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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

Held in the Centre William Rappard on 24-25 October and 17 November 2011

Chairpersons: Ambassador Federico A. González (Paraguay) (24-25 October) and Mr. Martin Glass (Hong Kong, China) (17 November)

The present document contains the record of the discussions which took place during the Council for TRIPS meeting held on 24-25 October and 17 November 2011.

1. In proposing the agenda for adoption, the Chairman said that item N on "Australia's Tobacco Plain Packaging Bill 2011" had been put on the proposed agenda at the written request of the delegation of Ukraine. Item O on "Enforcement of Intellectual Property Rights (Part III of the TRIPS Agreement)" had been put on the agenda at the request of the delegations of Australia, Canada, the European Union, Korea, Japan, New Zealand, Singapore, Switzerland and the United States. As indicated in paragraph 4 of the proposed agenda, in order to facilitate the participation of relevant experts, it was planned that the Council commence discussion of item G on the annual review of the functioning of the Paragraph 6 system in the morning of the second day of the meeting, in line with the procedure agreed for that annual review in 2010.

2. The representative of Ukraine asked whether item N could either be discussed or his delegation could make a statement concerning it before 11.30 a.m.

3. The representative of Pakistan asked the proponents of item O to clarify whether the proposed item justified its scope and whether they were seeking its inclusion on the agenda on a one-time or permanent basis. Since an earlier almost similar wording for a proposed item on the Council's agenda had been objected to by some delegations, including some of the proponents of the present item, he requested the proponents to clarify what was now different in terms of discussing the enforcement of IPRs.

4. The representative of Ecuador supported the statement by Pakistan.

5. The representative of India questioned the need for the inclusion of item O on the agenda at the last moment. If some Members wished to inform about the recent developments in this area, they could do so under item S on "Other Business," or it might be appropriate to make a notification under Article 63 so that the compatibility of the measures with the rights and obligations under the TRIPS Agreement could be scrutinized. He said that the proponents had systemically attempted over eight successive Council meetings from June 2005 to October 2007 to raise the enforcement issue, trying to create an impression that it was a permanent agenda item. During those meetings, enforcement had been taken up as an isolated issue, instead of treating enforcement as a part of the implementation of the TRIPS Agreement as a whole. He asked them to clarify whether the item was intended to be a standing or a one-time agenda item.

6. The representative of Australia, referring to the request by Ukraine, said that, while his delegation was flexible with the timing, the deputy head of his mission who would be making his delegation's intervention was not available until midday. In response to a request from the delegation of Ukraine, he had communicated this to it already the past week.

7. The representative of Brazil said that there was no need for item O. The proponents could inform the Council about the signing of Anti-Counterfeiting Trade Agreement (ACTA) under item S. She wished to understand the reasons for the proposed item. The too broad heading could more appropriately read "Information on ACTA".

8. The representative of China said that she shared the concerns of Pakistan, Ecuador, India and Brazil about the lack of information concerning item O. If the proponents wished to share information on ACTA, they could do so under item P on "Information on Relevant Developments Elsewhere in the WTO".

9. The representative of Plurinational State of Bolivia said that he did understand the purpose of item O, and that any information could be shared under item S.

10. The representative of Japan said that that the proposed item O on "Enforcement of Intellectual Property Rights (Part III of the TRIPS Agreement)" was a relevant issue for the Council. The Council had earlier agreed on this particular wording for a title of an item. The item intended to respond to earlier criticism about lack of transparency with regard to enforcement.

11. The representative of Egypt aligned himself with the concerns of Pakistan, Ecuador, India, Brazil, China and Bolivia regarding the inclusion of item O, and proposed that the issue be discussed under item S.

12. The representatives of Honduras thanked the Vice Minister from the Minister of Economy of Ukraine for his presence and asked that item N be taken up first, given the Vice Minister's pressing timeframe.

13. The representative of the United States said that the proposed item O was squarely within the Council's mandate. There would be a serious problem if WTO Members could not discuss a positive IP enforcement item in the Council dedicated to IP protection and enforcement issues. These objections were particularly problematic from the perspective of transparency.

14. The proposed item was intended to provide an opportunity to discuss ACTA and the promotion of IP enforcement. Specifically, it would offer the ACTA participants the chance to answer questions posed by WTO Members in the Council. He found the objections curious in the light of those questions. In 2010, there had been interest among many of those Members now objecting to discuss enforcement. In the June 2010 meeting, one Member had specifically sought to discuss ACTA, noting that the agreement was "mysterious". Members had asked questions about its provisions and objectives. China, for example, had noted in June 2010 that, based on the draft agreement and acknowledging that the text was in brackets, there seemed to be an intention to broaden the scope of piracy and counterfeit. To answer that question, ACTA did not broaden the scope of piracy and counterfeits. As provided in the definitions section of the agreement, counterfeit and pirated goods were defined the same way as they were defined in the TRIPS Agreement.

15. The agenda request satisfied the Council's procedural rules and surpassed them. The request had been submitted to the Secretariat prior to the ten-day notice to Members pursuant to Rule 3 and in writing pursuant to Rule 4 of the Rules of Procedure. In addition, the proponents had provided the ACTA text for the consideration of Members in the three official languages of the WTO. In the past meetings, it had not been common practice for Members requesting agenda items to provide additional written documentation. The item had been requested pursuant to the usual procedures for a meeting-specific agenda item. Any future requests would be subject to further consideration by the Members of the requesting group. He looked forward to questions under the item.

16. The representative of Cuba said that the matter under the proposed item O could be dealt with under item S. She believed that there was no mandate to reinforce the standards of enforcement. The topic should not be treated as a standing item of the agenda.

17. The representative of Indonesia said that item O should not be treated as a standing agenda item, and could be discussed under item S.

18. The representative of the European Union said that it was important to discuss the issue of enforcement in the TRIPS Council. It was not possible at one TRIPS session to be accused of lack of transparency and three sessions later, when his delegation wished to provide information in all transparency, to be confronted with objections. The concern about lack of transparency had earlier been raised under an enforcement heading. He looked forward to an informative debate at the present meeting and, if there was considerable interest by Members, it could be pursued in future meetings.

19. The representative of Pakistan said that if the rationale for presenting ACTA was to create transparency and share experiences, he wished the proponents to honour the request by many Members to raise the issue of the Nagoya Protocol and to invite the CBD Secretariat to share its experience and reflections, since that was also one of the areas that was very much within TRIPS. The Nagoya Protocol had been signed by a large majority of Members as opposed to the eight signatories of ACTA. He suggested that the title be changed into something like "Presentation of the ACTA", because he was not convinced that ACTA was a normative standard for enforcement, which was covered by Part III of the TRIPS Agreement. The mere heading of the agenda item could lead to an implication that this was becoming the normative standard, which he was not able to accept.

20. The representative of Switzerland confirmed that the inclusion of item O had been requested in conformity with Rules 3 and 4 of the Rules of Procedure. The intention was to have this as an item for the present meeting, not as a permanent item. Taking it up under "Other Business" was not adequate, because the purpose was not only to inform the Council about ACTA but also to discuss the topic of enforcement, which was very much within the scope of the TRIPS Agreement. It was important for many Members that the issue could be discussed in the Council.

21. He said that when a similar agenda item had been proposed by China and India at an earlier meeting, there had not been any objections from his or any other delegation to discuss an item on enforcement, the objection at the time had rather been against the particular formulation of the agenda item, which had been "TRIPS-plus Enforcement Trends". At that time, the Council had had no advance information from those Members what they wished to discuss under the item. Accordingly, the objection had not been against discussing an enforcement agenda item in the Council as such, but more to the particular formulation and the procedural aspects. The proposed title of the present item was exactly the same as the title of Part III of the TRIPS Agreement.

22. The representative of Canada endorsed the comments by Japan, the United States, the European Union, and Switzerland. It was appropriate to discuss the item at the present Council meeting, as it clearly fell within the scope of the TRIPS Agreement. The issue had not been put forward as a standing item, but to provide a basis for discussion and an opportunity to answer questions that had been raised in the past about ACTA.

23. The representative of India said that his delegation had mentioned enforcement trends during a previous Council meeting, but this had been done under other business, and the objective had been to inform the Council about the TRIPS-plus agenda under a plurilateral agreement signed by a few countries, and how this was going to undermine the TRIPS Agreement. While he was not against discussing enforcement, he said that TRIPS-plus or ACTA was not part of the TRIPS Agreement and should not be a permanent agenda item, and that the suggested title of the proposed item was not appropriate.

24. The representative of China said that no Member had any objection against sharing information on national experiences. The difference concerned what agenda item was appropriate for that discussion, be it item S, B or a separate item as proposed. When India and China had proposed an item on a TRIPS-plus issue, that had been opposed by few Members. The title had been changed into "Enforcement Trends", and in that form the agenda had been adopted. She hoped that the proponents could consider discussing the matter under "Other Business". She also shared Pakistan's concerns about sharing experiences by the CBD Secretariat on the Nagoya Protocol.

25. The representative of the Dominican Republic endorsed the request made by Ukraine and sought Australia's indulgence, given the time limits of the Vice Minister.

26. The representative of Brazil said that, while she agreed with the proponents' objective of promoting transparency, this objective could be achieved under items B or S. She was, however,

flexible if the heading could be changed, since it did not make clear that the item was only an exercise in transparency regarding ACTA.

27. The representative of the United States said that Rule 25 of the Rules of Procedure provided that "[d]iscussions on substantive issues under 'Other Business' shall be avoided". The proponents wished to share information on the substantive provisions of ACTA and he understood that some other Members had some views about them. Since this was a substantive issue, it was inappropriate to discuss it under "Other Business". The title was appropriate as proposed. As to Pakistan's question with respect to discussion of the Nagoya Protocol by the CBD Secretariat, he did not see any linkage. Items D, E and F of the current agenda would provide an opportunity to address the Nagoya Protocol by Members.

28. The representative of the Bolivarian Republic of Venezuela said that, in his view, it was difficult to talk about transparency since the ACTA process had begun behind the back of the multilateral system. He recalled that, in the past year, the Council had agreed to change the title of an item proposed by China and India. Rather than including a last minute item, the discussion could take place under item S.

29. The representative of Ecuador said that he agreed with Venezuela's view that ACTA negotiations had not been carried out in a transparent manner. The proposal by Brazil to review the title would be a good solution, or alternatively the matter could be discussed under item B.

30. After consultations, the Chairman suggested that the Vice Minister of Ukraine present his statement concerning item N first and that the Council then revert to the proposed agenda and continue the discussion of the matter under that item. He further suggested that the Council adopt the proposed agenda with item O amended to read as "Enforcement Trends".

31. The Council took note of the statements made and so agreed.

A. NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

32. The Chairman said that, since its meeting in June 2011, the Council had received a number of supplements and updates to earlier notifications of laws and regulations notified under Article 63.2 of the Agreement:

- China had notified its Revised Rules for the Implementation of the Patent Law; some of its provisions were relevant for the implementation of the Paragraph 6 System;
- the Maldives had notified its Law on Copyright and Related Rights; and
- the United States had notified the Leahy-Smith America Invents Act.

33. As regards notifications of contact points under Article 69 for the exchange of information and cooperation on trade in infringing goods, he said that an update to a contact point notified earlier had been received from Canada. The information on the Members' transparency toolkit page had been updated accordingly.

34. The representative of the United States said that President Obama had signed into law the Leahy-Smith America Invents Act. This Act would bring about the most comprehensive overhaul to the nation's patent system in over 60 years. The new law would afford more certainty for patent applicants and owners, and would provide the United States Patent and Trademark Office with the resources needed to operate efficiently and issue high-quality patents. Implementation of the new law

would occur over a period of months, and the USPTO would seek input from interested parties, and would provide updates, during the implementation process. Key elements of this new law included:

- a fast track option to allow patent processing within 12 months;
- a reduction of the current patent backlog, by providing more resources for patent examination;
- a reduction of litigation by: expanding the opportunity for parties other than the patent applicant to submit information to the USPTO in connection with the examination of a patent application; providing for supplemental examination at the request of the patentee; and by providing a post-grant review procedure; and
- the adoption of a first-inventor-to-file system, which was more efficient and predictable than the prior system.

35. The Chairman urged those Members whose initial notifications remained incomplete to submit the outstanding material without delay. He also reminded other Members of their obligation to notify any subsequent amendments of their laws and regulations without delay after their entry into force. He reminded in particular those Members who had made any changes to their laws and/or regulations to implement the Decision on TRIPS and Public Health and who had not yet notified such changes to the Council to do so.

36. The Council took note of the statements made.

B. REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION

37. The Chairman said that, as regards the reviews of national implementing legislation that had been initiated at the Council's meetings since April 2001, the reviews of three Members remained on the Council's agenda, namely those of Cuba; Fiji; and Saint Kitts and Nevis.

38. The representative of Cuba said that its legislation was in the final phase of the process towards approval, and she hoped that, in the course of 2012, Cuba would be able to make an appropriate notification.

39. The Chairman said that, at the Council's meeting in March 2011, the Maldives had informed the Council of its graduation from LDC status on 1 January 2011, and it had outlined the state of play of its implementation of the TRIPS Agreement. The Council had agreed to come back to the arrangements for the review of the Maldives' implementing legislation later in 2011, once it had received the necessary notifications of laws and regulations. As mentioned under the previous agenda item, the Maldives had now notified its Law on Copyright and Related Rights. The Maldives had also informed the Council's March 2011 meeting of other on-going work in the area of IP.

40. He said that, in scheduling the review of the Maldives' implementing legislation, enough time should be reserved for other Members to prepare questions to be posed to the Maldives in the context of this review. The Council would also need to ensure that the Maldives would have sufficient time to prepare its responses. Accordingly, he suggested that the Council schedule the review of the Maldives' legislation for the Council's second meeting in 2012, which had tentatively been pencilled in for 5-6 June.

41. In accordance with the standard procedures for the review of legislation, he proposed that the Council set the following target dates for the submission of questions and answers in this review:

- questions should normally be submitted to the Maldives, with a copy to the Secretariat, 10 weeks before the meeting in which the review would take place; accordingly, he suggested a target date of 27 March 2012;

- responses to questions posed within that deadline should normally be submitted four weeks before the meeting; accordingly, he suggested a target date of 8 May 2012.

42. The representative of the Maldives said that the Maldives' Law on Copyright and Related Rights No. 23 of 2010 (document IP/N/1/MDV/1) had been done in Dhivehi, the national language, and had been subsequently translated into English. It had been passed by the citizens of the Maldives in October 2010, just prior to the graduation. The Maldives was working to fully implement the provisions of the TRIPS Agreement. An industrial property act had already been drafted. The Maldives was also working with donor agencies to create capacity and raise public awareness in the area of IP. He thanked the WIPO Secretariat for its generous assistance in this work.

43. The Council took note of the statements made and agreed to proceed as suggested by the Chair.

C. TRANSITIONAL REVIEW UNDER SECTION 18 OF THE PROTOCOL ON THE ACCESSION OF THE PEOPLE'S REPUBLIC OF CHINA

44. The Chairman recalled that paragraph 18 of China's Protocol on Accessions required the TRIPS Council to review the implementation by China of the TRIPS Agreement each year for eight years and report the results of such review promptly to the General Council. Thereafter there was to be a final review in year ten, which was the year of the present meeting. He further recalled that paragraph 18 required China to provide relevant information including information specified in Annex 1A, to the TRIPS Council in advance of the review. The information submitted by China pursuant to this requirement, dated 20 October 2011, had been circulated as document IP/C/W/564. Questions in connection with the review had been submitted by Japan (document IP/C/W/556).

45. The representative of Japan said that his delegation appreciated China's efforts to address intellectual property problems through various measures including the development of new laws, but that counterfeiting and piracy remained a significant problem.

Counterfeiting and Piracy

46. As a large number of Japanese companies continued to face counterfeit and piracy problems in China he hoped that the Chinese Government would make further efforts to enhance intellectual property rights protection and to provide effective enforcement against any act of infringement of IPRs in China. His delegation was particularly concerned with three issues: first, the disposal by administrative authorities of counterfeiting goods outside the channel of commerce did not work in an effective manner (IP/C/W/556: paragraph 4). Second, the possibility of a judicial authority ordering a party to produce evidence, that was prescribed by Article 43.1 of the TRIPS Agreement, was not used in an appropriate manner (IP/C/W/556: paragraph 3). Lastly, thresholds for the criminal prosecution of counterfeiting cases were not applied in an effective manner, especially in cases where an infringer kept the amount in question below a legal threshold for criminal enforcement by destroying the evidence (IP/C/W/556: paragraph 5).

Technology Transfer Contracts

47. He said that a further concern related to China's Regulation on the Administration of Import and Export of Technology was the discriminatory nature of clauses for Chinese and foreign licensors (IP/C/W/556: paragraph 7) and discretionary restrictions applied by administrative officers to royalty

provisions in contracts (IP/C/W/556: paragraph 8). His delegation believed that these measures were contrary to the principle of freedom to license by intellectual property right holders.

Government Procurement

48. His delegation further maintained a continued interested in the National Indigenous Innovation Product Accreditation System and its relation to government procurement, and was looking forward to receiving any revised version of that System (IP/C/W/556: paragraph 11).

49. The representative of the United States said that for this final transitional review of China his delegation wished to share with Members its observations on China's first 10 years of WTO membership.

50. He recalled that the transitional review mechanism (TRM) had been created largely because China had joined the WTO before it had revised or adopted laws and regulations necessary to implement its WTO obligations, and had been allowed a variety of transition periods before full implementation. The annual TRM meetings therefore had provided Members with opportunities to review with China, in a multilateral setting, the efforts it had taken to implement specific commitments made in its Protocol of Accession, as well as obligations it had assumed under the many agreements that make up the WTO Agreement and its efforts to comply with those obligations.

51. Since the beginning of the transitional reviews, he said that the focus of the reviews had changed over time. While for the first five years of China's WTO membership the transitional reviews had focused predominantly on the scheduled phase-in of key commitments that China had made in its Protocol of Accession, the focus of the TRM had shifted and had focused more on China's compliance with its full range of WTO obligations, once the phase-in period had ended.

52. During the initial phase-in period, China had implemented a set of sweeping commitments, including reducing tariffs, eliminating non-tariff barriers that had been identified in its working party report, and had made legal improvements in IPR protections and in transparency. These actions had deepened China's integration into the international trading system, and had facilitated and strengthened China's rule of law and economic reform. Trade and investment had also expanded dramatically between China and its many trading partners.

53. He said that, since its accession, China had put in place a framework of laws and regulations which were aimed at protecting the IPR of domestic and foreign right holders, as was required by the TRIPS Agreement. However, some critical reforms were still needed in a few areas such as: the further improvement of China's measures for the protection of copyright and trademarks in the context of the Internet, correction of continuing deficiencies in China's criminal IPR enforcement measures, and the provision of remuneration to authors for the broadcast of their works that had occurred between 2001 and 2009 - the period when China had finally set default licensing rates for broadcasting recorded works.

54. His delegation was also concerned about the extent to which China had provided effective protection against unfair commercial use and unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. In its accession protocol, China had agreed to provide six years of protection against unfair commercial use for undisclosed test or other data that had been submitted to authorities in support of applications for marketing approval of pharmaceutical and agricultural chemical products which had utilized new chemical entities. This protection was to prevent any person other than the original applicant from relying on the submitted data for subsequent approvals for at least six years from marketing approval of the original product. He said that examples of marketing approval granted to applications for follow-on products *prior* to the expiration of the six-year period, and in some cases even before approval of the originator product, indicated that further work needed to be done to ensure consistent and effective application

of this obligation. The delegation looked forward to continued work with China on this and related matters.

55. While China's laws on the books had been extensively overhauled to better reflect international standards for IPR protection, he said the inability or lack of political will in China to enforce these laws and to deter continued IP theft had led to sustained and unacceptably high levels of retail and wholesale counterfeiting, online piracy, and software theft with severe adverse effects in the United States and third-country markets to which Chinese IPR-infringing goods were exported. Widespread IPR infringement continued to affect products, brands, and technologies of a wide range of industries, which included movies, music, publishing, entertainment and business software, apparel, athletic footwear, textile fabrics and floor coverings, consumer goods, chemicals, electrical equipment, industrial products, information technology, and clean energy technology, among many others.

56. He said that the United States was, however, encouraged by focused efforts to improve IPR enforcement in China in the past year. His delegation had closely followed the efforts made under China's "Special Campaign on Combating IPR Infringement and Manufacture and Sales of Counterfeiting and Shoddy Commodities" (Special Campaign), and he believed that the new coordination and leadership structure which had been developed for the Special Campaign had enhanced the effectiveness of IPR enforcement during the period of the campaign. The delegation urged China to create a high-level management team that could drive lasting improvements in IPR enforcement by making permanent the temporary leadership structure created to manage the Special Campaign, including the key role of the Vice Premier. Institutionalizing this structure would give greater credibility to China's efforts to make a sustained, long-term improvement in IPR enforcement.

57. As a result of the Special Campaign, his delegation understood, several websites and online portals had been shut down, and three website operators had been arrested, convicted, and sentenced to prison terms and assessed significant fines. The United States urged China to sustain its work on stemming piracy over the Internet. With respect to the use of the Internet to distribute counterfeits, the United States noted several positive developments in the past year, including new measures issued by the State Administration of Industry and Commerce that required Internet Service Providers to verify the identity of online traders and to take "necessary measures to protect registered trademarks." Reports indicating that local Administrations of Industry and Commerce (AICs) had demonstrated greater willingness to intervene directly against online advertisements of counterfeit and pirated products were also encouraging.

58. To effectively stem the manufacture of counterfeits, the United States urged the Chinese Government to ensure that equipment used to manufacture counterfeit products was also seized and destroyed, as counterfeiters could otherwise resume their operations as soon as law enforcement officers had left their premises. In addition, he said, it was important for China to permit direct acceptance of serious IPR infringement cases by the Public Security Bureau (PSB) which could search and arrest counterfeiters, while administrative agencies such as the local AICs could only seize counterfeits. Following the Special Campaign, the PSB should be given the authority to directly accept all cases involving manufacturers of counterfeit and pirated products.

59. In addition to the need for significant progress to fight counterfeiting and piracy, effective IPR enforcement in China also required attention to the protection and enforcement of patents, trade secrets and other IP rights. For example, the United States was troubled by several recent media reports of major cases of trade secret theft which had affected US firms doing business in China. His delegation was further concerned about the enforcement implications of a range of challenges which had affected patent quality in China. Patents that were of low quality, or unexamined, or both, could pose obstacles to Chinese and foreign innovators who sought to protect and enforce rights in legitimate inventions. The delegate stated that effective enforcement of patents and trade secrets was

not only key to the success of foreign companies, but was an essential for a business climate necessary to support investment from the kind of innovative industries that China would hope to attract and build.

60. He said that China's goal of becoming an innovative society by fostering "indigenous innovation" had created a troubling trend toward increased discriminatory policies which were aimed at coercing technology transfer. While his delegation recognised the critical role of innovation in the development and the improvement of living standards in the United States and China, he remained concerned with regard to China's innovation-related industrial policies that had discriminated against or otherwise disadvantaged US exports or US investors and their investments. The United States had been following the development of China's indigenous innovation and other intellectual property-related industrial policies and had paid particularly close attention to China's policies that required or compelled US parties to transfer their IPR to Chinese parties or to Chinese subsidiaries of US firms. Chinese regulations, rules and other regulatory measures frequently called for technology transfer, and in certain cases, conditioned, or proposed to condition, the eligibility for government benefits or preferences on intellectual property being owned or developed in China, or being licensed, in some cases exclusively, to a Chinese party.

61. In view of the IPR-related developments over the past ten years and looking towards the future he said that that China's legal framework for the protection and enforcement of IPR had been improved, but there were still many areas where further progress was required. While there was a growing awareness in China of the critical role of IPR protection and enforcement to China's long-term economic development, it was important that this awareness be translated into sustained efforts to protect and enforce IPRs of both domestic and foreign right holders. It was equally important that China's desire to develop an innovative and IP-intensive economy did not drive policies that discriminated against foreign IPR holders, either by according preferences to firms with indigenous IPRs and thereby limiting participation by foreign IPR holders, or by implementing government policies to compel technology transfer or terms and conditions of IPR licenses, which should instead be left to the commercial considerations of the parties without undue government interference.

62. The United States would continue to work with China in the future, both bilaterally and at the WTO, on IPR protection and enforcement strategies, innovation policies, and a range of other important IPR-related matters to ensure that China would fully comply with its WTO obligations, to the benefit of the United States, China and their trading partners.

63. The representative for the European Union said that his delegation acknowledged China's efforts and improvements in the protection of intellectual property rights such as Special Campaign on the Enforcement of IPRs or the removal of certain circulars on indigenous innovation. Since 2004, the European Union and China had established a solid cooperation on intellectual property issues through, in particular, an intellectual property dialogue and an intellectual property working group. IP was a topic that was always raised in the global economic dialogues or during the annual EU-China summits.

64. He said that the European Union's cooperation with China had addressed a wide range of IPR issues and progress had been noted in a number of those areas. In particular, China had made concrete efforts to improve IPR protection and enforcement. Despite these efforts, European businesses continued to face serious intellectual property problems in China. Further improvement was still needed, especially regarding the specificities of the digital world. The lack of effective protection and enforcement of IP in China continued to undermine the European Union's legitimate interests in areas such as high tech, quality and brand name products. IP rights violations remained a considerable problem for European businesses, with 85 per cent of all counterfeit goods seized at the

European borders in 2010 coming from China, and seven in ten European businesses operating in China reporting that they had been victims of intellectual property violations.

65. He said that access to the Chinese enforcement system, in particular, remained complicated and costly for foreign companies, notably small and medium-sized industries. In addition, apart from the concerns mentioned by the United States, the legalisation and notarisation requirements for litigation, the high thresholds for criminal enforcement and the failure of sanctions to pose a deterrent remained areas of grave concern for his delegation.

66. With respect to the Trademark Law, he said that the current revision process should be used to make further improvements. The European Union was submitting comments on the latest Chinese draft law, which included comments on the relationship between trademarks and geographical indications, and remained concerned with the practice of bad faith registrations in China by Chinese owners of European trademarks.

67. Further improvements should also be brought to the Copyright Law during the announced revision process. The European Union continued to consider that the introduction of broadcasting and public performance rights for sound recording producers and performers in the Chinese Copyright Law was a necessary and welcome step.

68. He said that the Chinese patent system, covering invention patents, utility models and industrial designs, was growing fast and had reached the accumulated number of five million patent applications in March 2009, with domestic applications growing 20 per cent faster than foreign applications. But the merit of patent registration policy should not be measured only by the number of patents registered per inhabitant, but should rather focus on the quality of the rights granted. The European Union was working together with China in this area, putting together a task force on patent quality, and his delegation hoped to see benefits from this joint exercise soon.

69. His delegation was also concerned by non-voluntary technology transfers through excessive standardization requirements, the requirement to disclose trade or business secrets, or other similar policies. The so-called indigenous innovation issue had also been a major concern vis-à-vis China over the last years, but the European Union believed that a breakthrough had been reached in December 2010, when China had indicated that it would not discriminate between products manufactured in China by foreign invested enterprises and those manufactured by Chinese domestic enterprises. He said it would be important now to monitor the implementation of this commitment both at the national as well as at the provincial level, and that this issue would remain very much at the top of European bilateral and multilateral discussions with China. His delegation would continue to work together with China with the aim of putting in place an effective system of intellectual property protection and enforcement.

70. The representative of India said that his delegation attached great importance to the transitional review under Section 18 of the Protocol on Accession of the People's Republic of China. With respect to China's rules prohibiting the grant of patent rights in respect of scientific discoveries, his delegation wished to request clarification of the meaning of the term "scientific discoveries" in Articles 5 and 25 of the Chinese Patent Law.

71. The representative of Korea said that the TRM had been a useful mechanism that had helped to provide transparency in China's IPR regime, and had allowed Members to better understand and assess China's progress in implementing and complying with its WTO obligations.

72. His delegation noted in particular the progress that had been made by China in the area of IPR during recent years, and appreciated China's continuous efforts to improve IPR enforcement and protection. It was his delegation's understanding that China had developed a detailed national IPR strategy which reflected its commitment to address IPR-related issues at the highest levels of China's

Government. China's positive initiatives in IPR legislation included the action plan for IPR protection for 2008, the National Intellectual Property Strategy, and the revision of its copyright law in February 2011, and his delegation looked forward to seeing China continuously pursue and intensify its efforts for an effective IP protection and enforcement system.

