized among Members, so we would like to make our intervention brief, highlighting some major points.

69. Our delegation shares the idea that appropriate and effective measures should be taken against misappropriation of genetic resources, traditional knowledge and folklore. At the same time, however, we believe that such measures should not have adverse effects on the intellectual property system and should not hinder innovation in this area.

70. Considering the mandatory disclosure requirement from this point of view, our delegation is still not convinced that the disclosure requirement is appropriate or effective because of its potential undue burden on applicants and legal uncertainty surrounding the patent system itself. Furthermore, this delegation has a strong concern that these possible negative effects on the IP system could stifle innovation utilizing genetic resources and associated traditional knowledge. Unfortunately, our concern has been materializing before our eyes. We hear a lot from our industries, including pharmaceutical industry and cosmetic industry, that they have decided to abandon developing new materials based on biological materials overseas because of the high risk and uncertainty associated with such development.

71. Finally, our delegation believes that WIPO/IGC is still the most appropriate forum for technical discussions on these issues. Moreover, we think that the WIPO seminar on Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions, which is scheduled late this month, is a good opportunity to share information and experiences. Japan is committed to constructively contributing to discussions on these issues.

5.19 Canada

72. Canada continues to firmly believe that the TRIPS Agreement and the Convention on Biological Diversity are mutually supportive, that there is therefore no need to amend the TRIPS Agreement. Canada also believes that WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore also known as IGC remains the best forum to discuss technical discussions on aspects of intellectual property related to genetic resources, traditional knowledge and traditional cultural expressions. Canada remains committed to the IGC and looks forward to continuing its work with other WIPO member states in the future at WIPO, and as part of a balanced overall WIPO work programme towards a mutually acceptable outcome.

73. Canada and many other Members, have on a number of occasions, sought further details on the experience of other members of the IGC with respect to patent disclosure issues, and sui generis protection of genetic resources, traditional knowledge and traditional cultural expressions. We remain keen to learn about other Members' practices in order to further advance discussions on these questions. We continue to believe that it is through this type of exchange and engagement that we can work towards a mutually agreeable and successful outcome.

5.20 Korea, Republic of

74. On these agenda items, Korea has been making clear its position in the TRIPS Council meetings as other Members do. We do not recognize any development warranting a change to our position this time around, so we would like to replace our intervention with our statement made at the previous meetings. (See previous IP/C/M/78/Add.1 paras 90-92).

> As there have been no developments regarding our position on these agenda items, we would like to reiterate our position briefly.
>
> Korea is not in favour of a revision of Article 27.3(b) as we believe that the current provisions offer the necessary flexibilities to allow Members to protect biotechnological inventions with their specific protection systems. In this regard, we believe that our work should focus more on implementation issues such as information sharing on individual Members' practices regarding the patentability of life forms and their implementation.

We do believe that the implementation of the TRIPS Agreement and the Convention on Biological Diversity (CBD) should be supportive of each other. However, we do not support the proposal to revise the TRIPS Agreement to ensure the implementation of the Convention on Biological Diversity, since the objectives and subject matters of the two agreements are different.

5.21 European Union

75. Regarding the review of Article 27.3(b) the EU stance has not changed, in that we do not see any reason to amend this Article as it currently stands. The TRIPS Agreement allows WTO Members sufficient flexibility to modulate patent protection of biotechnological inventions according to their needs, interests or ethical standards. Moreover Article 27.3(b) in conjunction with Article 27.2 on exclusions from patentability and Article 27.1 on patentability criteria provides considerable and sufficient leeway.

76. Regarding the protection of traditional knowledge and folklore, again, as in the past, the EU supports the work being carried out in WIPO on the three separate texts related to genetic resources, traditional knowledge and traditional cultural expressions.

77. Finally, regarding the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the EU would like to point out that our legislation to implement the Nagoya Protocol is now fully adopted, this regulation implements the EU's international obligations and it is being further developed by guidelines and by very concrete rules on how to proceed, and other than that our position has been expressed in the W/52 document and I have nothing to add to that.

5.22 Australia

78. Australia's positions on these issues are well known and so we will endeavour to keep our intervention to the point.

79. Australia regards WIPO as best placed to consider the complex intellectual property issues relating to genetic resources and traditional knowledge. Australia wishes to see WIPO members conclude this important, substantive work on which considerable progress has already been made.

80. Through informal processes, small-group initiatives and Secretariat-initiated seminars, we also have the chance to forge stronger understandings and common approaches. We continue to encourage Members to reflect on their positions and return to negotiations committed to achieving a meaningful and balanced outcome.

81. Australia regards the current flexibilities under TRIPS Article 27.3(b) as sufficient to allow Members to take decisions on the patentability of life forms in accordance with national policies. We regard it to be appropriate to retain these flexibilities. We consider that prohibiting patents that relate to life forms would have a profound adverse impact on innovation, limit scientific advancement and result in significant commercial impact.

82. As we have said at previous TRIPS Council sessions, Australia considers the TRIPS Agreement and the Convention on Biological Diversity are consistent. Australia fully implements its obligations under both agreements, which we view as mutually supportive.

AGENDA ITEM 6: NON-VIOLATION AND SITUATION COMPLAINTS

6.1 Brazil

83. Brazil has the honor of introducing the document IP/C/W/385/Rev 1 to the TRIPS Council. The document entitled "Non Violation and Situation Nullification or Impairment under the TRIPS Agreement" was submitted to this Council on 22 May, expressing the views of seventeen countries that consider non violation and situation complaints should be deemed inapplicable under the TRIPS Agreement. In order to present the revised version of a document, a brief historical

introduction is needed. I ask the indulgence of the Members to take us back to 2002, when a group of 14 countries submitted IP/C/W/385.

84. At that time, Members were struggling during TRIPS Council Sessions to consider the possibility of allowing non violation and situation complaints to apply to intellectual property disciplines. A number of WTO agreements, decisions and declarations refer to non-violation complaints. Nonetheless it was unclear how such an exceptional mechanism used in market access treaties would interact with the international IP System.

85. Even though GATT Article XXIII established the basic rules on non-violation and situation complaints and Article 26.1 of the Dispute Settlement Understanding provided basic procedures, Article 64.3 of the TRIPS Agreement requested a consensus on the adoption of scope and modalities prior to their use. According to the text of the treaty:

> 3. "(…) , the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of the GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process."

86. In 2002, a group of 14 Member states, comprised by Argentina, Bolivia, Brazil, Colombia, Cuba, Ecuador, Egypt, India, Kenya, Malaysia, Pakistan, Peru, Sri Lanka and Venezuela, submitted the document W/385, in order to express the view that the application of non-violation and situation complaints to TRIPS would raise systemic concerns that could adversely affect not only the IP system, but also the World Trade System and its dispute settlement mechanism. The elements that led to this shared interpretation are, inter alia, the understanding that non-violation and situation complaints would,

(i) introduce incoherence among WTO agreements by allowing something which a WTO Member has agreed to accept in one part of the single undertaking (e.g. the GATT or the GATS) to be challenged on the basis that it could nullify or impair benefits in another area (e.g. TRIPS);

(ii) upset the delicate balance of rights and obligations in the TRIPS Agreement by elevating private rights over the interests of the users of intellectual property – both within and between countries – and over other important public policy considerations in a manner inconsistent with Article 3.2 of the DSU;

(iii) undermine regulatory authority and infringe sovereign rights by exposing to challenge any measure that affects intellectual property and that could not have been foreseen at the time of the Uruguay Round;

(iv) limit use of the flexibilities inherent in the TRIPS Agreement to secure objectives relating to public health, nutrition, the transfer of technology and other issues of public interest in sectors of vital importance to socio-economic and technological development.

87. Taking into consideration the document W/385, communications from Canada, the European Communities, the United States, as well as discussions inside the TRIPS Council, no decision could be adopted on scope and modalities at the 4th Ministerial Conference. The MC4 oriented the TRIPS Council to "continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of the GATT 1994 and make recommendations to the Fifth Session of the Ministerial Conference. (…), in the meantime, Members (would) not initiate such complaints under the TRIPS Agreement."

88. Moratorium to the use has been approved in every Ministerial Conference, every two years, since the 4th Ministerial.

89. In 2013, the Bali Ministerial Conference extended the moratorium and Members agreed they would intensify their work in the TRIPS Council on NVNI complaints. Approximately one year ago,

on 10 June 2014, the delegation of the United States circulated the document IP/C/W/599. The communication intended to advance the Council's intensified examination of non-violation complaints under the TRIPS Agreement, while trying to address concerns raised by other Members. The US document presented, also, a new interpretation on the implementation of the Article 64.3 TRIPS. According to this interpretation, "questions regarding the implementation of Article 64 have to a great extent been answered, in part by the text of the relevant covered agreements and in part by the GATT and WTO dispute settlement system. Where additional questions remain, dispute settlement continues to be the mechanism agreed by WTO Members to further clarify provisions of the covered agreement, including Article 64".

90. Taking into account previous discussions as well as the contribution of the document W/599 to the debate, the group of co-sponsors of document W/385 intensified discussions on non-violation and situation complaints in order to produce an updated version of the document that would also encompass eventual changes in the last 13 years of discussion. This work involved new co-sponsors and a huge effort of coordination among Geneva delegates and capitals.

91. The result of our discussions is reflected in document W/385/Rev 1, circulated to Members on 27 May 2015, co-sponsored by Argentina, Plurinational State of Bolivia, Brazil, China, Colombia, Cuba, Ecuador, Egypt, India, Indonesia, Kenya, Malaysia, Pakistan, Peru, Russian Federation, Sri Lanka and Bolivarian Republic of Venezuela. Besides providing a document up to date, this group of countries conveyed a common understanding on the implementation of Article 64.3.

92. This group of countries understands that "non-violation and situation complaints only apply to the TRIPS Agreement in accordance with the procedure established under Article 64.3 and complying with this procedure should be a matter of priority for the Council for TRIPS". The document expresses the view that "non-violation and situation complaints would be applicable to TRIPS only when there is a consensus on the scope and modalities as envisioned in Article 64.3 of the TRIPS Agreement."

93. Taking all aforementioned into account the result of the discussion was that

> "introducing non-violation and situation complaints into the TRIPS Agreement is unnecessary and inconsistent with the interests of the WTO Members. Any benefits arising from the Agreement can be adequately protected by applying the text of the Agreement in accordance with accepted principles of international law. The absence of non-violation complaints in the TRIPS context does not in any manner threaten or dilute the enforceability of TRIPS related rights and obligations. On the contrary, the application of non-violation complaints in the TRIPS context could potentially present issues relating to rights of intellectual property right holders versus the legitimate exercise of regulatory policy choice by Governments."

94. Consequently, we propose that the TRIPS Council recommend to the Ministerial Conference that complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under the TRIPS Agreement."

95. The document is open to new co-sponsors that share the same understanding regarding non-violation and situation complaints.

6.2 Bangladesh, on behalf of the LDC Group

96. LDCs are concerned that Non-violation and situation complaints have every possibility to pose unnecessary problems to LDCs which can be otherwise available if we do not implement this provision under TRIPS. In this respect, we support the proposal IP/C/W/385/Rev.1 submitted by different developing countries. Our fundamental understanding is that TRIPS is not a market access agreement. The TRIPS Agreement was designed in a manner which only provides the minimum level of territorial protection to IP by the Members. Its operation is also unique and quite different from any other WTO agreement. While some other agreements are explicit about facilitating market access and concessions, TRIPS provides for a minimum level of protection and flexibility with a view to achieve the socio-economic objectives. Most of the IP issues are actually owned by individuals or business concerns, instead of being owned by the State. Therefore, to our best judgement, drawing any parallelism in terms of non-violation and situation complaints with

other WTO Agreements is not compatible with the context of TRIPS. Consequently, we do not see any scope of non-violation and situation complaints to be applicable in a sui generis system like TRIPS as the nature and scope of obligations under the TRIPS Agreement permit Members to determine the level of protection according to their respective domestic legal system and practices. So from the systemic point of view, non-violation and situation complaints will infuse huge legal uncertainty in the total system and the LDCs could be the worse victim of any abuse or misuse of the mechanism. Hence the LDCs support the permanent deletion of this provision from the TRIPS Agreement and until that time we should continue the current moratorium.

6.3 Ecuador

97. As a co-sponsor of document IP/C/W/385/Rev.1, Ecuador endorses the presentation given by the delegation of Brazil. We are co-sponsoring this new document because we are convinced that the application of non-violation and situation complaints raises fundamental concerns and is therefore unnecessary.

98. Other countries have joined the list of co-sponsors and many more will surely support the proposed document for the simple reason that the complaints provided for in Article XXIII:1(b) and 1(c) of the GATT 1994 are not applicable to the settlement of disputes under the TRIPS Agreement.

99. Ecuador reiterates its belief that the TRIPS Agreement does not seek to protect market access, as there is no exchange of tariff concessions, but rather it is a *sui generis* agreement that establishes minimum standards on the acquisition, exploitation, scope and exercise of intellectual property rights. Ecuador remains concerned that the application of non-violation complaints to the TRIPS Agreement threatens to undermine the regulatory authority of Members and may infringe sovereign rights by constraining their ability to introduce new measures on economic development, social welfare, health, the environment and culture in their countries.

100. Ecuador does not share the position expressed by the United States in document IP/C/W/599, which considers that, once the moratorium established under Article 64.2 has expired, application becomes automatic. Although Ecuador believes that Article 64.2 is an exception to Article XXIII of the GATT 1994, as the very nature of the TRIPS Agreement precludes non-violation and situation complaints from being set forth under its provisions, the application of paragraph 2 is not automatic. On the contrary, the scope and modalities for complaints are to be examined under Article 64.3, and any decision on the matter must be adopted by consensus by the Ministerial Conference.

101. It is clear that no consensus on this issue has been reached, as the discussions to define the aforementioned scope and modalities have not progressed, and no recommendations have been made to the Ministerial Conference. For this reason, we firmly believe that this item should be removed definitively from the agenda of this Council at the upcoming Ministerial Conference in Nairobi.

6.4 Argentina

102. As a co-sponsor of document IP/C/W/385/Rev.1, Argentina still considers that the non-violation and situation complaints identified in Article XXIII:1(b) and (c) of the GATT 1994 are not applicable to the TRIPS Agreement.

103. Complaints of this type are inherent in agreements where there is an exchange of concessions and where the parties reciprocally assume obligations that are directly linked to market access. In this context, the agreed concessions can be nullified or impaired by non-tariff measures.

104. The TRIPS Agreement is not a market access agreement but rather establishes minimum standards of intellectual property protection. Therefore, there can be no nullification of a benefit if there is no violation or infringement of an agreed rule.

105. The possibility of a non-violation or situation complaint would give rise to uncertainty as to the legality of governmental measures which a Member might legitimately adopt. It would also

open up the possibility of such measures, even when they were legal and legitimate, being called into question by other Members. Furthermore, such complaints would upset the balance of rights and obligations which exist under the TRIPS Agreement.

106. The Argentine delegation therefore supports the proposal contained in paragraph 57 of document IP/C/W/385/Rev.1 that this Council recommend to the Ministerial Conference that complaints of the type provided for under Article XXIII:1(b) and (c) of the GATT 1994 should not apply to the settlement of disputes under the TRIPS Agreement.

6.5 India

107. India is a co-sponsor of document IP/C/W/385/Rev 1 which Brazil has introduced in the TRIPS Council meeting today along with sixteen other WTO Members. The revised document is the reiteration of the serious concerns that we have with respect to the introduction of non-violation complaints in the TRIPS context. We extend our support to the statement of Brazil and Bangladesh on behalf of the LDC Group which have been made in support of the non-applicability of non-violation and situation complaints to TRIPS. Brazil has outlined the rationale and history of our position on non-applicability of non-violation complaints to the TRIPS and the basic thrust of the revised document.

108. Serious concerns on the ambiguity, incoherence and limit on flexibilities of Members due to the applicability of non-violation complaints in the TRIPS context continue. They have been discussed in great detail in previous meetings. Past GATT/WTO jurisprudence or explanations to the contrary by proponents do not allay our fears. Over the last year, intensive discussions on the applicability of non-violation complaints have taken place in the Council. This has re-affirmed our belief on the detrimental consequences non-violation complaints would have in the TRIPS context.

109. India would like to highlight only some of the issues that we consider pivotal in understanding our concerns on the applicability of NVCs to TRIPS. It is clear that when negotiating the TRIPS Agreement, non-violation complaints were made inapplicable to TRIPS under Article 64.2. This is in stark contrast to the GATT and GATS where NVCs were made applicable without any discussion on scope and modalities. This, by itself, clearly indicates the serious concern the Membership had in applying NVC in the special context of the TRIPS agreement.

110. Further, Article 64.2 clearly mandated that there had to be an agreement on the scope and modalities of NVCs in the TRIPS context. This, again, is not present in the context of GATT and GATS. The entire thrust of Article 64 and the intention of the negotiators clearly show that Members viewed TRIPS in a very different way in the context of applicability of NVCs. If this was not the case, there would have been no issue in applying NVCs like in the case of GATT without any debate or consensus on scope and modalities. It would also not be the case of proponents of NVCs in TRIPS that the TRIPS Agreement does not envisage a consensus on scope and modalities. If NVCs were to automatically apply after a time frame, there would be no need for Article 64.3. The fact that scope and modalities need to be discussed and agreed upon recognizes the unique nature of the applicability of NVCs to TRIPS. The negotiators recognized this and we must not interpret it otherwise.

111. The fears that many delegations, especially developing country Members, have expressed on the ambiguities that NVCs bring cannot be underestimated. Those fears have not been allayed by the discussion but have only strengthened. It strikes at the very ability of governments to function as well as the ability to deal with challenges to that ability. What are the circumstances in which they will be used to suppress Member's sovereign policy space. What are the limits? What are the various policy measures that will come under its scanner. I am afraid, there are no satisfactory answers to it and neither will there be any.

112. The TRIPS Agreement lays down a delicate balance between rights and obligations of Members. NVCs tilt that balance. The very nature of NVCs makes it impossible to lay down various practical scenarios on how they would impact a Members sovereign space. A new cause of action arises even when there is no textual violation of the TRIPS Agreement. Article 3.2 of the DSU states, inter alia, that the DSB recommendations cannot diminish the rights and obligations provided in the covered agreements. The applicability of NVCs to the TRIPS Agreement will widen

the rights and obligations of the Members under the TRIPS beyond the express terms of the TRIPS Agreement. This is how the delicate balance that now exists will inevitably be affected.

113. The ambiguity and lack of clarity that NVCs will usher in in the TRIPS context will especially affect developing countries and LDCs severely. Lack of legal capacity to handle such cases will be a serious issue. It would inevitably lead to addition of litigation cost. The vast array of measures that will suddenly be open to potential challenge will be insurmountable. India believes that this is an unnecessary burden that was not intended by the TRIPS Agreement.

114. India requests Members to seriously reflect on the concerns expressed by an overwhelming number of delegations in this meeting and earlier and should join the consensus that complaints on the grounds of nullification or impairment of the type identified in Article XXIII:1(b) and (c) of the GATT 1994 be determined inapplicable to the TRIPS Agreement, in the interest of the stability and certainty of the multilateral system.

6.6 South Africa

115. South Africa supports the statements of India, Brazil and other like-minded countries. South Africa as a Member of the WTO is fully committed to upholding its obligations and commitments as set out in the different WTO laws and regulations with specific reference to the TRIPS Agreement. The purpose and aim of Article XXIII is to ensure compliance with the GATT rules and principles by providing Members with an opportunity to make representations should the situation provided for in sub-paragraphs 1(a) and 1(b) arise - this is different to the TRIPS Agreement. The TRIPS Agreement is a *sui generis* agreement; it is not aimed at promoting market access or harmonizing the standards of Members with regards to the protection and enforcement of intellectual property rights. It is there to provide the minimum standards for protection and enforcement of intellectual property rights. The insertion of Article XXIII:1(a) and 1(b) of GATT 1994 under the TRIPS Agreement will undermine the sovereign rights of the respective Member states in as far as putting into place the laws that will protect intellectual property rights within their borders are concerned. The insertion will furthermore restrict the flexibilities provided to the Members and defeat the balance that that has been maintained under the TRIPS Agreement. South Africa recognises the need for the protection and enforcement of intellectual property rights, however we believe that the insertion of non-violation and situation complaints will not be practical under the TRIPS Agreement.

6.7 Colombia

116. Colombia is a co-sponsor of document IP/C/W/385, submitted by a group of Members in 2002, and now also co-sponsors the revised version thereof since it shares the view that Article 64.2 of the TRIPS Agreement should not be applicable to that Agreement.

117. Scarce case-law in this area and the resulting gaps in respect of major issues are yet further evidence that permitting non-violation nullification and impairment complaints under the TRIPS Agreement would upset the balance between the policies that a Member can adopt and the trade liberalization undertaken by that Member. Permitting such complaints also risks going against the very objectives and aims of the TRIPS Agreement and infringing the principle of predictability that is enshrined in the preamble of this Agreement, as well as creating uncertainty as to the scope of the commitments undertaken thereunder by each Member.

118. Colombia thus reiterates its wish that the TRIPS Council recommend to the Tenth Ministerial Conference that complaints on the grounds of nullification or impairment of the type identified in Article XXIII:1(b) and (c) of the GATT 1994 be determined inapplicable to the TRIPS Agreement.

6.8 Cuba

119. Cuba fully endorses the statement made by Brazil, supported by the Members that took the floor before us as well. Cuba was one of the initial proponents of this proposal in the first version in 2002. Consequently, we consider that the application of complaints in the TRIPS Agreement would seriously undermine the system of WTO standards, possible leading to distinct disequilibria amongst rights and obligations in connection with public policy. It would limit the policy of flexibility of agreements in TRIPS and would lead to practical problems which have been broadly

described in the proposal. We wish to highlight the fact that the document submitted today is a strengthened proposal in connection with the one submitted already in 2002. It has been strengthened in terms of its content and also in terms of a number of Members endorsing it now, which shows the importance of this topic for a considerable number of WTO Members. As has been well mentioned by others already, when representing this group of countries, their vision has to be taken into account in the context of decisions to be taken on the subject.

6.9 Venezuela, Bolivarian Republic of

120. This type of complaint does not apply to intellectual property cases, as explained at length in document IP/C/W/385/Rev.1, of which Venezuela is a co-sponsor. We support the request that the Council for TRIPS recommend to the Ministerial Conference to be held in Kenya in December 2015 that such cases be determined inapplicable to intellectual property issues, thereby putting an end to this long pending issue.