73. Despite China's efforts, he said, Korean industries had continued to report high rates of copyright infringement within China and had requested further improvements of copyright protection measures by China. In particular, it had been requested that an adequate system of equitable remuneration to be paid to performers and producers of phonograms for commercial uses would be introduced. Given the fact that in 2007 China had acceded to the WIPO Performances and Phonograms Treaty (WPPT) which provided that contracting Parties may provide for remuneration for broadcasting and communication to the public, his delegation looked forward to further efforts by China to ensure reasonable compensation to performers and producers.

74. The representative of Canada welcomed the many positive steps and improvements that had been outlined in the communication, and noted the recent large-scale enforcement operations against counterfeit products, the promotion of the use of genuine software by both the government and enterprises, as well as efforts to enhance the transparency of the intellectual property rights adjudication process.

75. Her delegation appreciated the challenges that China's size had posed in enforcing intellectual property rights, and was therefore pleased to note that China's communication reported a high level of cooperation between government ministries and agencies at the central, provincial and local levels, in addition to the coordinated participation of police departments and the judicial system. Canada greatly valued China's participation in the Council as well as their bilateral discussions on intellectual property matters, and looked forward to seeing further similar reports of continued improvements in China's administration and enforcement of intellectual property rights.

76. The representative of Mexico said that his delegation wished to express some concerns relating to paragraphs 256 and 342 of the Report of the Working Party on the accession of China. He said that while China had made significant progress in the area of IPRs by having put in place national plans and strategies, there remained concerns about the conformity of China's legislation with its TRIPS obligations, specifically with Articles 22, 23 and 24 of the TRIPS Agreement. The lack of protection for geographical indications and denominations of origin gave rise to serious concerns for Mexico as this could affect Mexican products protected by appellations of origin such as, for example, TEQUILA and MEZCAL.

77. He said that his delegation had detected counterfeit beverages that were not TEQUILA and which falsely indicated Mexico as their origin. A further case was the counterfeiting of the trademark "CORONA", which had still not been settled. "CERONO", a Mexican beer, was produced by Beijing Cerono Trade Limited Company, using bottles that were labelled with logos, lettering, colours and graphics identical to those used for the Mexican beverage.

78. In other WTO fora, his delegation had also expressed its concern over China's lack of compliance with the Memorandum of Understanding which had been signed by Mexico as part of China's WTO accession process. In that Memorandum China had committed to protect the denominations of origin of TEQUILA and MEZCAL, and to limit their use to products that originated from Mexico or from specific regions of the country and which had been manufactured under the rules applicable to these beverages. China had recently notified to the Committee on Sanitary and Phytosanitary Measures a draft regulation which reduced the maximum level of methanol for alcoholic beverages in a category which would prevent the commercialization of some types of TEQUILA and MEZCAL in the Chinese market. His delegation believed that this would violate obligations which China had assumed upon accession with regard to these two Mexican products.

79. The representative of China said that his delegation had submitted the information required in the Annex 1A of its Accession Protocol in document IP/C/W/564 which, he hoped, would help keep Members up to date with the latest development in both the legislative work and the enforcement efforts in China regarding the protection of intellectual property rights. His delegation had prepared detailed responses to the questions from Japan and would also touch on some of the issues raised by other previous speakers.

Trademarks

80. With respect to a service trademark which retailers would use in stores, he said that the Nice Agreement Concerning the International Classification of Goods and Services for the Purpose of the Registration of Marks ("Nice Agreement"), in his delegation's understanding, did not include the retail industry in the scope of service trademark protection, as what was being provided by retailers to consumers were tangible commodities rather than services. Therefore, like other members of the Nice Agreement, China did not accept service trademarks applications for retail services for the time being, but was currently examining whether or not such applications for registration could be accepted.

81. With respect to third party access to trademark documents, he said that documents concerning administrative decisions, the status of trademarks under review, or the opposition procedure, could be viewed at the official website of the trademark authorities (http://www.ctmo.gov.cn). He specified, however, that the trademark review decisions or the rulings on trademark opposition itself were not yet open to the general public. In the cases of review and adjudication of trademarks, since administrative decisions involved business information of the parties to the case, the Trademark Review and Adjudication Board, in dealing with applications of third party access to relevant administrative decisions concerning a trademark, would examine whether such access would damage the interests of the parties to the case. Only if the third party had obtained the consent of the parties to the case, or if there were other circumstances in which the interests of the parties to the case would not be affected, would the Board allow the third party to consult an administrative decision.

82. As to documents in judicial procedures, he said that judgments were pronounced in public by the Courts on all cases, and judgment documents including in trademark cases were open to the general public. Any third party could view trademark-related judicial documents at the website sponsored by the IPR Court of the Supreme People's Court (http://ipr.chinacourt.org), in addition to other websites for judicial documents sponsored by local Courts. For documents that had not yet been uploaded to the Internet, there were other channels available for consultation.

Enforcement

83. With regard to the consistency of the Civil Procedure Law of the People's Republic of China with Article 43 of TRIPS Agreement, he said that in the relevant judicial interpretations of the Supreme People's Court, namely the Several Provisions of the Supreme People's Court on the Evidence for Civil Actions, Article 17 stated that "if one of the following requirements is satisfied, a party concerned and his agent ad litem may apply to the Court for investigating and collecting evidence, the requirements are (1) the evidence under the application for investigation and collection belongs to documentary materials that shall be kept by the relevant authority of the State and must be transferred by the Court *ex officio*; (2) the evidence belongs to materials concerning State secrets, commercial secrets, or individual privacy; or (3) the evidence belongs to other materials that cannot be collected by the party concerned and his agent *ad litem* themselves due to impersonal cause." Therefore, if "the document held by the opposition party" in question met any of these requirements, an application could be made to the Court for investigation and evidence collection. Otherwise, he said, the Court would refuse such an application.

84. In relation to criminal procedures for investigating and handling IPR criminal cases, he said that according to the Criminal Procedure Law of the People's Republic of China, the police authority was to keep for examination any property and valuably items of the criminal suspects that had been seized, as well as the fruits accrued therefrom. Things that served as tangible evidence were to be transferred together with the case. After a judgment rendered by the Court had become effective, the police authority was to handle the items involved in the case in line with the judgment. In law enforcement practices, the police authorities followed these requirements seriously and destroyed a large amount of IPR-infringing products.

85. With respect to administrative law enforcement, he said that Article 53 of the Patent Law of the People's Republic of China provided that the Administrative Authority for Industry and Commerce could, upon having determined that an infringement had taken place, order the infringer to immediately stop the infringing act, confiscate and destroy the infringing goods and any implements that had been specifically used to manufacture the infringing goods and counterfeit representations of the registered trademark, and impose a fine.

86. With regard to the issue that a person carrying out IPR infringements may escape criminal punishment by keeping the amount in question below the relevant threshold, has said that at present for any one act of trademark or copyright infringement that did not reach the threshold of criminal punishment, the infringer could only be held responsible under civil liability or administrative responsibility to the IPR holders, and the relevant administrative authorities could investigate and handle the case in accordance with the law. However, if an infringer had carried out multiple IPR infringement acts and had kept the amount of each infringing act under the statutory threshold of criminal law enforcement with the aim of avoiding administrative handling or criminal punishment, the IPR holder could incur criminal responsibility under Article 14 of the Opinions of the Supreme People's Court, the Supreme People's Procuratorate and the Ministry of Public Security on Certain Issues of Application of Law in Handling the Criminal Cases of Intellectual Property Rights Infringement, which had been promulgated on 11 January 2011. That Article provided that "for anyone who has carried out multiple IPR infringement acts without administrative or criminal punishment, the illegal business amount, illegal proceeds or sales amount shall be accumulatively calculated. Anyone who has carried out multiple IPR infringement acts within two years without administrative punishment and whose accumulative amount constitutes a crime shall be convicted and punished according to the law, and the period for prosecution shall be subject to the relative provisions in the Criminal Law without being limited by the aforesaid two-year period."

87. Regarding repeated IPR crimes, he said that police authorities in China dealt with multiple IPR infringement acts in accordance with paragraph 2 of Article 12 of the Interpretation of the Supreme People's Court and the Supreme People's Procuratorate on Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights, which had been issued in 2004. If such an act reached the "criminal threshold" stipulated by relevant laws or judicial interpretations and the infringer had been suspected of a crime, the police authority would crack down on such an act. In the meantime, Article 3 of the Interpretation II of the Supreme People's Court and the Supreme People's Procuratorate on Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights issued in 2007 stipulated that suspended sentences generally did not apply to perpetrators of IPR crimes. In addition, it was stipulated in Article 65 of the Criminal Law of the People's Republic of China that "if a criminal commits another crime punishable by fixed-term imprisonment or heavier penalty within five years after serving his sentence of not less than fixed-term imprisonment or after receiving a pardon, he is a recidivist and shall be given a heavier punishment. However, this shall not apply to cases of negligent crime." The police authorities have also followed these stipulations when handling criminal cases of IPR infringement.

Regulations on Administration of Technology Import and Export

88. Concerning the relationship between certain provisions in the Regulations on Administration of Technology Import and Export and the national treatment principle, he said Article 24 of the regulation stipulated that "the technology supplying party shall ensure that he or it is the legitimate owner of the technology supplied, or one who has the right to assign or license the technology. Where the receiving party infringes another person's lawful rights and interests by using the technology supplied by the supplying party, the supplying party shall bear the liability therefore." Such provisions were consistent with Article 349 and Article 353 of the Contract Law of the People's Republic of China. Article 349 stated that the transferor in a technological transfer contract should guarantee legitimate ownership of the technology provided, and guarantee the technology provided to be complete, without fault, effective, and capable of attaining the contracted objective. Article 353 said that the transferor was liable for any infringements upon the legitimate rights and interests of others that occurred through the exploitation of the patent or utilization of the technological know-how by the transferee in compliance with the contract. Consequently, Article 24 of the Regulations on Administration of Technology Import and Export was not an obligation imposed only on the foreign right holder of technology.

89. He said that Article 27 of the Regulations on Administration of Technology Import and Export required that "within the term of validity of a contract for technology import, an achievement made in improving the technology concerned belongs to the party making the improvement." As the party making the improvement might be either the transferee or the transferor, the issue of a foreign holder of technology not enjoying national treatment did not exist. In addition, in accordance with Article 2 of the Regulations on Administration of Technology Import and Export, the criterion for judging whether a technology was imported or exported was the cross-boundary transfer rather than the nationality of the transferee or the transferor.

90. As to whether the Government could interfere with contract licensing fees, he said that under the Regulations on Administration of Technology Import and Export, imported and exported technologies were classified as prohibited, restricted, or those that could be imported and exported freely. In relation to the latter category, the contract for import or export was only required to be registered with the competent authority without substantive examination and there was no provision in the regulation to authorise the competent authority to change licensing fees. In practice, for technologies that could be imported freely, licensing fees were determined through consultations of the parties to the contract. As long as there had been no violation of law, the Chinese government would neither interfere nor demand enterprises to change prices in the contract.

91. With respect to the China IPR Protection Action Plan 2011, he said that the competent authority would, firstly, draft anti-monopoly guidelines in regard to the abuse of IPR in line with relevant stipulations in China's Foreign Trade Law. However, as the drafting would take some time and relevant studies were on-going, no specific timetable for the promulgation of such guidelines had been set.

92. Secondly, to implement the Patent Law of the People's Republic of China which had been newly amended in 2008, the Decision of the State Council on Amending the Regulations for Implementation of the Patent Law of the People's Republic of China (State Council Decree No. 569) had been promulgated on 9 January 2010. The amended regulation had been effective since 1 February 2010 and had been notified to the WTO, as noted by the Chair at the beginning of the meeting. In this regard, the representative noted the question by India concerning China's Patent Law and said that due to the technical nature of the issue, China could pursue the matter in detail bilaterally after the meeting.

Indigenous Innovation and Government Procurement

93. With respect to indigenous innovation and its relationship with government procurement, he said that his delegation wished to clarify that the administrative measure that had raised Members' concern, namely the Notice Regarding the Launch of the National Innovation Product Accreditation Work for 2009, issued on 30 October 2009, had been an invitation for application for accreditation so that the products of the applicants could be accredited as indigenous products. The purpose of the paper had been to encourage the applicants to strengthen their innovation activities.

94. In April 2010, China's relevant authorities had publicly solicited opinions and comments on the draft of the Notice Regarding the Launch of the National Innovation Product Accreditation Work for 2010. In this document, it had been confirmed that products by domestic and international manufacturers would be treated equally.

95. In June and July 2011, to further confirm that indigenous innovation policies and preferential government procurement treatment were no longer linked, China's relevant authorities had issued two Notices, according to which implementation of relevant administrative measures, including the Administrative Measures on Budgeting for Government Procurement of Indigenous Innovation Products and the Trial Measures for Administration of the Accreditation of National Indigenous Innovation Products, had been terminated.

96. With respect to the specific cases raised by the delegate of Mexico he urged the Mexican Government to contact China bilaterally or through the Embassy of China for more details, and said that he would also send that message back to his capital after the meeting.

97. In conclusion, his delegation wished to thank all Members for their constant support over the course of this transitional review, and their appreciation for China's efforts in further strengthening its protection of intellectual property rights. Since its accession to the WTO ten years ago, China had fulfilled its tremendous commitments made upon accession, and in this course, as noted in the last TPR of China, Members had observed the strong political will of the Chinese government in that regard. With respect to the TRIPS Agreement, China had not only established a sound legislative framework, but also an enforcement system that integrated both administrative and judicial measures. Another particular achievement was the enhanced awareness of IPR protection in the whole society of China as one of the largest developing countries. The Chinese government continued to attach great importance to IPRs and their protection as the value and importance of IPRs in an increasingly globalized world was well known. Although the transitional review of China had now come to an end, China believed that its exchanges with Members on IPR issues and their protection would continue, and be further enhanced, in the future. China would continue to participate in the work of the Council in an open and cooperative spirit.

98. The delegation of Nigeria said that the transitional review mechanism had been included in China's Protocol of Accession as a special precautionary instrument with the objective of monitoring and enforcing the implementation of WTO commitments, and in the case of the TRIPS Council, to monitor the implementation of the TRIPS Agreement, in addition to promoting transparency and exchange of information in trade relations with China. In view of his delegation the review exercise in the TRIPS Council had provided a broad review of the IP regime on a scheduled basis and he thanked China for its detailed responses to the questions that had been raised. Since Nigeria had been one of the first Members to recognise the market economy status of China, his delegation shared the view that China was moving in the right direction and at the right pace, in spite of the enormous challenges and cost of the commitments it had undertaken. The Nigerian delegation wished to encourage China to remain steadfast in its endeavour and, in particular, to pay special attention to the enforcement of the regulation relating to the export of sub-standard goods, which included copyright and patent infringement.

99. The Chairman thanked China for the information it had provided, as well as other Members for their contributions. Turning to the Council's reporting obligation to the General Council, he suggested that the Council follow the same procedure as in the past years, namely that the Chair, acting on his own responsibility, would again prepare a factual report. The content of the cover page to the report would be similar to that of the report submitted by the Council in 2009 and the part of the minutes reflecting the discussions held under this agenda item would be attached.

100. The Council took note of the statements made and agreed to proceed as suggested by the Chair.

D. REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B)

E. RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY

F. PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

101. The Chairman suggested that the Council continue to discuss the three agenda items together on the basis of contributions by Members as has been the practice at past meetings. He said that, at its meeting in June 2011, the Council had requested him to continue consulting on the suggestion that the WIPO Secretariat be invited to brief the Council on the work of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), and that the CBD Secretariat be invited to brief the Council on the outcome of the Nagoya meeting.

102. As regards the suggestion concerning the briefing on the work of the IGC, at the Council's meeting in March 2011, the delegation of El Salvador had, since, informed the Secretariat that it had recently been able to engage in the work of the IGC and had been, therefore, fully informed of its work. In the light of this, he said that there was no longer a need for such a briefing at the Council's meeting. However, the WIPO Secretariat was ready to assist any delegation who would wish to receive information on the current state of play. Furthermore, the WIPO Secretariat had informed him that, prior to the next meeting of the IGC foreseen for February 2012, it intended to organize an informal information session for all delegations on 31 January 2012.

103. As regards the possible CBD briefing on the outcome of the Nagoya meeting, at the Council's meeting in March 2011, Japan had made a presentation on that topic in its capacity as the host country for the CBD COP 10 in Nagoya. However, India and a number of other delegations had said that they still wished to hear from the CBD Secretariat, and reiterated their request that it be invited to provide a briefing on a one-time basis. In his consultations, these delegations had argued that while each Member had its own views, the CBD Secretariat had been neutral, had had the institutional memory and could report on all views. Some other delegations reiterated that it had been the viewpoints of the CBD members rather than the CBD Secretariat that would give WTO Members a more complete picture. Most delegations had been willing to consider, as a compromise, the possibility of a side event. The views continued, however, to diverge on whether there should be some formal link between such an event and the TRIPS Council's meeting. One delegation had presented a new idea of agreed terms of reference for the CBD Secretariat briefing at the Council.

104. The representative of the Plurinational State of Bolivia said that the adoption of TRIPS Article 27.3(b) gave legal impetus to biopiracy and had harmful effects on the developing countries, in particular the indigenous peoples of Bolivia. That article promoted appropriation and privatization of life forms and their parts. The negative effects could be seen not only in the fields of ethics and indigenous peoples' rights but also in the fields of agriculture, food, climate change and health. There was no other multilateral standard on this subject since the TRIPS Agreement had been adopted. Therefore his delegation would like to seek multilateral solutions.

105. Referring to documents IP/C/W/554 and IP/C/W/555, he said that his delegation could not deal with inventions in the biotechnical field in the same way as in other fields. Inventions could not be an isolation or characterization of biological forms, which was a mercantilist approach without considering humanity. To permit the patentability of life forms or their parts would require a profound analysis and review of the most recent progress made in international law, *inter alia*, the Declaration of the Rights of Indigenous Peoples adopted in the United Nations in 2007. National legislation as proposed by Bolivia had ethical, moral, and cultural effects and consequences on patents and technology, and access to and use of genetic resources. He reiterated that the Council must review and if necessary, amend Article 27.3(b) of the TRIPS Agreement.

106. The representative of the Bolivarian Republic of Venezuela supported Bolivia's proposal to review Article 27.3(b) of the TRIPS Agreement. As requested by him, the statement his delegation made at the Council's meeting in June 2011 is reproduced below[1].

> The representative of the Bolivarian Republic of Venezuela supported Bolivia's proposal in view of the need, and the ministerial mandate, to conduct a review of Article 27.3(b) of the TRIPS Agreement. Domestic legislation, specifically Articles 124 and 127 of the Constitution of the Bolivarian Republic of Venezuela, prohibited the registration of patents for life forms. The West had imposed its view of life, its institutions and its rules on the rest of humankind and these had been adopted as they were, for better or worse, by the entire world. It was well established that morals were the foundation and source of rules and the law, since the law was there to respond to forms of life in society - in other words the law could not exist without some "moral" basis, the word "moral" coming from *morada*, meaning a dwelling, a place where one lived. Thus, international agreements, which were nothing if not laws, must be based on morals and on ethics. Those principles and the laws of Venezuela could not be invoked in attempting to patent life in many forms it took in nature and to convert it into a tradable commodity that could be assigned a price, particularly now that the ever-forgotten indigenous peoples of Venezuela were represented in National Assembly and there was an undertaking, now in the form of a law, to respect their way of life, their customs, their genetic resources and their traditional knowledge.
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> He said that what Bolivia sought in its paper was a review of Article 27.3(b), as provided for in the last sentence of Article 27.3(b), which stipulated that there shall be a review after four years, but none had ever been conducted. The content of that Article would appear not to have been so construed by one Member at the meeting of October 2010 who had said that the review had been intended not so much to revise content as to focus on implementation. He disagreed, because Article 71 of the TRIPS Agreement already made provision for a full review of TRIPS implementation at regular intervals, and in light of the general principle of law that he who could do most could do least, the express provision - which was restrictive, specific and time-bound -to review Article 27 would be meaningless, since any law must be interpreted as a coherent and structured whole.
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> It clearly emerged from a reading of Article 71 that periodic review of the entire TRIPS Agreement was fully warranted and necessary, not only because it needed to be adapted to the constantly arising changes of a globalized world with its fast-developing technologies, but also, and more importantly, because the issue of intellectual property was closely linked to human rights such as food security, education, health and the right to self-fulfilment, among others, which must be

[1] Paragraphs 25-28 of IP/C/M/66.

reviewed on an on-going basis so that they could be increasingly enjoyed by more and more people, in full conformity with the principles of the United Nations and the Millennium Goals, which were established in an attempt to make them more universal.

Regarding the question of access to genetic resources, he highlighted the sovereignty of States and their indigenous peoples over their biological resources, and the authority to determine access to genetic resources therefore lay with national governments and was subject to national legislation. As regards traditional resources, they should not come within the traditional purview of intellectual property, and in the case of legislation of Venezuela, its sovereignty would be violated.

107. The representative of Ecuador shared the concerns expressed by the Plurinational State of Bolivia. He said that the Council should continue its discussion on Bolivia's proposal. He also supported the proposal of amendment of Article 27.3(b) to make a binding provision on the exclusion of patentability.

108. The representative of India said that, as one of the twelve mega-diverse countries, India already accounted for seven to eight per cent of the recorded species of the world with only 2.4 per cent of the land area. Its biological diversity was seen in its forests, its wetlands and in its marine areas. On account of that richness in biodiversity a large number of scientific, research and technological institutions were actively engaged in the activities relating to biodiversity. Pursuant to the ratification of the CBD, India had developed a comprehensive legislation on biodiversity setting up several institutions to deal with that issue.

109. India also possessed rich traditional knowledge of ways and means to treat diseases afflicting people. That knowledge had generally been passed down by word of mouth from generation to generation. Documentation of that existing knowledge available in the public domain on various traditional systems of medicine had become imperative to safeguard the sovereignty of that traditional knowledge and to protect it from being misappropriated in the form of patents on non-original innovations, which had been a matter of national concern.

110. In view of the large number of patents granted in developed countries which had to be later contested by India, the Government of India had established Traditional Knowledge Digital Library (TKDL) to provide information on India's traditional knowledge in languages and in a format understandable by patent examiners at international patent offices (IPOs). The TKDL was aimed at preventing the grant of wrong patents, and acted as a bridge between the traditional knowledge information existing in local languages and the patent examiners at IPOs. While, through the TKDL, India had created a defensive mechanism against erroneous patents, TKDL remained only one of the multiple tools required to address the much larger issue of misappropriation of genetic resources and associated traditional knowledge and could be a useful complement to a mandatory disclosure requirement in patent applications.

111. He said that it was unfortunate that the TRIPS Agreement continued to ignore the numerous IPR-related obligations in the CBD which were of interest to the developing countries. That contradiction not only obstructed the proper implementation of the CBD but also caused an imbalance in the TRIPS Agreement. The TRIPS-CBD issue was a critical implementation issue for the developing countries and a positive outcome on that issue would be an important deliverable for the developing countries. The Council had done a lot of work on that issue over a long period of time. The disclosure proposal contained in document IP/C/W/474 submitted in 2006 had been followed by document TN/C/W/52 submitted in June 2008 with the support of 108 countries. The latest submission on that issue - document TN/C/W/59 - had been proposed by a vast majority of the

membership. The submission captured the developments in the past, including the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) which had been signed by 192 countries and contained a significant implementing legislation for the CBD issues regarding prior informed consent and access and benefit sharing. The submission could be a good basis for future negotiations and would maintain the credibility of the patent system. India remained committed to move that process forward and expected constructive engagement from other Members.

112. Referring to the deadlock over the issue of formally inviting the CBD Secretariat for a briefing on the Nagoya Protocol, he said that it was unfortunate that while the CBD Secretariat had done the presentations in WIPO and WHO, the WTO had been deprived of its briefing on account of objections by only a few Members. He reiterated the demand for a formal briefing by the CBD Secretariat in the interest of the large majority of the developing countries.

113. The representative of China noted that the debate among Members on those three agenda items had mostly focused on whether the discussion should lead to an amendment of the TRIPS Agreement. Some Members believed that contractual arrangements and prior art requirements were enough to achieve the objectives of harmony and synergy between the CBD and the TRIPS Agreement, while many others believed that the mandatory requirement of prior informed consent and benefit sharing in patent applications was indispensable to achieve those objectives. In the view of China, the CBD had recognized and established a legitimate right over genetic resources, which must be respected and honoured by patent applicants when they accessed and used the genetic resources for their inventions. The disclosure requirement was consistent with the transparency principle established in the multilateral trading system. It would not be burdensome for the patent applicant to fill in a form with the information of prior informed consent and access and benefit sharing as indicated in document TN/C/W/59, considering the legitimate objective it would achieve.

114. Contractual arrangements and the novelty requirement in patentability were not enough for the protection of genetic resources because the contractual arrangement depended on voluntary behaviour and fulfilment of parties to contracts, and the novelty requirement played a second hand role in preventing erroneously granted patents. Databases and other information that patent examiners might have access to before granting a patent was limited compared to the large quantity of genetic resources existing in the world. As one genetic resource could generate thousands or even tens of thousands of patents, it would not be enough to rely upon patent examiners to prevent the use of genetic resources without prior informed consent and access and benefit-sharing requirement. The responsibility to respect the sovereign right over genetic resources should rely upon legal or natural persons who accessed or used the genetic resources and associated traditional knowledge at first hand.

115. She reiterated the proposal to invite the CBD Secretariat to make presentations in the TRIPS Council, which would facilitate the work of the Council and contribute to the cooperation between the WTO and other international organizations.

116. The representative of Turkey said that WTO Members should find appropriate solutions to prevent misappropriation of genetic resources and associated traditional knowledge and to avoid erroneously granted patents. She supported the introduction of an appropriate mandatory disclosure requirement in patent applications, which would contribute to transparency of utilization of genetic resources and associated knowledge, help to achieve shared objectives and combat biopiracy. She also reiterated that her delegation was open to the proposal to amend the TRIPS Agreement in order to introduce prior informed consent and access and benefit-sharing requirements. She expected significant movement on three TRIPS-related issues in 2012. In her view, the issues of TRIPS-CBD and GI extension were an integral part of the work programme and part of the Single Undertaking.

117. The representative of Korea said that review of Article 27.3(b) should not lead to denying the patenting of life forms. All fields of technology, including biotechnology, deserved adequate patent protection. The world had tremendously benefited from the recent advancement in biological science. Biotechnology had huge potential to enhance human welfare in public health, and therefore it should be incentivized rather than discouraged. In the absence of incentives provided by patent protection for research and development in that field, important pharmaceutical products would not be invented in the first place.

118. The representative of Brazil supported the introduction in the TRIPS Agreement of a mandatory disclosure requirement of the origin of genetic resources as well as prior informed consent and access and benefit-sharing. She also supported the proposal to invite the CBD Secretariat to make a briefing on the Nagoya Protocol in the TRIPS Council.

119. The representative of Peru said that his delegation's position on the three agenda items was fairly well known and was in line with what had been said by the delegations of India, China, Turkey and Brazil among others. In Peru's view, a multilateral and mandatory disclosure of origin requirement would be the most efficient way to address the international problem of misappropriation of genetic resources and traditional knowledge in that it would allow all countries to identify the supplying country by requiring patent applicants to disclose the country of origin as well as evidence of compliance with prior informed consent and benefit sharing.

120. That conviction had prompted Peru not only to co-sponsor, with some 110 Members, document TN/C/W/52 but also more recently to submit, together with a considerable number of delegations, document TN/C/W/59 which aimed at enhancing the relationship between the TRIPS Agreement and the CBD. In that proposal, the co-sponsors called for the inclusion of an Article 29bis in the TRIPS Agreement with a view to establishing a disclosure of origin requirement as well as evidence of prior informed consent and benefit sharing in patent applications involving the use of genetic resources and/or associated traditional knowledge.

121. Unfortunately, there had not been more opportunities to examine and discuss that proposal, especially given the current climate surrounding the Doha Round. However, his delegation wished to repeat that it could not imagine a successful conclusion to those negotiations without any results on the proposed. Any outcome in the negotiations must reflect the interests of the developing countries, particularly when it came to the protection of genetic resources, traditional knowledge and folklore. Only a solution that dealt with the problem of biopiracy would enable Members to establish a proper balance in the patent system and in the IP system in general for the benefit of all, particularly the local and indigenous communities of the developing countries.