121. Consensus is a fundamental principle of the WTO since, unlike other organizations; rulings are binding on all Members, with no possibility of reservations. The only possible case of reverse consensus under the WTO is during the establishment of a DSB panel in the event of the responding Member once again objecting on the second occasion that the establishment of a panel is requested by the complainant. WTO rules clearly stipulate that a panel will be established in such cases.

122. Were reverse consensus to apply under Article 64.2 of the TRIPS Agreement, which is how the United States claims it should be interpreted, it would simply be contrary to the principles of this legal instrument and should be deemed invalid and declared as such.

123. It does not, however, seem logical that an issue relating to national security and affecting public health and food security issues, inter alia, could have been regulated by our ministers in an agreement, only for others to rule on domestic issues on the basis of a reverse consensus.

6.10 Lesotho, on behalf of the Africa Group

124. I am making this brief intervention on behalf of the Africa Group. The TRIPS Agreement, unlike other WTO agreements, is a *sui generis* agreement, which is not designed to protect market access or the balance of tariff concessions. The TRIPS Agreement permits Members to determine the level of intellectual property protection according to their respective legal systems. As such its operation is unique as it provides for a minimum level of protection and flexibilities to developing countries and LDCs for their socio economic development objectives.

125. The Africa Group broadly shares and supports the concerns and views contained in document IP/C/W/385/Rev.1. Furthermore it is the view of the Africa Group that the application of non-violation and situation complaints raises systemic concerns.

126. The Africa Group supports the proposal that non-violation and situation complaints should not apply under the TRIPS Agreement.

6.11 Chile

127. This is an extremely important issue for our country. As mentioned previously, we support further extension of the moratorium, in the absence of consensus on its application to the TRIPS Agreement, under which consensus is required.

128. We thank the proponents of document IP/C/W/385/Rev.1, which was circulated recently, and welcome the explanations provided during this session. We are examining the issue, as we are interested in exploring a definitive solution, such as the one put forward in the aforementioned document.

6.12 Switzerland

129. We thank Brazil and the other delegations co-sponsoring document rev. 1 of IP/C/W/385. Whilst it reflects well-known positions expressed back in 2002, its structure has facilitated our reading of the document and preparing comments.

130. The list of points we are going to make may not be exhaustive. We reserve the right to further expand our comments, if need be or in light of delegations' comments at this meeting.

Market access agreement or not

131. My delegation is not going to address at great length the issue of whether TRIPS is a market access agreement by nature or not, an argument reiterated in IP/C/W/385/Rev.1, as this risks to be a rhetorical debate.

132. What my delegation wishes to observe in that context is that it was the TRIPS negotiators' concern in the Uruguay Round to adhere to the general GATT/WTO philosophy of market access. An example of this can be found in the very first recital of the preamble of the TRIPS Agreement where the goal of the TRIPS Agreement is referred to as "Desiring to reduce distortions and impediments to international trade…" etc. This confirms my delegations view that the TRIPS Agreement is about market access eventually. If not at "first sight", then undoubtedly at close look.

Flexibilities

133. A concern raised by the co-sponsors in Rev. 1 again and to which my delegation considers it important to respond is whether the application of NVCs under TRIPS has implications on the flexibility provisions foreseen in the Agreement.

134. By protecting the balance of rights and obligations under the WTO agreements as concluded in the Uruguay Round, NVCs do not apply to actions or measures taken by Members under a flexibility provision as identified and confirmed in the TRIPS Agreement. These provisions are, just as is Article 64, part of the balance of rights and obligations under TRIPS as agreed among Members in the Uruguay Round.

Necessary or Not

135. One proposition that is repeated in document IP/C/W/385/Rev.1 is that NVCs are said to be unnecessary. Unnecessary in GATT and GATS, and even more so in the TRIPS context.

136. Well, my delegation is not claiming that NVCs are a remedy under the WTO system that needs to or ever has been taken recourse to frequently. On the contrary, the instances where a panel or the Appellate Body have addressed or examined this WTO principle in a dispute case are very rare, indeed.

137. Some would say that this would justify the suppression of NVC. We disagree with such a conclusion. The risk of a single measure corresponding to NVCs would – and should speak in favor of applying NVCs under TRIPS, for the sake of legal certainty and trade security which should be guaranteed to all Members, no matter what is their size or economic importance at the international level.

138. Be that as it may, it doesn't matter whether my delegation believes that NVCs are frequently or rarely used, nor whether they are necessary or not. The fact is that Article 64 is part of the TRIPS Agreement and of the Uruguay Round deal that all WTO Members subscribed to at the time. Article 64 provides in para. 2 that during a limited period of five year, called a 'moratorium', NVCs shall not apply. This in the clear understanding that after these five years, i.e. once the moratorium ends, these complaints are applicable to TRIPS just as they are to the other two WTO pillars of GATT and GATS.

139. As far as the principle of applicability of NVCs to TRIPS is concerned, we are thus looking at a consensus dating back to the Uruguay Round. The TRIPS Council cannot renegotiate this consensus today by questioning whether such complaints are necessary or not.

Legally Imprecise Notion – Good Faith Principle Instead

140. Co-sponsors of IP/C/W/385/Rev.1 criticize the legally imprecise notion of NVCs. They recommend that instead, rights and obligations in the TRIPS Agreement should be performed through good faith application. While I personally would hope that this will be sufficient as a rule, I doubt whether the concept of good faith will not prove a criterion legally even more imprecise, certainly if you ask the two parties in a specific dispute case as to what they would consider that an action or measure in the situation at hand was taken in good faith or not.

141. The instrument of NVCs thus provides a clearer legal frame to the extent it is embodied in a set of rules and has to respect the examination of certain steps under the DSU to ensure a maximum of coherence.

DSU Guidance Sufficient or Not

142. Now co-sponsors repeat in in IP/C/W/385/Rev.1 that in their view, the DSU, GATT/GATS disputes provide too little guidance for panels and the AB to apply NVCs in the TRIPS context. As is well-known, my delegation believes that the DSU does provide the bodies of the DSM with sufficient guidance to apply such complaints also in the TRIPS Context.

143. If the delegations co-sponsoring IP/C/W/385/Rev.1 of 385 actually disagree with this position, my delegation would have hoped that, rather than repeating their position from 13 years ago, they would have helpfully proposed additional modalities they think necessary for such complaints to apply in the TRIPS context. This would have been a valuable contribution under the work of the TRIPS Council under its mandate from the Ministerial Conference and the very purpose of the moratorium and its extensions.

144. As this is not and has not been the case for the last 20 years, my delegation sees no merit in further extending this moratorium at the end of this year. Rather it should be recommended to the Ministers that, moratorium expired and thus NVCs applicable, the DSU shall provide the relevant guidance, should ever such a complaint be presented to the DSM under the auspices of the TRIPS Agreement.

6.13 Peru

145. Non-violation and situation complaints have been deprived of an advantage because of a measure taken by a government. Quite clearly, the idea would be to try to maintain the balances achieved in the multilateral negotiations. Despite the time that has run since 2002, when we co-sponsored document IP/C/W/385, Members with different positions to ours, such as the delegation that spoke just before me, have not given any example to support their position. Thirteen years after the submission of the document that I have just mentioned, our delegation is proud to co-sponsor this revised proposal. As it has been recognized by others, these cases are rare and exceptional. As was said by the panel in the case Japan Films and I quote "non-violation and situation nullification or impairment must endure a very cautious focus which should also be exceptional". So the group of Members that co-sponsor this proposal have presented a recommendation that the Ministerial Conference decide that this type of complaint is not applicable within the ambit of the TRIPS Agreement. Finally I would like to refer to consultations that you referred to when opening this item, that is how to carry forward the discussions in this area, because as you recalled, quite clearly, following an instruction from Ministers in Bali, which is to be found in MIN/13/31 of 11 December 2013, my delegation requests that before our next meeting in October, you hold regular consultations on this matter, so that we can find a consensus amongst Members and that such a consensus will then be submitted to the next TRIPS Council. I think also that there are two clear positions on this subject and there is still a lot of work to do, so we do hope that this is an issue that you will help us find a consensus on, Mr Chairman.

6.14 Nepal

146. The delegation of Nepal would like to thank and associate itself with Brazil, Argentina, India, China and other developing country Members who jointly submitted a paper contained in IP/C/W/385/Rev.1 on Non-Violation and Situation Complaints (NVSC). We also would like to join our voice with other delegations including Bangladesh who expressed their views supporting this document.

147. In our understanding, the application of non-violation and situation complaints, which is originally a GATT provision fits only in trade in goods and services but not in any *sui generis* type system like TRIPS. As NVSC is basically related with market access issue, it has less possibility and less relevance of application with regard to TRIPS which basically intends to provide minimum protection to IP-related instruments. Application of this in TRIPS regime is inappropriate and will reduce flexibility and policy space of many developing countries in general and LDCs in particular and prevent them from pursuing developmental goals through legitimate exercise of policy choices in the field of IPRs.

148. In this context the paper jointly submitted by Brazil and other developing country Members is a self-explanatory note which very clearly explains why NVSC is not applicable and is irrelevant in the field of IP. Against this backdrop, we cannot support any idea to bring non-violation and situation complaints within the ambit of TRIPS, as has been argued by some Members. We express our deep concern on views expressed by some delegations that MC 10 should end the moratorium given so far in this regard, which in our understanding does not reflect the sentiment of the majority of developing countries and LDC Members.

149. While supporting the paper put forth by developing country Members not to bring NVSC issue under TRIPS, we call upon Council to recommend to the 10th Ministerial Conference that complaints of the type provided for under subparagraph 1(b) and 1 (c) of Article 23 of GATT 1994, shall not apply to the settlement of disputes under the TRIPS Agreement.

6.15 Indonesia

150. At the outset my delegation would like to align ourselves with the statement made by Brazil, Bangladesh on behalf of the LDCs, India and other like-minded countries on the inapplicability of the non-violation and situation complaints to the TRIPS Agreement. Our view on this matter has not changed, we believe the NVSC is an ancient concept aimed at protecting the balance of tariff concessions in past non-comprehensive agreements, such as GATT pre-Uruguay Round or early bilateral agreements. When Members tried to apply this concept into a system with extensive rules on non-tariff measures and a binding dispute settlement system, like what we have now in the WTO, it becomes more of a stumbling block to the system. The NVSC would strongly contradict the basic principles of transparency, predictability and equitability which have so far been principles firmly upheld by the WTO. It would also create legal uncertainty which would undermine the predictability and security that the system seeks to provide to all WTO Members. This ancient concept is even inapplicable and unnecessary for TRIPS which is a *sui generis* agreement to establish minimum standards of IP protection and not designed to protect market access or the balance of tariff concessions. The uniqueness of TRIPS protecting private rights over public interest, if abused, may even undermine market access itself.

151. As a developing country Member who is trying to tap the full benefits of the system, Indonesia is learning and striving to observe and follow all its commitments in this rules-based organization over its highly-need interest to enlarge policy space for development. The NVSC would nullify these efforts by creating legal uncertainty and unpredictability even when all WTO rules and its commitments have been observed and followed.

152. Indonesia is also of the view that preserving the rule of consensus in the debate on scope and modalities for NVSC in TRIPS is a prerequisite to the implementation of this concept to the Agreement. In this light, Indonesia strongly supports that the proposal in document IP/C/W/385/Rev.1, i.e. that this Council recommend to the Ministerial Conference that complaints provided for under GATT 1994 Article 23.1(b) and (c), shall not apply to any settlement of disputes under the TRIPS Agreement.

153. Additionally, in an effort to move the discussion forward, our delegation would like to support the proposal of Peru, asking you, Mr Chairman, to hold a series of consultations to discuss this issue among the interested Members leading up to our next TRIPS Council meeting, and Indonesia would like to be included in such consultations.

6.16 Pakistan

154. At the outset, Pakistan wishes to echo what has already been stated by Brazil, India and other like-minded group Members. Being one of the co-sponsors of the document IP/C/W/385/Rev.1 on NVSC we reiterate our commitment and express our firm support on this issue. Pakistan has already been very expressive on this important and sensitive issue which is at the heart of the LDCs and the developing countries. At the same time we also welcome other Members who have expressed their interest to have a closer look at the document sponsored by us. TRIPS as we know has been crafted with a very delicate balance between the rights and the obligations, and non-violation and situation complaints might deserve that apple cart, so we have to be very careful in terms of whatever we state here as one of our distinguished Members stated. However, let us assure you that we, the co-sponsors, are having closer engagements and we also wish to be associated during your consultations in order to move ahead finding a way forward for the MC10.

6.17 China

155. China has also co-sponsored document IP/C/W/385/Rev.1 and agrees with many other Members that the application of non-violation and situation complaints to the TRIPS Agreement is unnecessary and raises many systemic concerns as well. Especially these types of complaints would bring significant uncertainty into the TRIPS Agreement, which is a delicate balance of interests among Members. Moreover, China notices many Members are concerned that such complaints might undermine the regulatory authority and infringe their sovereign rights.

156. Therefore, we propose that the Council for TRIPS recommend to the Ministerial Conference that these types of complaints shall not apply to the settlement of disputes under the TRIPS Agreement.

6.18 Korea, Republic of

157. We echo the concerns expressed by other delegations over applying non-violation and situation complaints to the TRIPS Agreement, so we would like to reiterate our position made at the previous meetings.

6.19 Norway

158. We would like to join the overwhelming majority of Members that have intervened today. In our view, non-violation and situation complaints should not be applicable to the TRIPS Agreement. We therefore favour a ministerial decision to this effect in Nairobi. Should no consensus on such decision be reached, the Ministerial Conference should extend the present moratorium.

6.20 Tanzania

159. My delegation aligns itself with the statement made by the delegation of Bangladesh on behalf of the LDC Group, and Lesotho on behalf of the African Group. We support the proposal introduced by the delegation of Brazil aimed at bringing to an end the use of non-violation and situation complaints in dispute settlement. We believe the TRIPS Agreement is balanced, negotiated by Members, to provide agreeable standards to serve the diverse interest of all Members. The non-violation and situation complaints raise some systemic concerns to some Members due to their subjective nature in defining the potential benefits of a Member. This creates an alternative to Members in preventing the TRIPS Agreement in applying flexible policies embedded therein. We urge Members to consider the revised proposal IP/C/W/385/Rev.1 as submitted by the concerned group of Members.

6.21 Russian Federation

160. The Russian Federation thanks the delegation of Brazil for introducing the document IP/C/W/385/Rev.1. We support the statements made by other proponents of the document. Also we would like to note that in comparison with the GATT or GATS where non-violation complaints provisions are supposed to protect legitimate commercial expectations that may go beyond obligations under these agreements, TRIPS is different. The TRIPS Agreement ensures the compliance of Members with a number of regulatory standards in intellectual property which is different from exchange of concessions under GATT.

161. Another important difference is that in TRIPS the exchange of rights and obligations defines the balance between the producers and users of intellectual property, and not between WTO Members. This sense of balance must be carefully maintained. Nevertheless, as it is stipulated in the above-mentioned document the application of non-violation complaints may upset the balance of rights and obligations under the TRIPS Agreement by elevating private rights over the interests of users of intellectual property, both between countries and other public considerations. This is another single risk of practical application of non-violation provisions as defined in the document. The other one is the possibility of state authorities to take measures designed to achieve important national policy goals such as the protection of public health and promotion of access to medicines. It is very important to maintain the confidence of Members on the possibility of the use of flexibilities of the TRIPS Agreement also in accordance with the Doha Declaration on TRIPS and Public Health.

162. Therefore, when considering the possibility of application of non-violation and situation complaints to the TRIPS Agreement the Russian Federation as a co-sponsor of document IP/C/W/385/Rev.1 suggests that the TRIPS Council recommend to the Ministerial Conference that the complaints of the type provided for under sub-paragraph 1(b) and (c) of Article XXIII of GATT 1994 shall not apply to the settlement of dispute under the TRIPS Agreement.

6.22 Egypt

163. Egypt would like to associate itself with Brazil, India, Lesotho and others. As a co-sponsor of document IP/C/W/385/Rev.1 our position is well-known. We continue to believe that the provisions of the type identified in Article XXIII.1(b) and (c) of GATT 1994 are not applicable to the TRIPS Agreement. We would like to support the proposal made by Peru that you Chair continue informal consultations in order to find a permanent solution on this matter.

6.23 Japan

164. We recall that we exchanged our views on this topic based on document IP/C/W/599, which was submitted by the United States last June. On top of that, this May, several Members revised document IP/C/W/385/Rev.1, which helps us to understand their recent views on this topic. We appreciate our colleagues' contributions to activating discussion on this issue.

165. Japan's view on this issue has not changed. Both clarity and predictability should be ensured when applying non-violation and situation complaints to the TRIPS Agreement. From this point of view, making factual analyses on specific and concrete circumstances in which non-violation and situation complaints should be available would facilitate examination on the scope and modalities of non-violation and situation complaints in the area of TRIPS.

166. This delegation has been and is willing to engage in discussions at this Council in a constructive and dedicated manner.

6.24 Chinese Taipei

167. Non-violation and situation complaints have been a longstanding issue at the TRIPS Council. We feel that this is an extremely complex issue with many sides to be considered.

168. The concept of non-violation and situation complaint is allowed if one government can show that is has been deprived of an expected benefit because of another government's action, or

because of any other situation that exists. The aim of the concept is to help preserve the balance of benefits struck during multilateral negotiations. However there are many concerns among Members over the applicability of non-violation and situation complaints to dispute settlement under the TRIPS Agreement.

169. We look forward to an in-depth discussion on the issue among Members, particular with regard to possible scope and modalities for the complaints in the context of the TRIPS Agreement.

170. So my delegation would like to associate itself with those that welcome the debate with a constructive spirit and look forward to continuing the discussion in the TRIPS Council.

6.25 Uruguay

171. The delegation of Uruguay would like to thank the co-sponsors of document IP/C/W/385/Rev.1 for the proposal and the explanations therein.

172. To avoid repeating what has already been said or the arguments put forward by the many delegations that have already taken the floor, we wish to echo the statements made by Brazil, Argentina, Venezuela, Colombia and Ecuador, *inter alia*.

173. We should therefore be grateful if Uruguay's support for the solution proposed in document IP/C/W/385/Rev.1 with regard to the non-applicability of such complaints could be placed on the record.

6.26 Hong Kong, China

174. We thank the group of like-minded developing country Members for the detailed paper. The non-violation and situation complaints issue is a long-standing problem waiting for a solution. In our view, a sustainable IP regime must strike a balance between the interests of rights holders and users as well as a balance between predictability and flexibility.

175. While experience from other WTO agreements provides great reference value, we must be careful when trying to apply it to the TRIPS context. Many delegations have pointed out the unique nature of the TRIPS Agreement before me, namely, it is a minimum-standards agreement and it does not address market access per se. It is vital to consider carefully the implications of our actions or inaction on the balance that the TRIPS Agreement currently provides before making any decisions.

176. It would also be important to continue the dialogue in a positive way. In this regard, Hong Kong, China stands ready to contribute constructively to the discussions to find a solution that is agreeable among the Membership.

6.27 Canada

177. Canada is pleased to contribute to the important discussion regarding the applicability of the NVNI remedy to the TRIPS Agreement. Our position on this issue is well-known and has remained unchanged over the years. Canada continues to believe that providing for NVNI under the TRIPS Agreement would be undesirable, considering the difficulty of defining what constitutes a benefit, such as could be nullified by a measure otherwise compliant with the TRIPS Agreement. Canada also believes that the TRIPS Agreement is not a market access agreement based on concessions, such that NVNI would be difficult to establish. Canada stresses its commitment to the TRIPS Agreement and to our work in this Council.

6.28 United States of America

178. We again look forward to the opportunity to discuss the topic of non-violation and situation complaints under the TRIPS Agreement with delegations today. The United States associates itself with the interventions of the delegation of Switzerland on this matter. We also thank the proponents of IP/C/W/385 from 2002 for resubmitting this document, with some limited additional clarifications.

179. The United States recalls its communication to the TRIPS Council on 10 June 2014, which was circulated to Members as IP/C/W/599, and notes that that communication responds to each of the issues identified in the W/385 document as well as to issues raised in the subsequent dozen or so years. We also recall that our interventions over the past two years on this issue, including most recently in the February and October meetings of this Council, have elaborated further on those issues and have introduced a series of new considerations as well.

180. Today, we wanted to address two issues – first to respond to one of the new aspects of the W/385 document regarding consensus, and second to return to our questions regarding the relationship of Articles XX and XXIII of the GATT 1994.

181. Turning to the first issue regarding Article 64 of the TRIPS Agreement and the issue of consensus, Section 2.2 of W/385 states that NVNI complaints are not automatically applicable to the TRIPS Agreement, and instead that there must be consensus on scope and modalities before such complaints would be applicable to the TRIPS Agreement.

182. We do not agree. The TRIPS Agreement is unambiguous on this point. Article 64.1 states clearly that non-violation complaints shall apply to consultations and dispute settlement under the TRIPS Agreement, subject to Articles 64.2 and 64.3. Article 64.2 established a five-year non-application period for such disputes, which was until 1 January 2000.

183. Finally, Article 64.3 provides that during the five-year non-application period, the TRIPS Council shall examine the scope and modalities for non-violation complaints and submit its recommendations to the Ministerial Conference. And "[a]ny decision of the Ministerial Conference to approve such recommendations or to extend the [non-application] period…shall be made only by consensus."

184. This provision is consistent with the consensus-based nature of the WTO as an institution. NVNI complaints shall apply after the five-year period, unless the Ministerial Council agrees to extend the non-implementation period by consensus. While that consensus was reached most recently in 2013 to extend the non-application period, consensus is again required to extend it at the 2015 Ministerial.

185. Likewise, if there are any recommendations on the scope and modalities, those recommendations must be made by consensus. Here, consensus has not been reached. That does not mean however that the failure to reach consensus on such recommendations alters the TRIPS Agreement requirement to reach consensus on extending the non-application period.

186. Some delegations suggest that the failure to reach consensus on such recommendations renders the requirement to reach consensus to extend the non-applications null and void. This is inconsistent with the clear language of Article 64 and would lead to a perverse result. In other words, the consensus requirement for extension does not simply vanish because the consensus requirement for recommendations is not met. Thus, it is clear that the non-application period will terminate at the next Ministerial Conference, unless consensus is reached to extend. And where consensus to extend is not reached under Article 64.3, Article 64.1 is clear – non-violation complaints apply to the TRIPS Agreement.

187. I should also respond here to the suggestion made today that NVNI complaints should not apply to the TRIPS Agreement. This position appears to be in fundamental tension with Article 64 of the TRIPS Agreement. As we have said, Article 64 is clear – NVNI claims shall apply to the TRIPS Agreement, except as provided under Articles 64.2 and 64.3. But, the suggestion that NVNI complaints shall apply to the TRIPS Agreement, except that NVNI shall not apply to the TRIPS Agreement would be a perverse outcome.

188. Second, we continue to look forward to delegations' views regarding the relationship between Articles XX and XXIII of the GATT 1994, in light of the views of some Members regarding possible impacts of NVNI claims on TRIPS Agreement flexibilities. While the W/385 document suggests that NVNI claims could limit the use of the exceptions in the TRIPS Agreement, it is unclear why that would be the case.

189. This suggestion raises many as yet unanswered questions in our view. Why, for example, would NVNI claims limit the use of the exceptions in the TRIPS Agreement, when NVNI claims have not been suggested to limit the use of the exceptions under Article XX of the GATT 1994?

190. Take the *EC – Asbestos* dispute, where the complaining party made an NVNI claim among other claims, and the defending party claimed an Article XX exception. In that dispute, the NVNI claim in no way limited the use of the GATT Article XX(b) exception regarding the use of measures necessary to protect human, animal or plant life or health. In fact, the panel found that the measure was justified under the chapeau and sub-paragraph (b) of the Article XX exception.

191. In fact, NVNI claims have been available for 63 years. As have GATT Article XX exceptions. Yet, we are not aware of instances in which an NVNI claim has imperilled or otherwise limited the ability of a GATT contracting party or WTO Member to adopt or enforce measures covered by GATT Article XX. In this context, the W/385 paper refers to measures addressing public health, nutrition, and other issues of public interest. Yet, these are the very issues covered by GATT Article XX. As delegations know, Article XX covers measures:

- Necessary to protect public morals;
- Necessary to protect human, animal or plant life or health;
- Relating to the products of prison labor;
- Imposed for the protection of national treasures of artistic, historic or archaeological value; and
- Relating to the conservation of exhaustible natural resources…

192. Anticipating one possible response, some may suggest that GATT Article XX is explicit on these issues, whereas the TRIPS Agreement is not. Yet, the TRIPS Agreement <u>is</u> explicit. The TRIPS Agreement has its objectives and principles. Beyond those provisions, the TRIPS Agreement provides for numerous obligations as well as exceptions. With regard to those exceptions, we remain interested to hear from other delegations as to why TRIPS Agreement exceptions are vulnerable with respect to NVNI complaints in contrast to the longstanding and harmonious use of GATT exceptions and GATT NVNI claims.

193. So, for these reasons, and those expressed in document W/599 and the interventions of the United States and Switzerland, we maintain our position that NVNI complaints are applicable to the TRIPS Agreement, that the moratorium should cease, and that it will cease without consensus to extend.

6.29 Barbados, on behalf of the ACP Group

194. The ACP Group has noted the points made in document IP/C/W/385/Rev.1 to the effect that applying non-violation and situation complaints to the TRIPS Agreement is not required to protect market access commitments made in other WTO Agreements. The Group further notes the arguments that non-violation and situation complaints are also unnecessary to protect market access commitments embodied in the GATT or GATS agreements. Having noted these, and other concerns, the ACP Group wishes to record its support for the proposal that non-violation and situation complaints should not apply under the TRIPS Agreement.

6.30 Venezuela, Bolivarian Republic of

195. It should be recalled that the WTO consensus rule is positive, never negative. Assuming that what the United States says is true, this rule would not be consistent with today's reality, and rules that fail to take reality into account lose their validity and should be amended. If there is such strict adherence to rules, why are the very same delegations that seek to implement these cases opposing the review of Article 27.3(b), which specifically provides for such a review after four years? The same delegation that is promoting this, say that it is not possible to do that.

AGENDA ITEM 7: REVIEW OF THE IMPLEMENTATION OF THE TRIPS AGREEMENT UNDER ARTICLE 71.1

196. No statements were made under this agenda item

AGENDA ITEM 8: REVIEW OF THE APPLICATION OF THE PROVISIONS OF THE SECTION ON GEOGRAPHICAL INDICATIONS UNDER ARTICLE 24.2

197. No statements were made under this Agenda item.

AGENDA ITEM 9: TECHNICAL COOPERATION AND CAPACITY-BUILDING

Agenda Item 9.1 Protocol Amending the TRIPS Agreement

9.1 Chile

198. Chile once again welcomes the proposed initiative and supports the Director-General's call to Members that have yet to deposit their instrument of acceptance of the Protocol amending the TRIPS Agreement under the terms of the "Paragraph 6 System". It should be noted that, based on the communication from the Director-General, Chile has incorporated the issue into its dialogue with trading partners that have still not deposited this instrument, in order to share its experience of accepting the Protocol.

9.2 India

199. India attaches high importance to the Doha Declaration on the TRIPS Agreement and Public Health, the Paragraph 6 System as established under the 2003 waiver decision and the Protocol. The Paragraph 6 System is also the first ever proposed amendment to the WTO Agreement in the form of the 2005 Protocol Amending the TRIPS Agreement. India had notified its acceptance of the Protocol in March 2007. We would like to congratulate Brunei Darussalam for depositing its instrument of acceptance of the Protocol since the last TRIPS Council meeting. However, in spite of the fourth extension of the period for acceptance until 31 December 2015, only 54 Members, including the European Union have accepted the Protocol so far. The fact that there is still a long way to go for it to enter into force, as acceptance by two thirds of the Membership is required, is not a positive signal.

200. While we reiterate our concern that the Paragraph 6 System was only used once so far and the System is too complex and administratively unwieldy for further use, we have always been of the view that the Doha Declaration on TRIPS and Public Health constituted a major landmark in the short history of the WTO because it recognized the primacy of public health needs and the preparedness of the Organization to take up the problems faced by the poor in developing countries. Along with several other Members, India had worked relentlessly on the Doha Declaration and the Decision. The Decision was expected to address the public health problems faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector.

201. According to the Trilateral study by WTO, WHO and WIPO on "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade" (2013), the Paragraph 6 System might assume a greater significance in the future in the following scenarios:

- Implementation of full patent protection for pharmaceutical products in key export countries like India could make it more difficult in the future to procure generic versions of new medicines;
- The System could be used more extensively in response to a pandemic or some other health security event, where effective treatments are more likely to be patented in established major supplier countries.

202. We would like to appreciate the Secretariats of WTO and WIPO for providing technical assistance for the process for entry into force of the amendment, and also for the implementation and use of the Paragraph 6 System. We would like to appreciate the initiative taken by the Director-General by addressing letters to all Members and encouraging those Members who are

yet to accept the Protocol Amending the TRIPS Agreement to complete the process as a priority. India is ready to share its experience and assist those Members who are yet to accept the Protocol Amending the TRIPS Agreement to complete the process.

203. We encourage Members who are yet to accept the Protocol Amending the TRIPS Agreement to accept the Protocol and notify their acceptance on a priority basis so that the Protocol will enter into force by the time of the Nairobi Ministerial.

9.3 European Union

204. Like our Indian colleagues, we very much appreciate and welcome the initiative by Director-General Azevêdo, and I would like to share with you the letter that our Commissioner Cecilia Malmström sent to him in reply:

> "Improving access to essential medicines is indeed of utmost importance for the European Union. We consider that the Protocol Amending the TRIPS Agreement provides an important contribution allowing WTO Members to export patented medicines to third countries with no manufacturing capacity in the pharmaceutical sector by making use of compulsory licence. Therefore the EU accepted the Protocol Amending the TRIPS Agreement already on 30 November 2007, within the original deadline of 1 December 2007. We agree with Director-General Azevêdo that the entry into force of the Protocol will be an important signal that will ensure a legally secure, predictable, effective and sustainable solution for those countries wishing to use the TRIPS flexibilities to get affordable medicines. Therefore, as suggested by Director-General Azevêdo, the European Commission will continue to encourage and assist the remaining WTO Members to accept the Protocol so that it can enter into force, if possible in time for the Ministerial Conference to be held in Nairobi".

9.4 Bangladesh, on behalf of the LDC Group

205. I am taking the floor on behalf of the LDC Group. May we inform you that the LDC Group is taking particular actions so that our Members may ratify and deposit instruments of acceptance very soon. While we are discussing under this agenda item, I will take the opportunity to make some general comments.

206. We all know that technical cooperation and capacity building in the area of IP remains an important cornerstone for creating the needed balance to ensure that IP serves as an effective tool to development and innovation. The LDCs appreciate the efforts of the Secretariat and thank those Members that are providing such support to the rest of us, as IP is a sector which requires maximum amount of technical cooperation and capacity-building.

207. For IP to truly serve as a development tool, much is required from the existing friends to the LDCs, especially data at a lower level of IP development. We would like to remind all Members the requirement and responsibility of the transfer of technology and knowledge. It will save all of us a huge amount of money and resources by avoiding the duplication of activities and wastage of time by repeating the same actions elsewhere. These efforts will ensure specific focus on assisting our economies and consolidating innovation and contribute to the sustainable development of the world we live in. Here we must emphasize that technical cooperation should be demand-driven and based on true requirements.

208. LDCs will therefore continue to emphasize the importance of enhanced assistance beyond mere workshops and seminars if real impact and tangible benefits are to be achieved. We appreciate those Members that have submitted reports on what they are doing in the area of IP and encourage those that have not shared their experience with this Council to do the same at the earliest convenience. We again thank the Members for their continued assistance towards the LDCs.

9.5 Australia

209. Australia adds its voice in support of the TRIPS Protocol's entry into force before this December's Ministerial Conference. This outcome will benefit Members by providing a permanent

legal basis for countries to import medicines to help address public health needs if they have no or limited capacity to produce medicines.

210. Australia commends Members from every region and at every stage of development that have already accepted this important instrument. We welcome the Protocol's recent acceptance by Brunei Darussalam. Australia encourages Members yet to do so to take this important step.

211. Australia accepted the Protocol in 2007, and while the Protocol's acceptance does not necessarily require legislative action, in February 2015 the Australian Parliament passed legislation implementing the Protocol in our domestic system. This will allow Australia to assist countries which do not have the capacity to manufacture or purchase their own medicines.

212. This scheme extends to non-WTO Members, consistent with the humanitarian principles underpinning the TRIPS Protocol. These measures will come into effect on 25 August 2015, and we will notify the measures in due course.

9.6 Brazil

213. The Paragraph 6 System exists today as a pending amendment allowing generic medicines to be made under "compulsory licences" exclusively for export to countries that cannot produce the medicines themselves. The system deals with a problem identified in Paragraph 6 of the 2001 Doha Declaration on the TRIPS Agreement and Public Health by removing a limit in the TRIPS Agreement's Article 31(f) and allowing nations to export under a compulsory licence to countries needing the medicines.

214. In the 20 years of TRIPS implementation and 19 years of our national industrial property law, only one compulsory license has been issued in order to allow access to medicines.

215. At that time, Brazil had the benefit of the fact that the medicine was not protected by patents in another WTO Member, allowing the international supply without the need to resort to the Paragraph 6 System. With the growing protection of IP throughout the globe, situations where a high-cost life-saving medicine is not protected by patents in manufacturing countries will grow scarce. In this context, the formal ratification and entry into force of the Paragraph 6 System becomes more urgent in order to grant to all countries the assurances that the TRIPS Agreement would not prevent Members from taking measures to protect public health.

216. Brazil urges all Members to expedite the implementation process of the Protocol. We are ready to share our experience with the acceptance of the Protocol with other Members.

9.7 Seychelles

217. Speaking on behalf of my delegation, I would like to give a brief update on our efforts to sign the amendment to the TRIPS Agreement. At national level there is engagement in finalizing the process with stakeholders. Once this step is completed, the Protocol Amending the TRIPS Agreement will be submitted to the Cabinet for their consideration and subsequent approval. Seychelles is expected to be in a position to sign by November this year.

9.8 Chinese Taipei

218. On behalf of my delegation, I would like to thank the WTO Secretariat for its efforts to promote the Paragraph 6 System. Public health problems afflict many developing and LDCs. We would like to highlight the need for the TRIPS Agreement to be part of the wider national and international action to address these problems. It would be also emphasized that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health and, in particular, to promote access to medicines for all.

219. This delegation supports the Paragraph 6 System and encourages other Members to notify their acceptance of the amendment so that it can enter into force by the 10th Ministerial Conference.

9.9 Pakistan

220. Pakistan shares the concerns raised in needing for an early ratification of this, and urges those Members who have not yet submitted the required Protocol to do so. Pakistan has already done so in 2007, and we look forward to this important issue, indeed the importance of public health and access to medicines cannot be over-emphasized. It is important, it is a matter of life.

9.10 Rwanda

221. My delegation welcomes the Director-General's efforts to ensure that ratification is done for this important issue relating to access to essential medicines for countries without manufacturing capacity. Rwanda has ratified and also it happens to be the only country that benefited from the Paragraph 6 System. We are willing to share experience in this process, including both ratification and access.

9.11 European Union

222. Following the intervention of my colleague from Bangladesh, the European Union much values this issue of technical cooperation and we take very seriously our obligations and commitments in this area. With Bangladesh, a few years ago, we had an extensive cooperation programme. I would propose to my colleague if they would like, on a future occasion, to discuss here at the TRIPS Council, their experiences and their assessment of how this programme went, and we would certainly be willing to work with them on this, so that maybe we could give an example, hopefully a best practice. I am taking a gamble here, because I do not know really what the evaluation of Bangladesh would be, but we would very much like to work with them and hopefully to present at a future occasion an example of what can be done, and what can be improved.

AGENDA ITEM 10: IP AND INNOVATION: THE ROLE OF INTELLECTUAL PROPERTY IN FINANCING INNOVATION

10.1 United States of America

223. The United States would like to thank the EU, Singapore, and Switzerland for co-sponsoring today's agenda item on Intellectual Property and Innovation: The Role of Intellectual Property in Financing Innovation.

224. Financing is a critical part of the innovation lifecycle that we have been discussing extensively under this agenda item at the TRIPS Council, and it is pervasive in every aspect of that life cycle. Innovation funding is a key part of our respective national innovation policies, and it is essential to the success of our innovative small-and-medium-sized enterprises (SMEs). It is a core consideration in research and development by universities and the startups they create as well as for social entrepreneurs seeking to maximize the social benefits of their IP. As we heard repeatedly at the WTO Innovation Fair, for innovators both large and small, the quest for capital is inextricably linked to the quest for innovation.

225. Whether we recall our discussions in this Council on green technology or sports, IP plays a central role in securing investment in climate change adaptation and mitigation technology as well as athletic competition at the local, national and international level. And as we have also explored in depth, innovation intermediaries – such as incubators and accelerators – often serve as essential companions for early-stage companies and inventors, including by simultaneously lowering the risk of innovation and increasing the incentives for investment, both by inventors and investors.

226. In its most elemental form, financing decisions are driven by a risk/reward calculus. IP protection mitigates the risk of innovation and can radically change the reward profile of R&D investment. We have devoted considerable time in this Council to supporting our own view that IP incentivizes innovation by investors. Today, we will look at a different dimension of IP's catalytic effect, and present what we view as prolific and compelling data demonstrating that IP also incentivizes innovation through financing. More simply put, IP couples creativity with capital.

227. We will focus our intervention on the role of financial intermediaries in the innovation life cycle. First, we will describe the significant and positive relationship between financing, innovation and IP. Having reviewed the extensive literature on the correlation between financing and innovation we will describe the unique and defining features – as well as the diversity – of capital structures and stages in the innovation life cycle, including venture capital.

228. Second, we will then discuss the role of IP as an asset that drives access to and lowers the cost of financing. Finally, we will turn to the role governments can and have played in this context.

The Significant and Positive Relationship between Financing and Innovation

229. Turning to the first issue, there is considerable data supporting the view that financing is critical to innovation. In their recent paper on "Financing Innovation", Kerr and Nanda cite to growing literature in support of the view "that well-functioning financial markets play a central role in driving economic growth through their ability to spur technological innovation."[1]

230. Their study focuses on the role capital markets and financial intermediaries play in impacting firm-level innovation. They conclude that "there is clear evidence that financing constraints have the possibility to be considerable in the context of firms engaged in R&D and innovation – with the ability to shape both the rate and the trajectory of innovation."[2] Numerous studies reach similar conclusions. For example, in their paper on "Financial Dependence and Innovation: The Case for Public Versus Private Firms", Acharya and Xu find that public listing on stock markets is beneficial to innovation firms in industries dependent on more external finance.[3]

231. Another study evaluates the innovation impacts on R&D firms during the Great Depression. This analysis by Nanda and Nicholas demonstrates negative effects of bank and stock market distress on innovation, in both quantitative and qualitative terms.[4] During that period, the severe constraints on the ability to raise public equity and debt finance not only stunted the rate of innovation, but also negatively impacted the type of R&D undertaken, with a move from greater risk to more conservative projects in those countries with higher economic distress. The authors conclude that the financial sector impacts both the immediate amount of innovation by individual firms as well as a "longer run effect on the trajectory of innovation that firms choose to undertake". And with economic recovery in the 1930s, came innovation recovery as well.[5]

The Nature of Innovation Financing

232. While financing impacts innovation positively, what is the nature of investment in innovative firms? Generally speaking, such firms, especially young R&D-intensive start-ups, are particularly reliant on financing and have unique demands beyond other entrepreneurs. For Hall and Lerner, R&D investment is different than ordinary investment in at least three key ways:

- that approximately half of R&D spending is on the wages and salaries of highly-educated scientists and engineers;
- that there can be a high degree of uncertainty associated with the output of R&D firms; and

[1] Kerr, W. and Nanda, R., "Financing Innovation", Working Paper 20676, National Bureau of Economic Research, November 2014, page 1. See Comin, D. and Nanda, R. "Financial Development and Technology Diffusion", Working Paper, 2014; Hsu, P.H., Tian, X. and Xu, Y. "Financial Development and Innovation: Cross-Country Evidence", Journal of Financial Economics, 112(1), 2014, pages 116-135; Brown, J.R. Fazzari, S.M. and Peterson, B.C., "Financing Innovation and Growth: Cash Flows, External Equity, and the 1990s R&D Boom", Journal of Finance, 2009, 64(1), pages 151-185; Levine, R., "Financial Development and Economic Growth: Views and Agenda", Journal of Economic Literature, 1997, pages 688-726; King, R.G., and Levine, R., "Finance, Entrepreneurship and Growth: Theory and Evidence", Journal of Monetary Economics, 32, 1993, pages 513-542; King, R.G., and Levine, R., "Finance and Growth: Schumpeter Might Be Right", Quarterly Journal of Economics¸108, 1993, pages 717-737.

[2] Kerr, W. and Nanda, R., "Financing Innovation", Working Paper 20676, National Bureau of Economic Research, November 2014, p.14.

[3] Archarya, V. and Xu, Z., "Financial Dependence and Innovation: The Case for Public Versus Private Firms", National Bureau of Economic Research, 2013, page 45.

[4] Nanda, R. and Nicholas, T., "Did Bank Distress Stifle Innovation During the Great Depression", Working Paper, Harvard Business School, 12-106, 2013, pages 24-25.

[5] Nanda, R. and Nicholas, T., "Did Bank Distress Stifle Innovation During the Great Depression", Working Paper, Harvard Business School, 12-106, 2013, pages 24-25.

- that there is often asymmetrical information between the innovator and investor.[6]

233. These factors were confirmed by several of the speakers at today's side event on "The Role of IP in Financing Innovation" sponsored by the EU, Switzerland and the United States. Kerr and Nanda highlight additional innovation-specific factors with respect to the R&D financing paradigm. In addition to uncertainty and information asymmetries, these include:

- the skewed nature of innovation returns, which makes evaluation difficult; and
- the high percentage of intangible assets, including intellectual property, held by innovative firms.[7]

234. The nature of innovation financing, therefore, can impact the capital structure of such investment. The relatively higher nature of risk involved in financing innovation coupled with the expertise required for valuation and management of innovative firms, often impacts the source and staging of capital. Debt and equity financing are both used to infuse much needed capital into the innovative process. However, while debt financing is available, innovators can be constrained in their ability or interest to use debt finance for R&D investment. This is because of the relatively lower risk tolerance and expertise of banks coupled with the higher cost of capital and challenges of debt serving faced by innovators, particularly young R&D intensive SMEs.[8]

235. Regarding equity financing, venture capital, angel investors, public and private equity, and hedge funds all play a role in financing innovation. We heard from two angel investors at today's side event, and will return to the significance of venture capital to innovation shortly. Before we do, it is important to note that investors may change at different stages. For example, in their intensive analysis of clean tech venture capital in 31 countries from 1996-2010, Cumming, Henriques and Sadorsky, identify four stages of clean tech innovation and financing:

- Stage 1 covers research and involves government funding as well as venture capital and private equity;
- Stage 2 covers development, where venture capital and private equity predominate;
- Stage 3 covers manufacturing and scale-up, where venture capital and private equity as well as public equity markets and mergers and acquisitions all provide financing; and
- Stage 4 covers roll out, where public equity markets, mergers and acquisitions, and debt markets finance clean tech commercialization.[9]

236. In addition, capital structures differ by country and region. Hall and Lerner, for example, identify distinctions by country in terms of the type of debt and equity financing, including data on the percentage of venture investments by GDP in 36 countries and a country-by-country share of worldwide seed and startup venture capital funding.[10]

237. Likewise, Groh, Liechtenstein and Lieser, rate the top ten countries for venture capital and private equity activity.[11]

Venture Capital and Innovation Financing

238. Turning specifically to venture capital, there is extensive analysis demonstrating the strong and positive impact of venture financing on innovation.[12] For example, Hellmann and Puri

[6] Hall, B. and Lerner, J., "The Financing of Innovation", *National Bureau of Economic Research*, Working Paper, 2009, pages 5-7.

[7] Kerr, W. and Nanda, R., "Financing Innovation", *National Bureau of Economic Research*, Working Paper 20676, Working Paper 20676, 2014, pages 3-4.

[8] Hall, B. and Lerner, J., "The Financing of Innovation", *National Bureau of Economic Research*, Working Paper, 2009, pages 14 and 34.

[9] Cumming, D., Henriques, Irene, and Sadorsky, P., "'Cleantech' Venture Capital Around the World", Draft Paper, September 21, 2004.

[10] Hall, B. and Lerner, J., "The Financing of Innovation", *National Bureau of Economic Research*, Working Paper, 2009, pages 13, 54 (Figure 4), and 55 (Figure 5).

[11] Groh, A., Lichtenstein, H., and Lieser, K., "The European Venture Capital and Private Equity Country Attractiveness Indices," *Journal of Corporate Finance*, 16(2), 2010, pages 205-224.