122. Finally, he supported the initiative to invite the CBD Secretariat to make a presentation to the Council on the results of the Nagoya Protocol negotiations.

123. The representative of Colombia said that the main issue to be discussed was the need to amend IP systems and incorporate mechanisms that would help address the difficulties in monitoring and following up biopiracy. It was necessary to identify points of convergence between the rules on IP protection and those relating to the conservation of biological diversity and the use of its components, including genetic resources, so as to ensure that both regimes were consistent with each other and were thus mutually supportive, pursuant to Article 16.5 of the CBD and Article 4 of the Nagoya Protocol. That in turn would make it possible to address the mandate provided for in paragraph 19 of the Doha Declaration in a constructive manner.

124. The proposal co-sponsored by Colombia had been prompted by the obvious need to implement tools for monitoring compliance with the provisions on access to genetic resources and traditional knowledge, such as the international certificate and disclosure of origin. It was also aimed

at discouraging biopiracy through the establishment of deterrent measures of an administrative, legal or criminal nature to. It was important to note that such a tool provided for checkpoints to monitor a genetic resource at every stage in keeping with the provisions of Article 17 of the Nagoya Protocol. In the case of a patent utilizing genetic resources or products derived therefrom and/or traditional knowledge, an initial step towards developing the principles agreed to in the CBD was to establish the country of origin. That step was a vital one in determining whether access had been legally obtained. Biotechnology developers needed to be quite clear that any profits derived from the application of their inventions should not only represent gains for themselves but should also for humanity as a whole.

125. That being so, Members could not ignore the fact that IPRs were a mechanism that sought to provide benefits to the inventor and thus encouraged investment. In an area such as biodiversity, however, the development of an invention based on such products should not impair legal access to the genetic material and/or its derivatives on which the invention was based. Further, it meant that not only that the inventor would be entitled to benefits from the invention but also the States providing the resources, and where appropriate, the traditional communities concerned.

126. The representative of Chile said that the three fundamental requirements for patentability set forth in Article 27.1 of the TRIPS Agreement, i.e. novelty, inventiveness and industrial applicability, should be applied and respected in full by IP offices, and were that to happen, there should be no contradiction or conflict with the appropriation of naturally occurring life forms. In line with the above, it was essential for national and regional patent offices to have access to all of the information available so as to avoid granting erroneous patents that did not comply with some of those patentability requirements. Databases could be very useful in that respect.

127. Chile possessed endemic genetic resources which was its unique heritage. Based on preliminary investigations, such genetic material, which might have economic potential for Chile was reportedly being unlawfully exploited. Chile was therefore considering the development of a legal framework that would provide adequate regulation in a manner consistent with international commitments. In that regard, Chile recognized the potential benefits of a disclosure of origin requirement for genetic resources. His delegation was extremely satisfied with the work being carried out within the framework of the IGC, where important agreements had been reached: namely, renewing the IGC's mandate and intensifying its meeting schedule in 2012. He was confident that the work of the IGC would make substantive progress.

128. The representative of the United States said that, at the June meeting of the TRIPS Council, Switzerland posed a number of questions regarding the contractual approach. He referred Members to his answers contained in paragraphs 99 through 101 of the Council's minutes (document IP/C/M/49). As to the specific question of how the contract approach would address the need for transparency in access and benefit sharing, he noted that certain agreements could be made available to the public. For example, the US National Park Service encouraged research in national parks, and might negotiate a benefit-sharing agreement with bioprospectors. Information about areas where research needs had been identified, and which permits had been issued, was posted on the National Park Service website: https://science.nature.nps.gov/research/ac/ResearchIndex. By posting where the National Park Service was encouraging research and information about granted permits, the contract-based approach of the US government provided certain avenues for transparency.

129. He said that it would not be appropriate to request for the CBD Secretariat to make a presentation to the Council on the Nagoya Protocol. The Nagoya Protocol had 65 signatories, but would only enter into force 90 days after deposit of the fiftieth instrument of ratification. No countries had yet deposited an instrument of ratification. The eleventh meeting of the Conference of the Parties of the CBD would take place in India from 8 to 19 October 2012, and was the target for convening the Nagoya Protocol's first meeting of the Parties. He was confident that the next year the

Government of India could, like Japan had done previously in the Council, provide an excellent explanation of the recent work of the CBD in that forum.

130. The representative of Nigeria reiterated the African Group's position on the amendment of the TRIPS Agreement to bring it in line with the provisions of the CBD. He said that the amendment of the TRIPS Agreement would ensure a multilateral disclosure requirement that would prevent misappropriation of genetic resources. Regarding the contractual approach, he said that it was highly difficult to prove that there had been a contractual obligation or agreement between the owners of those resources and the users. Some cases had run into ten to twenty years before they had been resolved. The African Group supported the suggestion that the CBD Secretariat be invited to make a presentation on the Nagoya Protocol in the TRIPS Council.

131. The representative of Japan stressed the importance of considering the problem of misappropriation of genetic resources by dividing it into two aspects: erroneously granted patents and the CBD compliance. An appropriate solution should be sought in each case, bearing in mind that such solutions should achieve each objective in a manner which would not have an adverse effect on the IP system.

132. Japan had proposed the establishment of one-click databases to prevent erroneously granted patents. His delegation would like to continuously hold discussions toward the implementation of the system with the broad support from other Members. He also attached a great deal of importance to the Nagoya Protocol, and expected Members' efforts toward the implementation of the modality of the Protocol.

133. With regard to the Bolivian proposal, he reiterated that the patent system provided a critical incentive for technical development in the field of biotechnology, which was essential for the world at large.

134. The representative of Ecuador said that Ecuador had four natural regions: Costa, Sierra, Oriente and the Galapagos Islands. Each one of those regions had different ecosystems and habitats, such that Ecuador was considered to be one of the most biodiverse countries in the world, having among the largest species of animals and plants per square kilometre. It ranked second in terms of diversity of endemic vertebrates, third in terms of the number of amphibians, fourth in terms of the diversity of birds, and had more than 16,087 species of vascular plants within its territory. In addition, Ecuador hosted a great diversity of cultures, with 14 nationalities, 17 indigenous peoples, the Montubio and Afro Ecuadorian peoples, and a variety of ancestral and rural communes and communities. That mega-diverse and multicultural heritage must be protected, preserved and promoted.

135. He said that traditional knowledge, traditional cultural expressions and genetic resources should be protected for a variety of reasons: (i) they constituted a human right; (ii) they had intrinsic value; (iii) they helped to overcome inequity; (iv) they formed part of an ancestral cosmo-vision; (v) there were IPRs associated with them; (vi) many helped to develop or facilitate scientific research and shorten the time devoted to bioprospecting; (vii) their protection was mandated by the Constitution and stemmed from international obligations that had been assumed; and (viii) it was one of the objectives of Ecuador's National Development Plan.

136. The genetic information derived from biodiversity was used to develop new and specific processes and products through biotechnology, in particular in the cosmetics, agricultural and pharmaceutical areas. The annual world market for products derived from genetic resources in particular in the above mentioned areas, was currently estimated at some US$50 to 800 billion. In other words, the economic and social importance of those resources was unquestionable, particularly

when genetic resources belonged to the State and it was the State's responsibility to protect public interests in them.

137. Ecuador approached that subject from the standpoint of collective rights. That did not mean that it did not recognize the individual contributions made, for example, by the shamans and wise persons, but that those contributions also formed part of the rights of communities, and that the communities owned the traditional knowledge and traditional culture expressions. It was therefore with the communities that access to traditional knowledge and traditional cultural expressions was negotiated, and it was the communities that received the fair and equitable share of the benefits, according to their own practices and customs. Both under the CBD and the national constitution, genetic resources and biodiversity in general were the property of the State. Consequently, the State was responsible for authorizing access to genetic resources, and it was with the State that the fair and equitable sharing of the benefits was negotiated.

138. Ecuador was still exploring the link between IP and traditional knowledge, genetic resources and traditional cultural expressions, but it had found certain areas of possible relationship. For example, with respect to copyright communities could, in accordance with their own consent rules (including among themselves), authorize phonographic, audio-visual or photographic productions to be made for subsequent sale, thus ensuring that they received a fair and equitable share of the benefits obtained. The same applied to designs and publications.

139. With regard to trademark law, there were cases in which third parties had registered, as trademarks, items relating to cosmo-vision and the history of the indigenous and local communities, not only within the country, but outside the country as well. There was concern over the use that was made in many developed countries of terms that were specific to indigenous cultures or to the natural endemism of megadiverse countries. For example, the case of "Palo Santo", in which the Italian company Linpha Vitale had filed a lawsuit against an Ecuadorian citizen, Mario Jerez, in Italy, to prevent that indigenous Ecuadorian native of the Otavaleno community from selling Palo Santo chips on the grounds that it was the owner of that trademark protecting essences and incense. There were no statistics on the number of violations that had been committed, or were currently being committed.

140. In the area of patent law, Ecuador advocated the disclosure of origin of genetic resources and declaration of the presence of traditional knowledge in relevant inventions that were the subject of patent applications. The importance of disclosure of origin related to the sharing of benefits. When a genetic resource was declared to have been taken from the sovereign territory of a State, that meant that the resource in question should have been obtained in conformity with the laws of that country.

141. Recognition of the geographical origin of a genetic resource was not only linked to the fair and equitable sharing of benefits, but also had to do with respect for the sovereignty of States and for human rights and legitimacy. Indeed, the removal of a country's resources without its consent was a form of biopiracy, aggravated by the fact that it often did serious damage to the biodiversity of the territory concerned, particularly in cases of endangered species. The problem with requiring disclosure of origin without considering the geographical area from which the genetic resource came was that it could be awkward for researchers who, in principle, would not necessarily need to know the geographical origin of the resources they were using in their invention and would perhaps only be required to reveal the source (for example, some foreign university). However, declaring only the source could lead to the granting of rights in respect of a genetic resource that had been biopirated.

142. He said that it was also important to declare geographical origin in the case of plant varieties. The Ecuadorian IP authority had received applications for plant breeders' rights from a European company which had declared that the material it had used for its plant breeding was from an African country without attaching the access contract for that resource. In those cases, cooperation and cross checking between offices was important. Ecuador would begin notifying the counterpart offices in

other countries of applications for rights relating to its genetic resources (once published in the Journal) and, where possible, to its traditional knowledge, its traditional cultural expressions, and other resources of its indigenous and local communities.

143. All of those data served to demonstrate the importance for mega-diverse and multicultural Members, notably the developing countries, of genetic resources, traditional knowledge and traditional cultural expressions. Consequently, the economic, technological and commercial potential of those resources needed to be protected, and they should remain the property of their legitimate right holders. That required a multilateral system that was consistent with those needs and respectful of those rights.

144. He reiterated his delegation's support for document TN/C/W/59 of 19 April 2011, which reflected the concerns and considerations mentioned above. He also reiterated his delegation's support for India's proposal that the CBD Secretariat should report, at a formal session of the Council, on the results of the Nagoya Protocol.

145. The representative of Cuba supported the amendment of Article 29 of the TRIPS Agreement, which would require patent applicants to disclose the source and country of origin of biological materials and to provide the evidence of prior informed consent and benefit sharing. She also supported the initiative to invite the CBD Secretariat to make a presentation in the TRIPS Council.

146. The representative of Angola, speaking on behalf of the LDC Group, said that, as highlighted in paragraph 19 of the Doha Ministerial Declaration, the discussion on review of Article 27.3(b) was closely linked to the discussion on the items of TRIPS-CBD and protection of traditional knowledge and folklore. He reiterated the LDC Group's position on review of Article 27.3(b), that is, to clarify the patentability of plants and animals as well as microorganisms and all other living organisms. The LDC Group was interested in ensuring that natural processes that produced plants and animals and other living organisms should not be subject to patent protection. He stressed the importance of maintaining flexibility with respect to the *sui generis* regime for the protection of plant varieties, that is, implementation should be based on an individual country's systems and needs. The flexibility would contribute to improving food security by ensuring that indigenous peoples' inventions were protected and access to seed was guaranteed.

147. He said that biodiversity was an important source of livelihood for the population living in rural areas in most of the LDCs. Yet benefits arising from the appropriation of such resources and use of their traditional knowledge by multinational cooperation had been shared with the community concerned. It was a matter of concern to the LDCs, which should be addressed by having a mandatory requirement under the provisions of the TRIPS Agreement for disclosure of the country of origin of the genetic resource and associated traditional knowledge used in the invention. It was equally important to ensure that patent applicants demonstrated that they had obtained or acquired prior informed consent from the competent authority in the country of origin of the genetic resource and that the arrangements to facilitate the sharing of benefits arising from the appropriation of such resource and traditional knowledge were in place.

148. The LDC Group took note of the progress made in other international forums, such as WIPO and CBD. The WIPO General Assemblies had renewed the mandate of the IGC and the Nagoya Protocol had been concluded in October 2010. Therefore, the LDC Group supported the request raised by India to invite the CBD Secretariat to make a presentation in the TRIPS Council. The observer status should be granted to other inter-governmental and non-governmental organizations, such as South Centre.

149. The representative of Australia said that, as a mega-diverse country with a unique indigenous culture, his delegation had a strong interest in a balance between holders and users of genetic

resources and associated traditional knowledge. As parties to the CBD, Australia shared the relevant objectives in relation to genetic resources and traditional knowledge. Australia had actively participated in the negotiations for the Nagoya Protocol and welcomed the outcome. The Nagoya Protocol set terms on how countries would permit access to genetic resources, share the benefits arising from their use, and cooperate with one another in allegations of breach of domestic requirements.

150. Australia considered that the TRIPS Agreement and the CBD were consistent and could be implemented in a mutually supportive manner. His delegation had strong interest in the issue and welcomed the significant progress made in the IGC, especially the recent decision of the WIPO General Assemblies to renew the IGC's mandate and would continue its constructive engagement in WIPO.

151. The representative of New Zealand said that his country had a high degree of unique endemic flora and fauna, and therefore his delegation had a strong interest in preventing the misappropriation of its genetic resources and associated traditional knowledge. As a party to the CBD, New Zealand was committed to the effective implementation of its three objectives, including the third objective related to the fair and equitable sharing of benefits arising from the utilization of genetic resources.

152. New Zealand also had a systemic interest in the stability of the patent system. Measures which prevented the granting of erroneous patents were critical to maintaining the integrity of that system. There was widespread agreement amongst Members over the need to prevent the misappropriation of genetic resources and associated traditional knowledge. There was, however, still much disagreement over the appropriate policy responses that would best achieve that objective. There were a multitude of different approaches in use to address misappropriation.

153. New Zealand's domestic policy was still evolving on the subject, but it was committed to engaging constructively in relevant international forums to address it. The IGC was undertaking a detailed consideration of the relationship between IP and genetic resources as well as traditional knowledge and traditional cultural expressions. It was currently working on a text of an international instrument or instruments on the protection of the three subject matters. New Zealand considered it to be an appropriate forum to discuss in detail IP issues related to traditional knowledge and genetic resources. New Zealand was active and constructive in the IGC and was committed to the fulfilment of the IGC mandate. The IGC would meet for eight days in February to focus on genetic resources issues, including options for a draft legal text.

154. In closing, she informed the Council of the recent release of the Waitangi Tribunal's report on the Wai 262 indigenous flora and fauna and IP claims. The relationship between the New Zealand Crown and Maori was founded on the Treaty of Waitangi which had been signed in 1840. The Waitangi Tribunal was a permanent commission of enquiry charged with making recommendations on claims brought by Maori relating to actions or omissions by the Crown that allegedly breached the Treaty of Waitangi. In July 2011, the Waitangi Tribunal had released its report on the Wai 262 claim. That claim had alleged that the Crown had failed to adequately protect Maori interests in relation to a wide range of cultural knowledge and cultural practices as well as in their relationships with indigenous flora and fauna. The Tribunal had distilled the issues of the claim into four key areas: IP and works based on Maori knowledge; access to and control over biological resources, flora and fauna and taonga species; the protection and expression of Maori knowledge, including Maori language and cultural customs; and relationships with the environment and with taonga species, environmental natural resources and conservation management and traditional medicines and healing. The report contained a number of non-binding recommendations across those four areas. The Government of New Zealand was currently analysing the findings of the report to determine the response to those recommendations. The report was available online at www.waitangi-tribunal.govt.nz.

155. The representative of Chinese Taipei believed that the flexibility provided by Article 27.3(b) allowed Members to implement relevant domestic provisions appropriately and to take into account their own needs and interests. Members were able to take advantage of that flexibility to suit their particular unique domestic conditions. The review of Article 27.3(b) should not lead to lowering of the level of patent protection for biotechnological inventions.

156. The TRIPS-CBD issue concerned a number of different stakeholders. For owners of genetic resources and traditional knowledge, a mechanism to ensure access and benefit-sharing and prior informed consent was needed. For investors, it was necessary to motivate inventions and innovation. For patent offices, the legal certainty of the patent system had to be maintained without increasing unnecessarily the burden on either patent examiners or applicants. On-going discussions and consultations should take those principles into consideration.

157. The representative of South Africa supported the proposal to amend the TRIPS Agreement to incorporate a mandatory disclosure requirement. He welcomed the developments at WIPO and the Nagoya Protocol, but said that they were not sufficient to address the problem in its entirety. That issue should be tackled by the Council because of the unique mandate of the WTO, particularly of the Council. He supported the statement made by Nigeria on behalf of the African Group, which proposed to invite the CBD Secretariat to make a presentation in the TRIPS Council, and also supported the timelines identified initially by India.

158. The representative of Canada said that, as not only a user but also a provider of genetic resources, Canada took that issue very seriously. The TRIPS Agreement and the CBD were mutually supportive, and therefore there was no need to amend the TRIPS Agreement. WIPO remained the best forum for technical discussions of aspects of IP related to genetic resources, traditional knowledge and traditional cultural expressions. The IGC had been given a clear, renewed mandate to undertake text-based negotiations to reach an agreement on the text of one or more international instrument or instruments to ensure the effective protection of genetic resources, traditional knowledge and traditional cultural expressions. Canada looked forward to working with other members as the IGC pursued its recently renewed mandate.

159. She said that provisions for review of Article 27.3(b) of the TRIPS Agreement were meant to focus on Members' implementation issues rather than on revising the content of that provision. Flexibilities should be maintained in that provision to allow Members to implement it domestically as appropriate. For example, Canada was committed to continuing its work to avoid the grant of erroneous patents, to secure compliance with national agreements on benefit-sharing regimes and to ensure patent offices have available the information needed to make proper decisions on patent grant. The existing patent system was well-equipped to prevent the grant of erroneous patents. He encouraged Members to consider other non-patent-based mechanisms to protect biodiversity and prevent misappropriation of genetic resources, such as developing broader, more globally accessible and functional prior art databases, using mutually agreed terms in material transfer agreements, licensing, codes of conduct and contracts between users and providers. Canada would be fully engaged in the ongoing consultative process on the outstanding implementation issues.

160. The representative of Indonesia highlighted the importance of the issues of TRIPS-CBD and protection of traditional knowledge and folklore. As a proponent of document TN/C/W/52, Indonesia remained consistent in its view that all Members should take bold steps to address that matter so that the Council not only produced fruitful results but also contributed to substantive progress on the subject. Given the fact that the protection of genetic resources, traditional knowledge and folklore was very crucial for developing countries, the disclosure requirement would undoubtedly contribute to the success of development. The WTO, as an organization that valued development, must come up with rules and parameters that would enhance the benefit of such a system for development. The potential of genetic resources, combined with traditional knowledge, could become one of the key

elements for economic welfare for people in the developing countries, especially that of megadiverse nations.

161. As the Nagoya Protocol had been adopted, he encouraged all Members to consider the importance of that issue. It would be in all Members' best interest to articulate further, through the TRIPS Agreement, with an aim to offer a sufficient level of protection to genetic resources and to provide fair practice for their use. It became more relevant and appropriate for Members to take the necessary steps to incorporate the values and principles of the CBD into the TRIPS Agreement and to create a regime that was truly beneficial so that the relationship between the TRIPS Agreement and the CBD could be developed in a mutually supportive way. He hoped that Members could sincerely engage in a constructive dialogue, strengthen their commitments and accomplish the desired result.

162. The representative of Pakistan, referring to the argument that existing patent systems were sufficient to address the problem of erroneously granted patents, questioned whether the existing enforcement systems were sufficient in the context of ACTA negotiations. Were the existing systems not in compliance with the TRIPS Agreement or not sufficient enough that Members needed to make them stronger?

163. As a member of the WIPO, his delegation respected all its mandates, and would like to refer to WIPO work in the TRIPS Council. He also supported the proposal to invite the CBD Secretariat to make presentations on the Nagoya Protocol in the TRIPS Council, saying that Members were able to refer to the work taking place in other relevant bodies, whether in or outside the WTO, which was consistent with the principle and rationale some Members opted for in other issues.

164. The representative of Zimbabwe joined those that had called for the review of the provisions of Article 23(b), and reiterated the position that had been articulated by the coordinator of the African Group. The protection of traditional knowledge and folklore and genetic resources would enable peoples and communities to benefit from their biodiversity.

165. The Council took note of the statements made and agreed to revert to the matter at its next meeting.

G. REVIEW UNDER PARAGRAPH 8 OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

166. The Chairman said that, as requested by the Council, he had held consultations with a number of Members on how best to structure the Council's discussions in order to make the review as useful as possible. In light of these consultations, he had faxed to the Members a list of topics and issues for discussion on 14 October 2011. The list merged the list of six topics for discussion prepared for the System's annual review at the Council's meeting in October 2010 with the list of issues for further discussion or information identified by Members which the then Chairman had faxed to Members in February 2011 to guide the discussion on the follow-up to the annual review at the Council's meeting in March. While the Chairman clarified that while this approach was based on the structure and content of the 2010 review and represented a natural continuation of what was well received at that time, it was not necessarily exhaustive. Members should therefore feel free to raise any additional issues during the review.

167. He said that during his consultations, some delegations had reiterated their proposal for an open-ended workshop involving all the key stakeholders. However, views continued to diverge on that proposal. The last topic on the list, namely "Next steps and recommendations", would enable the Council to continue the discussion of this point.

168. Regarding the purpose of the TRIPS Council's annual review and the report to the General Council, he said that paragraph 8 of the waiver Decision provided that the Council would annually review the functioning of the System set out in the Decision with a view to ensuring its effective operation and annually report on its operation to the General Council. Such a review would be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

169. The Secretariat had circulated a draft cover note for the Council's report modelled on previous years' reports (JOB/IP/4). It contained factual information on the implementation and use of the System established under the Decision, discussions regarding its operation, and the status of acceptances of the Protocol Amending the TRIPS Agreement. In accordance with the way that the Council had prepared its reports in previous years, the part of the minutes of the meeting that reflected the discussions held under the agenda item could be attached to the cover note.

170. The Secretariat had also circulated an update to the note on the status of acceptances of the Protocol that the Council had requested it to prepare at its meeting in October 2006 (IP/C/W/490/Rev.8). Since the circulation of that document, Argentina and Indonesia had deposited their instruments of acceptance on 20 October, and New Zealand had deposited its instrument on 21 October (WT/Let/830, 831 and 832, respectively). 37 notifications of acceptance of the Protocol, including from the European Union (formerly the European Communities), had thus been received. He reminded Members that the Protocol would enter into force for the Members concerned when it had been accepted by two thirds of the Members.

171. Turning to the consolidated list of topics and questions for discussion in the annual review, the Chairman said that this list combined the list of topics for discussion that had been prepared for the October 2010 review and the list of issues for further discussion or information identified by Members that had been prepared to guide the follow-up discussion at the Council's meeting in March 2011. The follow-up questions were grouped under the appropriate headings. The footnotes indicated the delegations that had posed those follow-up questions and the further information that had already been provided in response to those questions at the Council's meeting in March. Therefore, there was no need to repeat or duplicate what had already been said on the record. He said that structuring the discussion this way should help the Council carry out the review with most continuity on the basis already established, and thus ensure a productive and useful discussion of the System that would help Members better understand the Paragraph 6 System's operation and any concerns related to it.

1. Experience of Members who have used or considered using the Paragraph 6 System
2. Implementation of the System into domestic legislative and regulatory framework

172. The representative of Canada said that her delegation had provided extensive information on its experience at the last annual review of the Paragraph 6 System in October 2010. She updated Members on the status of Bill C-393, which had sought to amend Canada's Access to Medicines Regime (CAMR). It had died on the Order Paper at the end of the last parliamentary session before the May 2011 general federal elections in Canada. No similar bill had yet been introduced in the new session of Parliament.

173. She recalled that her delegation had asked a number of questions at the Council's meeting in October 2010, to which responses remained outstanding. The Paragraph 6 System, while a useful tool, should not be viewed as a panacea for the complex problem of ensuring access to medicines. The impact of intellectual property rights on access to medicines, in particular on their price and on healthcare as a whole, had to be viewed as commensurate with the role of intellectual property alongside other factors that affected the price and availability of medicines. Those factors included infrastructure, rational use of medicines, health systems, and tariffs on medicines and related commodities that merely taxed the sick.

174. The Paragraph 6 System should therefore not be viewed as the only solution - which it was not, and had never been intended to be - but rather as a mechanism that sought to modulate one of the factors, i.e. intellectual property rights, which affected the price of medicines. She recalled the genesis of the Paragraph 6 System, wherein Ministers had recognized the need for the TRIPS Agreement to be part of the "wider national and international action" that addressed grave public health problems such as HIV/AIDS, malaria and tuberculosis. The difficult negotiations that had ensued resulted in a mechanism that had not been designed to be a tool to lower medicines prices generally, but rather to help address acute public health crises.

175. She therefore urged Members to focus their efforts on ensuring that the Paragraph 6 System worked as it had been intended to and called on all Members that had not already done so to deposit their instruments of acceptance of the Protocol Amending the TRIPS Agreement. Innovative financing mechanisms, such as pooled procurement and voluntary licensing, should be welcomed. Key issues such as the need for prevention strategies and rational medicine use, the strengthening of health systems, and the training of health workers should also be addressed by WTO Members in the WTO and other multilateral fora, such as the WHO, as well as bilaterally.

176. The representative of China said that public health was a comprehensive issue and intellectual property rights were but one element of the framework that impacted public health. Given that it was difficult for her delegation to conclude that the Paragraph 6 System in its present form provided an expeditious solution to public health problems, she invited the Council to consider whether there was room for any improvement that could be made to the System. Recommendations could also be made regarding other factors that could have a role in improving public health. Work in the Council would benefit from looking at any burdensome elements, clarifying the issues and discussing the legal framework as established by the System.

177. Referring to Bill C-393, which had been introduced to the Canadian Parliament and had not been pursued because of elections in May 2011, she wondered whether the domestic debate in Canada had identified burdensome elements in CAMR, which needed to be improved. A review of those elements by the Council could also serve as an example for its work on the functioning of the Paragraph 6 System. She therefore suggested that the delegation of Canada share further information with the Council in that regard. For example, there was a range of conditions established by CAMR which were not required by the Paragraph 6 System, such as the limited list of products to which it applied, the two year limit which applied to any compulsory licence granted under CAMR, as well as limitations on prices and profit margins for genetic manufacturers. Her delegation would like to understand whether those elements had been reviewed in the parliamentary debate in Canada, or whether other WTO Members were concerned about them. For elements also required by the Paragraph 6 System, such as case-by-case decisions on a country-by-country basis or the need to make prior efforts to obtain a voluntary licence first, she asked whether they stood in the way of a well-functioning mechanism that provided effective and expeditious solutions.

178. While some of the elements referred to may have been touched upon, it was possible that they had not been thoroughly explored. As her delegation was not sure whether this could be addressed by the Council and did also not have any experiences to share in this regard, a dedicated workshop with the participation of all stakeholders could be a useful step to answer some of the open questions and to gather experiences. This would allow Members to better understand the functioning of the System.

179. The annual review had already been conducted eight times without reaching a conclusion as to whether the System worked well, provided an effective and expeditious solution, or could be improved. Her delegation was open as to how to conduct the review. If Members agreed that the exchange of experiences had been exhausted at their level, a dedicated open-ended workshop could be conducted in order to better understand the System's functioning and to look at possible recommendations to improve it.

180. The representative of India thanked the delegation of Canada for its role in initiating the implementation of the Paragraph 6 System and supplying much-needed medicines to Rwanda under CAMR. However, the fact that their actual delivery had taken almost three years was a matter of concern, as was the lack of any information on whether patients had received the medicines in time. His delegation had not obtained convincing replies to a number of basic questions during the System's annual reviews which the Council had conducted for several years. It would be interesting to learn more about the debate on Bill C-393 that had taken place in the Canadian parliament, in particular the objections that had been raised. He wondered whether the Bill would be reintroduced and whether the amendments that had been suggested would be reflected in the new version.