[12] *See* Kortum, S., and Lerner, J., "Assessing the Contribution of Venture Capital to Innovation", *The RAND Journal of Economics*, 31(4), 2000, pages 674-692, 675; Caselli, S., Gatti, S., and Perrini, F, "Are

evaluated 170 Silicon Valley innovative firms, including firms that were VC-backed and those that were not. They concluded that where a firm is engaging in an "inventor strategy" that firm was more likely to receive venture capital, to obtain it more quickly, and to experience significant time reductions in bringing its innovations to market.[13]

239. Generally, venture capital firms often serve as "specialized financial intermediaries" that intensively and expertly scrutinize innovative firms prior to providing capital and monitoring such investments thereafter.[14] Critically, venture capital also plays a vital role in assisting innovative companies, including clean tech startups, through the "Valley of Death", where there is a shortage of R&D and commercialization funding.[15]

240. Beyond financing, the research shows that venture capital provides additional added value. In their extensive review of 98 countries from 200-2011, Safari, Cumming and Cozzarin, identify a lengthy list of contributions made by venture intermediaries to innovative firms.

241. These important contributions include: board Membership and firm leadership; strategic business plan involvement; organizational and design assistance; internal process execution and improvement; internationalization advice; and the list goes on.[16]

IPR is Critical Factor in Innovation Financing

242. There is also growing research with respect to the positive impact of venture capital and the protection and diffusion of the innovation with intellectual property rights. Kortum and Lerner, for instance, survey 20 US industries over 30 years, and find that venture capital activities significantly increase patenting rates.[17] They also show that VC firms do not only promote patent protection, but other forms of IP as well, including trade secrets, as ways to protect important intangible assets.[18]

243. If, as the literature demonstrates, financing is critical to innovation, then IPR is critical to financing. IP is an important asset and value driver; and widely regarded as the sixth asset class after cash, real estate, stock, fixed income and private equity. Beyond sale and licensing, IP can also serve as collateral and can be securitized.[19] IP, from patents to trade secrets, copyright to trademarks, provides a basis for investors to risk their resources.[20]

244. Regarding collateralization, according to one commentator, "higher [IP] asset values may also help in negotiations with a company's bank and facilitates access to credit, or help to negotiate cheaper interest rates on credit".[21] Where IP is pledged, the size of the collateral pool grows in value and the possibility of a successful loan increases. In fact, Thomas Edison collateralized his patent on the incandescent electric light bulb to obtain financing for his startup – General Electric.

Venture a Catalyst for Innovation or Do they Simply Exploit It?", *European Financial Management Journal*, 5(1), 2009; Hirukawa, M., and Ueda, M., "Venture Capital and Innovation: Which is First?", *Pacific Economic Review*, 16(4), 421-465; and Hall, B. and Lerner, J., "The Financing of Innovation", *National Bureau of Economic Research*, Working Paper, 2009, page 35.

[13] Hellman, T., and Puri, M., "The Interaction Between Product Market and Financing Strategy: The Role of Venture Capital", *Review of Financing Studies*, 13, 2000, pages 959-984.

[14] Hall, B. and Lerner, J., "The Financing of Innovation", *National Bureau of Economic Research*, Working Paper, 2009, page 26.

[15] Cumming, D., Henriques, Irene, and Sadorsky, P., "'Cleantech' Venture Capital Around the World", Draft Paper, September 21, 2004, page 23.

[16] Safari, A., Cumming, D., and Cozzarin, B., "Venture Capital and Innovation around the World", pages 7, available at:http://www.law.northwestern.edu/research-faculty/searlecenter/events/entrepreneur/documents/Safari_Venture_Capital_and_Innovation.pdf

[17] See Kortum, S., and Lerner, J., "Assessing the Contribution of Venture Capital to Innovation", *The RAND Journal of Economics*, 31(4), 2000, pages 674-692, 675; and Safari, A., Cumming, D., and Cozzarin, B., "Venture Capital and Innovation around the World", pages 29, available at:http://www.law.northwestern.edu/research-faculty/searlecenter/events/entrepreneur/documents/Safari_Venture_Capital_and_Innovation.pdf

[18] See Kortum, S., and Lerner, J., "Assessing the Contribution of Venture Capital to Innovation", *The RAND Journal of Economics*, 31(4), 2000, pages 674-692, 675;

[19] WIPO, "Intellectual Property Financing; An Introduction", *WIPO Magazine*, 2008.

[20] Cardullo, M., "Intellectual Property: The Basis for Venture Capital Investments", WIPO,

[21] WIPO, "Intellectual Property Financing; An Introduction", *WIPO Magazine*, 2008.

245. Turning to securitization, IP is an amenable asset because it can have great value and has the potential to generate stable cash flows.[22] For example, David Bowie as well as Ashford and Simpson respectively issued copyright-backed bonds. Other forms of IP, including patents, are also securitized.[23]

Governments, Innovation Financing and IP

246. Finally, governments can play an important and positive role in the financing of innovation.[24] In some countries, for some sectors, public venture capital can be prevalent. Beyond direct financing, studies show that governance indicators are positively correlated with innovation financing.

247. For example, Cummings, Henriques, and Sadorsky, conclude that factors such as government effectiveness, regulatory quality, accountability, and rule of law have a positive and significant impact on clean tech venture capital activity. Likewise, increased contract enforcement, property right policing and effective judicial systems are found to be important determinants of VC financing in the clean tech sector.[25]

248. In short, financing increases where risk diminishes. While not the only driver of financing, IP can play a powerful role in attracting critical investment. Likewise, increased respect for IP, through protection and enforcement, can in turn, increase access to financing, while lowering the cost of such investment, particularly for capital-intensive innovative startups.[26]

249. To conclude, IP, Innovation and Finance form a virtuous triangle. Each begets the other, and governments can play a critical role in facilitating the necessary incentives to allow them to increase economic prosperity and development.

10.2 Switzerland

250. My delegation is pleased to co-sponsor this agenda item together with the Delegations of Singapore, the US and the EU. In previous TRIPS Council meetings we have looked at a number of factors which matter in a countries innovation landscape

251. Today, we propose to look at the important role that intellectual property plays in attracting capital to stimulate innovation. And yes, what is true for so many areas, is also true for the field of innovation: money makes the world go round! (Whether one likes it or not) In this particular case, financing helps to lubricate the various stages of the innovation cycle:

1 - Allowing an ingenious idea to be developed into an invention
2 - Making an innovative product out of this invention
3 - Bringing the innovative product to the market and make it a financial success
4 - Remunerating both the inventor and the investor for their efforts
5 - Allowing the financial reward to be invested in new inventive activity, thereby concluding – and restarting – the innovation cycle.

252. At a panel event over lunchtime we heard some fascinating insights by experts who showed us that IP can be highly relevant for an investor's decision to support the development of innovative products and services. The necessary funding can be decisive particularly for an innovation to take the final hurdle of entering the market successfully. The presentations demonstrated that IP can mean capital. Or in other words, as the WIPO summarises well on its website: IP turns intangible assets into property rights; it enables to claim ownership over the intangible assets and exploit them. As a result, IP assets of an enterprise regularly are worth more than its physical assets. The value of some of the international brands is estimated in value in the billions. To take a Swiss example, the brand *Nescafé* was estimated to be worth US$11 billion in

[22] Clarke, A., and Guedj, I., "Is Intellectual Property Amendable to Securitization", *Law360*, May 23, 2014.
[23] WIPO, "Intellectual Property Financing; An Introduction", *WIPO Magazine*, 2008.
[24] *See* Jeng, L., and Wells, P., "The Determinants of Venture Funding: Evidence Across Countries", *Journal of Corporate Finance*, 6, 2000, 241-289;
[25] Cumming, D., Henriques, Irene, and Sadorsky, P., "'Cleantech' Venture Capital Around the World", Draft Paper, September 21, 2004, page 21-22.
[26] Cardullo, M., "Intellectual Property: The Basis for Venture Capital Investments", WIPO.

2014. Let me emphasize, in this context, the myriad of SMEs in Switzerland that make active use of IP for their economic development.

253. An example of such a small start-up company is the Zurich-based "Doodle", an Internet calendar tool for time management and arranging meeting dates. The tool was developed in 2003 by a Swiss software engineer who was looking for an easy solution to arrange a meeting date for a dinner with a number of friends. In 2007, Doodle was registered as a trademark and thereafter several investors engaged with substantial investments. Today, Doodle is one of the world's most successful online meeting date arrangement tools, available in 17 languages.

254. So, why does capital like intellectual property? Intellectual property rights constitute a first available guarantee and value that the investor can calculate in. Intellectual property allows innovators to approach investors in a position of power, knowing that they have a substantive case that the investor is able to calculate with. They have a protected asset which can be included in a business plan.

255. It is not only for the bigger venture capitalists that IP matters for their investment decisions, but it represents an incentive to invest also for private individuals who consider investing their own money in a start-up, and have a particular interest in looking for securing the return on their investment. This may even apply to the recently become fashionable crowd-funding via internet-based platforms.

Case study: Innovative Medicine for the Tuberculosis Foundation - iM4TB

256. We would like to take up the case of a project discussed at the panel over lunchtime. The project spearheaded by the Swiss Federal Institute of Technology in Lausanne, EPFL.project is about fighting new forms of tuberculosis, The project is called - Innovative Medicine for Tuberculosis (or in short: iM4TB TB).

257. There are several forms of drug-resistant tuberculosis bacteria which have changed over time so that they can no longer be killed by the two best known antibiotics, isoniazid and rifampin. Usually, these antibiotics would be used to cure tuberculosis. The main reason for the bacteria to change and adapt is inconsistent use of TB antibiotics. One of the forms of drug-resistant tuberculosis is the so-called Multi-Drug Resistant Tuberculosis (MDR TB). Studies have shown that in 2013 more than half of the global burden of MDR TB cases was carried by the three countries of China, India and the Russian Federation.

258. The EPFL's iM4TB Foundation, founded in March 2014, is working on the development of a new antibiotic, carrying the name of PBTZ169, which is designed to kill drug resistant TB bacteria in a - compared to conventional therapies - shortened therapy. The medicine works by destroying the bacterium's cell wall that shields it against the immune system and antibiotics.

259. A US patent filed in 2011 was granted in 2014; further patent applications are pending at the European and at the Eurasian Patent Organisations, as well as in China, and the foundation is considering filing further patent applications.

260. In its search for a powerful new drug that would substantially diminish the risk of failure of a TB treatment, the EPFL was able to enter into a collaboration with Nearmedic, a Russian pharmaceutical, biotechnology and medical company. The cooperation was preceded by negotiations and an audit into the strength of the patent application filed. The terms and conditions transferred IP rights to Nearmedic for countries covered by the Eurasian Patent Organisation, and thereby allowed the EPFL to obtain, via the venture capital paid by Nearmedic, its return on investment. Apart from the financial aspect, the main terms between the parties stipulated a co-sharing of the drug's test results and exchange of experience in order to facilitate the further development and distribution of iM4TB in other countries.

261. It was thanks to iM4TB Foundation's patent portfolio and the data generated that the project could be developed to the advanced stage at which it has arrived today. The intellectual property, in conjunction with quality results of the research and development, triggered the interest of companies to further invest in the project. Eventually, those were also the major factors for

Nearmedic's decision to embark upon cooperation and participate in the development of that new treatment of tuberculosis.

262. Testing of the compound is in the pre-clinical phase and studies have shown PBTZ169 to be effective and quicker than the current TB drugs recommended by the World Health Organization. According to the pre-clinical studies, the chemical structure of the new compound and high specific activity provides a significantly higher safety profile than existing drugs which are associated with toxicity problems. The low toxicity of the new substance is essential for patients, taking into account the long duration of TB treatment.

263. This case study and other examples of projects mentioned in the lunch panel today show how innovators are able to turn their ideas into real inventions with the support of funding received from investors. In many of these cases, securing IPRs will be a key consideration for such investors to whether or not to engage in a start-up.

10.3 Singapore

264. Thank you for the opportunity to share Singapore's perspective on the positive impact that our intellectual property (IP) regime has had on our national innovation efforts. For knowledge-based economies like Singapore, IP is a key driver of business performance and economic growth. With a credible IP regime in place, businesses have the peace of mind to develop innovative technologies and ideas, as they know that their IP rights will be protected.

What Singapore has done in the realm of IP to help businesses and build a conducive environment for innovation

265. In Singapore, we have focused our efforts on building a conducive IP environment to facilitate innovation. Businesses are able to acquire a range of IP rights such as patents, trademarks and registered designs[27] to protect their products. We have tried to make the IP protection process as smooth and efficient as possible. For instance, businesses can make filings online through an integrated system called IP^{2}SG, which is a one-stop portal that facilitates patent, trademark and design related transactions and searches. Soon, businesses and innovators will also be able to tap on the quality search services and patent analytics offered by our multilingual patent search and examination team. Singapore was appointed as a WIPO Patent and Cooperation Treaty International Search Authority/International Preliminary Examining Authority last year, and we expect to be fully operational by September. Given the small size of our domestic market, we have also established international patent work-sharing arrangements to facilitate Singapore-based companies' expansion to other markets.

266. One good example is the ASEAN Patent Examination Cooperation (ASPEC), which is a regional arrangement among 9 ASEAN Member states for sharing search and examination results between IP offices. Under ASPEC, companies are able to fast-track patent applications in the ASEAN region using an initial examination report from any Member country's patent office. A patent application that used to take more than five years in some countries to process can now be completed in under two years. The establishment of such regional IP infrastructure plays an important role in supporting and spurring innovation efforts throughout ASEAN, as new products and services flow through the region.

Public-Private Partnership

267. We also have public-private partnerships in place to spur IP and innovation. For example, our Agency for Science, Technology and Research (A*STAR), encourages small and medium enterprises to leverage on emerging technologies, participate in research and development, and create their own novel products and solutions. Our two public universities have programmes to link their research with the relevant industries as well.

268. The Singapore government has also established an agency known as the IP Intermediary, which works with companies to market their technologies to overseas partners. IP Intermediary

[27] These are just a few examples – the whole range of IP covered in Singapore include patents, trademarks, copyright, registered designs, geographical indications, plant varieties protection, trade secrets and layout-design of integrated circuits.

also helps companies search for the best available innovation tools and partners to boost business growth.

Case study – Razer

269. Razer, an entertainment devices and software company, is one of numerous businesses in Singapore that have used IP protection to propel their growth. Razer has grown from its early days as a gaming peripherals start-up to become an established company selling computer peripherals, laptops, wearables and software platforms in over 60 markets around the world.

270. Razer's products are protected by a range of IP rights, including patents, registered designs, trademarks, trade secrets and copyrights. To supplement their in-house engineering and design work, they have put in place formal innovation processes and strategies for filing and enforcement. In this way, Razer has been able to use IP protection as a tool for marketing its products and defending its share in major consumer markets.

Outcomes

271. We have tried to create a virtuous cycle, where R&D is followed through by patenting activity to protect innovations. These efforts have borne some fruit. Between 2003 and 2013, there was a 7.3% year-on-year growth rate for the total number of patents first granted as a result of R&D in Singapore[28].

272. Singapore was ranked as the leading economy in Asia in the 2014 Global Innovation Index and the top Asia-Pacific economy in the World Economic Forum's Global Competitiveness Report for 2014-2015.

Conclusion

273. These are some of the steps that Singapore has taken to boost IP and innovation. We are continually strengthening our IP regime, and refining the support programmes so that the best possible environment can be in place to spur innovation and growth.

274. We hope that our sharing today has been useful, and we look forward to further discussions at the TRIPS Council on how Members, particularly developing countries, can successfully develop innovative economies by boosting their IP regimes.

10.4 European Union

275. It is our pleasure to participate once more in this series of debates on intellectual property and innovation and to co-sponsor it. Today I will present out of the wealth of studies and papers and work that has been done in financing by the European Union in this area, mainly two studies. You will see that these studies address a lot of the issues that were discussed during the lunchtime presentation except that they will not be illustrated by comics, so the presentation may be a little more boring but we hope it will still have interesting content, and it will only highlight a couple of points. I will provide the links to these studies. We also did not manage to squeeze in any examples with David Bowie, but that is us Eurocrats. But these are valuable studies that give a very extensive detailed and precise picture of the role of intellectual property in financing innovation in Europe.

276. Intellectual property rights play an increasingly important role in corporate strategy. The intangible assets created through the processes of innovation represent a major share of the value of today's businesses. The IP rights associated with those assets are the legal underpinning for potential returns on investment in that innovation.

[28] Source: A*STAR's 2013 National Survey of Research & Development in Singapore

European Expert Group on Intellectual Property Valuation

277. The European Expert Group on Intellectual Property Valuation assessed the commercialisation of innovative ideas, with the value of the IP asset acting as collateral. They looked especially at small and medium-sized enterprises. They found the role of IP in the financing process is often an indirect one. IP plays a supporting part in the bigger picture for the provision of loans and equity investments. In the regular banking, venture capital or private equity sectors IP is generally evaluated but not formally valued.

278. Equity investors typically invest into companies as a unit, but not into IP assets as such. In return for their investment investors receive an equity stake of a company which owns IP and intends to exploit the IP. Therefore, investors using this model are indirectly financing based on IP. The equity finance community considers the importance of IP when financing companies, but the actual value of IP assets per se is rarely considered important.

279. However, low quality IP can be a deal breaker for investors. An IP audit is considered by some Venture Capitalists as an important tool to assist the investment process by signalling the quality of the IP in possession of the investee. IPR may especially be of interest to a Venture Capitalist at exit if the buyer is a company. Investors may consider formal IP valuation to be fruitless in the case of SMEs as validity can be challenged when companies are still nascent and small companies find it difficult financially to defend their position.

280. The Expert Group notes that an issue that influences a company's decision to protect its IP, especially in the case of SMEs, is to what extent such rights are enforceable, the time and costs involved in litigation, and the foreseeable economic results. The quality of the enforcement system has an important impact in IP protection. SMEs, and large companies, need to be assured an accessible justice system for infringement, validity and other cases.

281. Large investment banks and private equity firms alike have raised and invested funds targeted at IP and other intangible assets. Rather than looking for entrepreneurs and start-up companies, these firms are looking to invest in IP and IA for development and commercialization purposes. These enterprises work with companies to either buy the IP/IA or invest in the company for commercialization of the IP/IA.

PATLICE Survey

282. The PATLICE Survey enquired about European firms patent licensing activities and found financial use is very important for SMEs. It looked at out-licensing and other use. The most important motive for SMEs to out-license is revenue-generating, especially from newly developed, core technologies. SMEs are also looking to earn revenue from non-core or mature technologies and to use out-licensing as an enabler for 'joint R&D and innovation'. Large firms out-license more to ensure Freedom-to-Operate and stop infringement.

283. In the pharma sector both SMEs and large firms are particularly motivated by earning revenue from core/newly developed technology. Patents are a currency for doing business with other firms and licensing is hence more commonplace. The health care sector puts also more emphasis on the motive to enable joint R&D and innovation.

284. The importance of licensing has increased over the years. Most firms report an increasing number of licensing deals and increasing licensing revenues over time. Out-licensing agreements usually cover more than just the patents and are more technology licensing. Growth in the number of licensing deals can be observed across all industries. Hence, the growing significance of licensing is not due to sectorial effects.

285. The most important other use of patents for all firms is to negotiate R&D collaboration agreements. There is a significant difference in the use of patents to obtain funding and finance by small and medium-sized enterprises and start-ups compared with larger firms. All types of finance uses are much more important for SMEs than for large firms. SMEs particularly use patents more for raising capital through private investors and venture capital and private equity.

10.5 India

286. My delegation would like to thank the delegations of the United States, Switzerland, the European Union and Singapore for tabling an agenda item on "Intellectual Property and Innovation: The Role of Intellectual Property in Financing Innovation".

287. Let me just recall our intervention when the agenda item on Intellectual Property and Innovation was first introduced in the TRIPS Council. Our statement is still relevant when we are discussing 'the Role of Intellectual Property in Financing Innovation' under the broad theme of Intellectual Property and Innovation. In that meeting India pointed out that the word "innovation" appeared just once in the TRIPS Agreement, in Article 7, which states that Intellectual Property Rights (IPRs) "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology," and not for the sake of innovation itself, but "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." Thus the TRIPS Agreement makes it very clear that the purpose of the Intellectual Property system is not solely to protect the commercial interests of the Intellectual Property holder but it is one of the many tools available to society to achieve technological development, social and economic welfare and innovation.

288. According to Petra Moser, faculty at Stanford University, U.S.A.:[29]

> *"Overall, the weight of the existing historical evidence suggests that patent policies, which grant strong intellectual property rights to early generations of inventors, may discourage innovation. On the contrary, policies that encourage the diffusion of ideas and modify patent laws to facilitate entry and encourage competition may be an effective mechanism to encourage innovation."*

289. Innovation should not be viewed within the narrow prism of intellectual property monopolies but framed within a holistic, knowledge ecosystem that includes open innovation, open knowledge approaches and de-linkage of R&D costs from product prices. According to the Trilateral Study by WTO, WHO and WIPO on "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade (2013)"(Page 126),

> "*Patent law is not a stand-alone innovation system. It is only one element of the innovation process, and one which can be deployed differently in diverse innovation scenarios. Patent law has little bearing on many other factors that lead to the successful development of technologies, e.g. the nature and extent of demand, commercial advantages gained by marketing and ancillary services and support, commercial and technical viability of production processes, and compliance with regulatory requirements, including through effective management of clinical trials data."*

290. The trilateral study also highlights that innovation in medical technologies for neglected diseases suffers from market failure as conventional IP-based incentives do not correspond with the nature of demand for treatments of these diseases. To overcome the market failure of the IP system for neglected diseases, the trilateral study mentions open innovation structures such as the Open Source Drug Discovery (OSDD) model of India's Council of Scientific and Industrial Research (CSIR), and collaborative research such as WIPO Re:Search - Sharing Innovation in the Fight against Neglected Tropical Diseases. The study also talks about the concept of delinking price of the final product from the costs of R&D by 'push' mechanisms such as grant funding and tax credits for investment in R&D and by 'pull' mechanisms that offer rewards for the final outcome of R&D of certain products like milestone or end prizes. The trilateral study also talks about the emergence of Product Development Partnerships (PDPs), which are constituted usually with the involvement of non-profit organizations, foundations and industry, to focus R & D towards diseases that disproportionally affect low- and middle-income countries (LMICs). Examples of Product Development Partnerships are Medicines for Malaria Venture (MMV), the international AIDS Vaccine Initiative (IAVI), the Aeras Global TB Vaccine Foundation, etc.,

291. The World Health Organisation (WHO) at the recently concluded 68th World Health Assembly (WHA) has adopted the '*Global Action Plan on antimicrobial resistance*'. The action plan, inter alia,

[29] "Patents and Innovation: Evidence from Economic History", *Journal of Economic Perspectives,* Volume 27, Number 1—Winter 2013—Pages 23–44

states that most pharmaceutical companies have stopped research and development of new antibiotics and calls it as a "serious market failure" and a "particular cause of concern". The action plan also suggests that "the cost of investment in research and development may need to be de-linked from price and the volume of sales to facilitate equitable and affordable access to new medicines, diagnostic tools, vaccines and other results from research and development in all countries". The G-7 countries yesterday came out in full support of the WHO Global Action Plan on anti-microbial resistance.

292. The Report to the President on Combating Antibiotic Resistance in September 2014, which was prepared by the United States President's Council of Advisors on Science and Technology (PCAST), while stating that market failure is the reason for the inadequate state of antibiotic development, it also talks about new mechanisms to incentivize the development of antibiotics, like 'push mechanisms (federal funding, subsidies etc.)' and 'pull' mechanisms (user licenses, lump sum prizes, patent buy-outs etc.).

293. India declared the decade of 2011-2020 as the Decade of Innovation. The spirit of innovation has to permeate all sectors of economy from universities, business and government to people at all levels. The future prosperity of India in the new knowledge economy would increasingly depend on its ability to generate new ideas, processes and solutions, and the process of innovation would convert knowledge into social good and economic wealth.

294. With regard to financing of innovation in India, there are many ways, but due to paucity of time, I would limit myself to few initiatives of the Government and private sector in India. CSIR-Tech Private Limited works with laboratories across India to commercialize their technologies and intellectual property; Grassroots Technological Innovations Acquisition Fund (GTIAF), which is operated by the National Innovation Foundation of India, is to obtain the rights of technologies from grass root innovators after compensating them for the same with the purpose to disseminate/diffuse them at low cost or no cost for the larger benefit of the society. Global Innovation and Technology Alliance (GITA), promoted jointly by Confederation of Indian Industry (CII) and Department of Science & Technology, Government of India, inter alia, has a mandate of professional management of Government Fund for the industry through flexible modes of funding support like grant, loan and equity. Some private sector initiatives that invest mainly in technology-led innovations include India Innovation Fund, a venture capital fund promoted by National Association of Software and Services Companies (NASSCOM) and IKP Knowledge Park, and Tata Capital Innovation Fund.

295. I would like to conclude by requesting the WTO to organize a symposium on "New Business Models for Fostering Innovation and Access: Innovation Inducement Prizes and Open Source Development Models." This could be organized by the WTO along with the WHO and the WIPO as part of their trilateral cooperation on intellectual property and public health.

10.6 Bangladesh, on behalf of the LDC Group

296. I am taking the floor on behalf of the LDC Group. We thank the proponents US, Switzerland, EU and Singapore for presenting this item for discussion and sharing their ideas to increase resources for innovation. We agree broadly with the general premise of the proposal, but we would caution against any one-size fits all approach, as the situation in developed and technologically advanced resource rich countries and the situation in LDCs are completely different. For example, availability of venture capital in LDCs and availability of venture capital in developed countries will be completely different unless the developed countries decide to provide to the LDCs. Since they have lots of priorities and very little resources and facilities, they do not have adequate allocation for any venture or adventure. We all know that innovation plays a vital role in the development of the socio economic scenario and the living standard of the people and we agree with the proponents on this premise and proposal.

297. However international standards and long-standing terms of intellectual property law do not always foster innovation everywhere in today's technologically advanced and interconnected world and they did not also play a similar role in the past. We consider that a strict intellectual property regime is not an essential prerequisite to promote innovation and technological diffusion when we examine and analyze the past history of development of the present developed countries. Intellectual property regimes and innovation propels the world to move further to a higher level of development, but unfortunately according to our experience, not all the countries of the world

benefited from intellectual property and innovation in the same way. Less than expected growth, the process of globalization, and competition have raised the stakes for IP policy to overcome this adverse situation for LDCs. LDCs need to have a flexible policy and ambiance for promoting innovation as the promotion of innovation has become a key growth strategy for all nations irrespective of the level of development. However, availability of money or resources does not necessarily guarantee innovation, as we have seen that great innovations in history actually derived from human genius rather than availability of vast resources. So we feel that there is no natural inevitable correlation between IP and financing innovation, rather encouraging and flexible rules, regulation and ambiance and availability of proper facilities will largely contribute towards innovation and development.

298. We again thank the proponents for drawing our attention to a very important issue and we hope that all of us will gain from this free discussion on how to increase allocation for innovation without depleting scant resources that we have at our disposal.

10.7 Chile

299. Firstly, I would like to thank the proponents of this proposal and note that, as demonstrated by the presentations given during the lunch break, the use of intellectual property as an intangible asset tends to be of great benefit to major enterprises. The development of this idea at national level is consistent with Chile's national public agenda for innovation, which seeks to transform our production structure from one that is commodity-based into one that is more diverse and innovation-oriented.

300. In order to achieve this, not only do innovators need to be directly empowered, but an ecosystem that indirectly promotes and facilitates innovative processes implemented by enterprises also needs to be created. The elements required for the successful development of the national innovation system include the use of intellectual property as collateral for the granting of funding to enterprises.

301. Intellectual property rights are intangible assets that allow for the ownership and value of innovations to be determined. The correct valuation of these assets should enable innovators to use them as collateral for funding from financial institutions.

302. Nevertheless, in Chile the valuation of intellectual property rights is not recognized, and there is a general lack of trust in the use of IP rights as collateral for such funding. Consequently, many entrepreneurs who become established as a result of their efforts and government funding for innovation face a financing problem when they want to expand their business.

303. This is why the necessary mechanisms should be developed to enable intellectual property rights to be assimilated as an additional asset, and not only in the case of large enterprises, but also for small- and medium-sized enterprises. This requires the provision of training for accountants, bank employees, entrepreneurs, venture capitalists and other actors in the market to enable them to duly consider and value this type of asset, which opens up opportunities and effectively contributes to the implementation of the country's innovation plans.

10.8 Chinese Taipei

304. My delegation would first like to join others in thanking the United States, Singapore, European Union and Switzerland for adding this important, newly-emerging item to the Agenda, and for their introduction to the subject.

305. We are very pleased to have the opportunity of sharing with fellow-Members the experiences we have had with our own policies in this area, and of learning from the experiences of other countries at the same time.

306. We fully identify with the observation made by several Members that corporations are only just beginning to tap into the potential of IP, and that recent multi-billion dollar deals on patent and trademark portfolios, as well as IP assets-backed financing, have kick-started what looks like being a sustainable trend. This innovative approach to IP - which could turn into a new pillar of

cooperate finance - is a growing trend that will surely consolidate and give Members a distinctive edge.

Small- and Medium-sized Enterprise Credit Guarantee Fund (SMEG) .

307. As you may be aware, the main focus of our policy on local industrial development is to assist SMEs - which account for nearly 98% of all local companies - with using intellectual properties in their financing arrangements. Being an intangible asset, the actual value of an intellectual property is very difficult to measure, so banks tend to place a relatively higher level of risk on loans provided to SMEs using IPs as collateral. Our government, therefore, has set up a special organization, the SMEG, (Small- and Medium-sized Enterprise Credit Guarantee Fund), to help SMEs engaged in innovation and R&D to secure loan finance from banks and to facilitate risk diversification for the banks themselves.

308. When assessing loan applications from SMEs using IPs as collateral, the SMEG would place much more emphasis on evaluating the future business potential and profit outlook for the intellectual property/ies in the market, rather than focusing solely on an estimate of the current value of the IP being proposed as loan collateral. In addition to that, the SMEG would carry out comprehensive reviews of both the enterprise and its IPs, including assessment of the management teams, future prospects in the industry, its business models and the feasibility of its programmes.

309. Since the start of 2013 up to April of this year (2015) the SMEG has facilitated the completion of 235 cases, resulting in loans to the value of US$3.86 billion in total.

Government assistance to financial institutions in their evaluation of an intangible asset.

310. Intellectual properties such as patents, trademarks, copyrights, and other IPRs are intangible assets, and a range of specialist professional skills and expertise are required in the areas of industrial know-how, legal compliance, market forecasting, etc. in order to properly assess their true and potential value. Our government quickly realized that enhancing the skills and expertise of financial institutions in evaluating IPs would be a vital factor in helping enterprises to secure loans from banks. Thus, the Ministry of Economic Affairs and the Financial Supervisory Commission (the FSC) have launched a series of relevant training programmes for financial institutions to upgrade their capabilities in the evaluation of intangible assets.

311. One of these is our *International Certified Valuation Specialist (ICVS) Programme,* and there are *other training programmes* as well, aimed at enhancing skills and expertise in this area.

312. The Ministry of Economic Affairs introduced the ICVS (International Certified Valuation Specialist) training programme on intangible asset valuation in 2006, and since then a total of 174 valuation specialists have been trained, of which 58 have obtained the International Association of Consultants, Valuators and Analysts (IACVA) credentials.

313. The FSC also launched a plan for financial sectors to support the creative industries from January, 2014. The plan consists of a training programme, a fundraising programme, a consultation platform and corresponding measures. In this training programme, by the end of April 2015, the FSC had already hosted more than 58 seminars and courses for a total of 3,279people.

314. Concerning the fundraising aspect, the FSC has been actively encouraging the generation of funds through various channels from bank financing and insurance funding, to the "Go Incubation Board for Start-up and Acceleration Firms". By the end of April, 2015, the Incubation Board, for example, had successfully assisted 13 companies from the creative industries in raising funds of US$26.71 million and had cooperated with the SMEG in raising the loan-to-value ceiling from 80% to 90%.

315. As for corresponding measures, the FSC has a programme to encourage local banks to provide loans to enterprises in the creative industries with sound risk management practices. By end-April 2015, the outstanding balance of loans to enterprises of the creative industries from local banks was NT$285.7 billion. In addition, on 3 January 2014, the FSC gave its approval to the

Financial Asset Services Corporation to launch intangible asset valuation services for the creative industries. The Financial Asset Services Corporation has already succeeded in establishing a database for 15 different industries, including the film-making and TV programme-making industries, as well as the music, advertising and digital content industries.

316. Today, there are still some challenges to be faced. For example, fraudulent and misleading valuation reporting, such as overestimating the software turnover and growth rates, leads to overpricing. When the investment being considered is in an intangible asset with no active market there will always be some difficulty in making a true and fair value assessment. Valuations based on the subjective judgement of so-called specialists and valuators are easily doubted as well. For these reasons, we believe we must continue to enhance the knowledge and expertise of our valuation specialists in all types of intangible assets, such as patents, trademarks, copyrights and other forms of IPR, as well as improve the quality of the appraisal operations and the credibility of appraisal reports.

317. I would also like to raise some questions here, if I may, for Members' further discussion and reflection.

- How can patents secure a stable banking infrastructure?
- How can we convert an asset or a stream of cash flows into marketable securities?
- How can we achieve win-win situations for both the IP owners and the investors?

318. So, as I hope I have shown you, my delegation attaches great importance to this item, as we assume all WTO Members do. We very much look forward to hearing about other Members' policies and their experiences with various practices and programmes.

10.9 Korea, Republic of

319. This delegation thanks the proponents of this important and interesting agenda item. Korea also recognizes the importance of innovation in productivity, job creation, new market creation and economic development as a whole. In this regard, Korea adopted a serious of policies to promote innovation under the new policy initiative of creative economy which is based on innovative science and technology.

320. In line with new national agenda, Korea has established a new value chain that extends from the inception of an idea to its eventual commercialization in order to protect fledgling invention and encourage its commercialization.

321. Korea established a financing system in which companies possessing outstanding patents technologies can access to bank loan even without other assets for collateral. In the past practices, banks usually requested other collaterals in addition to patents.

322. When such company applies for loan, the bank asks one of the Korean Intellectual Property Office (KIPO)-designated organizations to estimate the value of outstanding patent and technologies. Then the bank provides loan based on the value estimation. This system allows SMEs and start-ups to access to bank loan which is essential to commercialize patents and ideas.

323. To make IP-based financing operational, KIPO concluded a MOU with Korea Development Bank, Korea Credit Guarantee Fund in 2013 and Industrial Bank of Korea in 2014. These financial entities provided 303 companies with US$150.7 million loan during the year 2014.

324. KIPO also established the Korea Institute of Intellectual Property Evaluation & Transaction (KIPET) in January 2014 with a view to sophisticate IP valuation system which is an essential factor for IP-based financing. And KIPO is making efforts to make more companies eligible for the IP-based financing.

10.10 Japan

325. This delegation would like to express its gratitude to the United States, Switzerland, the European Union and Singapore for proposing this interesting agenda item. Japan fully recognizes

the importance of the role of intellectual property in financing innovation. Japan appreciates this opportunity to share its experience on how we have been promoting the use of intellectual property to finance innovation. We believe that our experience is useful for other Members.

326. Firstly, since 2014, the Japan Patent Office, or JPO, has been providing an assessment report on small and medium-sized companies that utilize intellectual property. This report, which is free upon request by any financial institution, assesses how the companies' intellectual properties and technologies contribute to their business. It can help financial institutions make informed decisions on whether to issue loans and financing for companies.

327. So far 22 institutions used this service. One of them provided funding to a plastics manufacturing company to develop beads cushion products, taking advantage of the assessment report made by the JPO. As stated by the financial institution, the objective analysis in the report facilitated the evaluation of the company's competitive edge over others in the same industry from different perspectives. It also outlined the growth potential of the business. Successful cases like this will result in an increasing number of financial institutions using this service and vitalizing local economies through innovation.

328. Another initiative this delegation believes worth sharing with other Members is an initiative taken by the Ministry of Economy, Trade and Industry, or METI. Since 2005, the METI has focused its attention on the importance of "Intellectual Asset-Based Management" and promoted assistance to raise public awareness on it, especially for small-medium enterprises. Under "Intellectual Asset-Based Management," enterprises recognize and value their intellectual properties for generating revenue. The disclosure of such management principle based on recognition and valuation of their intellectual properties gives them an advantage when it comes to receiving funding. This is because they are able to show financial institutions the appeal of their enhanced credibility and certainty, based on the value of their intellectual properties. The METI operates a portal site to provide financial institutions and small-medium enterprises with wide-ranging information on intellectual asset-based management. The portal site includes different guidelines and manuals the Japanese Government has produced on this subject, as well as reports on relevant seminars. This one-stop service also raises awareness on intellectual asset-based management.

329. As an example, the METI holds an "Intellectual Asset - Based Management Week" every year. This initiative is recognized as a valuable opportunity to share best practices and to develop cooperative relations among stakeholders from industry, academy and government.

330. Finally, this delegation would like to touch upon one case demonstrating the important role of intellectual property in financing innovation. A Japanese metal fabrication company, SEKI Press, developed a new technology called "Warisaki" in 2011. The technology allowed complex and three dimensional-shaped metal products to be manufactured with higher productivity at lower costs. In this field, technologies were generally protected as know-how rather than as patents. However, since the company was convinced that the new technology could be a key to their global business development, they obtained patents for the technology worldwide.

331. With regard to this case, this delegation would like to bring one thing to your attention. The Company, SEKI Press, took part in a competition called "business award 2012", organized by a local financial institution in order for local companies to obtain financing to further develop their technologies and expand their businesses overseas, the objective of which was to encourage local companies to develop new industries and to vitalize the local economy by creating an innovative business plan. And the company won the highest award in this competition, because the local financial institution gave high recognition not only to SEKI Press' original technology itself but also to the fact that the technology was protected by patents globally. The local financial institution group said that it would support commercialization of this new technology.

332. In summary, Japan, which attaches great importance to the use of intellectual property in financing innovation, is undertaking a number of initiatives to further advance such financing targeted for innovation through the use of intellectual property. Japan continues to develop new initiatives in the hope that they can contribute to further promoting innovation and economic growth. We would welcome other Members' insightful comments on this issue.

10.11 Brazil

333. We would like to thank the delegations of US, Switzerland, EU and Singapore for proposing this discussion item "IP and financing of innovation". Brazil welcomes the discussion. This theme is clearly described in the objectives of TRIPS. In article 7, objectives, the legal text states that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation. The rationale behind this objective is that intellectual property is capable of fostering investment through the legal certainty provided by the IP protection.

334. Beyond this, it is important to recall that the mere existence of IP rights, by itself, is not sufficient to promote technological innovation. As it was mentioned in one of the presentations in a parallel event held today, "IP is only one part in a package" when we discuss financing innovation. In fact, deficient financing for innovation, based only in IP rights, can also generate anticompetitive practices or deprive research areas from necessary and sometimes essential resources. Research on basic science and on pharmaceuticals for the treatment of neglected diseases are examples of intangibles that cannot be satisfactorily financed through the monopolies provided by the IP system.

335. In a nutshell, Brazil understands that all elements related to an optimal innovation system should be taken into account when building a balanced national innovation system. In the same way as Bangladesh, Brazil does not favor interpretations that suggest that "one size fits all" approaches can be applied to national innovation systems.

336. As a last remark, we would only like to recall a point that we have made in previous TRIPS Council sessions when discussing IP and Innovation: An IP system that provides good quality patents is an important element to foster innovation, since it can provide the guarantee to entrepreneurs and their financers that innovative businesses would not be a target of frivolous litigation based on low quality patents.

10.12 Pakistan

337. Pakistan wishes to join others in thanking the co-sponsors of the side event on the Role of IP in Financing Innovation, indeed an innovative tool for knowledge creation and management. It was useful, yet we wish to have a closer look at what we heard today. At the same time due diligence with respect to market failure owing to information asymmetry and moral hazard issues ought to be addressed, especially when it comes to IP along with the unknown externalities because we do not exactly know at this point in time. Although financing innovation and technological developments are crucial and we deem them to be critical, it raises several cross-cutting legal and public health issues as well. It raises a lot of important things and elements which are difficult to address at the moment. I wish in the room we had one personality by the name of Ben Bernanke that we remember still today.

10.13 Canada

338. Canada is pleased to take the floor to offer food for thought on the role of IP and financing innovation and we wish to thank the co-sponsors for having proposed a discussion of these important issues. Canada believes that these issues are as much about awareness of and accessibility to IP rights by entrepreneurs and small business that may not necessarily realize that they are creators and innovators and that their creations and innovations hold value, as they are about the importance of those rights themselves. In a way the innovation ecosystem has at its core a sort of positive feedback loop, that is, innovation can lead to the acquisition of IP rights, the acquisition of IP rights can lead to new sources of funding through both the sale of products or services and the credit opportunities that both the new IP realized value and the related income create and funding allows investment in further innovation, promoting growth and so on. While this is admittedly a very simplified outline, Canada believes this process can apply to and benefit businesses of all sizes, including micro, small and medium-sized enterprises. It can help launch small business and enhance the competitiveness of existing ones.

339. But particularly for enterprises at the smaller end of that scale, this feedback loop can only really be positive in Canada's view if three key ingredients are present. Foremost is access to IP rights through the provision by governments of easily-accessible affordable, effective and small

business friendly IP services. IP rights nurture and support creative and innovative entrepreneurs by providing them with the certainty that they will be able to protect and monetize their investments, enhance value, create jobs and opportunities, attract investment and grow.

340. Second is a general awareness of IP itself and of its benefits and value, including an appreciation of the monetary and non-monetary value of the intangible assets imbedded in creative and innovative products and services. Third is access to credit and finance, including at the smallest scale such as micro finance. Here awareness of the value of IP by lending institutions and investors of all sizes can be instrumental in getting even the smallest innovative business off the ground and is necessary for leveraging IP assets for financing and growth and ultimately attract inward foreign investment, further expanding the loop.

341. Of course, these are complex issues that are the subject of intensive and widespread research. Canada is certainly not pretending to hold any answers, but we thought that we could offer a few thoughts for discussions and further reflection.

10.14 European Union

342. Apologies for taking the floor a second time, I would like to say how much we have appreciated this discussion today, and we note that other Members of the TRIPS Council are also recognizing the importance of intellectual property for financing innovation. Because we have a close relation with one of these Members in the area of research and technological development and also because in the European Union we have a new competence in the area of investment, I would like to call attention to an important and interesting document called Investment Opportunities in India- Make in India. The "Make in India" strategy aims to create a conducive environment for the protection of intellectual property rights of innovators and creators by bringing about changes at legislative and policy level. The plan highlights the importance of IP in many sectors. It notes one of the main reasons to invest in Biotechnology is that India adopted the product patent regime in 2005.

343. On space it notes the Indian Space Research Organization has forged a strong relationship with a large number of industrial enterprises to implement its space projects and that it licensed a number of technologies for commercialisation. The Make in India strategy notes that Semiconductor Wafer Fabrication (FAB) manufacturing facilities are being set up in India with a total investment of US$10.5 billion. This is only possible with solid IPR rules and enforcement, as the World Semiconductor Council, the body of the world's leading semiconductor industry associations noted at its May 2015 meeting in China. Effective protection of intellectual property is crucial to protect semiconductor investments and promote further innovation.

The plan highlights the Indian film industry is expected to reach US$3.5 billion by 2018, up from US$2 billion in 2013 with an increasing number of digital screens and 3D films. The music industry is expected to grow to US$284 million by 2018 whereby Mobile Internet and the arrival of 3G is likely to lead to a surge in paid digital downloads. All this would not have been possible without good copyright rules and enforcement.

10.15 Australia

344. Australia thanks the cosponsors for bringing this item to the agenda. The Australian Government is taking an active interest in the role that intellectual property can play in securing finance for businesses seeking to develop, commercialise and market their innovations.

345. It is well recognised that access to finance can be made more challenging when the main asset of a business is an intangible asset, such as an intellectual property right.

346. Traditional models of lending and debt finance are not always suited to such businesses. This is because of the difficulties in valuing, securing and liquidating such assets and in understanding the risks involved in successfully commercialising innovating intellectual property. Australia, therefore, welcomes the contributions from WTO Members today, which will enrich consideration of policy options in this area.

347. We have been interested to hear about case studies and initiatives that have assisted innovative businesses secure finance on the basis of the value held in their intellectual property rights.

AGENDA ITEM 11: REQUEST FOR AN EXTENSION OF THE TRANSITIONAL PERIOD UNDER ARTICLE 66.1 FOR LEAST DEVELOPED COUNTRY MEMBERS WITH RESPECT TO PHARMACEUTICAL PRODUCTS AND FOR WAIVERS FROM THE OBLIGATION OF ARTICLES 70.8 AND 70.9

11.1 Bangladesh, on behalf of the LDC Group

348. I have the honour to raise one issue of extreme importance to the LDC Group under this agenda item. You may recall that our Ministers in Doha recognized the gravity of the public health problems afflicting many developing and LDCs, especially those resulting from HIV AIDS, tuberculosis, malaria and other epidemics. They also felt and agreed that the TRIPS Agreement did not, and should not prevent Members from undertaking measures to protect public health, while redirecting their commitment to the TRIPS Agreement, they affirmed that the Agreement could and should be interpreted and implemented in a manner supportive of WTO Members right to protect public health and in particular to promote access to medicines for all. Accordingly, WTO Members adopted the decisions IP/C/25 and WT/L/478 to exempt LDCs from TRIPS obligations in respect of pharmaceutical products.