181. In response to the questions raised by the delegations of China and India, the representative of Canada said that Bill C-393 had not been put forward or supported by her Government. Since a private member had introduced the Bill, it was not possible to predict whether there would be another initiative of this kind. Her Government had no intention of amending CAMR. It had opposed the Bill because it was convinced that CAMR worked in its present form, reflecting Canada's commitment to improving access to medicines.

182. Taking up the point made by the delegation of India with respect to the time it had taken for the medicines to reach Rwanda, she said that government action had been expedited and the licence had been granted within 15 days. This indicated that the system had worked and that the delay had not been caused by lengthy administrative procedures.

3. Process of acceptance

183. The representative of New Zealand said that her Government had deposited its instrument of acceptance with the WTO on 21 October 2011. In 2008, when the Government had initially agreed to the acceptance of the Protocol, it had been made contingent upon the passage of domestic implementing legislation. Provisions that would enable New Zealand to become an exporting Member under the System had been inserted into the draft Patent Bill, which currently awaited its second reading before Parliament. Having reached the understanding that the acceptance of all WTO Members' entitlement to use the Paragraph 6 System was distinct from the domestic implementation of the System, her Government had agreed to accept the Protocol in advance of the current deadline for acceptance of 31 December 2011. Her delegation remained fully committed to the principles underpinning the Protocol. By accepting the Protocol, it had committed to accepting that the additional flexibilities for all WTO Members became an integral part of the TRIPS Agreement. She encouraged other Members to deposit their instruments of acceptance in order to reach the two-thirds majority required to bring the amendment into force.

184. The representative of Turkey said that her delegation attached great importance to the Paragraph 6 System, which provided additional flexibilities to facilitate access to medicines under the TRIPS Agreement. It supported the entry into force of the Protocol Amending the TRIPS Agreement in order to make the System established under the 2003 Decision a permanent part of the TRIPS Agreement. Her delegation had initiated domestic procedures for the acceptance of the Protocol and hoped to finish them as soon as possible.

185. The representative of Costa Rica said that his country's legislative assembly had approved the acceptance of the Protocol Amending the TRIPS Agreement on 2 October 2011. The instrument of acceptance would be submitted once the remaining formalities were completed.

186. The representative of Indonesia said his delegation had submitted its instrument of acceptance of the Protocol Amending the TRIPS Agreement to the Director-General of the WTO on 20 October 2011. With the WTO Ministerial Conference approaching, he invited Members to seize the momentum and submit their acceptances.

187. The representative of the Secretariat updated the Council on the work of the Secretariat in supporting Members in the acceptance process. In view of the interest that had been expressed during the System's annual review in the Council's meeting in October 2010, the Secretariat had provided further information in order to help Members draw up their instruments of acceptance of the Protocol, based on the discussions that had been recorded in the minutes of that meeting. He stated that many delegations had sought practical information on procedures for the acceptance of the Protocol and that similar questions had often arisen in capacity building activities on TRIPS and public health. The Secretariat had therefore developed a webpage which described the acceptance procedure and provided a model instrument of acceptance.[2]

188. He recalled that a Member could accept the Protocol independent of domestic implementation of the Paragraph 6 System as the two actions were clearly distinct. Acceptance of the Protocol was a legal act whereby a Member expressed its consent that all Members were entitled to use the System. The process of acceptance needed to follow both the relevant Member's own constitutional requirements, and the content requirements which applied to the instrument of acceptance. A Member that wished to take advantage itself of the additional flexibilities provided in the Protocol might need to put in place implementing laws or regulations through normal domestic legislative and regulatory processes. On the other hand, the additional flexibilities under the Paragraph 6 System were already available under the waivers that had been provided in the 2003 Decision. A Member could therefore also choose to put in place domestic implementing legislation before having deposited its instrument of acceptance.

189. The representative of the Bolivarian Republic of Venezuela said that accepting the Protocol was different from the implementation of the System into domestic legislation, which made the introduction of new flexibilities possible. The fact that his delegation had not yet accepted the Protocol reflected a lack of trust in the System, which would persist until further clarification was obtained. The advent of the TRIPS Agreement had further complicated access to medicines because of the requirement to provide for full patent protection in the pharmaceutical sector. He said that the Members who had signed the Protocol were the main producers of medicines. While the System had been established to address public health problems in an expeditious manner, there was still a need for further clarification of issues related to its functioning and the problems Members were encountering in the process of accepting the Protocol. In support of the delegation of China, he therefore agreed on the importance of having an open-ended workshop, which would involve all key stakeholders, including from civil society and industry. No convincing argument against holding such a workshop had been brought forward since last year's annual review.

4. Capacity building on the Paragraph 6 System and related TRIPS flexibilities

190. The representative of the Secretariat provided an update on technical assistance activities that had been undertaken with a bearing on the Paragraph 6 System and other flexibilities as they related to public health. The implementation, legal and policy context, and the acceptance process of the Paragraph 6 System had been a major theme of technical assistance activities conducted by the Secretariat in increasingly close collaboration with sister organizations, in particular the WHO and WIPO.

191. A specific example of this cooperation was the most recent workshop on intellectual property and public health held by the Secretariat in collaboration with WHO and WIPO. The seventh in its series, the workshop had been a specialist programme for 23 developing country officials that had been convened earlier in the month. Its focus had been building the participants' capacity to help their countries make use of flexibilities for pharmaceuticals under the TRIPS Agreement. To this end, the workshop had utilized presentations, discussions and practical exercises to study the TRIPS

[2] Available at: http://www.wto.org/english/tratop_e/trips_e/accept_e.htm.

Agreement and the management of intellectual property rights as applied to concrete health-related projects. Participants had been familiarized with the key concepts under the TRIPS Agreement and other intellectual property instruments, and how those provisions, including the Paragraph 6 System, could be implemented in national law.

192. Among other issues covered had been pricing and procurement policies as a key element in securing access to medicines, as well as ensuring the safety, efficacy and quality of medicines, technology transfer and local production, the role of competition policy, and intellectual property rights provisions in regional or bilateral free trade agreements and their link to public health.

193. A diverse range of speakers had shared their practical experiences and views on key issues directly relevant to public health, including a wide range of expertise on legal, policy and economic issues from WTO, WHO and WIPO, as well as UNCTAD, representatives from some WTO Members, including Geneva delegations, the Commissioner of the South African Competition Commission, the President of the Ecuadorian Institute of Intellectual Property, the research based and generic industries, Médecins sans Frontières (Doctors without Borders), the Global Fund, the Medicines for Malaria Venture, and Health Action International. These experts had provided a well-rounded view of the issues at the crossroad between intellectual property rights and public health.

194. He said that TRIPS flexibilities in the area of public health had also figured prominently in other WTO national and regional technical cooperation events. In addition, in order to advance cooperation between the WTO, WHO and WIPO and to focus on technical cooperation and enhance available information materials, a series of policy symposia were being undertaken. A third in the series was expected early next year. The working materials developed in this programme of trilateral cooperation, along the lines of the themes and content of the first trilateral symposium held in 2010, were being developed and collated in the form of a trilateral study prepared as a resource for continuing technical cooperation and capacity building. In addition, as a further tool for technical assistance, a set of models for notifications under the Paragraph 6 System had been made available on the WTO website.[3]

195. The representative of the WIPO Secretariat recalled that the Development Agenda, agreed upon by the Member States of WIPO in 2007, contained 45 recommendations to enhance the development dimension of the Organization's activities. Key among those were Recommendations 13, 14, 17, 22 and 25, focused on enhancing the understanding and use of flexibilities in the intellectual property system. Since its inception, the Committee on Development and Intellectual Property (CDIP) had met twice each year at WIPO to discuss the planning, implementation and mainstreaming of Development Agenda projects within WIPO's work.

196. As regards the implementation of flexibilities under the Development Agenda, he said that at the fourth session of the CDIP which had been held in November 2009 the Committee had, in the context of discussions on Recommendation 14, requested WIPO to prepare a document on flexibilities in the area of patents. Accordingly, WIPO had prepared a document on Patent-Related Flexibilities in the Multilateral Framework and their Legislative Implementation at the National and Regional Levels (CDIP/5/4 Rev.). At the Committee's request, WIPO had subsequently prepared the second part of the document on flexibilities in patents (CDIP/7/3). In total, those two documents provided information on implementation of ten patent-related flexibilities.

197. At its fifth session, in April 2010, the Committee had requested WIPO to prepare a proposed future work programme on flexibilities for its consideration. At its sixth and seventh sessions, in November 2010 and May 2011 respectively, the CDIP had considered a document setting out a future

[3] Available at: http://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.pdf.

work programme on flexibilities at WIPO (CDIP/6/10). In response to a request made at the seventh session, the Secretariat had updated the strategy for implementation of the work programme on flexibilities and revised the annex providing details of WIPO's activities in this area, addressing work in the area of patents, and taking stock of WIPO's activities relating to flexibilities in the IP system and technical assistance in the use of flexibilities (CDIP/8/5).

198. He informed the Council of WIPO's implementation of the agreed components of the work programme on flexibilities. Information on IP flexibilities had been incorporated in the WIPO technical assistance programme. The Regional Bureaus and the concerned sectors had been requested to ensure that, at the request of member States, information on flexibilities was appropriately included in the provision of technical assistance.

199. Furthermore, a webpage dedicated to flexibilities in the IP system had been developed and published in English, French and Spanish on the WIPO website.[4] As agreed upon by the member States, the webpage contained (i) a roadmap providing guidance on WIPO's work on flexibilities in the substantive sectors and Committees; (ii) a database containing provisions on national legislation related to flexibilities in the IP system, drawn from the agreed documents on patent-related flexibilities in the IP system; and (iii) links to literature and resources on flexibilities produced by the Secretariat and WIPO-commissioned experts, as well as links to resources on flexibilities produced by other relevant international organizations, such as the WTO, the WHO, the FAO, and UNCTAD. In this respect, WIPO was actively collaborating with other international organizations involved in work related to flexibilities in order to gather information and ensure a coordinated and effective provision of resources on the issue to the Member States. WIPO had researched and provided links to the work of such organizations, and would continue this outreach to ensure the most effective use of resources in this area.

200. In addition, steps had been taken through internal communications and briefings to ensure that staff involved in providing technical assistance across the sectors of the Secretariat were aware of this strategy on the use of flexibilities in intellectual property, and continued to integrate appropriate techniques for diffusion of information to Member States. Finally, at the request of member States, national and regional level seminars had been organized and were planned in future activities with a view to exchange practical experiences on the implementation of flexibilities. In this respect, in March 2011, a Regional Seminar on the Effective Use of Several Patent-Related Flexibilities had been held in Bangkok, Thailand, involving participants from 16 countries in the Asia and Pacific Region for discussions on patent-related flexibilities and enabling sharing of experiences on the implementation of flexibilities at the national level.

201. The representative of WIPO said that over time, the joint participation of WHO, WIPO and WTO in a number of activities and their participation as observers in respective meetings of the three organizations had contributed to building up a well-functioning working relationship among the three organizations on issues related to public health, intellectual property and trade. This working relationship, which was supported by WIPO's Development Agenda Recommendation 40 to intensify cooperation on IP-related issues with UN agencies, had matured into the informal and practical trilateral cooperation his organization had reported in earlier meetings. One example of this cooperation in the current year was the Workshop on Patent Searches and Freedom to Operate, held on 17 February 2011, which had introduced participants to the basic concepts involved in carrying out patent searches and freedom to operate analyses.[5] Other collaborative activities included (i) the Joint Technical Symposium on Access to Medicines, Patent Information and Freedom to Operate, held on 18 February 2011,[6] which had addressed the growing importance of patent information for public

[4] Available at: http://www.wipo.int/ip-development/en/agenda/flexibilities/.
[5] http://www.wipo.int/meetings/en/details.jsp?meeting_id=22342
[6] http://www.wipo.int//meetings/en/2011/who_wipo_wto_ip_med_ge_11/

health with respect to freedom to operate strategies, procurement of medicines, technology transfer and setting of research priorities and strategies; (ii) the WTO Workshop on Intellectual Property and Public Health, organized in Geneva by the WTO Secretariat in collaboration with the Secretariats of WHO and WIPO from 10 to 13 October 2011; and (iii) work on a trilateral study on "Promoting Access and Medical Innovation: Intersections Between Public Health, Intellectual Property and Trade" that would be combining the three Secretariats' specific expertise in order to support and objectively inform technical cooperation and policy discussions.

202. He said that the agenda of the 16th session of the WIPO Standing Committee on the Law of Patents (SCP)[7] from 16 to 20 May 2011 had included an agenda item on Patents and Health. The delegation of South Africa had submitted a proposal to the SCP on behalf of the African Group and the Development Agenda Group (SCP/16/7). The WIPO Secretariat, as well as representatives from the WHO and the WTO, had briefed the SCP on work being carried out in relation to that agenda item. The topic would remain on the agenda of the 17th session of the SCP.

203. He also informed the Council that, as of 13 October 2011, the Access to Research for Development and Innovation (ARDI) programme of WIPO had become a full member of Research4Life. Research4Life was a public-private partnership between WIPO, WHO, FAO, UNEP, the International Association of Scientific, Technical and Medical Publishers (STM), Cornell University, Yale University, and several technical partners, including Microsoft. The goal of the partnership was to enable free or low-cost online access in developing and least developed countries to critical scientific research, with ARDI providing a particular focus on applied science and technology.

204. He drew the Council's attention to the launch of "WIPO Re:Search – Sharing Innovation in the Fight Against Neglected Tropical Diseases"[8] on 26 October 2011. Through WIPO Re:Search, a range of public and private sector institutions had come together to increase the availability of valuable intellectual property assets to the global research community in order to address the challenges represented by neglected tropical diseases, particularly the need for more research. The WHO was supporting this initiative by providing technical advice to WIPO. WIPO Re:Search was founded on the belief that intellectual property and knowledge could be used creatively to stimulate greater investment in research and development for new health solutions. The mechanism worked entirely on a voluntary basis for all participating parties, namely providers and users, and had no impact on any legal instrument. WIPO Re:Search allowed public and private sector organizations to make valuable intellectual property, including compounds, compound libraries, unpublished scientific results, regulatory data and dossiers, screening technologies, platform technologies, know-how licenses and patent licences, available to qualified researchers anywhere in the world seeking to develop new solutions for neglected tropical diseases, malaria and tuberculosis. Licenses for product distribution in least developed countries would be royalty-free.

205. The representative of the WHO Secretariat said that special emphasis had been given in his organization's capacity building activities to the implementation and use of flexibilities in accordance with the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health. The aim had been to ensure that public health interests were adequately taken into account in the formulation of national policies and legislation on trade and intellectual property. Many of the activities, especially in the field of training, capacity building and technical assistance, thus encompassed TRIPS flexibilities. Support was directed towards assisting Member States on how to safeguard public health interests while adhering to their obligations under international trade agreements. In particular, this included developing public health sensitive patent legislation and

[7] http://www.wipo.int/meetings/en/topic.jsp?group_id=61
[8] More information available at: http://www.wipo.int/research/en/.

incorporating TRIPS flexibilities into domestic legislation. Technical support was carried out in close collaboration with WHO country and regional offices and relevant international organizations.

206. Turning to specific activities, he reported that in March 2011, WHO, along with the United Nations Development Programme (UNDP) and UNAIDS, had published a policy brief on the use of TRIPS flexibilities to improve access to HIV/AIDS treatment. The paper reviewed how countries could use and had used TRIPS flexibilities in order to increase access to HIV treatment. To provide ministries of health in the Eastern Mediterranean Region with a clear analysis of the public health implications of provisions included in bilateral free trade agreements, the WHO Regional Office for the Eastern Mediterranean had also published a policy guide on "Public health related TRIPS-plus provisions in bilateral trade agreements".

207. In 2011, WHO had taught for the first time a module on "Public health and Intellectual Property" in the framework of the Master's Degree in Intellectual Property at the Africa University in Zimbabwe, jointly organized by WIPO, the African Regional Intellectual Property Organization (ARIPO) and Africa University.

208. He recalled that WHO had provided substantial support to the organization of the annual WTO "Workshop on Intellectual Property and Public Health" that took place in Geneva in October 2011. The workshop had addressed TRIPS provisions and flexibilities of relevance to public health as well as other relevant issues ranging from procurement to regulatory questions and prices of medicines. WHO Headquarters and the WHO European Regional Office had collaborated with WTO in the organization of a Regional Workshop for Central and Eastern European and Central Asian Countries on Intellectual Property and Public Policy that had taken place in Vienna in January 2011. WHO Headquarters and regional offices had also continued providing, upon request and in collaboration with relevant international organizations, technical and policy support to favour use and management of intellectual property in a manner that maximized health-related innovation and promoted access to medical technologies.

209. The representative of the European Union said that it had been reported to his delegation that the WTO Workshop on Intellectual Property and Public Health had provided informative and helpful support to those Members seeking to utilize TRIPS flexibilities. Specific presentations on pricing had been particularly useful. They had clarified that there were many components relevant to the pricing of pharmaceuticals in addition to intellectual property. The inclusion of external speakers with various backgrounds had stimulated an open debate.

210. The representative of Nigeria recognized the work done to build capacity to use the Paragraph 6 System, and asked whether there existed a model voluntary licensing agreement that could be used to guide developing countries in dealing with companies to establish or enhance their local manufacturing capacity.

5. Any alternatives to the use of Paragraph 6 System to achieve the objective of access to medicines, procurement policies, and other related aspects affecting access to medicines raised by Members

211. The representative of the United States said that his delegation strongly supported the Paragraph 6 System as established under the 2003 waiver Decision and the 2005 Protocol Amending the TRIPS Agreement in order to allow medicines to be exported under a compulsory license under the terms set out in that decision and the accompanying Chairman's Statement. His delegation had been the first Member to notify its acceptance of the amendment. Members who had already notified their acceptance were developed, developing, and least developed countries and that though some were pharmaceutical producers, most were not. He encouraged other Members to notify their acceptance of the amendment so that the amendment could enter into force.

212. Although the Paragraph 6 System represented an important failsafe, it was only one tool for addressing the larger issue of access to medicines. In discussions with stakeholders in recent years, his delegation had consistently heard that the issue of access to safe and effective medicines was being addressed by a variety of other means. His Government had also been actively working to address the factors that had been shown to reduce access to safe and effective medicines, including tools to deploy trade policy to promote trade in, and reduce obstacles to access, innovative and generic medicines. It had also been supporting the innovation and intellectual property protection that was vital to developing new medicines and achieving other medical breakthroughs.

213. Those tools included (i) enhancing legal certainty for manufacturers of generic medicines; (ii) eliminating tariffs on medicines and medical devices, thereby decreasing costs for hospitals, clinics, aid organizations and consumers, among others; (iii) reducing customs obstacles to medicines by minimizing import barriers, such as discriminatory, burdensome, and unpredictable customs procedures, that impeded access to innovative and generic medicines; (iv) curbing trade in counterfeit medicines by making customs and criminal enforcement measures available to prevent medicines bearing counterfeit trademarks from entering national markets, and thus supporting efforts of countries to address the serious risks to patients posed by such counterfeits; (v) reducing internal barriers to distribution of medicines by guaranteeing importing, exporting, and distribution rights with respect to medicines and minimizing internal barriers that could stand in the way of efficiently distributing medicines to those in need; and (vi) minimizing unnecessary regulatory barriers by promoting transparent and nondiscriminatory regulatory structures to facilitate the availability of safe and efficacious medicines to the public, while also improving coherence of future rules across the region. He recalled that his delegation had elaborated those systemic issues in the Council's annual review carried out in 2010 (IP/C/M/57, paragraphs 198 to 201). The list of other tools demonstrated that one policy alone could not solve the challenges relating to access to medicines. Rather, a variety of tools, including the Paragraph 6 System, were needed to promote access to medicines.

214. Regarding the proposal of some Members to hold a workshop which would include non-governmental actors, he said that his delegation did not support the idea of having the Council organize such a seminar. Members were free to bring into the Council's review of the Paragraph 6 System perspectives they had gleaned from stakeholders, such as companies or civil society. What Members got out of the review was very much a function of what they put into it. His delegation had hoped that Members would provide information on their experiences as input for the Council's discussions of the System's functioning at the current meeting, but it was disappointed by the details of experiences that had been provided. It could be that the Paragraph 6 System had not been necessary, and for this reason many Members had not implemented it, or that capital-based experts from health ministries could simply not attend the Council's meeting because of other competing demands. He reiterated his delegation's interest in hearing other Members' experiences and views on how best to gather additional information.

215. The representative of Ecuador said that the System was not effective and could be further improved. His Government was therefore not ready to proceed with the acceptance of the Protocol. His delegation, like other Members, had considered alternatives to the use of the Paragraph 6 System by compiling and evaluating other countries' practices in respect of the implementation of Articles 30, 31 and 44 TRIPS. Those practices were of significant importance in enabling Members to take informed policy decisions as they strove to transform into reality the spirit of the Doha Declaration on the primacy and safeguarding of public health and the promotion of access to medicines.

216. In that context, he requested that the European Union provide clarification on the Italian Competition Authority's granting of three compulsory licences between 2005 and 2007, which seemed to have occurred under Article 31(k) of the TRIPS Agreement. Under that provision, the conditions established in Article 31(f) could be waived if a licence was granted to remedy a practice determined after judicial or administrative process to be anti-competitive.

217. In the first case, the Italian Competition Authority had launched an investigation in February 2005 regarding the abuse of dominant position by Merck for its refusal to grant licensing rights in respect of the patent-protected active ingredients, which were used to produce the antibiotic Imipenem Cilastatin. On 21 June 2005, the Italian Competition Authority had granted a compulsory licence on the relevant patents for the active ingredients needed for the manufacture of the antibiotic concerned. The product had been patented only in Italy and not in other European countries. The Italian generics industry had sought a licence to produce and market the product in the rest of Europe (not for the Italian market), where this product had not been protected.

218. The second case concerned a decision by the Italian Competition Authority of 8 February 2006 to grant a compulsory licence for the manufacture in Italy of the patent-protected active ingredient Sumatriptan Succinate needed to produce medicines to treat migraine. The licence had been requested by the chemical company *Fabbrica Italiana Sintetici SpA* (FIS), following GSK's refusal to negotiate a voluntary licence. Initially, FIS had used the compulsory licence primarily for the purpose of supplying the export market by selling its product to generic companies, which marketed it in other countries such as Spain, where the relevant patent had expired. This had been done outside the Paragraph 6 System, from which the EU and its member States had opted out of as beneficiaries.

219. The third case related to the Italian Competition Authority call upon Merck on 21 March 2007 to "grant free licences to allow the manufacture and sale in Italy of the active ingredient Finasteride and related generic drugs two years before the 2009 expiration of the Supplementary Protection Certificate". Finasteride was the active ingredient of a drug initially marketed under the brand names Proscar and Propecia. It was used to treat prostatic hypertrophy, prostate cancer and male pattern baldness. The royalty-free compulsory licences issued by the Italian Competition Authority had remedied Merck's refusal to license its patents to local manufacturers of pharmaceutical active ingredients. Those licences had once again involved exports to other European countries.

220. He asked the delegation of the European Union to provide the Council with further information on these three compulsory licences including, but not limited to, administrative procedures, decision-making processes and the legal and factual basis for the grant of the licences. He also requested that the European Union provide examples of other uses under Article 31(k) relating to the export of medical technologies.

221. The representative of India said that the issue of Members' experiences using alternatives to the Paragraph 6 System to achieve the objective of access to medicines had been raised and discussed for several years, but Members were still short of inputs. He therefore reiterated his delegation's demand for a dedicated workshop that would, as the delegation of Ecuador had mentioned, help strengthen the Paragraph 6 System and where Members would have an opportunity to discuss other experiences. The workshop would also help those delegations develop faith in the System who had cited a lack of faith as the reason for not accepting the Protocol Amending the TRIPS Agreement.

222. Turning to the role of compulsory licensing to provide access to medicines, he recalled that Articles 30 and 31 of the TRIPS Agreement provided a mechanism to that extent. Article 30 was a substantive exception which detailed three criteria to be met for any exception to apply to exclusive patent rights. Article 31, in contrast, was primarily procedural in nature, detailing a list of requirements that applied to other uses without authorization by the patent right holder. Both provisions taken together defined the scope of limitations to exclusive patent rights available under the TRIPS Agreement. Additionally, Article 44 outlined flexibilities with respect to the right to provide permanent injunctions.

223. He drew Members' attention to two particular cases in the United States. Shedding light on those cases could help address the problem of providing access to medicines without recurring to the

complicated Paragraph 6 System. In eBay v. MercExchange, the US Supreme Court had determined that the plaintiff in infringement cases had to satisfy a four-factor test before a court could issue a permanent injunction. This four-factor test included demonstration of the following elements by the plaintiff, i.e. that: (i) he had suffered full and irreparable injury; (ii) remedies available at law such as monetary damages were inadequate to compensate for that injury; (iii) considering the balance of hardships between the plaintiff and defendant, a remedy in equity was warranted; and (iv) public interest would not be disserved by a permanent injunction. In Edwards Lifesciences v. CoreValve, a compulsory licence had been granted for manufacturing a medical device in the United States exclusively for exportation. He requested that the United States and other countries where similar judgments had occurred explain to Members why the restrictions on exports under compulsory licences as established by Article 31 of the TRIPS Agreement did not apply in those cases.

224. The representative of Switzerland referred to his delegation's intervention at the last annual review, which was recorded in paragraph 175 of the Council minutes (IP/C/M/64). In response to the question from the delegation of Ecuador on programmes put in place by his Government to address public health problems in developing countries, he noted that his delegation was active in many such programmes. Public health was one of the focus points of its development work at both the bilateral and multilateral levels. As regards programmes specifically linked to intellectual property, he referred to the reports that his delegation had submitted on technical cooperation, as well as on the obligation under Article 66.2 to provide incentives to transfer technology to least developed country Members. The 2011 report provided more details, in particular in paragraphs 28, 29 and 34 (IP/C/W/558/Add.5). Regarding programmes with a particular focus on development and health, but not specifically linked to intellectual property, more information could be accessed on the website of the Swiss Federal Agency for Development and Cooperation.[9]

225. With respect to any alternatives to the use of the Paragraph 6 System, he referred to his delegation's intervention at last year's annual review (IP/C/M/64, paragraphs 285 to 287). Turning to the proposal for an open-ended workshop to be held to gather information on the functioning of the System, which had been made by some delegations who considered that the exchange of experiences among Members had been exhausted, he maintained his delegation's view that holding such a workshop at this stage was premature. So far, it had not heard much from countries that were potential beneficiaries under the Paragraph 6 System. Most countries that had intervened were either potential exporting countries or countries with manufacturing capacity. However, those were not the countries that WTO Members had had in mind when devising the Paragraph 6 System. While his delegation was not in principle against the idea of holding a workshop, it was important to first establish within the Council the problems that potential beneficiaries had encountered, as well as their concerns with respect to the Paragraph 6 System. Before having heard those concerns, it would be difficult to even decide who should be invited to such a workshop and what specific problems should be highlighted and discussed.

226. The representative of Japan recalled that the Paragraph 6 System aimed at enhancing access to medicines in Members with insufficient or no manufacturing capacities in the pharmaceutical sector. He noted that according to the information that had been provided at the trilateral Symposium on "Access to Medicines: Pricing and Procurement practices" that had been organized by the WHO, WIPO and WTO in July 2010, only 5 per cent of the medicines on the WHO list of essential medicines were protected by patents. Therefore, the Paragraph 6 System was only one of many tools to address public health problems. Other important elements included the procurement of medicines and tariffs.

227. The specific concerns of potential importing Members were indispensable parts of the review. Those Members were best qualified to share their experiences with the Council regarding specific

[9] http://www.deza.admin.ch/en/home/themes/health

obstacles or concerns faced, but only a few Members had done so. Until discussions within the Council were completed, it would be premature to hold a workshop on the Paragraph 6 System.

228. The representative of Cuba shared the concerns expressed by other delegations on the implementation of the Paragraph 6 System. As regards the acceptance of the Protocol Amending the TRIPS Agreement, she noted that it was the responsibility of Members to create suitable rules that provided a lasting solution and did not require frequent revision. In that context, it was important that further discussions be held in the Council before Members rushed to accept the Protocol. Those should aim at clarifying any doubts about the System's functioning, and address the reasons why it had been rarely used. To this end, the organization of a workshop would be desirable in order to provide greater clarity on the effectiveness of the implementation and operation of the System.