349. These decisions are due to expire on 1 January 2016, and considering the gravity of the situation of lack of access to medicines and proper healthcare, LDCs require adequate time to reasonably overcome their public health problems. Under the circumstances, we had submitted a duly motivated request, in WTO document IP/C/W/605 dated 23 February 2015, for the extension of the transition period for pharmaceutical products and for a waiver from TRIPS Article 70.8 and 70.9.

350. I seek your approval to invite the delegation of Uganda, our focal point for TRIPS, to present a comprehensive picture of the current situation and resulting requirements for the understanding of all Members.

11.2 Uganda, on behalf of the LDC Group

351. I make this presentation on behalf of the LDCs Group. During the last Council meeting our coordinator Bangladesh submitted a duly motivated request on the extension of the transition period under Article 66.1 of the TRIPS Agreement for the LDC Members with respect to Pharmaceutical Products and for Waivers from Obligations of Article 70.8 and 70.9 of the TRIPS Agreement. That request is reflected in document IP/C/W/605. Today is the first opportunity for the Group to formally present this request.

352. It will be recalled that the current pharmaceutical transition period, which is set to expire on 1 January 2016 is comprised of two WTO decisions, TRIPS Council Decision, IP/C/25, dated 1 July 2002, addressing pharmaceutical product patent and data protections; and General Council Decision, WT/L/478, addressing market exclusivity rights under Article 70.9. This 2002-2016 transition period was specifically without prejudice to the right of LDCs to seek and obtain further extensions. This special pharmaceutical transition period was first agreed upon in Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health in recognition of the gravity of the public health problems afflicting LDCs and their acknowledged right to maximum flexibility to take steps to ensure access to medicines for all.

353. The classification of LDCs is contingent on a number of key human development indicators including levels of poverty, literacy, infant mortality and economic vulnerability. There are currently 48 countries which meet these criteria. 34 of these countries are Members of the WTO. Four countries have so far graduated out of this category, namely: Botswana in 1994; Cape Verde, in 2007; Maldives in 2011 and Samoa in 2014. To try and illustrate our point and put things into perspective, we would like to invite the Council on this short trip of numbers.

354. The LDC Report of 2014, prepared by UNCTAD, entitled *Growth With Structural Transformation: A Post-2015 Development Agenda*, observed that in 2013, the LDC current

account deficit reached US$40 billion. According to the market access study undertaken by the WTO in 2014**,** the LDCs share in world merchandise trade in 2013 was at 1.24%, with a staggering deficit of US$60.6 billion. Our participation in world services exports was a paltry 0.68%. Investment going to LDCs is not any different. According to the 2013 UNCTAD Investment Report, inflows to the LDCs represented only 1.9% of global inflows. According to the 2013 UNIDO Report, the share of manufacturing value added for LDCs actually declined from 2% in 1992 to 1% in 2012.

355. That notwithstanding, in 2013 UNCTAD also reported that the population growth is projected to double to 1.7 billion by 2050. Many LDCs are now at a critical stage of development whereby population growth is high, and the socio-economic challenges are massive. 400 million of our people, i.e. 46% of our population**,** live below the poverty line (US$1.25 a day). They disproportionately suffer health risks associated with poverty such as malnutrition, unsafe water and poor sanitation. About 50% of health expenditure in LDCs is also out of pocket. LDCs are the world's most impoverished countries with the weakest technological capacity.

356. It was with this in mind that the framers of the TRIPS Agreement recognized in its preambular paragraphs, the special needs of the LDC Members in respect of providing maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.

357. This now brings us to the substance of why we are here. Our request is premised on Article 66.1 of the TRIPS Agreement. It states as follows: "In view of the ***special needs and requirements*** of least-developed country Members, their ***economic, financial and administrative constraints***, and their ***need for flexibility to create a viable technological base***, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS ***shall***, upon duly motivated request by a least-developed country Member, ***accord*** extensions of this period." [emphasis added]

358. As we have highlighted in our request, access to affordable pharmaceutical products is a prerequisite, to deal with the numerous public health challenges facing LDCs. LDCs are home to some of the world's most vulnerable people and bear considerable health burdens. They face growing burdens of neglected, infectious, and chronic non-infectious diseases. Because of market failure in the patent-based innovation system, diseases that mainly affect poor people in lower income countries – so-called neglected diseases, including Ebola – still do not have many treatment options.

359. In 2011, some 9.7 million of the 34 million people living with HIV worldwide, lived in LDCs. 4.6 million were eligible for antiretroviral (ARV) treatment in accordance with the 2010 World Health Organization HIV treatment guidelines, however only 2.5 million were receiving it.

360. In 2013, the situation was different. UNAIDS and UNDP observed in their statement of support issued on 21 May, that people living with HIV who are not receiving anti-retroviral therapy has reduced from 90% in 2006 due to the effective use of the transition period to scale up access to treatment for HIV and its co-infections by importing or manufacturing lower-cost generic medicines. However the treatment gap remains massive. At the end of 2013, 63% of the 10.7m people living with HIV in LDCs do not have access to anti-retroviral therapy.

361. According to UNAIDS, "there is concern that without extension of the transition period, access to antiretroviral therapy and other key medicines in LDCs will face real challenges." Further, that the situation regarding availability and pricing of HIV-related medicines will be more complex than the situation in 2001 when the Doha Declaration was adopted….and the progress that has been made to improve access to HIV-related medicines in these countries will be reversed."

362. LDCs also bear increasing health burdens of Non Communicable Diseases (NCDs) than in higher income countries. According to a WHO Status Report of 2010, on non-communicable diseases, in the African Region, a region with many LDCs, the prevalence of NCDs is rising rapidly and is projected to cause almost three-quarters as many deaths as communicable, maternal, perinatal, and nutritional diseases by 2020, and to exceed them as the most common causes of death by 2030. In the specific case of cancer, data from low-income countries suggests that

cancer incidence is expected to rise by 82% from 2008 to 2030, whereas in high-income countries incidence is expected to rise at a much lower rate of 40%, in part due to widespread access to vaccines and medicines.

363. The UN Human Rights Council adopted Resolution A/HRC/23/L.10/Rev.1 of 11 June 2013 on access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; the 2011 UN Declaration on HIV and AIDS; the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020; and the 2012 RIO+20 United Nations Conference on Sustainable Development have all urged States to promote access to medicines for all, including through the use, to the full, of the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights which provide flexibility for that purpose. The extension of the transition period, therefore, is critical to enable LDCs to be able to import affordable generic medicines as well as to strengthen local production capacity.

Bilateral consultations

364. Upon submission of this request, we engaged the partners in bilateral consultations, both developed and developing. The objective was to understand their concerns with the view to explaining our request. A number of issues were raised, but we would like to address four of them, which seemed common to almost all the meetings we had: (i) what is the relationship between the 2013 general transition period and the 2002 pharmaceutical decision; (ii) whether or not LDCs had utilized the pharmaceutical transition period afforded by Paragraph 7 of the Doha Declaration and adopted by the TRIPS Council in 2002; (iii) the rationale behind the request for waivers from Articles 70.8 and 70.9; and (iv) the question of duration.

The general transition period vis-a-vis the 2002 pharmaceutical decision

365. It will be recalled that in 2001, WTO Members agreed to Paragraph 7 of the Doha Declaration on TRIPS & Public Health, which accorded LDCs a specific pharmaceutical transition period for 15 years until 2016. In 2002, Paragraph 7 of the Doha Declaration was formally adopted as a TRIPS Council decision (IP/C/25). It is important to recall that this specific pharmaceutical transition period was granted to supplement the general transition period that continued until 2005. It was adopted in recognition of the gravity and magnitude of public health challenges afflicting LDCs. Clearly it was also recognized that unlike other intellectual property, pharmaceutical products, and access to such products, deserve special attention and measures, as it is a matter of life and death. It is for this reason, that the duration granted for the pharmaceutical transition period was much longer than the general transition period at the time.

366. It is important to stress that the negotiations and the decision of the 2013 general transition period, did not give any special consideration to the matter of pharmaceutical products. This is evidenced by the 2013 decision text which states that it is "without prejudice" to the 2002 pharmaceutical decision and the right of LDCs to seek further extensions. This phrase can only be interpreted, in good faith, as the WTO Members' confirmation that the 2013 general extension does not affect or preclude the right of LDCs to request for further extensions of the 2002 pharmaceutical transition period. LDCs consented to the text of the 2013 decision on the basis of this understanding. Their position would have been different if any Member had expressed at that time the view that LDCs would have no right to such further extensions.

367. A specific decision on pharmaceutical products is critical to address the public health needs of LDCs. Unlike the 2013 extension, which is general, the 2002 pharmaceutical extension specifically mentions that "with respect to pharmaceutical products", LDCs do not have to "IMPLEMENT OR TO APPLY" patents or test data protection or "TO ENFORCE" such "rights". The specificity and clarity of Paragraph 7 of the Doha mechanism and the 2002 pharmaceutical decision has provided LDC governments, donors and suppliers, the certainty to confidently supply and procure affordable generic medicines. Thus it is without a doubt that a specific pharmaceutical decision is important to enable procurement of affordable generic medicines.

368. The 2002 pharmaceutical extension decision does not have any real or perceived conditionalities whatsoever. It provides certainty among policy makers with regard to the application of the transition period by LDCs. Given the critical importance of pharmaceutical products and the known concerns of the effects of intellectual property on access to medicines, LDCs need an unconditional decision as granted in 2002 that is explicit that there is no obligation

to implement, apply or enforce patents and test data obligations with respect to pharmaceutical products.

369. For the reasons we have described about the particular health challenges faced by LDC populations what the LDC Group is requesting of the TRIPS Council is merely a continuation of the Para 7 understanding in Doha. The 2013 decision does not preclude the need for a specific extension addressing the issue of pharmaceutical products.

Whether the 2002 specific pharmaceutical transition period has been valuable to LDCs?

370. Yes. The 2002 TRIPS Council Decision has been used extensively by LDCs and has been invaluable in assisting LDCs to access affordable pharmaceutical products. According to available information, following the adoption of the 2001 Doha Declaration, more than 20 LDCs have relied on Paragraph 7 of the Doha Declaration and the 2002 pharmaceutical decision, for the importation of generic medicines. Several LDCs such as Sierra Leone, Djibouti and Zambia relied on the 2002 pharmaceutical decision and issued declarations with regard to non-enforcement of patents for certain medicines to facilitate importation, and to speed up the supply of the medicines. In addition, inspired by the 2002 pharmaceutical decision and with the aim to improve their health situation, several LDCs including Uganda, Rwanda and Burundi have excluded pharmaceutical products from the scope of patenting.

371. Recently the IDA Foundation, a non-profit provider of generic drugs to LDCs sent a letter to our coordinator, the Ambassador of Bangladesh, where they expressed their full support for the LDC Group request. It observed that the pharmaceutical waiver "allows LDCs to authorize the importation of generic medication regardless of patent status" and the existence of "the pharmaceutical waiver and specifically the provisions of Paragraph 7", gave IDA "the necessary legal protection to be able to supply ARVs on a large scale without fear of patent infringement suits". It also stresses that the use of the pharmaceutical waiver is not limited to ARVs but is "relevant for both the production and procurement of products increasingly needed in LDCs, such as those for the treatment of non-communicable diseases". The IDA Foundation letter illustrates that in the absence of a TRIPS Council decision continuing the pharmaceutical extension, suppliers of medicines and procurement agencies would be very, very reluctant to supply medicines that are patented or whose patent status is unknown for fear of patent infringement suits.

372. Further, UNITAID, which is an organisation that funds projects to improve access to medicines for HIV, TB and malaria in 94 countries, including many LDCs, in its statement of support for the extension acknowledged the fact that "this exemption has facilitated access to affordable medicines in LDCs, and UNITAID urges WTO Members to unconditionally approve the request by the LDCs."

373. To that end therefore, it serves to show that Paragraph 7 of the Doha Declaration and the 2002 pharmaceutical decision have been effective and successful in promoting access to medicines and saving lives in LDCs. Civil society organizations from around the world have in their letter dated 5 June to WTO Members referred to the Paragraph 7 mechanism as "one of the most successful provisions of the Doha Declaration on TRIPS and Public Health".

The waiver from Exclusive Marketing Rights (EMR) obligations under Article 70.9

374. Exclusive Marketing Rights or EMRs in short confer patent-like rights and are another form of monopoly. If LDCs are bound to grant EMRs, the value of a pharmaceutical transition period would be very limited, since access to medicines and other pharmaceutical products could be effectively blocked for at least five years.

375. The transition period would be redundant if its basic objective of enabling access to affordable generic medicines is curtailed. Therefore, following the 2002 pharmaceutical transition period, the WTO General Council in 2002 granted a waiver from obligations to grant Exclusive Marketing Rights. If this obligation had not been waived, LDCs would have been required to recognize monopolies of patent applicants for pharmaceutical products for 5 years, delaying the introduction of generic medicines and thus limiting access to affordable medicines. There is need to renew this waiver along with the pharmaceutical transition period.

The waiver from mailbox obligations under Article 70.8

376. The mailbox obligation requires LDCs not recognizing pharmaceutical patents at the time of entry into force of the WTO Agreement to create a system for receiving such patent applications to be examined at the end of the transition period. The mailbox obligation should be waived for the following reasons:

377. The requirement to install patent filing systems implies considerable financial and administrative efforts that will place additional burdens on vulnerable LDCs. Further, requiring LDCs to install mailbox when they don't even have to grant any patents (under the General extension) does not make sense. The mailbox obligation may also have a chilling effect on generic producers, who may be deterred from investing in generic production of pharmaceuticals, which could in future be patented. This will have an adverse effect on the availability of affordable generic medicines for LDCs.

The issue of duration for as long as we are LDCs

378. It would be remiss if we closed our presentation without tackling the issue of duration. As we highlighted before in our opening paragraphs, the health challenges facing LDCs are massive – with communicable and non-communicable diseases. The state of economy remains appalling; while poverty levels remain high.

379. It would be unconscionable for WTO Members to grant LDCs – the most vulnerable segment of countries – a time limited transition period, requiring them to repeatedly seek extensions. A time limited transition period creates an *uncertain environment* for the producers of affordable medicines, procurement agencies, donors as well as LDC governments that rely on the specific pharmaceutical transition period to produce and import affordable medicines. This in turn jeopardizes the health situation of the people and communities within LDCs, with especially adverse consequences for the scaling up of HIV/AIDS treatment. LDCs cannot deal with increasing communicable and non-communicable disease burden without the assurance of continuous availability of generic medicines as long as they remain LDCs. This view has been echoed by the Communities Delegation of People living with HIV, in their statement of support issued on 5 May 2015. In the same vein, in 2012, the Global Commission on HIV and Law recommended that "WTO Members must indefinitely extend the exemption for LDCs from the application of TRIPS provisions in the case of pharmaceutical products".

380. By granting a renewable transition period, Article 66.1 recognizes that for as long as a country remains an LDC, it will face various constraints, and will need an exemption from TRIPS obligations. Previously a time-limited duration was given; yet during this period, the socio-economic situation in LDCs has worsened and the health needs remain even greater. You have heard the numbers.

381. In closing, considering that our health needs persist, and in many ways are growing because of the continued threat of infectious, neglected, and non-communicable diseases and other new emerging diseases. As evidenced by our continuing LDC status, we still face unrelenting development and capacity challenges. To address these pressing public health needs, to secure the ability to progressively realize the right to health, and to ensure our continuing right of access to more affordable medicines of assured quality, we the LDCs call upon you and the Council to grant the extension of the transitional period under Article 66.1 of the TRIPS Agreement for LDCs with respect to Pharmaceutical Products, and for waivers from the obligation of Articles 70.8 and 70.9 for as long as the Member is an LDC.

11.3 Lesotho, on behalf of the Africa Group

382. I am making this brief intervention on behalf of the Africa Group. At the outset, the Africa Group fully supports the Extension of the LDC Transition Period for Pharmaceutical Products under Article 66.1 of the TRIPS Agreement, and Waivers from the obligations of Article 70.8 and Article 70.9.

383. The challenging circumstances faced by LDCs in addressing their public health issues cannot be overemphasised. LDCs still face developmental challenges that affect their social and economic

development due to high burdens of infectious and non-infectious diseases. Access to affordable medicines and vaccines is a necessary basic requirement for LDCs to address the scourge of diseases including HIV/AIDS, tuberculosis, and other pandemics.

384. The flexibility under Article 66.1 was given to LDCs in recognition of the special needs and requirements, their economic, financial and administrative constraints, as well as their need for more time to create a viable technological base. LDCs maximum flexibility to address their special needs and requirements, which include their special needs for access to affordable medicines and development of a local pharmaceutical industry remains important for their development to this day.

385. The Africa Group supports the unconditional extension of the transitional period under Article 66.1 and the Waivers from the obligations of Article 70.8 and Article 70.9. In conclusion, the Africa Group aligns itself with the interventions made by Bangladesh and Uganda on behalf of the LDC Group that the extension should be in place for as long as a Member is an LDC.

11.4 South Africa

386. I wish to start by recalling that as far back as 2001 in recognition of the unique circumstances of LDCs in particular, the need to improve access to public health by bringing life-saving drugs within reach of those in dire need, the WTO granted LDCs a specific exemption for pharmaceutical products in Paragraph 7 of the Doha Declaration on TRIPS and Public Health which was later adopted as a TRIPS Council decision.

387. Almost 15 years later the conditions that gave rise to the initial request continue to exist in many LDCs. Severe public health challenges continue to confront LDCs. As we have seen recently in West Africa, such public health challenges persist even after a country graduates from LDC status. We therefore fully support the LDCs request to be granted an unconditional expansion linked to graduation or for as long as a country remains an LDC. Article 66.1 of TRIPS states: "the Council for TRIPS shall, upon duly motivated request by [an LDC] Member, accord extensions of this period".

388. Accordingly we as the TRIPS Council are obliged to approve without conditions the duly motivated request that the LDCs submitted. The request that the extension of the transition period for LDCs to implement TRIPS be so long as they remain an LDC is fully justified under Article 66.1. Thus we request that all WTO Members honour their legal obligation under Article 66.1 and unconditionally accord to the LDCs their request that demands, in particular, a TRIPS Council decision expanding the transitional period with respect to pharmaceutical products for as long as a Member remains an LDC and lastly a General Council decision granting a waiver to LDCs from Article 70.8 and Article 70.9 obligations for as long as a WTO Member remains an LDC.

11.5 Nepal

389. The delegation of Nepal supports the statement made by Bangladesh on behalf of LDCs. I also appreciate and endorse the statement and presentation made by Uganda on this subject.

390. As highlighted by Bangladesh and Uganda, extension of the transitional period for LDCs with respect to pharmaceutical products under Article 66.1 is a very important issue for LDCs. As we all know a still significant portion of the population in LDCs lives below the poverty line without having access to safe drinking water, nutritious food and primary health care facilities, making them highly vulnerable to many communicable and non-communicable diseases.

391. In addition, due to low income, these poor people cannot afford the high price for medicines, including life-saving drugs, which are under patent and are normally sold at high prices in the international market. Access to life saving generic medicines and other pharmaceutical products at an affordable price is a great challenge for many LDCs, but an essential component of the right to health and ensuring health services to poor and vulnerable communities.

392. Available data and survey reports prepared by different international organizations reveal that LDCs bear increasing health burdens of both infectious and non-infectious diseases and they have to increasingly confront several health risks. Indeed, LDCs are disproportionately exposed to

several health risks associated with poverty, malnutrition, unawareness and poor sanitation. A report published by WHO in 2010 discloses that cancer incidence is expected to rise 82% from 2008 to 2030 in low income countries compared to 58% in upper-middle and 40% in high-income countries. In the similar way, of the 35 million people living with HIV worldwide in 2013, about 10.7 million, or almost one-third of these people lived in LDCs. LDCs also lack adequate technological base and local pharmaceutical manufacturing capacity to cope with these alarming diseases.

393. Considering LDCs' vulnerable condition in the health sector, in 2001, in Doha, WTO Members recognized the special needs of LDCs and their need for maximum policy space to address their public health challenges. Thus WTO Members agreed to Paragraph 7 of the Doha Declaration on TRIPS and Public Health which explicitly states that LDCs do not have to implement, apply or enforce patents and test data obligations until 1 January 2016 without prejudice to the right to seek further extensions. Following the adoption of the Doha Declaration on TRIPS and Public Health, this specific extension on pharmaceutical products was formally granted by the TRIPS Council in 2002.

394. This specific pharmaceutical extension has been used extensively and successfully by many LDCs including Nepal. Several LDCs have authorized the importation of generic antiretroviral (ARVs) medicines to treat HIV/AIDS and other diseases relying on this decision. This decision has given generic companies as well as suppliers of generic medicines such as the IDA Foundation the necessary confidence and legal protection to promptly supply the LDCs with much needed affordable medicines. It is without a doubt that the specific pharmaceutical extension has been supportive in facilitating access to affordable medicines in LDCs. As this existing pharmaceutical extension is going to expire on 1 January 2016, it is of great concern to LDCs. Thus they submitted a duly motivated request to extend the specific pharmaceutical extension for a WTO LDC Member until they graduate from the LDC status.

395. The LDC Group is requesting a continuation of Paragraph 7 of the Doha Declaration, which as mentioned, has been used successfully. Even in 2002, all WTO Members recognized the need to complement the General transition period, with a specific pharmaceutical transition period, which was more explicit, and for a much longer period, in view of the seriousness of the public health situation in LDCs. The situation today is no different.

396. In addition, when the General transition period was negotiated in 2005 and 2013, it was agreed that the general transition period was "without prejudice" to the 2002 pharmaceutical transition period and the right to request a further extension of this transition period. So arguments that use the General transition period to refuse LDCs an extension of the 2002 pharmaceutical transition period are unjustifiable and cannot be accepted.

397. With regard to the duration, we stress that a short time-limited transition requires LDCs to repeatedly request extensions. This is extremely burdensome on LDCs that are already resource constrained. Besides, a short transition period creates an uncertain and unpredictable environment for the producers of affordable medicines, donors as well as LDC Governments. So considering the special needs and circumstances of LDCs, we urge Members to sympathetically consider and grant our request to tie up the extension of the pharmaceutical transition period to the point of LDC graduation. This is very much in line with Article 66.1 of the TRIPS Agreement.

398. Similarly, we strongly support the idea that LDCs must be exempted from complying with TRIPS Article 70.8 and 70.9, which create an obligation for LDCs to maintain a mail box and provide exclusive marketing rights (EMR). These are not only burdensome for LDCs, but also oblige LDCs to confer patent-like rights in their territories. Hence, if LDCs are legally bound to grant EMRs, the value of pharmaceutical transition period would be very limited or say meaningless. As the flexibility given by the extension decision can be curtailed or constrained by these two articles, we strongly argue for waivers to be given to LDCs from complying with these two Articles for as long as a WTO Member remains a LDC.

399. I would end by saying that the LDC Group request before the WTO TRIPS Council is an extremely modest request, considering the massive challenges LDCs have to face on a daily basis. It is seeking to continue with Paragraph 7 of the Doha Declaration on TRIPS and Public Health, a measure that has been successfully used by LDC governments and donors to facilitate access to

affordable medicines in LDCs. For the LDC population it is a matter of life and death. Clearly a positive decision by this Council will go a long way in saving many lives in LDCs.

11.6 Myanmar

400. The delegation of Myanmar fully endorses the statements delivered by Uganda and Bangladesh the previous day on behalf of LDCs.

401. LDCs have a lot of challenges in confronting disease and illness due to the socio-economic and financial constraints along with lack of adequate technological base and local pharmaceutical manufacturing capacity. In this regard, the extension of the pharmaceutical transition is extremely crucial for the LDCs for being able to access affordable pharmaceutical products and to strengthen local pharmaceutical manufacturing capacity.

402. In this regard, we would like to request and urge Members to support the LDC proposal which requests an extension of the transitional period (that ends on 1 January 2016) for as long as the WTO Member remains an LDC.

11.7 Barbados, on behalf of the ACP Group

403. I make this intervention on behalf of the African Caribbean and Pacific Group. The ACP Group supports the request for the extension of the LDC transition period for pharmaceutical products under Article 66.1 of the TRIPS Agreement and for waivers from the obligations of Articles 70.8 and 70.9. Less developed economies face significant social and economic challenges brought on principally by the very poor and vulnerable communities and this affects their ability to deliver the level and quality of healthcare and support necessary to raise the quality of public health delivery. It is therefore critical that improved access to affordable medicines and vaccines be accommodated in order that they can combat infectious and non-infectious diseases.

404. For this reason Article 66.1 of the TRIPS Agreement is important for LDCs as it offers more time and therefore greater opportunity to address this special and severe health related challenges. To the extent that LDCs are able to use the flexibility offered to take advantage of this extension, then the quality of public health can be improved as we learnt from the comprehensive presentation yesterday from Uganda on behalf of the LDCs. The ACP Group therefore fully supports the unconditional extension of the transitional period under Article 66.1 of the TRIPS Agreement on the terms requested by LDCs and for waivers from obligations of Article 70.8 and 70.9. We urge all WTO Members to support the LDCs request.

11.8 Cambodia

405. Cambodia associates itself with the statement made by Bangladesh on behalf of LDCs and the presentation made by Uganda, LDC focal point on TRIPS. As we all know, LDCs including Cambodia face serious challenges as they lack access to medicines and proper health care. Many millions of people living with various diseases can therefore not afford to buy medicines for treating their diseases and illnesses.

406. We have found that most LDCs have been using the 2002 decision to partly tackle those challenges. In order to continue fulfilling the needs of LDCs and to overcome the existing confrontation as well as to ensure our continuing right of access to affordable medicines, we would like to echo in urging you and all Members for a positive response to the February 2015 LDCs' request for an extension of the transitional period under Article 66.1 of the TRIPS Agreement for LDCs with Respect to Pharmaceutical Products, and for waivers from the obligation of Articles 70.8 and 70.9 of TRIPS Agreement as long as the WTO Member remains a LDC.

407. Finally, an unconditional extension will enable LDCs to reap economic benefit from the use of affordable medicines, which will therefore ensure the sustainable development in LDCs and help many millions of people to release from diseases and poverty.

11.9 Tanzania

408. My statement aligns with the statement by the delegation of Bangladesh as LDC Coordinator, and well-elaborated by the focal point, the delegation of Uganda. We highly value the importance of ensuring accessible and affordable medicines to save human lives, especially in a country where there are immense challenges of prevalent chronic diseases such as HIV AIDs, hepatitis B and C, tropical diseases such as malaria and others. We appreciate the continued global commitment being always exhibited in the United Nations by according health matters with a higher priority. We have witnessed this in the Millennium Development Agenda. It was one of the goals being pursued again in the new sustainable development goals to be adopted by the UN in September, where health matters have been included. For this goal to be realised in developing countries, especially LDCs and particularly in my country, affordable medicines and vaccines must be made available. Therefore an extension of the waiver for the WTO TRIPS Agreement on pharmaceuticals should be a commitment from all Members of the WTO as we ascribe all together to the global agenda. So most of the Members here understand that LDCs are weak, they lack the right capacity to establish a sound and viable technology base in the pharmaceutical sector. In view of this we request an extension of the waiver, as well elaborated by Uganda, until an LDC graduates.

11.10 India

409. My delegation would like to thank the delegation of Bangladesh for submitting, on behalf of LDC Members, a duly motivated request under article 66.1 of the TRIPS Agreement. We would also like to thank Uganda and other LDC Members for introducing their proposal contained in the document IP/C/W/605 and providing Members very convincing reasons for seeking an extension of the transitional period under article 66.1 of the TRIPS Agreement for LDCs with respect to pharmaceutical products and for waivers from the obligations of Articles 70.8 and 70.9 of the TRIPS Agreement.

410. In 2001, recognizing the special circumstances of LDCs, WTO Members granted LDCs a specific exemption for pharmaceutical products in paragraph 7 of the Doha Declaration on TRIPS and Public Health, which was later adopted as a TRIPS Council Decision contained in document IP/C/25 dated 27th June 2002. This decision exempted LDCs from having to implement the provisions of the TRIPS Agreement relating to the protection of pharmaceutical patents and clinical data until 1 January 2016 in order to enable their access to low-cost generic medicines given the high prevalence of both communicable and non-communicable diseases in LDCs like HIV/AIDS, malaria, cancer etc. The General Council also granted a waiver (WT/L/478 dated 12 July 2002) to LDCs from their obligation under Article 70.9 of the TRIPS Agreement to grant exclusive marketing rights (EMRs).

411. The 2002 TRIPS Council decision (WT/C/25) supplemented by the General Council waiver (WT/L/478) has facilitated access to affordable medicines in LDCs. However, LDCs continue to bear high burdens of infectious and non-infectious diseases and face numerous challenges in confronting disease and illness.

412. In June 2013, WTO Members agreed to extend the transition period for LDCs to implement the overall TRIPS Agreement until July 2021. We would like to recall statement made by India at the TRIPS Council meeting held in June 2013. While joining the consensus to extend the transition period until July 2021, we said in the June 2013 meeting of the TRIPS Council that we have consistently supported the LDCs' request for an extension of the transition period under Article 66.1 of the TRIPS Agreement without any conditionalities and we hoped that any future request by the LDCs for extending the transition period for pharmaceuticals, which will expire in 2016, would be looked at in a positive manner without any conditionalities being imposed on them. The statement made by India in June 2013 is still relevant today.

413. We would like to reiterate that Article 66.1 of the TRIPS Agreement which states "the Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period." We are of the view that the language used in Article 66.1 is mandatory in nature, in that it does not give the TRIPS Council any discretion to deny a request for extension of the transition period or to impose any further conditions on LDCs.

414. Since July 2002, the two transition periods-one general and one specific to pharmaceutical products - are in force. We are of the view that a specific decision on pharmaceutical product transition period is absolutely critical to provide suppliers, procurers and donors of affordable medicines in LDCs the clarity and certainty to manufacture, export and import generic medicines. In addition, the LDCs request for waivers from Articles 70.8 (mailbox obligation) and 70.9 (exclusive marketing rights) are fully warranted as these obligations create further obstacles to access to affordable pharmaceutical products to LDCs.

415. Importantly, according to the June 2013 decision, the general extension was "without prejudice to the Council Decision of 2002" on the extension of the LDC transition period for "certain obligations with respect to pharmaceutical products" that expires in 2016 and to the right of LDCs to seek further extensions of the period provided for in para. 1 of Article 66 of the TRIPS Agreement.

416. I conclude by reiterating India's support for the proposal of the LDCs contained in document IP/C/W/605 and request all Members to support the above proposal without any conditionalities.

11.11 Norway

417. Norway would like to thank the LDCs for their submission, and for explaining it in more detail yesterday. Norway recognizes the gravity of the public health challenges faced by the LDCs. Indeed, the representative of Uganda yesterday painted a stark and troubling, yet realistic, picture of the situation on the ground in the LDCs. In our view, the TRIPS Agreement should not prevent Members, and particularly those in dire need like many of the LDCs, from taking measures to protect public health. In this regard, access to affordable medicines is particularly important.

418. Norway acknowledges the relationship between the protection of patent rights and pricing of patented drugs. Access to essential medicines depends heavily on prices. This is particularly true for Members who have neither the production capacity nor the means to provide prevention, treatment or care for their inhabitants. This may very well be an issue of life and death.

419. With this in mind, Norway fully supports the LDCs' request for an extension of the transition period under Article 66.1 as regards pharmaceuticals. We also support the request for waivers from the obligations of Articles 70.8 and 70.9 of the TRIPS Agreement with respect to pharmaceuticals.

420. Norway notes that the LDCs have been granted a general extension of the transition period up until 2021. We still see merits in a particular extension of the transition period for the provisions in question as regards pharmaceuticals. In our view, this would ensure the legal certainty that the LDCs and the relevant operators need in order to ensure access to medicines vital to life and health.

421. We also support the request that the extension and waivers shall last as long as a Member remains an LDC. As we know, a Member does not self-designate itself as an LDC. That status depends on particular socio-economic indicators. As long as a Member is an LDC, it will have institutional and financial constraints, as well as lack of adequate technological base and pharmaceutical manufacturing capacity. It will therefore need flexibility and maximum policy space to enable it to confront its health challenges with effective and affordable strategies. An extension for as long as a Member is an LDC will also ensure legal certainty and predictability, which may contribute to keeping costs for medicines down and ensuring investment in the pharmaceutical sector of the LDCs.

422. To conclude, Norway is of the firm opinion that the request from the LDCs is "duly motivated" and we call upon the Council to grant the extension in accordance with Article 66.1, as well as to recommend to the General Council that the requested waivers be adopted.

11.12 Mali

423. My delegation would like to join those who have spoken before me to thank the focal point of the LDCs for TRIPS for the statement that they have made on behalf of the LDC Group – the clarity and exactitude of illustrations I think make this a very somber but realistic statement. On the state

of affairs and diseases of our population we can also add the Bamako Initiative to our current hopes which is well known by most countries. By most LDCs especially from West Africa. This is an initiative which has helped to save thousands of people in LDCs in Africa.

424. The delegation of Mali would also like to associate itself with the other delegations to give strong support to the statement made on behalf of the LDC Group, so as to obtain an additional extension for pharmaceutical products which will allow our countries to gain access to these products which are extremely pricey for our populations. My delegation supports the request put forward by the LDCs and we would also like to thank the LDC Group for requesting the inclusion of this item on the agenda.

11.13 Cuba

425. Cuba would also wish to speak to fully support the statement made by Bangladesh and Uganda on the request put forward by LDCs for the approval without any conditions of an extension of the transitional period which, as we all know, comes to an end in January 2016. Cuba also agrees that it is extremely important to go through with Articles 70.8 and 70.9 of the TRIPS Agreement. Both the extension and the waivers should remain in place as long as these countries are considered as LDCs. We are talking about the poorest countries in the world with the weakest technological capacities, indeed, the countries which are most exposed to health hazards due to poverty. That is why Cuba would like to stress the need there is to take into account this request in accordance with the flexibilities laid out in Article 66.1 of the TRIPS Agreement.

11.14 Brazil

426. We thank the delegation of Bangladesh for sharing the LDCs request for extension of the transition period under Article 66.1 of the TRIPS Agreement, as well as the delegation of Uganda for the very eloquent intervention that recalled us the dire public health situations faced by LDCs.

427. Brazil would like to restate its longstanding position about the need for a balance between the interests of users and producers of intellectual property, so that our societies can reap the benefits from the system. If this is true for all areas dealt with in the TRIPS Agreement, it is even more pertinent when it relates to matters of public health.

428. We understand document IP/C/W/605 as a duly motivated request in the terms of Article 66.1 of the TRIPS Agreement. Thus, we are ready to support the request made by LDCs to extend the transition period under Article 66.1 for LDC Members with respect to pharmaceutical products and for waivers from the obligations of Articles 70.8 and 70.9 of the TRIPS Agreement.

11.15 Yemen

429. The Yemen delegation associates itself with LDC Group Coordinator presentation as well as LDC delegations and other Members who spoke before in support of the LDCs extension request. Therefore, extension of the transition period under Article 66.1 of the TRIPS Agreement for LDCs with respect to pharmaceutical products as well as for waivers from obligations of Article 70.8 and 70.9 of the same Agreement is quite timely and appropriate.

430. Yemen with 25 million people continues to face many health-related challenges that need to be addressed seriously. Indeed, the gravity of the health-related problems affecting LDCs and thus right to ensure access to medicines remain similar to the 2002 situation when the TRIPS Council decision was taken to address such concerns.

431. We hope that WTO Members shall favorably support the LDCs request, accordingly, as this matter is vital for the livelihood of millions of people living under extremely difficult situations.

11.16 Argentina

432. Argentina supports the request submitted by Bangladesh and Uganda on behalf of the LDCs, contained in document IP/C/W/605.

433. We believe that an extension of the transitional period under Article 66.1 for LDC Members with respect to pharmaceutical products and for waivers from the obligations of Articles 70.8 and 70.9 would give LDC Members the flexibility, policy space and time they need to address serious and urgent public health issues relating to communicable and non-communicable diseases and access to medicines.

11.17 Togo

434. Togo would like to highlight that as an LDC we join our voice to all of those that have taken the floor in asking for an extension in as far as pharmaceutical products issue is concerned. Coming back to the reasons underlying this new request – those reasons were eloquently stated already by the LDC coordinator and by the focal point, the distinguished representative of Uganda. Nevertheless, allow me to say that there are many sick people in LDCs suffering great distress and this is why LDCs believe it is important to grant an unconditional extension concerning pharmaceutical products. I would like to say that the Members of the WTO were on the right side of history in accepting this. They must bear in mind the concern to stay on the right side of history. Human life is what is most important on this earth and we should work together to protect it.

11.18 Canada

435. Canada would like to thank the LDC Group for its detailed and very useful intervention yesterday and the openness it has demonstrated in recent weeks in engaging with Canada and other parties on the issue of its proposal. We understand this proposal to seek first an extension of the transition period granted in 2002 in TRIPS Council decision IP/C/25 and ending on 1 January 2016 for LDCs to not be obliged to implement or apply Sections 5 and 7 of Part 2 of the TRIPS Agreement, or to enforce rights provided for under these sections for as long as the WTO Member remains an LDC.

436. Second, the proposal seeks a renewal of the waiver of the obligation under TRIPS Article 70.9 for as long as the WTO Member remains an LDC and a new waiver of the obligation under TRIPS Article 70.8 for as long as the WTO Member remains an LDC.

437. Canada is supportive of a meaningful solution that would effectively allow LDCs to address their difficulties in implementing TRIPS obligations and better integrate the international trading system, and we are committed to working with all Members towards this goal. Canada is of the view that the general extension of the transition period to implement TRIPS that was granted to LDCs in 2013 does apply to pharmaceutical products. We have had informal discussions with many Members on this proposal and we look forward to continuing these conversations and to reaching a better understanding, for example, of the LDCs position on the Article 70.8 mailbox provision, and to what extent LDCs already have mailbox systems in place. We look forward to working constructively with all Members towards a solution.

11.19 China

438. China always values the concerns of LDC Members and would like to try its best to devote to the capacity building of the latter. Considering the economic, financial and administrative constraints of LDC Members, as well as the close relation between the access to certain pharmaceutical products and human life, China hereby echoes many other Members and completely agrees to the request that the transitional period under Article 66.1 with respect to pharmaceutical products and waivers from the obligations under Article 70.8 and 70.9 of the TRIPS Agreement should be extended. We also urge the developed country Members to provide more incentives to promote and encourage technology transfer to LDC Members as required by Article 66.2 of the TRIPS Agreement.

11.20 Japan

439. This delegation would like to thank the LDC Members for their proposal numbered IP/C/W/605. Japan is aware of the importance of this issue to the LDC Members, and therefore, we are ready to play an active role in future discussions on this issue to make a constructive contribution.

440. Today, we would like to make some comments on this proposal. Firstly, this delegation recognizes that the 11 June 2013 decision by the TRIPS Council, IP/C/64, also applies to pharmaceutical products, for which the LDC Members are requesting an extension of the transitional period in the current proposal. It means that without any further decision on the extension of the general transitional period for pharmaceutical products, the LDC Members can benefit from the transitional period under Article 66.1 until 1 July 2021. In this connection, this delegation considers that the necessity and its rationale for the extension of the transitional period for pharmaceutical products should be further examined in future discussions.

441. Secondly, if the obligations under Articles 70.8 and 70.9 are waived, the expiry for such waivers should also be stated in the decision, according to Article 9.4 of the Marrakesh Agreement Establishing the World Trade Organization. In this connection, it should be noted that all waivers granted so far in the WTO have expressly provided their own expiration dates.

442. Furthermore, this delegation is of the view that the TRIPS Council decision, IP/C/64, does not affect the obligations under Articles 70.8 and 70.9, since these Articles clearly oblige Members to take measures "notwithstanding the provisions of Part VI". Therefore, while the obligation under Article 70.9 has been waived by the decision of the General Council of 8 July 2002, WT/L/478, Members have been already obliged to take measures, as required under Article 70.8. In this connection, this delegation considers that these aspects need to be elaborated in future discussions.

443. What Japan also puts emphasis on is that IP rights are important instruments to support economic development. The protection of IP rights makes it possible that more investments would be made in research and development activity, which lead to promoting innovation. IP rights, therefore, are conducive to promoting economic development. In the discussions on this subject, due consideration should be given to this crucial role of IP rights.

11.21 Chinese Taipei

444. I would like to thank Bangladesh as representative and coordinator of the LDCs for that valuable proposal circulated in IP/C/W/605. We recognize the seriousness of the public health problems facing many LDCs, particularly involving HIV/AIDs, tuberculosis, malaria and other tropical diseases. We stress the fact that it is necessary for the TRIPS Agreement to assist in solving these national and international problems. The TRIPS Agreement should not prevent Members from taking measures to protect public health. That is why the LDCs benefit from an extension of the transitional period in order to implement protection measures within the TRIPS Agreement, thus supporting efforts at improving the public health issues in LDCs.

445. The WTO has granted a specific exception for pharmaceutical products, this is set forth in the Doha Declaration on TRIPS and Public Health, adopted subsequently as a decision of the TRIPS Council. This is a credit to those who took these decisions - it is difficult for LDCs to become involved in patent issues. They have been given a date of 1 January 2016. Also exceptions have been granted to LDC obligations under Article 70 of the TRIPS Agreement in order to guarantee exclusive marketing rights. This decision of the WTO is a crucial one in order rapidly to enable pharmaceutical products to become available in LDCs at an affordable price to combat epidemics. The use of this mechanism is helped by proposals and provisions from Doha concerning TRIPS and Public Health.

446. My delegation believes that all Members of the WTO should help the LDCs to promote public health within the TRIPS Agreement. My delegation also supports the idea that all WTO Members should provide assistance to the LDCs for them effectively to participate in the multilateral trading system. Nevertheless the LDCs proposal for an indeterminate extension for the whole transitional period may mean that there is little flexibility for possible adjustment in the future. That is why,

like Canada, we are quite in favour of bearing this in mind in a constructive spirit in order better to understand the needs of the LDCs. We would be pleased to continue this discussion in the TRIPS Council.

11.22 Sierra Leone

447. We deeply appreciate the support already provided to LDCs in response to their health challenges. Our delegation fully endorses the position contained in the respective presentations made by the delegates of Bangladesh, the coordinator of the LDC Group, as well as that of Uganda, of the Africa Group and of the ACP Group including other like-minded delegates all relating to the request for extension of its transition period for pharmaceutical products and the relevant waivers in favour of the LDC Group. My delegation earnestly looks forward to a positive outcome of this request.

11.23 Turkey

448. The special needs of LDCs as well as the economic and financial constraints that they have been facing particularly in affording pharmaceuticals are well known. According to the World Health Organization in 2011, out of 4.6 million people living in the LDCs who were eligible for anti-retroviral treatment, only 2.5 million were receiving it. The obstacles LDCs have been facing in terms of accessing essential medicines require specific flexibilities and exceptions to be foreseen for them. In this regard we welcome the request circulated by Bangladesh on behalf of the LDCs and support the extension of the transitional period for LDCs with respect to pharmaceutical products.

449. On the other hand, regarding the duration of the transition period, we prefer to follow the precedent and to mention a specific date, as was the case in the decision taken by this Council on 27 June 2002.

11.24 Haiti

450. We endorse the statement made by Bangladesh as coordinator of the LDC Group, and also the statement by the delegate of Uganda speaking as focal point requesting an extension of the transitional period for pharmaceutical products. Given the situation and vulnerability of LDCs which have to confront epidemics and have vulnerable populations, we stress the need for the extension and the waiver to be granted in as far as these countries have LDC status.

11.25 Congo, Democratic Republic of

451. The delegation of the Democratic Republic of Congo endorses the statements by Bangladesh and Uganda on behalf of the LDCs.

452. Rather than launching into a long speech, I will restrict myself to expressing our support for the request made by the LDCs to extend the transitional period that is due to end on 1 January 2016, with respect to pharmaceutical products and for waivers from the obligations of Articles 70.8 and 70.9.

453. There is no need to reiterate the innumerable health issues faced by LDCs. Based on paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, I therefore ask all Members to grant the request made by the LDCs until they are no longer in this category.

454. This is a question of life or death! Let us choose life, for this is written in the Word of God. I therefore encourage recalcitrant Members to give serious thought to this matter, as it is also written that it is a sin to know the right thing to do and then not do it.

11.26 European Union

455. The European Union would like to thank in particular Uganda for the detailed presentation further detailing the request submitted by the LDC Members for an extension of the transition period to provide protection for pharmaceutical products under the TRIPS Agreement.