229. The representative of the European Union said that access to essential medicines for developing countries was of utmost importance to his delegation. This explained why it had taken an active part in the negotiations that had led to the 2003 waiver decision and to the TRIPS amendment. Subsequently, it had taken the necessary steps to implement the Paragraph 6 System at the EU level and to accept the amendment. He stressed the need to make the System work, as well as the fact that his delegation was committed to do so. Rather than reopening a debate on the System as a whole, it was important to have a focused discussion within the framework of the Council's annual review. To that extent, the list of issues for discussion which the Chairman had circulated was helpful. However, his delegation was disappointed about the debate, as it had hoped to learn more about the reasons why the developing countries for whom the System had been designed, apart from Rwanda, had not used it. He disagreed with those Members that claimed that the operation of the System would be hindered by legal, procedural, commercial and other obstacles. There were few conditions required for the System to work properly.

230. Several reasons could explain why the System had not been used more often. These included the fact that 90 per cent of essential medicines were in the public domain. Least developed countries were also not obliged to implement any TRIPS obligations with respect to patents and test data protection in the area of pharmaceuticals until 1 January 2016. Moreover, there were other channels developing countries could use to get access to cheap medicines, including, for instance, through the use of existing TRIPS flexibilities and direct negotiation with pharmaceutical companies. The Paragraph 6 System was equally effective when it was used as when it was not used due to its effect as both a negotiating chip and a strong deterrent. It would be interesting to hear more about the System's impact on negotiations and on pricing since it had been put in place.

231. In his delegation's view, those who criticized the System as being too burdensome without real life experience of the matter were discouraging developing countries from using an instrument which could help them secure access to affordable medicines. Positions taken by some countries like Ecuador who had said that they would not accept the System were unfair, since those countries had domestic manufacturing capacities that other countries that really needed the System lacked.

232. In response to the questions which the delegation of Ecuador had addressed to his delegation, he said that it was not clear whether those were meant to demonstrate how the System had been put in place or whether they were addressing an unrelated matter, such as the use of compulsory licences under normal circumstances. He clarified that, in any event, European countries were not using the System as importers. Addressing those issues would require some research, but his delegation would be prepared to do so under the relevant agenda item.

233. As regards the two judicial decisions referred to by the delegation of India, the representative of the United States clarified that those decisions had specifically addressed procedural aspects of the provision on injunctive relief. The findings in those cases were therefore limited and the analysis

which the delegation of India had made of them was not necessarily within the scope of the matters before the courts.

234. Noting his country's experience regarding the import of generic medicines under the Paragraph 6 System, the representative of Rwanda supported the permanent incorporation of the System through the proposed amendment to the TRIPS Agreement. He informed the Council that his Government would ratify the Protocol Amending the TRIPS Agreement no later than by the extended deadline for acceptance.

235. Taking note of the response given by the delegation of the European Union, the representative of Ecuador further clarified the issues he had raised in his earlier statement. The Paragraph 6 System constituted one of the mechanisms to waive the otherwise applicable condition under Article 31(f) TRIPS and to issue compulsory licences for export purposes. Other provisions that could also assist Members who faced difficulties with the restrictive condition established by Article 31(f) included Article 31(k) which permitted unauthorized usage to remedy a practice determined after a judicial or administrative process to be anti-competitive. In the three cases he had referred to before, compulsory licences had been granted under Article 31(k). His delegation would welcome learning more about such practice, which seemed to represent a valid and useful alternative to overcome problems posed by the implementation of Article 31(f).

6. Next steps and recommendations

236. The Chairman said that the discussion of this topic should provide the Council with an opportunity to discuss whether there was a need for a follow-up to the annual review, and, if so, what it should be.

237. The representative of the Bolivarian Republic of Venezuela noted that many Members who had intervened on the issue were developed countries who had stated that there was no need to re-open the discussion on the System's functioning. His delegation's concern was that Members who had not yet accepted the Paragraph 6 System and thus could not share their experiences were reluctant to speak on the issue. The fact that they had not implemented the System combined with their silence indicated the existence of unaddressed concerns and the need for greater clarity.

238. The representative of Turkey said that, in the interest of understanding the Paragraph 6 System well, holding a workshop open to all stakeholders could provide a good opportunity to introduce it to potential users. Such a forum would allow the civil society, the pharmaceutical industry, exporting Members and least developed country Members to share their views, experiences, and questions on the implementation of the System.

239. The representative of China said that the Council needed to make a decision regarding the follow-up to the eighth annual review. There appeared to be a lack of consensus among Members on whether the legal procedures or commercial stakeholders prevented developing countries from using the Paragraph 6 System. Her delegation therefore strongly supported that an open-ended workshop for all stakeholders be held. It would help achieve greater transparency, promote a holistic understanding, and perhaps a solution to the current deadlock.

240. The representative of Canada supported the delegations of Switzerland and Japan in that it would be useful to hear more specific views and experiences from potential beneficiaries regarding any obstacles posed by the System. It was not clear what could be gained from an open-ended workshop that could not be gained through discussions in the Council. Delegations could gather information from stakeholders and share it with the Council.

241. The representative of the European Union said that his delegation shared the views expressed by the delegations of Canada, the US, Japan, and Switzerland. Experiences with the System heard so far either indicated that the System had worked, that it had had some impact even when it had not been used in the end, or that it had been a useful negotiating chip. Holding an open-ended workshop would therefore be premature and unnecessary.

242. The Chairman suggested that he consult on next steps, including the issue of a possible workshop.

243. The Council took note of the statements made and so agreed.

244. Turning to the draft report to the General Council on the annual review of the Paragraph 6 System, the Chairman recalled that the Secretariat had circulated a draft cover note for the Council's report modelled on previous years' reports (JOB/IP/4). It contained factual information on the implementation and use of the System established under the Decision, discussions regarding its operation, and the status of acceptances of the Protocol Amending the TRIPS Agreement. In accordance with the way that the Council had prepared its reports in the previous years, the portion of the minutes of the meeting that reflected the discussions held under the specific agenda item could be attached to the cover note.

245. As regards paragraph 15 of the report, he recalled that Argentina, Indonesia and New Zealand had recently accepted the Protocol. There was also a minor error in the paragraph, namely that Uganda should have been included in the list of Members that had notified their acceptance. This paragraph would be updated and corrected accordingly.

246. The Protocol had originally been open for acceptance by Members until 1 December 2007. Upon proposals by the TRIPS Council, the General Council had twice extended that period for further two-year periods. The period for acceptance was currently due to expire on 31 December 2011. Given the proximity of that date, the Chairman suggested that the Council consider again submitting a proposal to the General Council for a decision to extend the period for the acceptance of the Protocol. For that purpose, a draft decision that could be submitted to the General Council for adoption was included in Annex 2 to the draft report. It did not yet contain a new deadline for the extended period for acceptances. In the light of the consultations he had held on this matter, he suggested that the Council propose to extend the period by a further two years until 31 December 2013.

247. The representative of Turkey supported the approach suggested by the Chairman. This would also provide her delegation with additional time to complete its internal procedures.

248. The Chairman proposed that the Council agree on forwarding to the General Council the proposal for a decision to extend the period of acceptance by Members of the Protocol Amending the TRIPS Agreement until 31 December 2013. He suggested that the last paragraph of the draft decision by the General Council contained in Annex 2 to the draft report (JOB/IP/4) be complemented by inserting this date. He also proposed that the Council agree to the cover note to the report contained in JOB/IP/4, and also that the Council minutes containing the record of the discussion be attached to it.

249. The Council took note of the statements made and so agreed.

H. NON-VIOLATION AND SITUATION COMPLAINTS

250. The Chairman recalled that, at the Seventh Session of the Ministerial Conference, Ministers had directed 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

GATT 1994 and to make recommendations to their next Session. It was agreed that, in the meantime, Members would not initiate such complaints under the TRIPS Agreement. The eighth Ministerial Conference was to be held in Geneva on 15-17 December 2011.

251. He further recalled that, at the Council's meeting in June, he had indicated his intention to hold consultations on the issue with a view to enabling the Council to agree on its recommendation to the Ministerial Conference at the present meeting. While most delegations that he had consulted had indicated that their preference remained to determine non-violation complaints inapplicable to TRIPS, they had nonetheless been willing to compromise by agreeing to recommend the extension of the moratorium until the next Ministerial Conference. In particular, it had been suggested that the language should follow as closely as possible the language used by Ministers in their Decision of 2 December 2009 on "TRIPS Non-Violation and Situation Complaints". A few delegations had said that their view continued to be that the non-violation moratorium should expire. However, they had shown flexibility in being ready to engage with a view to reaching a decision.

252. The representative of the United States said that he looked forward to engaging constructively with the Chair and other Members on the issue. His delegation maintained that non-violation complaints were fully appropriate in the context of the TRIPS Agreement. The possibility of non-violation disputes had been part of the GATT dispute settlement system since the beginning. The TRIPS Agreement had been carefully negotiated to accommodate different legal regimes and Members' needs to achieve policy objectives. The availability of non-violation complaints would merely assist Members in their efforts to preserve the balance of concessions and to protect against measures that frustrated legitimate expectations. A failure to allow for the possibility of non-violation disputes in connection with the TRIPS Agreement could invite Members to seek creative ways to avoid their TRIPS obligations. His delegation thus continued to be of the view that it was entirely appropriate for non-violation and situation complaints to be applicable to the TRIPS Agreement and, further, that the moratorium should expire at the next Ministerial conference.

253. The representative of Nigeria, speaking on behalf of the African Group, said that non-violation and situation complaints should not apply to the TRIPS Agreement. The Agreement was not designed to protect market access or balance of concessions, but rather served to establish minimum standards of intellectual property rights. Article 3.2 of the Dispute Settlement Understanding provided that both panels and the Appellate Body must be guided by the rules of treaty interpretation as set out in the Vienna Convention, and that the recommendations and rulings of the DSB could not add or diminish the rights and obligations provided in the WTO Agreement. As the Council had not reached agreement on the scope and modalities of the non-violation complaints, the issue at present was whether the moratorium should expire. If so, it might be left to panels and the Appellate Body to consider the application of Article 3.2 of the DSU. A pragmatic way to move the process forward would be to extend the moratorium. In the absence of any consensus, he encouraged the Chair to continue with his consultations with a view to arriving at a decision.

254. The representative of India said that the Doha Decision on Implementation-Related Issues had underlined the importance of the on-going examination mandated under Article 64.3. His view was that, unless and until the scope and modalities of non-violation and situation complaints were finalized, the moratorium should be extended.

255. The representative of Pakistan thanked the Chair for his continued efforts and expressed his appreciation for the flexibility that the delegation of the United States had demonstrated in relation to this issue. He expressed the hope that a solution might be found by the Ministerial Conference in December.

256. He asked those delegations that deemed that non-violation complaints were appropriate to clarify, first, how they would quantify the expected or accrued benefits to the rights holder; and

secondly, how they would hold the State responsible for non-violations. The nature of IP transactions was different from goods: with regard to IP transactions most of the rights and use or misuse of rights were between private parties without essentially involving a filter or a control by the State. On the other hand, in the case of goods one might have border measures, or other fiscal and other measures to address those concerns. However, in the context of IP and especially in the light of technological advancements, it would be difficult to ask the State to have an enforcement role. So in that sense, would the State be held responsible for actions that were beyond the State's legal or jurisdictional systems; if something was not working due to the lack of the capabilities or capacity, would that constitute a situation of non-violation?

257. Only a few cases of non-violation and situation complaints had been brought under the dispute settlement system. In services there had only been one complaint, in which case the complainant had failed to prove that there was non-violation or denial of the benefits due to non-violation. In the context of IP it would be even more difficult to prove. Therefore, it might be useful to have at some stage a real substantive debate to understand whether non-violation was practicable or not. Considering that the Ministerial Conference would take place shortly, it would be advisable to extend the moratorium so as to allow the Council to establish how better to deal with those questions.

258. The representative of South Africa, supporting the statement by the delegation of Nigeria, said that the issue had been on the Council's agenda since the Ministerial Conference in Hong Kong. He recognized that Members clearly had different views concerning the application of subparagraphs 1(a) and 1(b) of Article XXIII of GATT 1994 under the TRIPS Agreement. As a Member of the WTO, South Africa was fully committed to upholding its obligations and commitments as set out in the various agreements of the WTO, including the TRIPS Agreement. The purpose and aim of Article XXIII subparagraphs 1(a) and (b) of GATT 1994 was to ensure compliance with GATT rules and principles by providing Members with an opportunity to make representation under the situation provided for in subparagraphs 1(a) and (b).

259. On the other hand, TRIPS was a sui generis agreement. It was not aimed at promoting market access or harmonizing the standards of Member States with regard to the protection and enforcement of intellectual property rights. It provided for minimum standards for the protection and enforcement of intellectual property rights. The insertion of Article XXIII subparagraphs 1(a) and 1(b) of GATT 1994 under the TRIPS Agreement would undermine the sovereign rights of the respective Members in putting into place laws for the protection of intellectual property within their jurisdictions. Furthermore, such an insertion would restrict the flexibilities provided to Members and defeat the balance that had been maintained under the TRIPS Agreement. While recognizing the need for the protection and enforcement of intellectual property rights, he considered that the insertion of non-violation and situation complaints would be impractical under the TRIPS Agreement.

260. The representative of Brazil said that the application of non-violation and situation complaints to the TRIPS Agreement was a matter of concern to Brazil. Unlike the other WTO Agreements, the TRIPS Agreement was sui generis: it was not designed to protect market access or the balance of tariff concessions, but rather it served to establish minimum standards of IP protection. Hence he considered that the application of non-violation and situation complaints under the TRIPS Agreement was not appropriate and could be problematic. For instance, it could prevent developing countries from successfully using the flexibilities contained in the Agreement, including those related to the protection of public health. The extension of the non-violation remedy to the TRIPS Agreement might also entail consequences for the predictability and security of the multilateral trading system. The uncertainties surrounding the remedy would make it harder for countries to rely on the text of the Agreement to define their rights and obligations. Moreover, it might give rise to incoherence among the WTO Agreements. Furthermore, such uncertainty was likely to increase further public concern over the impact of the TRIPS Agreement on important issues, such as public health, biodiversity protection and transfer of technology. For that reason, his position was in line with that of other

Members who had suggested that, until they had found a definite solution, the moratorium should be extended for another two years.

261. The representative of China, associating her delegation with the positions of the African Group as articulated by the delegation of Nigeria and of India, South Africa and Brazil, said that the nature and structure of the TRIPS Agreement differed from GATT 1994. China therefore considered that the application of non-violation and situation complaints to the TRIPS Agreement was highly inappropriate and problematic and, moreover, susceptible to fundamental concerns among Members of the WTO. However, in a spirit of flexibility and aiming at a successful conclusion of the Ministerial Conference at the end of the year, she suggested that Ministers at the Eighth Ministerial Conference agree to a further extension of the moratorium on non-violation and situation complaints under the TRIPS Agreement, at least until the next Ministerial Conference in 2013.

262. The representative of the Bolivarian Republic of Venezuela said that non-violation and situation complaints should not be applicable to the TRIPS Agreement. For the time being there appeared to be little likelihood of achieving a resolution of the issue. Therefore, he was willing to be flexible with regard to the extension of the moratorium until the next Ministerial Conference.

263. The representative of Angola, speaking on behalf of the LDC Group, supported the statement by Nigeria that had articulated the position of the African Group, and thanked the Chair for his efforts to achieve a compromise solution according to which the moratorium would either expire or be further extended. Noting that the Chair had based his evaluation on what he had heard from the majority of Members, he said that the Chair should consider suggesting that the moratorium be extended for another two years until the Ministerial Conference in 2013.

264. The representative of Ecuador believed that the view that non-violation and situation complaints should not be applicable to the TRIPS Agreement had merit. However, in order to facilitate the Council's work, he recommended a temporary solution for the Ministerial Conference, which would ensure minimum legal certainty in the field of IPRs. His delegation shared the willingness expressed by various other delegations to extend the moratorium.

265. The representative of Colombia said that a transparent, predictable and equitable mechanism for settling trade-related disputes in the context of IP was of crucial importance. However, the TRIPS Agreement, unlike other WTO Agreements, provided for minimum standards of IPR protection. Non-violation and situation complaints were unnecessary to protect the balance of rights and obligations inherent in the TRIPS Agreement, which were reflected in the Agreement's principal obligations and flexibilities. The Agreement explicitly stated that WTO Members were not obliged to implement more extensive protection. He reiterated his delegation's view that the moratorium should be extended. Accordingly, he expressed his delegation's readiness to work towards a satisfactory solution in the short term with a view to reaching an agreement to extend the moratorium at the Ministerial Conference in December.

266. The representative of Peru, endorsing the statements by the delegations of Pakistan, Nigeria, South Africa, Brazil and others, recalled that in 2002 his delegation had presented a document IP/C/385 jointly with 14 other delegations outlining its position on the matter. Non-violation and situation complaints were unnecessary to protect the balance of obligations inherent to the TRIPS Agreement. Those were already reflected in the main obligations and flexibilities of the Agreement. The Agreement specifically provided that Members were not obliged to apply broader protection. Peru thus considered that non violation and situation complaints were inapplicable under the TRIPS Agreement. However, in a spirit of compromise, his delegation was in favour of an extension of the moratorium from the upcoming Ministerial Conference until the next.

267. The representative of the European Union said that his delegation's view was that non-violation and situation complaints were not applicable to the TRIPS Agreement. However, it was willing to go along with the growing consensus on an extension of the moratorium.

268. The representative of Cuba stressed that, since it had been shown that there was no consensus on the expiry of the moratorium, there was no choice other than extending it. The grounds for disputes under subparagraphs 1(b) and 1(c) of Article XXIII of the GATT 1994 did not apply to IP. The moratorium which prevented their application should remain in force. However, he also referred to the existing consensus of unlinking the obligation of that article to the TRIPS Agreement.

269. The representative of Chile said that, since the Council was unable to overcome their substantive differences concerning non-violation and situation complaints, he supported the renewal of the moratorium for a two-year period until the following Ministerial Conference.

270. The representative of Switzerland said that his delegation's view on the application of non-violation complaints under the TRIPS Agreement was well known, and referred delegations for details to statements made by his delegation under that agenda item in previous meetings of the TRIPS Council. Both from a systemic and a legal point of view, Article 64.2 and 64.3 of the TRIPS Agreement was clear and unambiguous with regard to the principle that non-violation complaints were applicable under the TRIPS Agreement once the moratorium expired. Broadly speaking, the TRIPS Agreement was part of an overall WTO regulatory framework for market access. His delegation considered that the Dispute Settlement Understanding provided sufficient guidance with regard to non-violation and situation complaints in the TRIPS context. The moratorium provided for under Article 64 allowed for an examination of the scope and modalities of such complaints in the TRIPS context. However, since the moratorium had been further extended, no proposals or submissions had been received by the Council on the issue of such scope and modalities. Accordingly, his delegation was of the opinion that the moratorium should expire at the forthcoming session of the Ministerial Conference in Geneva. He said that his delegation took a constructive approach to the Chair's continuing his consultation on the way forward and thanked him for his efforts.

271. The Chairman proposed that the Council agree to keep this agenda item open and that he continue his consultations. He said that he hoped to be able to reconvene the Council once the further work was sufficiently mature, with a view to the Council agreeing on a recommendation to the Ministerial Conference.

272. The Council took note of the statements made and agreed to proceed as suggested by the Chair.

273. The Council reconvened on 17 November. In view of the absence from Geneva of the Chair of the Council, Ambassador González (Paraguay), the Council elected Mr. Martin Glass (Hong Kong, China) as an interim Chair for the reconvened meeting.

274. The Chairman recalled that, at its meeting of 24-25 October 2011, the Council had agreed to keep open the agenda item on non-violation and situation complaints and that the Chair continue his consultations on the matter. In the light of the consultations Ambassador González and he had held on the matter, he suggested that the Council agree to recommend, pursuant to the 2009 Ministerial Decision on "TRIPS Non-Violation and Situation Complaints" (WT/L/783), that the Eighth Session of the Ministerial Conference decide as follows:

> "We take note of the work done by the Council for Trade-Related Aspects of Intellectual Property Rights pursuant to our Decision of 2 December 2009 on 'TRIPS Non-Violation and Situation Complaints' (WT/L/783), and direct it 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 GATT 1994 and make recommendations to our next Session, which we have decided to hold in 2013. It is agreed that, in the meantime, Members will not initiate such complaints under the TRIPS Agreement."

275. The representative of the United States said that the US position on this issue was well known. Her delegation believed that non-violation and situation complaints were fully appropriate in the context of TRIPS Agreement and that a consensus decision of the TRIPS Council was required to extend the moratorium on the use of such complaints, which was set to expire at the upcoming Ministerial Conference. The possibility of non-violation disputes had been part of the GATT dispute settlement system since the beginning. The TRIPS Agreement had been carefully negotiated to accommodate different legal regimes and to accommodate Members' need to achieve policy objectives. The availability of non-violation complaints would merely assist Members in their efforts to preserve the balance of concessions and to protect against measures that frustrate legitimate expectations.

276. As her delegation had noted in the past, the failure to allow the possibility of non-violation disputes in connection with the TRIPS Agreements could invite Members to seek creative ways to avoid their TRIPS obligations. It continued to be of the view that it was entirely appropriate for non-violation and situation complaints to be applicable to the TRIPS Agreement and further, that without a consensus decision of the TRIPS Council, the moratorium would expire at the upcoming Ministerial Conference. However, her delegation was prepared to join consensus at the present meeting and could agree to extend the moratorium on non-violation and situation complaints until MC9. Of course, its decision at the present meeting was without prejudice to its continued position that non-violation and situation complaints were fully appropriate in the context of the TRIPS Agreement.

277. The representative of Switzerland said that his delegation's position on the matter was well known. It was particularly for systemic reasons that it was of the opinion that non-violation and situation complaints should apply to all WTO Agreements and therefore also to the TRIPS Agreement. However, it was prepared to join the consensus and was ready to have the moratorium extended until the ninth Ministerial Conference.

278. The Council agreed on the recommendation as proposed by the Chair.

I. REVIEW OF THE IMPLEMENTATION OF THE TRIPS AGREEMENT UNDER ARTICLE 71.1

279. No statements were made under this agenda item.

280. The Council agreed to revert to the matter at its next meeting.

J. REVIEW OF THE APPLICATION OF THE PROVISIONS OF THE SECTION ON GEOGRAPHICAL INDICATIONS UNDER ARTICLE 24.2

281. The Chairman recalled that Article 24.2 provided that the Council shall keep under review the application of the provisions of the GI Section of the Agreement. The principal tool used to coordinate the review process had been a Checklist of Questions contained in document IP/C/13 and Add.1, which a number of Members had submitted, but many had so far not completed.

282. In addition, at its meeting in March 2010, the Council had agreed to encourage Members to share information on and notify to the Council bilateral agreements related to the protection of geographical indications, which they have entered into. This had already produced some useful and

informative material. Peru and Korea had provided information on various bilateral agreements (documents IP/C/W/547 and IP/C/W/547/Add.1, respectively). At the Council's meeting in June 2010, Peru and Korea had provided additional information on bilateral agreements that were under negotiation and which had not yet entered into force. The United States had indicated that it was party to a number of bilateral and regional free trade agreements with provisions that addressed GIs and trademarks, and that these were available from the USTR's website. Brazil and Croatia informed the Council that they had not yet concluded any bilateral agreements on geographical indications.

283. At the Council's meeting in October 2010, the European Union informed the Council that it was party to a number of bilateral and regional free trade agreements with provisions that addressed the protection of geographical indications and that those agreements could be found on the website of the Directorate-General for Agriculture of the European Commission. China also informed the Council of two FTAs which contained a chapter on geographical indications, one of which had already been notified by Peru in document IP/C/W/547. The other FTA could be found on China's portal for FTAs at http://fta.mofcom.gov.cn, which contained English language versions of FTAs.

284. In line with the Council's recommendation made in March 2010, the Chair encouraged any Member that was party to any such bilateral agreement and had not yet shared such information with the Council to do so.

285. As the question of GI protection remained a continuing interest and discussion, he urged those delegations that had not yet provided responses to the Checklist of Questions to consider doing so. Equally, those Members that had already provided responses could provide updates to the extent there had been any significant changes to the way they provided protection to geographical indications. There was a considerable benefit to having up-to-date, accurate and geographically more representative material available as the basis of the on-going review process.

286. The Council took note of the information provided and agreed to revert to the matter at its next meeting.

K. NINTH ANNUAL REVIEW UNDER PARAGRAPH 2 OF THE DECISION ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT

287. The Chairman recalled that, at its meeting in February 2003, the Council had adopted a decision on the "Implementation of Article 66.2 of the TRIPS Agreement". Paragraph 1 of the Decision provided that developed country Members were to submit annually reports on actions taken or planned in pursuance of their commitments under Article 66.2. To that end, developed country Members were to provide new detailed reports every third year and, in the intervening years, updates to their most recent reports. Those reports were to be submitted prior to the last Council meeting scheduled for the year in question. The third set of detailed annual reports under the Decision had been presented to the Council's meeting in October 2009. At its meeting in June 2011, the Council had requested developed country Members to submit a second set of updates to those reports for the present meeting. The Secretariat had issued on 28 July an airgram (WTO/AIR/3788) to remind developed country Members of that request.

288. The Council had received updates to the third set of detailed annual reports from the following developed country Members: Norway; Japan; New Zealand; Australia; Canada; Switzerland; the United States; and the European Union and individual member States, namely, Austria, Denmark, Finland, France, Ireland, Lithuania, Slovakia, Spain, Sweden and the United Kingdom. This documentation had been circulated in document IP/C/W/558 and addenda. The report from the European Union had been circulated as an advance copy.

289. In addition, the Council had received two submissions from the delegation of Angola: document IP/C/W/561 containing a proposal by the LDC Group for a format for reports on the implementation of Article 66.2; and document IP/C/W/562 containing questions posed by the LDC Group concerning the reports that had been submitted for the eighth annual review and circulated in document IP/C/W/551 and addenda.

290. He recalled that, as regards the purpose and conduct of the review of that information, paragraph 2 of the Decision on the Implementation of Article 66.2 of the TRIPS Agreement explained that the annual review meetings should provide Members with an opportunity to pose questions in relation to the information submitted and request additional information; to discuss the effectiveness of the incentives provided in promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base; and to consider any points relating to the operation of the reporting procedure established by the Decision.

291. Since some of the information had been received only recently and most of it was available only in its original language, he said that he intended to provide an opportunity, at the Council's next meeting, for Members to make further comments on the information submitted thus far that they might not yet have been able to study, and to comment on any additional information that might yet be provided before that meeting.

292. He said that for the fourth year in a row the Secretariat had organized, at the request by LDC Members, a workshop on transfer of technology under Article 66.2 of the TRIPS Agreement, back-to-back with the Council's end-of-year meeting. The workshop had been convened on the morning of Friday, 21 October. It had again brought together LDC and developed country experts to discuss the subject at a very practical level, building on earlier workshops. It was his understanding that the workshop had provided an opportunity once again for a constructive exchange of views, which had been useful to both LDC and developed country delegations.

293. The representative of the United States said that his delegation had submitted an extensive report on its efforts relating to the implementation of Article 66.2, detailing many activities undertaken by enterprises and institutions in the United States for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base. He highlighted two aspects of the report: the US activities with respect to international students; and best practices of universities that facilitated technology transfer.

294. With respect to international students, he said that the United States promoted the enrolment of students worldwide in its national universities. US universities were largely established as tax-exempt entities, and the education they provided was subsidized by the US taxpayer in the form of foregone tax revenues. Welcoming foreign students to universities in the United States not only helped in building a sound technological base in developing countries, but also enhanced the US university system with the unique experiences of international students.

295. In 2010, 690,923 international students were enrolled in US institutions of higher education, representing 3.5 per cent of the total US higher education enrolment. The top three countries of origin for foreign students in the United States were China (127,628 students), India (104,897) and South Korea (72,153); and the top four fields of study for foreign students were business and management, engineering, physical and life sciences, and mathematics and computer science, all of which were significant sources for technology transfer. The least developed country with the most students enrolled in US institutions of higher education in 2010 was Nepal with 11,233 students. The total 2010 enrolment in US institutions of higher education for all least developed countries was 26,685 students altogether.

296. Once their education was completed, many of those students returned home, bringing with them new technologies, new processes, new research approaches and an understanding of the role of open markets and democracy in the US innovative society. They had the skills to create and enhance their own nation's sound and viable technological base, including contacts in the United States and throughout the world who could contribute to that process.

297. He said that the best practices that encouraged technology transfer from US universities included:

- The publication of research results in open academic literature that were accessible globally through the Internet;
- Personal interaction between creators and users of new knowledge (e.g. through professional meetings, conferences, seminars, industrial liaison programs and other venues);
- Collaborative research projects;
- Entrepreneurial activity of faculty and students occurring outside the university without involving university owned intellectual property (IP); and
- Licensing of IP rights to established firms or to new start-up companies.

298. The representative of Australia reaffirmed her country's commitment to assisting least developed Members in the area of technology transfer pursuant to the Council's Decision on the implementation of Article 66.2 of the TRIPS Agreement. She welcomed the holding of workshops on that issue, in which Australia had participated since their inception in October 2008, including the most recent meeting held the previous week. The workshops provided a useful forum for an exchange of views to enhance understanding on both sides on the preparation and reading of the reports.

299. Australia had submitted an updated report for 2011 providing examples of development assistance over the preceding year which might have a technology transfer component. In Australia's report, technology transfer was understood to include training, education and knowledge. Australia recognized that technology transfer was best fostered in an open and market-based economy and fundamental to that requirement was good governance. Australia provided extensive governance capacity building and technical assistance to least developed countries. Australia considered that education of LDC nationals and their training in the use and management of technological equipment constituted two of the most effective means for the transfer of technology and knowledge. A significant proportion of Australia's assistance was directed at providing education and training. In Australia's updated report the total value of Australian assistance to least developed countries in 2010-2011 was approximately $A860 million.

300. The representative of Switzerland thanked the Secretariat for organizing another useful workshop. In that context he referred to the suggestion by Angola, on behalf of the LDC Group, for a standardized format for reports submitted by the developed country Members under Article 66.2 and of how future reporting could be streamlined. Although some standardization could be envisaged, he stressed the need for further discussion. He emphasized that, generally, reporting should be kept as lean as possible and should not be reporting for its own sake. The longer and more complicated reports became, the bigger the risk that they were not being read and made use of. With regard to the LDC Group's list, Switzerland might give consideration to points 1, 2, 11, 12, 13 and 14 as relevant for its reporting, as well as who was a beneficiary in which country, and possibly also the field or sector of technology transfer, provided that there was a set of relevant and defined categories to choose from. He said that he would take the LDC Group's feedback and proposal back to capital and

that the input would be further examined in connection with the drafting of the following year's new report.

301. The representative of Angola, speaking on behalf of the LDC Group, thanked developed country Members for their 2010 reports concerning the implementation of Article 66.2, as well as for their availability and the responses provided at the workshop. He also thanked the Secretariat for its valuable contribution to the work and for holding the workshop.

302. The mechanism established by the 2003 Decision of the TRIPS Council for ensuring the monitoring of Article 66.2 had laid the groundwork for improving the full implementation of developed Members' obligations in providing incentives to enterprises and institutions for the purpose of promoting and encouraging technology transfer to least developed countries. The overall objective was to assist LDC Members in designing their contribution to move forward significantly the implementation process articulated in Article 66.2. To that end, it required the adoption by developed countries of incentive measures for promoting and encouraging technology transfer to the least developed countries. The optimal objective was to enable them to create a sound and viable technological base for development in accordance with the position articulated by the LDC Minister in the Dar-Es-Salaam Declaration of 2009. In the light of that final objective, developed countries were therefore required to provide their annual updated report to the Council to be in compliance with their obligation.

303. An analysis of the 2009 reports submitted by developed countries under Article 66.2 on measures undertaken the previous year shed light on some key points for ensuring effective implementation of that provision. In the first place, it demonstrated that the content and format of reports should be structured and harmonized in order to ensure consistency of data from all developed country Members. He said that some progress had been made at the individual level by some developed country Members. For example, Canada had made substantial progress in following the structure of the table presented by LDCs during the previous workshop, and also Switzerland had made use of it.

304. Two substantive issues remained critical, namely, a lack of a common definition of technology transfer coupled with a lack of common understanding of the type of incentive required for effective technology transfer. The reports revealed a lack of common definition, in particular in the area of technology transfer. In his view technology transfer was a process involving/requiring physical objects or equipment. Incentives for technology transfer could encompass financial incentives, a grant facility, a loan, a tax exemption scheme, an investment, but they could also include technical advice, training, infrastructure-related to programmes and the like.

305. In his view, further work was needed to address those issues. There was also need for greater clarity in defining and circumscribing the beneficiaries of Article 66.2. Article 66.2 required developed countries to provide incentives for the purpose of promoting and encouraging technology transfer to least developed countries. Even so, some of the projects contained in the reports related to developing countries in some cases. For example, the EU report referred to several programmes that were unrelated to LDCs, including one project related to an IP office in Ukraine.

306. He stressed the non-binding nature of the working document and that it could be improved through their debate. There was a need for agreement on the key points, namely what should be seen as technology transfer and what types of incentives should be provided. It would also be important to know whether the enterprise benefiting from the incentive was located a least-developed, or developing country or elsewhere.

307. The representative of the Secretariat recalled that the purpose of the workshop convened by the Secretariat at the request of the LDC Group had been to enable the Members most concerned to

discuss current documents in a more detailed and informal way than was possible in the Council itself. A very interactive discussion had taken place on the extensive reports from each of the reporting developed countries. He had observed a positive feedback loop, a discernible effort by reporting developed countries to take up some of the proposals from previous workshops to develop more focused and more LDC-specific information.

308. One of the cross-cutting issues concerned how to distil from broader reports on overseas development assistance the specific technology transfer component, both in terms of defining particular activities, and in terms of the actual expenditure or the size of the funding behind that component of the activities. One of the continuing themes in that workshop, as in preceding workshops, was exactly how to define the scope of "technology transfer".

309. One other practical aspect concerned the overlap between reporting under item Article 66.2 and the broader process of reporting TRIPS-related technical assistance programmes under Article 67. There were discussions on exactly how to draw that distinction between these two reporting processes as well as comments that there were inevitably overlaps between the two and in some cases those were deliberately reported under both items.

310. He said that there had been a positive and productive spirit in the workshop, and a strong interest in continuing that kind of process to keep the feedback loop working. Unless other procedures were set up, he said that the Secretariat was prepared to organize a similar workshop at the same juncture next year, a particularly important juncture given that 2012 represented the due date for the full detailed report, rather than the updated report from developed countries. He thanked, on the part of the Secretariat, the delegations concerned for their participation and for their efforts in preparing for three very productive mornings' work. He also thanked his colleagues in the IP Division for their hard work and said that their energies where indispensable in making the workshop a success workshop.

311. He said that, from a purely practical and operational point of view within the Secretariat, given its central task of processing and dealing with the information submitted in that process, the increasing use of the material to respond to the demands of technical cooperation in this area, the growing resource implications for the WTO in presenting and formatting this information, and the practical challenges that users of this information had in gaining a synoptic overview of the extensive information submitted in the notifications, there might be some practical value in continuing the discussions about more systematic or more convergent formats and structures for notifications, particularly in view of the fact that it was in the coming year, 2012, that the next batch of new detailed reports fell due. Similar considerations might also apply to the submission of updates and reports under item L on technical assistance, given especially the acknowledged overlap between reports under both items that was discussed at the workshop.

312. The representative of Angola, speaking on behalf of the LDC Group, said that he believed that developing countries that were in a position to do so could also be invited to make contributions on a non-compulsory basis on South-South cooperation. As regards the suggestion by some developed country Members that LDCs identify the needed technology, he said that the needs assessments for technical cooperation conducted by six LDCs mentioned the need for research centres to have information exchange between academics, researchers, and experts in terms of innovation, creativity, and the like. This could be another basis on which delegations could work. In addition, a technology assessment had been conducted through the national adaptation programme of action called NAPA in the framework of negotiations on the environment. Forty-seven countries had already submitted their needs assessments, including the least developed countries who had submitted their needs in terms of technology, adaptation, etc. That was another source that could be consulted.

313. He looked forward to continuing discussion on the proposed format for reports under Article 66.2 and expressed the hope that the following year the majority of reports would take into account one or two areas of the suggested format and that a specific format would be decided for more particular information.

314. The representative of Norway said that some questions had been posed concerning its report under Article 66.2. Since her delegation had been unable to participate in the workshop, she said that it would reply to those questions in writing.

315. The representative of Haiti welcomed the very constructive workshop organized by the Secretariat that had provided an opportunity for Members to speak freely. He expressed his appreciation to the delegations whose reports had included Haiti as a beneficiary of some of the programmes. He expressed the hope that other delegations would also include his country in the context of the implementation of Article 66.2. He trusted that the fifth workshop which would undoubtedly be convened the following year would ensure more clarity, with a focus on enhanced understanding and broader application in terms of transfer of technology. To that end, he fully supported the communication presented by Angola on behalf of the LDC Group Members concerning the proposed format for reports submitted by the developed country Members under Article 66.2. He believed that focusing on the various issues raised by Angola should help in improving the quality of reports and moving forward even more. He looked forward to achieving progress towards enhancing the quality of the reports and was confident that the Secretariat would facilitate the achievement of that common objective, with a continuing focus, whether by developed or developing country Members, to permit efficient participation of developing countries in the multilateral trading system.

316. The Chairman expressed his appreciation to the delegations concerned and the Secretariat for their contributions and preparations that had made the workshop held the previous week very useful and constructive. He encouraged those delegations to continue their discussions in order to facilitate their work and enhance the quality of reporting. He urged those developed country Members who had not yet provided reports to do so as soon as possible, and reiterated his intention to provide another opportunity, at the Council's next meeting, for Members to make further comments on the information submitted for the present meeting that they had not yet been able to study.

317. The Council took note of the statements made.

L. TECHNICAL COOPERATION AND CAPACITY-BUILDING

318. The Chairman recalled that the Council had agreed at its meeting in June 2011 to hold its annual review of technical cooperation at the present meeting. He suggested that, in that context, the Council also discuss other issues relating to the agenda item, including LDC priority needs for technical and financial cooperation.

319. In preparation for the annual review, developed country Members had once more been requested to update information on their technical and financial cooperation activities relevant to the implementation of the TRIPS Agreement in time for the meeting. Other Members who had also made available technical cooperation had also been encouraged to share information on those activities if they so wished. The Secretariat had issued on 28 July an airgram (WTO/AIR/3787) reminding Members of that request. In addition, intergovernmental organizations who were observers to the Council as well as the WTO Secretariat had also been invited to provide information.

320. The Council had received information from the following developed country Members: Norway; Japan; New Zealand; Australia; Canada; Switzerland; the United States; and the European Union and individual member States and agencies, namely Austria, Belgium, Bulgaria, the Czech Republic, Finland, France, Germany, Italy, Lithuania, Portugal, Romania, Slovenia, Spain, and

the United Kingdom, as well as the European Patent Office (being circulated in document IP/C/W/560 and addenda). Updated information had been received from the following intergovernmental organizations: the WCO, WHO, UNCTAD and WIPO (document IP/C/W/559 and addenda). Updated information on the WTO Secretariat's own technical cooperation activities in the TRIPS area could be found in document IP/C/W/557.

321. In addition, Canada had provided an update to its notification of a contact point for technical cooperation on TRIPS. The information on the Members' transparency toolkit page had been updated accordingly.

322. With regard to LDC needs assessments, he recalled that paragraph 2 of the TRIPS Council's 2005 decision on the "Extension of the Transition Period under Article 66.1 for Least-Developed Country Members" provided that "with a view to facilitating targeted technical and financial cooperation programmes, all the least-developed country Members will provide to the Council for TRIPS, preferably by 1 January 2008, as much information as possible on their individual priority needs for technical and financial cooperation in order to assist them taking steps necessary to implement the TRIPS Agreement". Such information had been received from six Members, namely Sierra Leone, Uganda, Bangladesh, Rwanda, Tanzania and Senegal.

323. The Council's 2005 Decision also provided that developed country Members were to provide technical and financial cooperation in accordance with Article 67 in order to effectively address the needs identified by LDCs. Furthermore, the Decision called for the WTO to enhance its cooperation with WIPO and other relevant international organizations with a view to making technical assistance and capacity building as effective and operational as possible.

324. He recalled that, at the Council's meeting in June 2009, the LDC Group had requested the WTO Secretariat to arrange a series of events to discuss LDCs' priority needs and the coordination of technical assistance to respond to the needs identified by LDC Members. Following up earlier similar activities it had organized in response to that request, the Secretariat had held the previous week a three-day Symposium on LDC Priority Needs for Technical and Financial Cooperation, which was convened to build on the lessons learned from individual needs assessments and from the series of regional workshops held in 2010. The purpose of the Symposium was to bring together key representatives from the least developed countries, cooperating partners in developed countries and international and regional organizations with a view to sharing experiences on the process thus far, as well as on-going activities and outstanding needs to complete the process.

325. The representative of the Secretariat said that the details of its technical cooperation activities concerning TRIPS undertaken between 1 October 2010 and 30 September 2011 could be found in document IP/C/W/557. The report recalled that the Secretariat's technical cooperation activities relating to TRIPS continued to focus on assisting Members to understand the rights and obligations under TRIPS, including flexibilities and the full range of available policy options. An increasing focus was laid on building self-sustaining capacity in developing countries, including through the training of trainers and strengthening regionally-based expertise rather than relying on centralized expertise. Technical cooperation continued to be essentially demand driven against a background, however, that Members were expressing an increasing diversity of needs and interests. This in turn was leading to an increased tailoring and focussing of technical assistance activities on specific areas of interest or sectoral policy themes, complementing long-standing activities that provided general overviews of the TRIPS Agreement.

326. The past focus on ensuring complementarity and cooperation with other inter-governmental organizations had been further enhanced with a particular focus on coordinating on public health and IP technical assistance with its sister organizations, the WHO and WIPO.

327. Highlighting two Geneva-based specific activities, he first mentioned the eighth joint WIPO-WTO Colloquium for teachers of IP from developing countries. The colloquium corresponded with a broader programme objective of building capacity within the academic community in developing countries, so as to strengthen self-sustaining know-how and research and policy analysis capacity in those countries, with a view to strengthening the independent and teaching capacities of developing countries on IP law and policy. The papers presented at the Colloquium in 2010 were of such a quality and value that they had been collated and published jointly by WIPO and the WTO as a resource, so as to provide a unique and authoritative insight for researchers and analysts covering contemporary IP and TRIPS issues within a wide range of developing countries, a wider range that was often covered in conventional academic publishing.

328. The same period saw the third joint WIPO-WTO Advanced Course on Intellectual Property, which drew on the experience of earlier successful colloquia for teachers of IP, and applied a similar programme structure and pedagogic strategy, but was tailored and focused on government officials and public sector policymakers from the developing world. The course was able to work from a truly advanced baseline given the high level of applications and expertise involved among participants and thus was able to explore cutting edge issues through interactive debate and practical case studies, so as to strengthen the capacity of government officials and policy makers to critically review policy options and their implications, and to learn from the wide range of practical experiences that were available in those programmes.

329. The technical cooperation activities outside Geneva had been led by the evolving demand from Members leading to an increasing focus on the interplay between TRIPS and specific areas of public policy, including public health, but also biotechnology, traditional knowledge and biodiversity, geographical indications, current copyright issues and environmental issues, including climate change. A key objective had continued to be a focus on health-related flexibilities in the TRIPS Agreement and policy options in the public health field, including the implementation of the Paragraph 6 system. The planning of such activities followed a new and improved format designed to respond to demands from Members to put WTO and TRIPS technical assistance into the larger context of policy choices with a particular focus on current developments and challenges.

330. The reporting period had also seen an increased focus on activities with the sister organizations that applied especially in the field of public health. The Secretariat had organized jointly with WHO and WIPO a technical symposium on "Access to Medicines, Patent Information and Freedom to Operate". The objective of the symposium had been to build on the first event in that series of joint symposia but more specifically to highlight the value of access to patent information in the context of ensuring access to medicines. It had provided an opportunity for participants with different backgrounds from government, civil society organizations and industry to share experiences, to take stock and look at future needs in that field.

331. The symposium on the LDC needs assessment process had been a structured activity stemming from the 2005 Decision of the TRIPS Council concerning LDC individual priority needs relating to TRIPS implementation and in particular the request made by Angola and Tanzania on behalf of the LDC Group at the Council's meeting in June 2009. That process included regional workshops for Francophone Africa, for Anglophone Africa and for the Asia-Pacific region and so the previous week's activity had been a culminating event that had drawn together experience harvested in each of those regional workshops and to consider informally the way ahead. The structure of the workshop conceptually followed the main elements of the 2005 Decision of this Council, involving the three steps of the identification of individual priority needs by LDC Members; the response by developed country Members to the needs identified; and the coordination role of the WTO vis-à-vis other international organizations. In particular, the workshop had focussed on the experience of the Members concerned, particularly those Members who had notified the Council of their individual priority needs. It also considered the role of intergovernmental organizations, including the WTO,

WIPO, UNCTAD and active NGOs involved in the needs assessment process, i.e. the ICSTD, as well as reports by a number of active developed county Members on their relevant technical assistance programmes so as to promote coordination between the needs identified and the responses available.

332. The Symposium had used a process that had worked very well in the regional symposia, namely a series of informal bilateral meetings, matchmaking meetings that enabled the least developed countries concerned to sit down with donors, IGO and developed country programmes so as to look for opportunities concretely for responding to the needs identified. The programme concluded with a roundtable review session which touched on a number of important points of potential follow up. Among those was the challenge of meeting the needs that had been identified, in particular the needs identified in the six submissions already tabled to the Council. The discussion had focused on strategies to ensure availability of coordinated and effective resources to address the needs identified. Proposals included better use of contact points, the existing contact point list established under the Council for technical assistance, as well as developed countries taking up specific elements in the assessments and looking for follow-up in those areas.

333. A proposal had been discussed concerning specific coordination events that would focus on the specific needs assessments that had been tabled, country by country, and that would bring together development assistance partners for a coordinated discussion and follow up on the specific elements of needs assessments, particularly those elements that had not been responded to so far. Those activities could be stand-alone or could be incorporated in other events, such as a further series of such symposia, if it was agreed to go ahead with a further series.

334. He said that there was a strong focus on better coordination for existing technical assistance programmes that went beyond the obvious label of TRIPS implementation and touched on other areas of development cooperation that were relevant to TRIPS and sectoral interests under TRIPS implementation, as well as better use of the notifications made to the Council under Article 67 to identify relevant programmes. In addition, a toolkit was under development that would draw together a great deal of the experience in that area and that would be used as a repository for sharing practical experience so far as well as identifying relevant programmes.

335. A continuing focus had been on improving inter-agency coordination with the possibility of more frequent coordination meetings than the relatively infrequent meetings that had been taking place so far, as well as looking at the important role of regional and subregional organizations, and communicating practical experience with optimal national strategies for both coordinating on the needs assessment process and the responses to needs identified. He said that the Secretariat would continue to do what it could to support further coordination in the light of directions received from Members, including from the Members most concerned, the Group of LDC Members.

336. The representative of Angola, speaking on behalf of the LDC Group, thanked the Secretariat and the other relevant organizations, in particular WIPO and UNCTAD, for the work they had undertaken in relation to the needs assessment process. He said that, since the implementation of the Decision of the Council for TRIPS of 29 November 2005, only six LDC Members had submitted their individual needs assessment between 2005 to 2008, namely, Sierra Leone, Uganda, Rwanda, Tanzania, Bangladesh and Senegal, and to date no clear response had been received concerning funding. He cited the example of Uganda, who had identified its priority needs and submitted its needs assessment to the Council in 2008. The total amount that it had requested in order to introduce reforms on the domestic level to implement the TRIPS Agreement was US$11,000 dollars over five years, a figure known to the World Bank. To date there had been no response. He also cited the example of Senegal who had submitted its needs assessment to the Council in 2010 and had assessed its needs as amounting to US$8.5 million. That assessment had been evaluated by WIPO but to date no response had been forthcoming to their funding request. Furthermore, in 2006 Bangladesh had carried out its assessment amounting to US$71.4 million, which included the enhancement of a

research centre for the implementation of the TRIPS Agreement. However to date no response had been received.

337. He noted that of the 32 LDC Members of the WTO most still had to submit their needs assessment reports. The workshop had raised a crucial point concerning the lack of available funding to conduct needs assessments, in the light of the economic and financial crisis, and budgetary problems. It was well known that countries were affected by the current crisis, in particular the developed country Members, which had led to a lack of follow up in financial assistance. In light of the economic crises, the LDC Group of Members were unsure whether they were in a position to fulfil their obligations within the additional transition period under the 2005 decision that would expire. For that purpose, they would welcome any financial assistance to support them.

338. He believed that it was crucial to give careful consideration to a possible extension of the transition period for instance until 2020. The LDC Group intended to submit a proposal based on the same reasoning that was put forward for the waiver in 2005 which continued to be valid. It believed that an extension should be requested in the light of the economic crisis to assist LDC countries and obtain the necessary funding.

339. The representative of Nigeria, speaking on behalf of the African Group, expressed his appreciation of the reports on the implementation of Article 67 of the TRIPS Agreement. As regards the needs identified by Sierra Leone, Uganda, Rwanda, Senegal and other LDCs, he noted that there had been some movement in some of the areas with regard to the requests but not in others. To that end, he suggested that, if acceptable to it, the Secretariat would prepare a note at least trying to indicate the areas that had been implemented in those countries that had submitted their needs assessment, as well as the outstanding areas. That would give the Council a general picture of what was happening and would help Members to see how to implement Article 67.

340. The representative of the World Health Organization said that, given its distinctive mandate, the WHO only undertook technical cooperation activities to further the interest of public health. Technical cooperation activities on IP were not undertaken with the purpose of implementing the TRIPS Agreement as such, but to support the application and management of IP in a manner that enhanced health-related innovation, especially to meet the R&D needs of developing countries, and promoted access to medicines for all.

341. The WHO technical cooperation was driven by demand and based on its mandate derived from the Global strategy and plan of action on public health, innovation and IP as well as other relevant resolutions adopted by the World Health Assembly. The focus of implementation activities was on technical cooperation, including transfer of technology, capacity building and training as well as direct technical assistance to Member States. Details of the activities carried out in the past two years were contained in document IP/C/W/559/Add.1.

342. Further to the adoption of the Global strategy and plan of action, the WHO, WIPO and WTO had strengthened their efforts to coordinate work in the field of public health and IP to foster the understanding of public health policy and IP and to increase efficiency in capacity building and technical cooperation. Within the scope of that trilateral collaboration, the three organizations had started to organize a series of joint technical symposia to enhance the dialogue between the relevant organizations and provide a platform for exchanging information and experiences. The second symposium on "Access to medicines, Patent Information and Freedom to Operate" had been held in 18 February 2011 at the WHO in Geneva.

343. Currently, the three organizations were preparing a joint study on "Promoting access and medical innovation: intersections between public health, intellectual property and trade". The study was meant to be a sequel to the joint study by the WHO and WTO Secretariats on WTO agreements

and public health published in 2002. The study would not only cover the relevant IP issues, but also issues about procurement, regulatory issues, mark ups in the supply chain, voluntary license agreements and tiered pricing, taxes, tariffs and other elements.

344. Following the negotiations on Pandemic Influenza Preparedness Framework, WIPO and the WHO had been jointly developing a global patent landscape on patenting trends in the field of vaccines. Until then, no comprehensive overview on patent trends in the field of vaccines existed. The patent landscape report was intended to provide an overview on what was being patented in terms of disease targets and approach, who was doing the patenting, where patents were filed and on how patent policies had changed over time.

345. To implement the 2006 Global Pandemic Influenza Action Plan (GAP), the WHO had facilitated transfer of influenza vaccine production technology to eleven developing country vaccine manufacturers.

346. To facilitate access to live attenuated influenza vaccine technology for producing a high-yield low-cost vaccine that was easy to administer, the WHO, on behalf of developing country vaccine manufacturers, had negotiated and acquired a transferable non-exclusive licence to that technology. Sub-licences to that technology had been granted to three developing country vaccine manufacturers and one of those was already marketing the resulting vaccine.

347. In vaccine production, adjuvants were used to enhance the immune response to an antigen, and enable the use of less antigen per dose of vaccine and hence, an increase in the number of doses that could be produced. To overcome current know-how barriers, the WHO had facilitated the establishment of an adjuvant technology transfer hub that was using the information described in patents on adjuvants to establish production processes in developing countries where the patents were not filed or granted. The technology had thus far been transferred to one developing country and technology transfer to another developing country was in process.

348. As part of the on-going trilateral collaboration, the WHO had also participated actively in training and capacity building workshops organized by and in collaboration with the WTO and WIPO.

349. In response to a question earlier raised by Nigeria with regard to voluntary licences, he said that the WHO had seen an increase in voluntary licensing programmes by research-based pharmaceutical industry in the past years. Those voluntary licence agreements concentrated on HIV Aids products and anti-viral treatment against influenza. While welcoming that development, he agreed with the delegation of Nigeria that little research had been undertaken concerning the detailed provisions in such licence agreements and what criteria from a public health perspective should be included. Further research and guidance was needed to increase the public health impact of such agreements.

350. The representative of the United States said that he wished to take the opportunity to reflect further on Nigeria's proposal with respect to a report to be produced by the Secretariat. On a preliminary basis, he said that he had some questions concerning the entity which should be responsible for collecting and providing that information. He welcomed a further chance to review those elements.

351. The representative of the European Union said that the European Union had played a significant role in helping least developed countries to fulfil their TRIPS obligations, and not only those who had submitted their needs assessments to the WTO. In particular, it had already funded technical assistance with Bangladesh, Uganda and Zambia and had engaged in talks on how to provide assistance to Sierra Leone. It had also funded regional work, including with COMESA, OAPI and ARIPO.

352. The European Union funded its assistance in the ACP and overseas territories through the European Development Fund, and with other regions through the Development Cooperation Instrument. There were also EPA (Economic Partnership Agreement) components within the European Development Fund, such as the EPA Eastern African Community Support Programme – those had been used to provide IP-related assistance.

353. The European Development Fund financed a number of organizations who worked closely with least developed countries in the ACP region, including TradeCom, BizClim, and the ACP-MTS Programme, who could assist least developed countries in formulating requests for technical assistance.

354. As to the more recent submissions by Bangladesh, Rwanda and Tanzania, the European Union would be looking to help them and see how it could provide assistance in the context of existing EU programmes and in coordination perhaps with other projects.

355. Uganda, who had submitted its individual needs earlier, had recently benefited from two projects financed by the European Union within existing programmes. The first project involved technical assistance by BizClim with the objective of strengthening public-private dialogue to update Uganda's national IP policy legal and regulatory framework; the second co-involved technical assistance by TradeCom to the Uganda Ministry of Tourism, Trade and Industry in the area of IPRs. The European Union was also in contact with Sierra Leone who had submitted its individual needs recently.

356. Following on from the excellent Symposium that had been held in the WTO the previous week over three days, the European Union looked forward to dealing with requests as they came in. He assured Members that they would be given serious consideration.

357. The representative of Tanzania supported the statement by the delegation of Angola and expressed her appreciation to the developed country Members for their reports. She said that Tanzania had submitted its assessment of priority needs for technical and financial cooperation in October 2010 pursuant to the Decision of the TRIPS Council of 29 November 2005. According to paragraph 2 of that Decision, all the least developed countries were required to submit their priority needs assessment preferably by 1 January 2008. However, given the various difficulties they faced, the deadline had not been met by many LDCs.

358. With regard to the submission of its assessment, Tanzania had benefited from the support of some Members, which had led it to believe that it would receive the necessary technical and financial support from developed Members and donors with a view to building its IPR trade-related capacity. However, one year afterwards, no Member or donor had fulfilled their obligations as yet under Article 66.1 following the submission of Tanzania's priority needs assessment.

359. Her delegation called on Members to fulfil their obligations to support LDCs pursuant to the TRIPS decision and requested developing country Members who were in a position to do so to help in that common task. Tanzania was in need of their assistance at present more than ever before, and with it other Members who had already submitted their needs assessments.

360. The representative of Rwanda welcomed the trade support provided by the European Union, especially to the countries that had already submitted their needs assessment and urged it to continue its support. His delegation looked forward to discussing how to best provide such support.