456. The European Union has always supported extending the transition periods for LDCs in relation to pharmaceutical products and related requirements and continues to do so.

457. The EU was part of a unanimous decision on 11 June 2013 by the World Trade Organisation's Membership to extend the transition period for LDCs to comply with TRIPS provisions in general until 1 July 2021, which covers also the pharmaceutical related provisions.

458. The EU is willing to look at how to resolve any legal uncertainty and ensure LDCs flexibility not to provide patent protection for pharmaceutical products. The Commission is examining the request submitted by Bangladesh on behalf of the LDCs as a matter of priority against the background of the general extension granted to LDCs in 2013. In that sense, the submissions made at this TRIPS Council yesterday and today were highly valuable and informative and we look forward to the discussion among WTO Members between now and the next TRIPS Council.

459. The main urgency should however remain the efforts to solve the problem in a more holistic perspective and seek ways to address the current and very real obstacles faced by LDCs in providing their population with pharmaceuticals and health treatments. The WHO, WIPO and WTO have, for example, in a recent study on *Promoting Access to Medical Technologies and Innovation* noted the many access determinant other than IP, such as lack of access to quality health care, poor infrastructure, lack of distribution and supply systems, and lack of quality control, that affect access to medical technologies.

460. The European Union consistently tries to address these challenges and ensure that trade policy does not undermine these efforts. It has supported countries in reforming and in strengthening their health care systems, and is a major donor to organisations and funds dedicated to achieving improvements such as WHO, UNICEF, Global Fund, and GAVI.

11.27 Chile

461. Chile welcomes the proposal by Bangladesh on behalf of the LDCs, and the presentation by Uganda. The request in document IP/C/W/605 includes elements that have already been reviewed by this Council, in addition to new elements that were explained yesterday.

462. In our view, LDCs are faced with major public health issues and there is clearly a need for low-cost medicines. For Chile, exceptional situations obviously call for an exceptional response, particularly when human lives may be at stake. This is a question of basic justice, and the international community should therefore provide the support required to help LCDs overcome this and other issues.

463. We thus support the proposal and hope that it will meet with the consensus of WTO Members.

11.28 Uruguay

464. The delegation of Uruguay would like to thank Bangladesh for the proposal submitted on behalf of the LDC Group, and Uganda for the detailed substantiation provided to Members yesterday afternoon.

465. I do not want to dwell too long on this item, since I believe that other delegations have already given sufficient clear and convincing reasons that compel us to accede to this request.

466. Accordingly, we wish to express Uruguay's support for the requests set out in document IP/C/W/605.

11.29 Rwanda

467. My delegation would like to fully endorse the statement made by Bangladesh and the comprehensive elaboration by Uganda. Like the previous speaker I will not get into health problems in LDCs, I think many delegations have already elaborated that, I will limit my intervention to comparing the two extensions – the one general extension of 2013 and the

extension of 2002, because I hear that some are saying that the general extension covers also pharmaceuticals.

468. It is not appropriate at all because the 2002 extension was a very clear straightforward legal decision, clear to everyone, while the general extension is vague and with conditions. It is vague because in some parts you see together the determination of LDCs to apply the TRIPS Agreement and flexibilities. But more importantly it has a condition of no rollback of laws – the famous no rollback of laws provision which ensures that during the transitional period no changes in law of LDCs would result in a lesser IP protection. This means that any LDC currently, with a law protecting pharmaceutical products, and there are many, would not be allowed to amend its law if manufacturing capacity is acquired. So with those incentives, and the no rollback laws, I am not sure whether we would be taking the right decision for this huge health problem. As Chile stated, for exceptional problems it is required to have exceptional solutions. So I hope that the Council will take the right decision.

11.30 Switzerland

469. My delegation thanks Bangladesh for introducing the LDC Group's submission in IP/C/W/605 and Uganda for its presentation, giving the Council an update and overview of the challenges LDCs face in regard of the health situation in their countries. My delegation considers this an important task of the Council, to reassess the situation and new developments in the matter at regular intervals. Switzerland fully acknowledges the special needs and requirements of LDC Members, particularly where health issues are concerned. TRIPS or patents cannot be said to be a barrier to affordability or availability of pharmaceuticals in LDCs. They have not applied to LDCs for the last 20 years, during which the situation in LDCs, according to Uganda's information yesterday, has not improved, if not worsened. This is certainly unsettling news.

470. Switzerland is supportive of a further extension of the transitional period recognizing the special vulnerability, the formidable challenges and the many pressing priorities that LDCs face in sustaining their population, economy and public health. Therefore the scarce resources and capacity should first and foremost be dedicated to addressing these challenges. As a corollary of our support to extending the general LDC transitional period in 2013, Switzerland supports that the further extension shall apply also to the TRIPS provision in relation to pharmaceutical products.

471. My delegation will examine further the modalities for this extension as proposed by Bangladesh yesterday, and additional information received at this Council meeting. Should we need further information or clarification we will seek advice of the LDC Group. My delegation looks forward to discussing this matter further with Members and to come to a decision swiftly.

11.31 Australia

472. Australia thanks the LDC Group for its proposal and appreciates the deep importance of this issue. We recognise the challenge LDCs face in tackling disease and illness, including in our own region. We welcome discussions had today and yesterday and the ongoing efforts of the LDC Coordinator and Focal Point to engage Members on this issue.

473. While an outcome today may not be possible, we hope we, as a Council, can move efficiently toward an outcome that responds to the unique position of LDC Members while continuing to recognise the role intellectual property can play as a tool for supporting innovation, investment and development.

11.32 Holy See

474. I join previous speakers to congratulate you on your election. The World Health Organization (WHO) estimates that about one-third of the population lacks regular access to essential medicines and vaccines. It believes that 10 million lives could be saved annually if such resources were more readily available.

475. The LDCs, as the poorest and weakest segment of the international community, are most vulnerable. The classification of LDCs is contingent on a number of key human development

indicators, including levels of poverty, literacy and infant mortality. At the beginning of the Millennium, the LDCs enjoyed the strongest and longest growth rates since the 1970s, benefiting from sustained global growth, surging commodity prices and buoyant capital flows. Between 2000 and 2008, the average annual growth of this Group's real gross domestic product (GDP) exceeded 7%, raising hopes that some LDCs may be able to graduate from this category within the present decade. However, with the global financial crisis in 2008 and the drastic change in external conditions, LDCs have experienced a slowdown of economic activity. As a result, their economic growth has been much weaker during the past five years. It has been well below the target rate of 7% annual growth established in the Istanbul Programme of Action (IPoA) which is considered necessary for attaining the Millennium Development Goals (MDGs).

476. With the recovery of the global economy remaining slow and uneven, the LDCs faced a challenging international environment in 2013. This sluggish global economic growth, which translated into weaker international demand for commodities and a consequent decline in their prices, adversely affected the economic growth and export performance of several LDCs. The outlook for the LDCs in the short and medium term remains uncertain. While global output is expected to strengthen moderately in the medium term, uncertainty about the pace and the strength of the recovery persists. A fragile and uncertain global recovery could hinder LDCs' economic performance due to weak international demand and lower commodity prices. Adjusting to a changing external environment has always been a key challenge for these economies, but this is now exacerbated by a weak world economy and prevailing uncertainties. The less favourable external environment, coupled with LDCs' weaker growth performance, suggests that achieving the MDGs, or the SDGs that are planned to succeed them, will be difficult.

477. As underlined in the Istanbul Program of Action, LDCs are the most "off-track" in the achievement of the internationally agreed development goals. Their productive capacity is limited, and they have severe infrastructure deficits[30]. In 2011, of the 34 million people living with HIV worldwide, some 9.7 million lived in LDCs. Of these, 4.6 million were in need of antiretroviral treatment (ART); however only 2.5 million had received it[31]. Up to one-half of those deprived of treatment were expected to die within 24 months[32]. In the 49 countries designated as LDCs by the United Nations, non-communicable diseases as well are rising much faster than in higher income countries.

478. Some LDCs have used the transition period as a major selling point for attracting investment in their local pharmaceutical industry[33]. However, some LDCs have provided patent protection for medicines despite the availability of the transition period or have signed free trade and investment agreements that may contain IP provisions curtailing any benefits arising from the transition period. In this context, the report observed that the transition period in itself, though important, will not be sufficient to attract generic companies to invest in local pharmaceutical production[34]. However, the transition period is intended to provide LDCs with the necessary policy space to take measures that would facilitate the growth of industrial capacity in desired sectors without being impeded by the existence of patents, which could hinder the development of the local industry.

479. Since 2000, there has been a noticeable decline in the number of new HIV infections in LDCs since 2000, as in the developing world as a whole, reflecting improvements in early diagnosis, access to treatment, nutrition, and responsible behaviour change. However, despite such improvements, the goal of universal access to anti-retroviral treatment is far from achieved and requires continuing investment and both health and community system strengthening. Moreover, the deficiencies of health systems in LDCs have been sharply highlighted during 2014 and 2015, in conjunction with the significant outbreak of the Ebola Virus Disease in Coastal West Africa. Such

[30] Istanbul Plan of Action (par.4) doc. A/CONF.219/3. http://ldc4istanbul.org/uploads/IPoA.pdf

[31] *TRIPS transition period extensions for least-developed countries,* UNDP and UNAIDS Issues Brief,/13 February 2013.

[32] Mr. Michel Sidibé, UNAIDS Executive Director, Report to 31st UNAIDS Programme Coordinating Board, December 2012, http://www.unaids.org/en/media/unaids/contentassets/documents/speech/2012/12/20121211_SP_EXD_31st_PCB.pdf

[33] UNCTAD (2011), Investment in Pharmaceutical Production in the Least Developed Countries: A Guide for Policymakers and Investment Promotion Agencies (UNCTAD Secretariat, Geneva, New York), pp. 40-42, available at http://unctad.org/en/Docs/diaepcb2011d5_en.pdf (last visited 3 June 2015)

[34] Ibid.

health emergencies could jeopardize, or even reverse, the achievements of several LDCs in terms of human and economic development.

480. We have before us a critical opportunity to help LDCs to reach health and sustainable development goals and the failure to do so could put millions of lives at risk. Access to adequate healthcare, including affordable medicines, remains a key challenge in most LDCs. The current flexible intellectual property arrangements for LDCs are a crucial tool for improving health. In fact, the flexibility agreed in TRIPS Article 66.1 has been accepted in recognition of the economic, financial, and administrative constraints preventing LDCs from immediate observance of all the obligations set out in the TRIPS Agreement. The general transition period may be useful in supporting the development of a strong chemical industry that could gradually move toward production of active pharmaceutical ingredient (API). Long-term sustainability of the local pharmaceutical industry would require the development of the internal capacity to manufacture generic formulations thus reducing dependency and the high import costs for obtaining APIs. In particular, there is a need to develop a second line HIV treatment which, at present, is more than double the price of the first line regime. Moreover, the costs for a third line HIV treatment could be as much as 15 times the price of first line treatment. Clearly, in this context, the establishment of a pharmaceutical industry is particularly important.

481. As clearly stated by the TRIPS Agreement, a well-designed intellectual property system "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, in a manner conducive to social and economic welfare, and to a balance of rights and obligations"[35].

482. In conclusion, the Holy See Delegation hopes that a sense of common responsibility, as shown in the decision adopted, will bring us all to recommend to the General Council a waiver for LDCs from obligations under Articles 70.8 and 70.9 of the TRIPS Agreement for as long as they remain LDCs.

11.33 Brazil

483. I apologise for taking the floor on the same subject, but, as stated by Rwanda, I believe it would be beneficial to the discussion to draw a clear distinction between the two TRIPS extensions currently in force related to obligations from LDCs.

484. The general transition period, extended in 2013, was based on administrative, financial and economic limitations faced by LDC capacities. Against this background, WTO Members decided to grant extended flexibility so LDCs could build their national IP systems without international constraints until 2021.

485. Regarding the extension related to pharmaceutical products, a very specific situation on the ground was the reason of existence of this extension. In 2002, in the Doha Declaration on TRIPS and Public Health, all WTO Members agreed that the reason of existence of this specific extension was "the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics". We understand that this background should guide our discussions.

11.34 WHO Secretariat

486. Universal health coverage is the central policy objective in global public health and part of the future UN Sustainable Development Goals. Universal health coverage means that all people obtain the full spectrum of essential, quality health services they need without suffering financial hardship. This requires a strong, efficient, well-run health system that meets priority health needs through people-centred integrated care. Health systems must provide for a system for financing health services, a sufficient capacity of well-trained health workers and be able to ensure access to safe, effective and affordable essential medicines and technologies.

[35] Article 7 TRIPS Agreement.

487. Access to essential medicines is also recognized as part of the human right to health as an integral component of primary health care. Unfortunately, we as a community have not yet achieved this aim in all countries. There are many reasons for this gap, which include inadequate health systems, lack of political commitment, lack of good governance and insufficient investment in health in general. Where people have to buy medicines out of their pocket, it is essential that patients are provided with financial protection and essential medicines are affordable. This is particularly true for those countries that the UN classifies as LDCs.

488. Currently, LDCs that are Members of the WTO are not required to apply most of the substantial rules of the TRIPS Agreement until 1 July 2021. In particular, they have no obligation to provide any protection for clinical test data or to grant patents, including on pharmaceutical products or processes. In parallel, LDCs benefit from a specific transitional period with respect to the pharmaceutical field under the 2001 Declaration on TRIPS and Public Health which if not extended, ends on 1 January 2016.

489. Being exempted from granting patents allows LDCs to either locally produce or to import generic products even when those are still under patent in other countries. This can help countries in expanding health coverage by allowing the health sector to rely on more affordable generic suppliers. Being able to do competitive procurement, including from local or foreign manufacturers is in particular important in the area of HIV as well as for the new treatments for highly prevalent conditions like hepatitis.

490. The possibility not to grant patents on pharmaceuticals can also play a crucial role for LDCs to enhance local production of generic versions of essential medicines through strategic joint ventures. This can strengthen domestic manufacturing which can contribute to achieving public health objectives by ensuring security of supply as well as creating a knowledge economy.

491. Consequently, the LDC Group stated that the request aims at facilitating access to affordable medicines in LDCs and is motivated by the massive health challenges resulting from communicable and non-communicable diseases in LDCs, their socio-economic and financial constraints, as well as the lack of adequate technological base and local manufacturing capacities in the pharmaceutical sector.

492. WHO welcomes and supports the LDC request for extension as part of an overall effort to facilitate access to essential medicines in these countries and urges the Council for TRIPS to favourably consider this request.

11.35 Bangladesh, on behalf of the LDC Group

493. We thank all Members for their responses and we are encouraged to see that Members took serious interest in this important issue. We thank wholeheartedly the Groups and Members and International Organizations that expressed instant support. We also thank other Members who are in the process of examining the proposal and hope that they will come back to us with positive responses soon. Actually there is hardly any need to explain or justify the causes and requirements for this position. We are hoping for sympathetic comprehension of Members and we are waiting for the same efforts and understanding that Members have demonstrated a number of times in the WTO, including the previous extension of transition periods. However Members will notice that in spite of severe constraints, many LDCs progress significantly to implement these provisions.

494. Meanwhile we have taken note of the comments and queries of the Members regarding the proposal and we will come back to them accordingly. The LDC Group is at the disposal of all Members to provide further information and clarification if required and we will be intimately engaged in the process. We also thank you for your indication to help the process and we rely on your wise guidance. We also thank the WTO Secretariat for their continuous support with various WTO documents and voluntary statistics. I again thank all the Members for their kind support.

11.36 Uganda, on behalf of the LDC Group

495. I join my colleague from Bangladesh in expressing our profound appreciation for the extensive support that we have received from all the distinguished Members in this Council,

Members of Parliaments in various jurisdictions who have written letters of support to their respective Governments urging them to grant this request; and International Organizations, such as the WHO, UNDP and UNAIDS, UNITAID, the NGO delegation to UNITAID; and Communities Delegation on the Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria; hundreds and hundreds of Civil Society Organizations and networks from around the world as well as suppliers of generic medicines in LDCs. We also express our appreciation to the WTO Secretariat for all the support we have received, and continue to receive.

496. We also express our sincere appreciation to all the partners who have raised concerns and expressed keen interest in learning more about our request. We have attempted to address most of those concerns by highlighting the four areas in our presentation emerging out of our bilateral consultations. We look forward to further engagement that would make it easy for our partners in their own consultations with the view to ensuring a quick conclusion of this matter with the adoption of the decision to extend the transition period consistent with our request

497. We have tried to demonstrate the rationale for this request. We have shown you the numbers. We have also demonstrated that this is not the first time that this request has been granted on top of an existing general waiver. We have shown the distinction between the 2013 text and the 2002 Decision. In 2002, there was a general extension that would elapse in three years, but yet the Members granted us this specific extension on pharmaceutical products. This was because of the recognition of the challenges that we continue to face as highlighted in paragraph 1 of the Doha Declaration on TRIPS and Public Health.

498. In closing, I would like to conclude with a quote from the statement made by UNAIDS and UNDP. They said: "WTO Members have before them a critical opportunity to help Least Developed Countries to reach health and sustainable development goals-failure to support them could put millions of lives at risk."

AGENDA ITEM 13: OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

13.1 India

499. India supports the granting of permanent observer status to three intergovernmental organizations- South Centre, the CBD Secretariat and the International Vaccine Institute.

500. South Centre is an intergovernmental organisation with 51 developing countries as members and South Centre already has observer status in WIPO, WHO, CBD and many other UN bodies.

501. The Convention on Biological Diversity (CBD) fulfils all the required parameters for observership of the WTO. The WTO Secretariat has observer status at the CBD and regularly participates in the CBD meetings. So as a matter of reciprocity, the CBD Secretariat shall be granted observer status.

502. We would also like to support the request from the International Vaccine Institute (IVI) for observer status in the Council for TRIPS. The International Vaccine Institute, which was created initially as an initiative of the United Nations Development Programme (UNDP), is the world's only international organization devoted exclusively to developing and introducing new and improved vaccines to protect the world's poorest people, especially children in developing countries. The Institute conducts research in more than 20 countries of Asia, Africa and Latin America on vaccines against enteric and diarrheal infections, Japanese encephalitis, and dengue fever, and develops new and improved vaccines at its headquarters in Seoul, Republic of Korea.

503. India again urges the Council to positively and expeditiously consider the request of South Centre, the Secretariat of the Convention on Biological Diversity (CBD) and the International Vaccine Institute (IVI) for observer status and, until then, ad hoc observer status on a meeting-by-meeting basis should be granted to them.

13.2 Bangladesh, on behalf of the LDC Group

504. Taking cue from the comments of India, the LDC Group also feels that the legal position and capacity of observers in the WTO are very weak. Still, they could provide important information and inputs to support Members to understand and analyze complex issues. In this respect the LDC Group also supports the application of the South Centre, the CBD Secretariat and International Vaccine Institute whenever there is an opportunity.

13.3 Ecuador

505. Ecuador is in favour of the South Centre receiving observer status, or at least ad hoc observer status, in this Council.

13.4 Indonesia

506. With regard to the Observer Status for the CBD Secretariat and South Centre, Indonesia firmly holds its position to grant the observer status to these organizations. Their positive and valuable contribution to the work and discussion of this Council are still imperative for developing country Members to tap the full benefits of the Agreement as well as rectifying the existing provisions in accordance with the development interests of such Members.

13.5 Nepal

507. Nepal supports the views expressed by Members including Bangladesh on behalf of LDCs, India, Indonesia and Ecuador that observer status should be given to some of the international intergovernmental organizations on their merit who have been closely working on IP-related issue, for a long time. In this regard we strongly support the CBD Secretariat, International Vaccine Institute and South Centre to be given observer status of this esteemed Council. Granting observer status to these three international organizations will not only help co-operation between the WTO and those international organizations, but also help Members become familiar with other activities and events being undertaken by these Organizations through regular exchange of views and experience-sharing. Hence we support granting observer status to these organizations which are directly engaged in, and associated with the work of the TRIPS Council and dealing with IP matters.

13.6 Brazil

508. Brazil would like to add its voice to the statements made by the delegations of India, Bangladesh, Ecuador, Indonesia and Nepal regarding granting of observer status to a number of organizations, especially to the CBD Secretariat and the South Centre.

13.7 United States of America

509. The United States is not in a position to support the request proposed in the previous interventions.

AGENDA ITEM 14: OTHER BUSINESS

Agenda Item 14.1 Invitations to ad hoc observers

14.1 United States of America

510. As we have in the past, we support the ad hoc observership status of the organizations you have identified. We are also in a position to support their permanent status as observers of this Council and would suggest a decision by the Council on that basis.

14.2 Nigeria

511. Just to lend a voice from the Africa Group, we support the proposal by the United States.

Agenda Item 14.4: Contribution of Intellectual Property to Facilitate the Transfer of Environmentally Sound Technology

14.3 Ecuador

512. Ecuador has requested to speak on this agenda item in order to keep the Membership duly informed of the developments under way concerning the proposal in document IP/C/W/585 of 27 February 2013.

513. In this regard, Ecuador is pleased to announce that on 12 May 2015, a workshop on the contribution of intellectual property to facilitating the transfer of environmentally sound technology was organized in Crozet, France, with the collaboration of the Friedrich Ebert Foundation.

514. The objective of the workshop was successfully achieved, as from the very beginning of the event, opinions were freely exchanged on the Ecuadorian proposal by sector specialists who were participating as speakers, and by the country representatives invited, who demonstrated their support and sympathy for the proposal.

515. The sector specialists who attended the workshop were from the International Centre for Trade and Sustainable Development (ICTSD), the United Nations Conference on Trade and Development (UNCTAD), the South Centre, the World Trade Organization and the Advisory Centre on WTO Law.

516. The main conclusions from the workshop were as follows:

(i) The issue is very current and should continue to be addressed by the TRIPS Council, which is the only forum that discusses the role of intellectual property rights in the transfer of environmentally sound technology;

(ii) the link between environmentally sound technology and intellectual property is vital for sustainable development;

(iii) the key is that the flexibilities exist as permissive provisions under the Agreement, and therefore should be used;

(iv) the review of the proposal should determine the objective and the types of technology required;

(v) intellectual property should reflect global interests, which are constantly changing, and take into account developments in sustainable technology;

(vi) technology is essential for confronting the adverse effects of climate change and is a key part of the solution to the issue;

(vii) the TRIPS Agreement contains not only protective provisions but also rules on flexibilities, which could be useful for addressing the challenges posed by climate change;

(viii) Ecuador will keep the Members of this Council informed of the steps that will be taken in the future, both at national level and with other countries and international organizations;

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