361. The representative of Switzerland thanked the WTO Secretariat for organizing the recently held symposium. It had provided an opportunity for least developed and developed country Members to share their views on the needs assessment process, as well as focusing on the steps required for

further implementation, and making contact and exchanging information. He commended the delegations of Senegal, Tanzania, Rwanda, Bangladesh, Uganda and Sierra Leone for the work achieved and for sharing the information among WTO Members.

362. The symposium had shown that a number of open questions remained to be answered. Smaller countries needed to provide assistance with a focus on LDC Members in which they had substantial experience and resources available for development cooperation. Over the last year, Switzerland had intensified its work in the context of its technical assistance with Bangladesh. The next significant step towards implementation of the projects was planned to be taken shortly. Switzerland's bilateral cooperation for technical assistance could then be intensified.

363. His delegation expressed its interest in following closely the Secretariat's on-going work to ensure enhanced coordination between the various stakeholders involved. Those efforts and any further exploration of the crucial funding issue would facilitate their moving to the next stage of meeting the important needs of LDCs stemming from their priority needs assessment.

364. The representative of Nigeria noted the statement by the delegation of Tanzania welcoming the pledge by the European Union to provide support, and said that Sierra Leone and Uganda had submitted their needs assessment already in 2007 and 2008, respectively. He wondered how the Chair intended to proceed with his suggestion that the Secretariat prepare a note with a view to engaging Members in the next Council meeting, also noting that that the delegation of the United States had said that it needed some time to consider the matter.

365. The Chairman proposed that, since a delegation had indicated that it needed further time for consideration, the Council revert to the suggestion by Nigeria at its next meeting.

366. The Council took note of the statements made and so agreed.

M. LETTER FROM THE CHAIR OF THE GENERAL COUNCIL CONCERNING WAYS TO IMPROVE THE TIMELINESS AND COMPLETENESS OF NOTIFICATIONS AND OTHER INFORMATION FLOWS

367. The Chairman recalled that, at its past few meetings, the Council had had on its agenda the letter from the Chair of the General Council concerning ways to improve the timeliness and completeness of notifications and other information flows in the area of its responsibility. In order to facilitate the Council's consideration of that issue, the Secretariat had presented to the October 2009 meeting a factual background note (IP/C/W/543) it had prepared at the Council's request that summarized the relevant procedures and provided information on the use of those procedures. It also contained suggestions on how to improve the transparency and user-friendliness of the notification system. Furthermore, at the subsequent meeting, the Secretariat had orally reported on further developments in that area. Those delegations that had spoken on the issue had supported the suggestions contained in that note to improve the transparency of the system, and encouraged the Secretariat to continue to pursue that task. At its last meeting, the Council had agreed to revert to the agenda item at the present meeting so as to provide Members with a further opportunity to share any comments that they might have on the matter, and also to allow the Secretariat to inform the Council on any further enhancements to its services improving the transparency and user-friendliness of the notification system.

368. The representative of the Secretariat said that a core objective of the work on the timeliness and completeness of notifications and other information flows was to make that material available in a more user-friendly way. The exercise was undertaken entirely within the parameters already set by the Council's own decisions and by the TRIPS Agreement itself, and followed directly the outline set out in document IP/C/W/543. The current focus was on reviewing the body of notifications, a collection of over 15 years' worth of documents that amounted to a massive body of data, data which

was indispensable and highly useful for a number of practical uses, but taken together represented a significant information management challenge. Hence the increasing focus was on examining ways of using appropriate information technology tools to improve the usability and the accessibility of those data and to reduce wasteful and expensive paper-based approaches. That work took place within the context of a broader effort across the Secretariat towards a more integrated holistic approach to managing notification data.

369. In addition, there was a particular focus to address the backlog of notified material that was not yet available in text-searchable form. A further focus would be to work towards more user-friendly web tools for accessing and using the information contained in notifications, notifications that were essentially circulated or had been circulated solely as Council documents, rather than more accessible forms of information. That work would build on the initial work already undertaken as a pilot project in converting the contact point lists from a series of Council documents to a more easily consulted drop-down web list. The successful implementation of the common portal with WIPO for the submission of legislative texts and the improvement in timeliness and completeness of notifications that it had facilitated suggested that it might be possible also to look at other avenues for further cooperation along those lines, given the overlapping responsibilities between the WTO and WIPO that were recognized in the TRIPS Agreement itself. Other avenues might include facilitating the submission of texts through a notification tool and the continuing focus on suggested standard notification formats to facilitate the work, both of delegations and of those seeking to manage and process the data.

370. The notification materials were increasingly being used in technical cooperation activities responding to the demand from Members for information at a very practical level and in a factual way of the approaches taken by Members in relation to various areas of IP, law and policy. Further technical assistance activities had also promoted understanding of the notification processes, so as to advance the timeliness and completeness of notifications under the TRIPS Agreement.

371. The Chairman suggested that the Council revert to this agenda item at its next meeting so as to provide Members a further opportunity to share any comments they might have on the matter, and also to allow the Secretariat to inform the Council of any further enhancements to its services improving the transparency and user-friendliness of the notification system.

372. The Council took note of the statements made and so agreed.

N. AUSTRALIA'S TOBACCO PLAIN PACKAGING BILL 2011

373. The Chairman said that this item had been put on the agenda at the written request of the delegation of Ukraine.

374. The representative of Ukraine said that his delegation had already expressed its concern over Australia's proposed Tobacco Plain Packaging Bill 2011 at the Council's meeting in June 2011, stating its view that enacting the proposed legislation into law as drafted would violate a number of Australia's WTO obligations. These included several obligations under the TRIPS Agreement as well as certain provisions of the Paris Convention for the Protection of Industrial Property that had been incorporated into the TRIPS Agreement.

375. Since the Council's last meeting, he said, there had been a number of important and highly troubling legislative developments in Australia on the Tobacco Plain Packaging Bill 2011 and the accompanying Trade Mark Amendments Bill 2011, as the legislation had passed the House of Representatives in late August without any substantive amendments and was currently pending before the Senate, where it was expected to be voted on and passed soon. He said that it was not yet clear whether there would be substantive amendments to the legislation in the Senate that would render it

more compatible with Australia's international treaty obligations, but his government continued to hope that such amendments would be offered and passed in the Senate.

376. The plain packaging measures contained in the legislation now moving through the Australian Parliament continued to be controversial and of serious concern to the Ukraine and several other governments, as well as to IP and business groups both within Australia and internationally. These concerns had recently been recorded directly in writing with the Australian Parliament in the context of enquiries carried out first by the House Standing Committee on Health and Aging in July and August prior to the passage of the legislation in the House and then by the Senate Legal and Constitutional Affairs Committee in August and September. In both these enquiries, the committees in question had requested and received comments from the public in the form of written submissions, which were then posted on the websites of these committees for public scrutiny.

377. He said that his delegation would like to thank Australia for inviting comments in connection with its Parliamentary enquiries. He noted that that the Government of Ukraine had made a written submission to the Senate Legal and Constitutional Affairs Committee expressing its regret that the Government of Australia had provided no substantive responses to Ukraine's questions and concerns regarding the WTO consistency or the efficacy of the proposed plain packaging measures. The submission had also urged the Australian Senate to take up amendments to the legislation in conformity with Australia's WTO obligations.

378. He said that from the perspective of IP, which was the focus of this Council, the enquiries by the Australian Parliamentary committees were particularly instructive because in their submissions, leading IP and business organizations both from Australia and around the world had described in detail the violations of international law and the adverse business impact for individual trademark holders that these measures would entail, as well as the broader negative implications for IP protection in general.

379. In order to illustrate the breadth and depth of concern about the plain packaging measures from an IP perspective, he said that it was worthwhile recalling some of these organizations who had voiced concerns. The Institute of Patent and Trade Mark Attorneys of Australia had made a submission on 2 September 2011 to the Australian Senate Standing Committee on Legal and Constitutional Affairs. On 26 July 2011, the International Association for the Protection of Intellectual Property (AIPPI), a politically neutral, non-profit organization headquartered in Switzerland with more than 9,000 members representing more than 100 countries, had expressed concerns on behalf of its Australian members to the Australian House Standing Committee on Health and Ageing. The International Trademark Association (INTA), which represented 5,700 trademark owners and professionals from over 190 countries, had written to the House Committee on Health and Ageing on 22 July 2011. The International Chamber of Commerce (ICC) and it Business Action to Stop Counterfeiting and Piracy (BASCAP) had written to the Senate Legal and Constitutional Committee on 30 August 2011. From among leading international business groups, BusinessEurope, the pan-European business organization, as well as the US Chamber of Commerce, which is the world's largest business federation representing the interests of more than three million businesses had written to the Senate Legal and Constitutional Committee.

380. He said that, as already previously stated, his delegation did not question the health objectives of the Government of Australia as all governments devised and implemented health policies that best served the welfare of their citizens, but simply requested that that Australia and all governments formulated their health policies in a manner consistent with their international obligations. With respect to TRIPS, his delegation had indicated both to this Council and directly to the Australian Government its view that the plain packaging measures passed by the Australian House of Representative and now pending before the Australia Senate violated important TRIPS obligations of Australia. As he had already noted, a number of other governments and numerous leading IP and

business organizations in Australia and around the world shared this view. He expressed his delegations' hope that the Australian Senate would take eth necessary steps to ensure the conformity of the pending plain packaging legislation with Australia's international treaty obligations, including those under the TRIPS Agreement.

381. The representative of the Dominican Republic said that his delegation wished to reiterate its concern about the plain packaging measures that had been introduced in the Australian Federal Parliament in the course of the year and were currently being considered in the Senate, including the detailed draft implementation regulations for cigarettes and other tobacco products, such as cigars. He said that the Dominican Republic, along with other WTO Members, had expressed its concern regarding these unprecedented measures both in the Council for TRIPS and in the Committee on Technical Barriers to Trade and various trade associations representing a wide range of industries had also stated their concern.

382. He said that the Australian plain packaging measures were not an issue exclusively concerning tobacco, but were to be viewed more generally as a threat to the protection of IP, a vital component of international trade, and should therefore be a matter of concern to all WTO Members. The proposed measures specifically ran counter to Australia's obligations under the TRIPS Agreement and the Paris Convention, incorporated into the TRIPS Agreement.

383. As the term itself suggested, "plain packaging" as stipulated in the bill and its regulations required all packets for retail sale to be of the same size, shape and colour. Trademarks were removed, since the proposed measures banned the use of design and trademark features. Although the measures permitted use of the brand name and variant of the product, these could only appear on the lower part of the front and the top and bottom of the packet. Moreover, the brand name and the variant name had to be displayed in a statutorily standardized font style, size and colour. The graphic health warnings would cover 75 per cent of the front and 90 per cent of the back of the packet. By definition, the Australian plain packaging measures would therefore make it impossible to differentiate between competing products.

384. His delegation considered that these measures would violate IPRs and would not succeed in promoting the public health goals pursued by Australia. On the contrary, unwanted effects might lead to higher rather than lower tobacco consumption as prices tend to drop as a result of the "commoditization" of tobacco products and plain packaging would make it easier to produce counterfeit tobacco products and thus facilitate trade in illicit products.

385. Regarding the legal implications, he said that the Dominican Republic considered Australia's plain packaging measures to violate Article 20 of the TRIPS Agreement and Article 10*bis* of the Paris Convention. Analysis of the measures in the light of Article 20 showed that the "use" of trademarks relating to tobacco products would be "encumbered" by "special requirements" as the measures prohibited the use of any design feature on packets of tobacco products for retail sale, allowing only the brand name and variant to be used in a predetermined font style and size on an identical background. These special requirements imposed by Australia were detrimental to the trademark's capability to distinguish the goods or services of one undertaking from those of other undertakings.

386. At the previous Council for TRIPS meeting in June 2011, Australia had contended that the measures in question were justified by objectives of public health, and had referred to a number of studies, but his delegation understood that the scientific evidence underpinning Australia's plain packaging measures had been challenged in public documents submitted to the Australian Government. The Dominican Republic requested an explanation from Australia as to how it reconciled the divergent views on scientific evidence.

387. The plain packaging measures would also violate Article 10*bis* of the Paris Convention, which prohibited "all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor". As stated at the previous meeting of this Council, the measures in question posed a serious risk of confusion as they would eliminate all design features and impose virtually identical packaging for all tobacco products. The Dominican Republic therefore urged Australia to reconsider its position and to take into account the concerns raised in this statement, and consequently to honour its obligations under the WTO Agreements.

388. He said that his delegation considered this to be a very serious case. Tobacco was an indigenous product of the Dominican Republic which exported more than $400m worth of tobacco products, and where tobacco represented 10 per cent of the domestic agricultural sector and more than 100,000 domestic jobs. In addition, tobacco was called a democratic product because it was produced by small producers and small shareholdings. Furthermore, more than half of the 100,000 workers in tobacco production were women who had special facilities in this respect. While his delegation acknowledged that there may be a health problem, imposing measures that banned the use of trademarks on products that carry health risks was not an option and would not only violate the TRIPS Agreement, but create a serious impediment for world trade.

389. The representative of Brazil said that the interplay between public health and IP had now been discussed for a number of years from different angles and in different fora, and the international community had now agreed on a solid international regulatory framework to deal with this issue. At the World Health Organization's Conference on Social Determinants of Health held in Rio de Janeiro, Brazil's foreign minister, Ambassador Antonio Patriota, had stressed the fact that "the whole international community acknowledges that the flexibilities included in international treaties on intellectual property constitute a consolidated legal framework, either in the WHO, at the WTO or at WIPO."

390. With respect to the WTO, he said that Article 8 of the TRIPS Agreement specifically authorized Members to adopt measures necessary to protect public health and nutrition in addition to those intended to promote the public interest in sectors of vital importance to social, economic and technological development. The Doha Declaration on the TRIPS Agreement and Public Health also made it clear that the TRIPS Agreement did not and should not prevent Members from taking measures to protect public health and that it could and should be interpreted and implemented in a manner supportive of the WTO Members rights' to protect public health. Finally, in the WHO, 172 countries, parties to the Framework Convention on Tobacco Control had reaffirmed in the Punta del Este Declaration their commitment to prioritize the implementation of health measures designed to control tobacco consumption and had reasserted the right of states to define and implement national public health policies to protect their people.

391. In conclusion, he said that it was Brazil's view that all countries were allowed, by the present body of international rules on IP to adopt whatever measure they deemed it fit to protect the public health of their respective populations. Tobacco control was clearly a public health priority worldwide and nation-wide.

392. The representative of Mexico said that her delegation requested Australia to provide information on the status of the proposed measures in terms of implementation and instrumentation. It also asked Australia to respond to the formal request Mexico had lodged with the relevant focal point in May 2011, and provide information that would explain how the proposed measure was consistent with the TRIPS Agreement.

393. The representative of Nigeria said that his delegation had referred the matter of Australia's plain packaging bill of 2011 to capital for consideration. As Nigeria had important manufacturing

facilities in the tobacco sector that generated employment and provided revenue for the government, his delegation was trying to assess the impact that Australia's bill would have on the sector in Nigeria. It was his delegation's view that the proposed measures would be inconsistent with Australia's obligation under Articles 20 of the TRIPS Agreement and Article 10*bis* of the Paris Convention, as a ban on use of the logo on cigarette packages would make it difficult to distinguish one brand of cigarettes from another, thereby confusing the product purchaser. In view of the concerns raised in the Council today and on previous occasion, Nigeria wished to ask Australia to bring its proposed tobacco measures into consistency with the TRIPS Agreement.

394. The representative of Cuba said that, since this was the second time the Tobacco Plain Packaging Bill was debated in the TRIPS Council, her delegation hoped to receive satisfactory replies from Australia at this time. Since the bill had been discussed for the first time in the Council in June 2011, it had been approved by the House of Representatives in August and would soon go before the Senate. Its scope remained unchanged and it appeared that neither the questions nor the concerns raised regarding its commercial impact would be taken into account. Her delegation's concerns were further heightened by the fact that the measures which the Australian Government submitted to public enquiry on 30 September would also be applied to non-cigarette tobacco products.

395. She was concerned that banning the use of a trademark's distinctive features on all tobacco retail packaging, including for products sold per unit, negated the functions of a trademark, in particular brand association of a product with an origin, a producer, or a tradition. Under the proposed measures, it would no longer be possible to use the seal of guarantee which identified and ensured a product's authentic Cuban origin which was especially relevant for artisanal Cuban tobacco that was hand-made and 100 per cent natural. Applying the bill to such a product would prevent consumers' association between the Cuban trademarks and the product, and therefore strip the products of their commercial value in Australia while at the same time restricting the consumer's right to choose on the basis of the quality of a product associated with its trademark.

396. Her delegation was further concerned by the rising trade in illicit tobacco products, knowing that it would become much easier to produce counterfeit packaging if use of a trademark were to be prohibited. The method proposed to prevent the production of counterfeit goods was a unique alphanumerical code, but this code could also be reproduced on counterfeit packaging. It was not obvious what effect the measures would have on consumers for whom it would be impossible to know whether they were in fact consuming a real or a counterfeit product.

397. She said that Cuba continued to recognize the importance of protecting public health and the responsibility of governments in that regard. Nevertheless, it remained an open question whether Australia had considered the possibility of implementing other, less restrictive measures that would achieve the same health objectives. She noted that Articles 5, 11 and 13 of the WHO's Framework Convention on Tobacco Control did not require the use of plain packaging and that, in almost five years since the Convention had come into effect, Australia was the first country to adopt such a measure.

398. She said that, in light of Article 8 of the TRIPS Agreement, her delegation insisted on the need for scientific evidence for a direct link between the proposed measure and the health protection objectives sought. Australia had still not provided guarantees to protect the rights of trademark owners under Article 16 of the TRIPS Agreement, or to ensure that owners were protected from counterfeiting or unfair competition. Her delegation would be grateful for any effort on the part of the Government of Australia to allay its concerns, and to take them into consideration during the process of final approval of the bill in the Senate.

399. The representative of Nicaragua said that his delegation wished to join previous speakers who had expressed concerns regarding Australia's Tobacco Plain Packaging Bill 2011 and the

implementing regulations thereof. The consultation paper confirmed that the measure would apply not only to cigarettes but also to cigars, one of Nicaragua's main export products, and proposed making retail packaging for cigars the same ugly dark grey as proposed by Australia for tobacco products. This measure would seriously undermine the protection of IPRs and unnecessarily restrict trade in cigars in the same way as the measure that the Australian Government seeks to apply to cigarettes.

400. He said that the Government of Nicaragua and various other governments had already raised concerns and questions regarding the legislation that Australia was now seeking to apply with equal effect to cigars and other tobacco products, both at a bilateral level and within the WTO. Unfortunately, the Australian Government had not provided any substantive responses to these questions and concerns regarding the WTO consistency of such measures. Nicaragua recognized Australia's right to legislate to protect public health, provided that such measures were consistent with WTO rules and other existing international treaty commitments. However his delegation believed that, regrettably, the proposed measures fall far short of WTO compliance and would set a harmful precedent that would undermine protection for IPRs in Australia and other countries.

401. It was his delegation's view that, while the measure would not hinder tobacco consumption in Australia, it would have significant negative economic and social repercussions in a considerable number of the countries represented in the WTO, the vast majority of which were developing countries with small economies.

402. The representative of Honduras said that her delegation wished to join the Dominican Republic and other delegations who had expressed concerns regarding the Australian Bill which would effectively prohibit the use of trademarks on the packaging of all tobacco products such as cigars, cigarettes and Havana tobacco, allowing only the brand name to be displayed in a standard font on a small part of the packet.

403. Her delegation believed that in establishing a plain packaging requirement, Australia would be in contravention of its commitments under Article 20 of the TRIPS Agreement, which clearly stated that: "The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings". In her view, any measure that constituted a "special requirement" in respect of one of the uses listed in this Article - such as use with another trademark or use in a special form - meant that the use of a trademark was, by definition, being "unjustifiably encumbered".

404. Consequently, her delegation believed that the restrictions on trademarks set out in the proposed Australian measures violated this Article by imposing "special requirements" in the case of logos and design marks and by requiring the use of a brand name in a special form in the case of word marks. Australia's measures therefore imposed prohibitions and restrictions on the use of trademarks that clearly impaired its capability to distinguish the goods of one undertaking from those of another.

405. While respecting Australia's intention in adopting this kind of measure, her delegation believed that the end did not justify the means. Such measures needed to be duly backed up by evidence that demonstrated both that they met the public interest objectives which warranted their implementation and that the mechanisms employed tallied fully with the set objective. In this case, Honduras believed that there was insufficient evidence to prove that plain packaging was genuinely effective in discouraging tobacco consumption. Furthermore, she said that measures should not be more restrictive than necessary to achieve the set public health objective. Finally, and more importantly, her delegation believed that any measure adopted to achieve such objectives had to be fully consistent with the commitments undertaken under the various trade agreements, in this case the TRIPS Agreement.

406. Although her delegation recognized Australia's right as a sovereign state to adopt legitimate public health policies, her intention was to underline that the measures adopted had to meet the commitments made in the WTO and take into account the negative impact they would have on trade for small producers in the small and vulnerable economies of developing countries, as these would set a detrimental precedent in this organization. In view of the foregoing, her delegation considered it necessary to find a suitable balance between public health measures and the protection of IPRs of trademark owners.

407. The representative of Zimbabwe said that his delegation associated itself with the statements of Ukraine, Cuba, the Dominican Republic, Nicaragua, Honduras, Nigeria and Mexico. He said that, although this controversial Plain Packaging Bill 2011 was meant to protect health, it would not be in keeping with Article 2.2 of the TBT Agreement which stated that "technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create" and that "in assessing such risks, relevant elements of consideration are, *inter alia*, scientific evidence and technical information, related processing technology or intended end-use of products".

408. He said that the TBT Agreement further required all "technical regulations" to be "no more trade restrictive than necessary" to pursue a legitimate objective. As there was no evidence that plain packaging influenced consumer behaviour, imposing this new technical regulation would restrict trade without doing anything to achieve a legitimate objective, and therefore create unnecessary obstacles to international trade. It would also be in violation of Article 12.3 of the TBT Agreement which required Members to ensure that their technical regulations "do not create unnecessary obstacles to exports from developing country Members".

409. Furthermore, he said, plain packaging could not be justified under the TRIPS Agreement. Plain packaging had to be seen as an unjustifiable encumbrance under Article 20. Article 8.1 of the TRIPS Agreement stated that any measure adopted to protect public health must be consistent with the provisions of the TRIPS Agreement, which plain packaging was not. Article 17 further stated that only limited exceptions to the rights under the TRIPS Agreement were permissible and that the legitimate interests of trademark owners always had to be taken into account. By completely prohibiting the use of some marks and strictly mandating the form of use for others, plain packaging could not be considered a "limited" exception and did not even attempt to consider the rights of trademark owners in its "one size should fit all" approach.

410. He said that Zimbabwe, as one of the major tobacco producers, would be adversely affected by the proposed bill as it would negatively affect its trade, and the social impact on thousands of people whose livelihoods depended on the production of tobacco products would be severe. His delegation once again urged the Australian Government to realign its proposed Bill to conform to the relevant articles of the TRIPS Agreement.

411. The representative of Uruguay said that his delegation wished to reiterate its support for Australia's Tobacco Plain Packaging Bill. Protection of public health fell clearly within the sovereign authority of States and accordingly every country was entitled to legislate in the public interest, a fact recognized by all countries, including the proponents of this agenda item. Australia had undertaken not to violate its international obligations in the defence of its public health interests and Uruguay agreed with the explanations and justifications it had provided. His delegation further endorsed Brazil's statements with regard to the concept of flexibility within the scope of the international IP treaties and wished to add that this defence of flexibility in the implementation of IPRs should be coherent and consistent in all instances. Against that background, Uruguay was of the view that Australia's proposed measures were clearly not in breach of Article 20 of the TRIPS Agreement.

412. He added that his delegation objected to the description of tobacco products causing "health problems", as this description did not adequately reflect the matter of life and death that these products presented. On the same grounds he rejected any parallels being drawn between cigarettes and other products that caused "health problems" as a review of the related figures sufficed to illustrate the vastly different health impact.

413. The representative of Norway said that public health in general, and tobacco control in particular, was a topic very dear to her delegation. Apart from implementing revisions to its tobacco policy, Norway was currently working on a new five-year tobacco-related strategy that would be implemented from 2012 to 2016. Her delegation was therefore very interested in, and supportive of, similar processes in other Members. The FCTC could make the greatest single contribution to preventing non-communicable diseases. Implementation by parties of the provisions of this international framework convention was a pressing public health issue. As most WTO Members were parties to this convention, her delegation did not see an inherent contradiction between regulating the use and presence of tobacco products and other international obligations. It was within the rights of each Member to regulate the health needs of its people. Article 8 of the TRIPS Agreement provided Members the flexibility to adopt measures necessary to protect public health and it was Norway's firm view that the FCTC and the WTO rights and obligations were mutually supportive.

414. Tobacco control policies and preventive measures such as the ones being proposed by Australia had the legitimate objective of protecting public health by reducing smoking. Article 11 in the FCTC and the accompanying guidelines explicitly mentioned plain packaging as one of the options for achieving this objective. Norway wished to signal clear support to Australia concerning the right to introduce plain packaging as a measure designed to fulfil its obligations under this international convention in order to protect public health. Her delegation trusted that Australia's legislation would be implemented in a way that complied with all their international treaty obligations. Norway would continue to follow this case with a very keen interest and was prepared to continue to defend the interests of public health while complying with all its international treaty obligations.

415. The representative of Chile said that, at the previous Council meeting, his delegation had referred on a preliminary basis to two systemic aspects it considered noteworthy in the light of the information provided by Australia and the issues raised by the Dominican Republic, Ukraine and other delegations. Chile shared Australia's concern for public health protection and in particular the noxious effects of tobacco, and, like Australia, Chile believed it legitimate to take measures to reduce tobacco consumption, in particular among the youngest members of the population. To put this into context, he said that the reduction in the prevalence of tobacco consumption, particularly smoking among school-goers and women of child bearing age was also among the specific objectives that Chile's health sector had set itself.

416. His delegation had indicated previously that the Plain Packaging Bill which Australia was seeking to implement further strengthened the legitimacy and importance of the flexibility afforded by the TRIPS Agreement, particularly in the field of public health, since this case illustrated that the Agreement's flexibilities were useful and necessary not only for developing countries, but are also for developed countries. Having said that, pointed out that the use of flexibility provided in the TRIPS Agreement had to be consistent with the provisions governing the protection of IPRs, in this instance those pertaining to trademarks under Article 15 *et sequitur* of the Agreement. Article 8 of the TRIPS Agreement was clear on this matter, allowing Members to take measures to protect public health provided that these were consistent with the Agreement.

417. He said that Chile would continue to scrutinize the Australian bill, in particular its relation to Article 20 of the TRIPS Agreement and the relevant provisions of the Paris Convention, and his delegation reserved the right to return to this issue in the future.

418. The representative of New Zealand said that her delegation welcomed the Australian Government's decision to legislate for the plain packaging of tobacco products. The negative effects of smoking, which was the leading preventable cause of early death in New Zealand, could not be overstated. She said that it was within a Member's right to implement necessary measures to protect public health and her delegation had noted the clear assurances by Australia in past discussions that it had paid close attention and respected its WTO obligations in developing its plain packaging proposal. She further noted the numerous scientific studies demonstrating that plain packaging of tobacco products could lead to positive public health outcomes by reducing the attractiveness and desirability of smoking and increasing the prominence of public health warnings. It was her delegation's view that, as part of a comprehensive suite of tobacco control measures, plain packaging could contribute to efforts to reduce smoking rates.

419. The representative of El Salvador said that her delegation thanked the Dominican Republic for having presented this concern in the last meeting of the Council and shared the concerns with respect to the identification of products. She said that while her delegation was analysing the documentation received so far and reserved the right to intervene once again on this point, El Salvador wished to indicate that it would submit a number of questions to Australia with respect to the implementation of this draft bill. She noted that her delegation had also followed up on Australia's presentation of the concerned measures in the TBT Committee and said that notification and analysis of the measures and their implementation in the TRIPS Council was equally important given the systemic concerns raised by the measures. At the same time, she said that her delegation recognized Australia's right to establish measures protecting public health for its own citizens, and noted that El Salvador also had domestic legislation regarding labelling and packaging that contained health warnings. Her delegation would follow up on this matter both in the TRIPS Council and the TBT Committee.

420. The representative of China said that the Australian bill had the legitimate objective to protect human health by introducing plain packaging of tobacco products with the aim of reducing the appeal to consumers and increase the effectiveness of health warnings. A second bill provided some assurance for the effect of trademarks or industrial designs, stipulating that use of a trademark or industrial design could be prevented on tobacco products on the condition that such use could be specified. In the context of the debate on the compatibility with the TRIPS Agreement, China believed that Members should have the right to take measures to protect public health, and that such measures should not contravene the TRIPS obligation. His delegation would continue to follow the development of this issue.

421. The representative of Switzerland said that his delegation shared Australia's concerns with regard to the damaging effects of smoking for individuals and public health and was thus generally supportive of public health measures in the area of anti-smoking. However, his delegation also wished to reiterate that such health measures - as any other measures - needed to be compatible with international obligations and fundamental rights, including proprietary rights such as those of trademark holders. Among these international obligations to be respected were the substantive provisions of Part II of the TRIPS Agreement, as confirmed for public health measures in Article 8.1 of the TRIPS Agreement.

422. He said that such public health measures had to be appropriate, i.e. proportionate and effective. In this respect, his delegation noted that the consultation paper on the plain packaging amendment, submitted to interested stakeholders for comments in spring 2011, mentioned on page 11 that the draft legislation made a caveat to the full ban of use of a trademark, meaning that under certain circumstances a trademark could be used on the packaging of the product under the new legislation, albeit under restrictions imposed by a regulation. His delegation wished to request the delegation of Australia to inform the Council on what Section 11(2) of the draft Bill provided in this respect in its latest version, as well as the regulation referred to in the consultation paper and whether

the consultation process had resulted in any new considerations and adjustments in the draft submitted to the House of Representatives or to be submitted to the Senate.

423. The representative of India said that the issue raised very important questions on the interplay between the TRIPS Agreement and the right of a Member to protect public health. While refraining from specific comments on the Australian measures, his delegation wished to make some observations on the larger systemic issue of protection of public health and the TRIPS Agreement. He said that the framers of the TRIPS Agreement had provided inherent flexibility to create a delicate balance between the rights of the IP holders and the interests of the people. While Article 1 provided the Members had certain freedom to implement the provisions of the agreement, Article 8 of the TRIPS Agreement provides enough flexibility to Members to adopt measures necessary to protect public health and nutrition and to promote public interest in sectors of vital importance to their socio-economic and technological development. This had also been reiterated by the Doha Declaration.

424. With respect to the Australian tobacco plain packaging bill he said that Members' views differed between those preferring to protect trademarks, and others preferring to advance public health through initiatives like plain packaging to discourage the consumption of attractiveness of tobacco. Some countries felt that these initiatives could be more focused rather than targeting all tobacco products, and other expressed concern over a potential increase of counterfeit products and illicit trade, thus adversely affecting public health. Against this background, his delegation believed that the TRIPS Agreement provided for enough flexibility to address the issue of public health, but that this should be addressed through an approach based on studies, facts and empirical data.

425. The representative of the European Union said that his delegation was closely examining the proposal from Australia and, in the TBT Committee, had requested information on the scientific data, studies, impact assessment summary and background that had prompted Australia to propose the Bill. The European Union would also be interested in learning whether Australia had evaluated other legislative solutions and why these alternative solutions had been considered less effective than the proposed approach for achieving the legitimate health objective pursued. In this regard his delegation recalled that the legitimate public health interests needed to be consistent with the provisions of TRIPS, including its trademark rules. Finally, his delegation also wished to enquire about the envisaged legislative process and timing for the adoption of the proposal.

426. The representative of Australia said that her delegation welcomed the interest of other Members in its proposed legislation on the plain packaging of tobacco products and the support received for these important measures. Since the last meeting of the TRIPS Council in June 2011, the Tobacco Plain Packaging Bill 2011 and the associated Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011 had been introduced into the Australian Parliament on 6 July 2011. Both Bills had passed the House of Representatives on 24 August 2011 with no amendments and were expected to be considered by the Senate before the end of 2011. She said that Australia's Minister for Health and Ageing, Nicola Roxon, had issued a media release on 12 October 2011, indicating that as a result of the delays in passing the Bill, the Government was now reconsidering implementation timelines in the context of which representations from industry about the timelines were also being considered.

427. She said that in recent months her delegation had met with all WTO delegations that had raised this issue in previous TRIPS Council and TBT Committee meetings to explain the purpose and details of the proposed measures and to provide detailed information in relation to the questions raised.

428. With regard to the purpose of the measures, her delegation had outlined at the previous meeting of the Council that Australia was implementing this legislation in the interests of promoting public health and in particular in the area of reducing tobacco consumption. She said that three million Australians still smoked, and 15,000 of them died every year causing a staggering bill of

$A36 billion to the Australian tax payer. In that context, her delegation was confident that, as part of a comprehensive package of tobacco reforms, the bill would make an effective contribution to reducing smoking, and thereby reduce the health impact of smoking on Australian individuals and the community at large. Tobacco packaging was one of the last remaining forms of tobacco advertising in Australia and the plain packaging legislation was therefore the next logical step in Australia's tobacco control efforts.

429. She said that the effect of the legislation would be that tobacco company branding, logos, symbols and other images that might have the effect of advertising or promoting the use of the tobacco product would not be able to appear on tobacco products or their packaging. The brand name and variant name would continue to be allowed on packaging, as would be information required by other legislation or regulations, such as trade descriptions and graphic health warnings.

430. The plain packaging of tobacco products was designed to reduce the attractiveness and appeal of tobacco products to consumers, particularly young people; to increase the noticeability and effectiveness of mandated health warnings; to reduce the ability of the tobacco product and its packaging to mislead consumers about the harms of smoking; and, through the achievement of these aims in the long term, as part of a comprehensive suite of tobacco control measures, contribute to efforts to reduce smoking rates. She said that plain packaging needed to be considered in the context of Australia's long term efforts on tobacco control. Over the past 30 years Australia had implemented a number of measures to reduce smoking rates, including extensive and continuing public education campaigns on the dangers of smoking; age restrictions on tobacco purchase; pricing measures through excise and customs duties; comprehensive bans on tobacco advertising, promotion and sponsorship; bans on smoking in certain places to reduce the impact of second hand smoking; bans and restrictions on the retail display of tobacco products; mandatory graphic health warnings on tobacco product packaging; and 'quit smoking' support services including free counselling and subsidised pharmaceutical products.

431. Guidelines agreed by the Conference of the Parties to the WHO Framework Convention on Tobacco Control (FCTC) in 2008 for the implementation of Articles 11 and 13 of the FCTC recommended that Parties consider the introduction of plain packaging. The proposed legislation was consistent with recommendations made to the Government by Australia's National Preventative Health Taskforce which had been based on extensive research evidence that explored the impacts of tobacco packaging and tested the reactions of respondents exposed to different packaging options under experimental conditions. The weight of the evidence indicated that a plain packaging requirement, as part of a comprehensive suite of tobacco control measures, would help to reduce smoking rates. Her delegation wished to urge Members to examine carefully any so-called evidence to the contrary which was funded by the tobacco industry. She said that her delegation had been responsive to comments from trading partners and other stakeholders, and that Australia remained fully committed to its international obligations to protect IPRs, including the rights of trademark owners.

432. Her delegation had notified the measures to the WTO on 8 April 2011. As noted by Ukraine in its intervention, the Australian Government had undertaken extensive public consultation on the proposed legislation. Prior to the introduction into Parliament of the Bills, the Australian Government had also consulted widely with trading partners, including tobacco exporting developing countries, through a series of outreach meetings to explain the proposed measures. These comments were taken into account and had led to changes to the Bill and draft regulations where the changes were in line with the Government's policy objectives. This included responding to concerns about the protection of the rights of trademark owners, with changes made to ensure their effective operation.

433. Amendments to the Tobacco Plain Packaging Bill had been proposed to ensure the trademark owners' ability to protect their trademarks from use by other persons, and the ability to register and

maintain the registration of a trademark had been preserved. A parallel Trade Marks Amendment Bill had been introduced to allow the Government to strengthen those protections should uncertainty arise. The import offences for non-compliant tobacco products had also been removed from the bill in response to submissions received and public consultations. This change allowed tobacco products to be imported into Australia in non-compliant retail packaging, and then repackaged for retail sale in Australia. She said that the bill required compliance with plain packaging requirements from the first on-sale (whether wholesale or retail) of imported products in the supply chain in Australia.

434. She said that her delegation did not accept claims that Australia's plain packaging proposal would have a significant impact on illicit trade in tobacco products. Trade in illicit tobacco in Australia was low and her delegation did not expect this to change as a result of these measures. It was important to understand that counterfeiters now seemed to have little trouble replicating branded tobacco packages and it was worth repeating that smoking of any tobacco product, whether licit or illicit, was fundamentally harmful to human health. Nevertheless, given concerns were expressed about counterfeiting and illicit trade in tobacco products, allowances had been made to ensure that protective markings could be used for anti-counterfeiting purposes. These included the use of unique alphanumeric code markings on each pack and cigarette stick, and covert markings in compliance with other aspects of the Bills.

435. With respect to the applicability of the measure to other products she said that the proposed plain packaging legislation related only to tobacco products and retail packaging of those products and the Australian Government did not consider extending the measure to other products.

436. According to the World Health Organization, "tobacco is the only legal consumer product that kills up to half of those who use it as intended and recommended by the manufacturer." She said that tobacco products cause extraordinary harm and require appropriate measures. At the same time, she said that Australia was fully committed to its international obligations to protect IPRs, including the rights of trademark owners. She said that, in framing its policy on plain packaging, Australia had paid full regard to its obligations under the TRIPS Agreement and would ensure that the new policy was implemented in a manner that consistent with that Agreement.

437. The representative of Zimbabwe said that he would encourage Australia to be broad enough in its consultations to include Zimbabwe.

438. The representative of the World Health Organization thanked the Council for the opportunity to address the floor on this critical public health issue. As previously stated in this forum, tobacco use was one of the greatest threats to public health the world has ever faced, and the single most preventable cause of death in the world. Globally, tobacco consumption had killed nearly six million people a year through both direct use, and the deadly effects of second-hand smoke - more than 70 per cent of whom resided in low- and middle-income countries. In addition, tobacco represented the leading modifiable risk factor in the fight against the growing epidemic of non-communicable diseases (NCDs). NCDs, primarily cancers, diabetes, cardiovascular and chronic lung diseases, were accountable for 63 per cent of all deaths worldwide. Those diseases killed an astounding 36 million people each year, with nearly 80 per cent of deaths were occurring in low- and middle-income countries.

439. He said that, as strong tobacco control measures were implemented in developed countries, the tobacco industry, through aggressive marketing and interference practices, had shifted its focus to new markets in the developing world. As a result, tobacco-attributable mortality was rapidly increasing in developing countries, and, by 2030, more than 80 per cent of the world's tobacco deaths would occur in low- and middle-income countries. Given that smoking caused 30 per cent of all cancers, which included over 70 per cent of all lung cancers, 40 per cent of chronic respiratory diseases, and nearly 10 per cent of all cardiovascular diseases, it was a critical moment in the global

fight against the tobacco epidemic for the introduction of strong public health interventions like the measure under consideration.

440. He said that that the economic costs of tobacco use were equally as devastating as the public health costs. Although the tobacco industry had routinely cited the economic contribution of tobacco, the reality had been that tobacco use puts an enormous financial burden on countries, in addition to the fact that tobacco and poverty were inextricably linked at the individual level. Nationally, the costs of tobacco use encompassed increased health-care costs, lost productivity due to illness, premature death, and widespread environmental damage. Thus, he said, as tobacco consumption rates and tobacco-related illnesses increased in developing countries, so did tobacco-related healthcare costs. Additionally, conservative estimates suggested that tobacco's more than US$500 billion drain on the world economy exceeded the total annual health expenditures in low- and middle-income countries. The economic burden of NCDs, with tobacco representing the largest risk factor, was also staggering.

441. Recent macroeconomic simulations suggested that, over the next two decades, cardiovascular disease, chronic respiratory disease, cancer, and diabetes, would cause a cumulative output loss of more than US$30 trillion, which represented 48 per cent of global GDP in 2010. This in turn would push millions of people across the planet below the poverty line. Because NCDs would result in long-term macroeconomic impacts on labour supply, capital accumulation and GDP worldwide, with the consequences most severe in developing countries, strong public health interventions, like the plain packaging measure under deliberation, were relevant in addressing both health and economic concerns.

442. The representative noted that the impact of tobacco and NCDs on both public health and country economies has been highlighted at the recent United Nations High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, which had been held in September 2011 in New York. There, the UN General Assembly, comprised of Heads of State, had adopted a Political Declaration recognizing the fundamental conflict of interest between the tobacco industry and public health; and wherein Member States unanimously had committed to the advancement of the implementation of multi-sectoral, cost-effective, population-wide interventions in order to reduce the impact of NCD risk factors.

443. He said that the WHO was of the view that the implementation of plain tobacco product packaging, which represented a legitimate tobacco control measure, would have a substantial impact on tobacco consumption, was fully in line with the spirit and intent of the outcome of the UN High-level Meeting, and was in accordance with international legal obligations under the WHO Framework Convention on Tobacco Control.

444. Regarding the relevance of the WHO Framework Convention on Tobacco Control (FCTC) in this context, another representative of the WHO said that the FCTC, in force since 2005, had been negotiated under the auspices of the WHO in response to the globalization of the tobacco epidemic. Its provisions were based on evidence and had been specifically designed by the international public health community to be effective in the face of the tobacco epidemic. As with other international legal instruments, states that were parties to the FCTC undertook certain obligations pursuant to it. Since the last time the Council had met, the number of parties to the Convention had risen to 174 - only 12 of the 153 WTO Members were not party to the FCTC.

445. She said that the FCTC contained a number of provisions that were relevant to the issue of plain packaging of tobacco products. As had been noted during the last session of the TRIPS Council, the FCTC set out in Article 3 the collective objectives of the parties in the establishment of the FCTC, as well as the general Article 5 obligation on parties, which included, inter alia, the obligation to "develop, implement, periodically update and review comprehensive multi-sectoral national tobacco control strategies, plans and programmes in accordance with" the FCTC.

446. The recognition by the States Parties of the effectiveness of comprehensive multi-sectoral measures in the fight against the global tobacco epidemic was a theme that recurred throughout the Convention and the obligations it contained. It was through the implementation of such a comprehensive multi-sectoral approach that the tobacco control measures contained in the FCTC were most effective. In relation to the plain packaging measures for tobacco currently under discussion, the representative noted that Article 11 of the Convention required Parties to adopt and implement effective measures in respect of the packaging and labelling of tobacco products, which included health warnings and other appropriate messages.

447. In accordance with the recent party reports on implementation, which were required pursuant to Article 21 of the Convention, 65 per cent of parties - i.e. 88 of them - had banned descriptors on packaging and labelling that were misleading, deceptive or likely to create an erroneous impression of the product; and 82 per cent - or 111 parties - had adopted policies which required tobacco product packaging to carry health warnings which described the harmful effects of tobacco smoke. In addition, 74 per cent of parties - or 100 of them - had introduced measures to ensure that health warnings are large, clear, visible and legible. Moreover, after five years of implementation, Article 11 was one of the Articles of the Convention which attracted the highest implementation rates among Parties.

448. She said that another specific provision of the FCTC previously noted in the Council was Article 13, which required Parties to undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. That comprehensive ban had to be read in light of the broad definition of “tobacco advertising and promotion” which, in accordance with Article 1(c) "means any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly.” The Guidelines for the implementation of Article 13 which were adopted by consensus by the parties included "packaging and product design features" on the indicative list of forms of advertising, promotion and sponsorship. She noted that the most recent Party reports indicated that 55 per cent of Parties - i.e. 74 of them - had introduced a comprehensive ban on tobacco advertising, promotion and sponsorship.

449. Information submitted by parties that had reported twice had allowed an analysis of the progress in implementation of various obligations under the Convention. Between one-third and one-half of Parties that had reported twice had registered progress through the introduction of stronger health warnings and in banning advertising, promotion and sponsorship. This indicated that Parties were undertaking progressively more stringent tobacco control measures in accordance with their Article 11 and Article 13 obligations.

450. Finally, as had been noted in the Council during its June session, the governing body of the Convention, the Conference of the Parties or COP, had met for its 4th session in November 2010. At that session, the COP had adopted the Punta del Este Declaration (FCTC/COP4(5)) in relation to public health policy, international trade and the activities of the tobacco industry. The Punta del Este Declaration reiterated the firm commitment of Parties to the FCTC "to prioritize the implementation of health measures designed to control tobacco consumption" and made specific reference to Articles 7 and 8 of the TRIPs Agreement, as well as to paragraphs 4 and 5(a) of the Doha Declaration on the TRIPs Agreement and Public Health, which was adopted by the 4th session of the WTO Ministerial Conference in November 2001.

451. In light of concerns expressed regarding illicit trade in tobacco products, she noted that the negotiation of the first protocol to the FCTC, the draft Protocol to Eliminate Illicit Trade in Tobacco Products, was in its final stages, and the last session was expected to be held in 2012. Moreover, work was continuing in respect of the identification of economically sustainable alternatives to tobacco growing in relation to Articles 17 and 18 of the Convention.

452. The representative of South Africa said that his delegation recognized the sensitivity of this issue and the tension between on one hand the right to protect and promote public health and on the other hand the right of the intellectual property right holder. As the debate in this Council had not yet matured in any degree, his delegation suggested that Members fully and sufficiently apply their minds to it before the discussion was broadened. He said that, while he appreciated the views and the unquestionable expertise of the WHO, he felt that at this point it was best to allow Members to apply themselves to the issue. His delegation wished to emphasize again that it recognized both the right of Members to protect and advance public health in the same way that it recognized the rights of the right holder of the IP.

453. The representative of Zimbabwe said that he had listened to the WHO representatives and wondered whether or not they were making a pitch on behalf of Australia. While it was clear that Australia had the sovereign right to present its case, he said he was puzzled as to the basis of their interventions and looked forward to the manner in which the Chair would conclude.

454. The Chairman recalled that, as Members were aware, the rules of procedure established that observer international intergovernmental organizations take the floor once all Member delegations had spoken. It was in applying these regulations with Members' agreement that the WHO, which enjoyed observer status, had been given the floor to make its statement.

455. The Council took note of the statements made.

O. ENFORCEMENT TRENDS

456. The Chairman said that this item had been put on the proposed agenda at the written request of the delegations of Australia, Canada, the European Union, Korea, Japan, New Zealand, Singapore, Switzerland and the United States and that, at the adoption of the agenda, its title had been amended to read "Enforcement Trends". In advance of the meeting, the Council had received a communication from Australia, Canada, the European Union, Korea, Japan, New Zealand, Singapore, Switzerland and the United States entitled "Enforcement of Intellectual Property Rights" (IP/C/W/563).

457. The representative of Japan offered his delegation's appreciation for the opportunity to report on the latest developments related to the Anti-Counterfeiting Trade Agreement (ACTA) and hoped that he could respond to Members' interest in the Agreement as well as their requests for transparency.

458. After ACTA had been discussed in the Council twice in the past year, and following the completion of translation and technical work, the Agreement had been opened for signature on 1 May 2011. On 1 October 2011, the Government of Japan had hosted a signing ceremony in Tokyo, which had been attended by representatives of all ACTA participants. Representatives of eight governments who had already completed their respective domestic procedures had signed the Agreement, namely Australia, Canada, Japan, Korea, Morocco, New Zealand, Singapore and the United States. His delegation looked forward to the other participants - the European Union, Mexico and Switzerland - signing as soon as was practicable. ACTA would remain open for signature until 1 May 2013 and would enter into force 30 days after the sixth instrument of ratification, acceptance or approval was deposited with the Government of Japan, the Depository of the Agreement.

459. The magnitude of proliferation of counterfeit and pirated goods in recent years had been significant. Reasons for this proliferation included the rapid advancement of digital technology and thus of sophisticated counterfeiting and pirating techniques. To tackle this and to maintain sustainable development of economic activities including IP related ones, countries had been working on ACTA.

460. Beyond a general argument of "TRIPS Plus or Minus", ACTA presented a concrete set of provisions and framework for enhanced IPR enforcement, which ACTA participants believed to be

not excessive, but rather practical and pragmatic in addressing current issues and global development in the 16 years since TRIPS had come into effect. Moreover, he noted that some WTO Members were already equipped with domestic system or practice that corresponded, even if partially, to the provisions of ACTA. This exemplified the Agreement's concurrence with the needs and requisite practices for fighting against IPR infringement, particularly the proliferation of counterfeiting and piracy, in the new century.

461. With respect to the apprehensions and concerns that had so far been expressed with respect to the Agreement, he reiterated that ACTA had no provisions that were in direct conflict with any specific provisions of TRIPS. In implementing the Agreement, it was the Parties' utmost concern to ensure that trade distortions were avoided. On the issue of balance between right holders and defendants, for example, the Agreement provided that competent authorities would have the authority to require a right holder requesting suspension at borders to provide a reasonable security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse (Article 18). Throughout ACTA there were numerous optional provisions, carefully crafted definitions, and a huge amount of flexibility that would allow autonomous regulation to be designed by Parties in accordance with their respective needs and contexts.

462. ACTA also specifically provided for international cooperation including information sharing and capacity building, and ACTA participants were open to constructive advice on implementation from other Members. His delegation, together with colleagues from other ACTA participants, welcomed other WTO Members' interest in this Agreement and was willing to respond to any request by Members for explanation, exchange or discussion on the Agreement, either individually or in other appropriate formats.

463. He concluded by inviting Members' attention to the fact that ACTA was open for signature not only by the original participants but also by WTO Members until 1 May 2013 and that the window for participation would still be open after that date.

464. The representative of the United States said that his delegation appreciated the opportunity to share with colleagues from other WTO Members its views on the importance of enforcement and to provide some additional information on ACTA. The parties had concluded ACTA because counterfeiting and piracy had been spreading faster than governments could effectively react, robbing individuals and businesses of billions of dollars. They had realized that because this was a global problem it needed a global solution.

465. For example, counterfeiters and pirates could currently move shipments through multiple ports to hide the origin of the shipment and lower the risk of detection by customs. The Internet had also provided counterfeiters and pirates with an extremely fast and efficient tool to distribute their illicit products – with the ease of a click of a mouse, pirated movies, music and games could be uploaded or downloaded; counterfeit foods and medicines could be sold and sent. That had not been the case when the TRIPS Agreement had been concluded.

466. The key substantive chapters of ACTA dealt with the legal framework, enforcement practices, and international cooperation. The Legal Framework chapter of the Agreement concerned the legal tools that were needed by enforcement authorities to effectively respond to current counterfeiting and piracy problems. The Enforcement Practices chapter encouraged the creation of mechanisms to combat the proliferation of those illicit products. Finally, the chapter on International Cooperation, a very important element of the Agreement in his delegation's view, encouraged close global cooperation.

467. ACTA would promote the enforcement of IPRs through a variety of means. It would:

- create a first-of-its-kind alliance of trading partners who would represent more than half of world trade and cooperate in the fight against piracy and counterfeiting;

- require that border enforcement authorities be empowered to act on their own initiative against both imports and exports of counterfeit and pirated goods;

- require Parties to make criminal penalties available when piracy or counterfeiting was carried out for commercial advantage (such as companies using pirated software);

- require that criminal authorities be able to act on their own initiative (*"ex officio"*) in IP cases rather than having to wait for a complaint;

- include new commitments as well as commitments on criminal seizure and destruction of fake goods, seizure of the equipment and materials used in their manufacture, and seizure of the criminal proceeds from IP offenses; clarify existing international requirements for remedies against circumvention of technological protections used in the digital environment (such passwords or encryption) and trade in circumvention devices;

- call on Parties to address widespread distribution of pirated copyrighted works on digital networks while preserving fundamental principles such as freedom of expression, fair process, and privacy; and

- enhance the TRIPS Agreement framework on civil enforcement provisions and deal with issues such as damages, provisional measures, recovery of costs and attorneys' fees, and destruction of infringing goods.

468. ACTA would promote practices that contributed to effective enforcement of IPRs, such as specialization, data analysis, internal coordination, stakeholder consultation, risk management, transparency, and public awareness. He concluded by noting that ACTA was open to any WTO Member to apply to join.

469. The representative of the European Union said that products and services based on IPRs were usually difficult and expensive to create but were cheap to replicate and reproduce. Organized and large-scale infringement of IP had become a global phenomenon and was causing worldwide concern. Copycats deprived creators of appropriate rewards, created barriers to innovation, harmed competitiveness, destroyed jobs, decreased public finances and potentially threatened the health and safety of citizens.

470. In order to boost the competitiveness of producers abroad, it was essential that their innovations, creation and brands were adequately protected in their export markets through IPRs. ACTA therefore aimed at improving the level and effectiveness of enforcement of IPRs internationally. It had been negotiated by the EU and 10 other parties[10], in a total of 37 countries.

471. ACTA did not create new IPRs but instead was concerned with procedures and measures to enforce existing rights and to act against large scale infringements, often pursued by criminal organizations. It was not about limiting civil liberties or harassing consumers and was in line with the current EU regime for enforcement of IPRs – which fully respected fundamental rights, freedoms and civil liberties such as the protection of personal data.

[10] Australia, Canada, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland and the United States.

472. With ACTA, creators, innovators and brand holders within the "ACTA space" would be able to count on efficient and clear enforcement rules, very similar to the ones that were in place in the European Union, regarding the kind of action they could obtain from police, from customs or from a court, how damages would be calculated, what kind of urgent protection they might get, what kind of evidence would be collected and preserved, what would happen to seized fake goods, etc.

473. He said that ACTA contained rules on civil enforcement, border measures, criminal enforcement measures (for more serious violations, made wilfully and on a commercial scale by criminal actors) and digital environment measures (for specific infringements taking place on the internet or involving technical protection mechanisms). It also contained a number of enforcement "best practices" and provisions that would ensure better international cooperation between enforcement entities.

474. ACTA would benefit a wide range of exporters that relied on copyrights, trademarks, designs, geographical indications and, in certain situations, patents. He noted that the European Union had a wide and diversified basis of right-holders; a farmer who produced products protected by geographical indications or a textile company creating designs could also be victims of counterfeiting and needed to be protected.

475. The Agreement would therefore help the European Union's export businesses, of all sizes, protect their work from violations, especially in the arts, culture, agriculture, industry and science sectors, and thus maintain their competitiveness and jobs. At the same time, ACTA would be able to strike an appropriate balance between the need to protect innovations and creations and the rights of citizens and the concerns of stakeholders such as consumers or internet providers. There were no provisions in ACTA that could directly or indirectly affect legitimate trade in generic medicines or, more broadly, global public health. On the contrary, ACTA contained the necessary guarantees to safeguard access to medicines and internet freedom. Moreover, these principles have been re-affirmed by all ACTA negotiating parties on numerous occasions.

476. ACTA provided its parties with the necessary flexibility to establish a balance that would take into account their economic, political and social objectives, as well as their legal traditions. This was to be expected from an agreement that had been negotiated with a view to be inclusive and welcome accessions from other countries.

477. The representative of New Zealand said that, after many years of discussion about the standards of protection that should be provided to various IPRs, it was timely to have a discussion on how those standards needed to be enforced. The worldwide trade in counterfeit goods and pirated copyright works had been growing steadily over the past decade and had become a global problem in need of a global solution. The sale of counterfeit goods and pirated works deprived not only New Zealand business, but all businesses of legitimate earnings and undermined the investment in producing quality goods. Counterfeit goods also misled and deceived consumers as to the source and quality of goods and potentially exposed them to significant health and safety risks from sub-standard products.

478. International cooperation had to be an essential ingredient if enforcement efforts were to be successful. Enhanced cooperation would allow countries to effectively break up distribution lines of illicit goods without disrupting trade in legitimate goods. ACTA thus provided a cooperative framework to base Parties' collective efforts at tackling the international problem of counterfeit trademark goods and pirated copyright works. The provisions in Chapter III focused on promoting and encouraging better domestic enforcement practices and Chapter IV provided the basis for international cooperation and the sharing of information concerning the enforcement of IPRs.

479. She stated that there had been many misleading statements made about the possible negative impacts of ACTA, and that it was timely to address some of those misperceptions in the current forum. Firstly, ACTA was not a vehicle to introduce new standards for the protection of IPRs. Instead, ACTA created a new benchmark for IPR enforcement that was consistent with the TRIPS Agreement. In addition, ACTA could not create any obligations for non-signatory states.

480. ACTA had also been unreasonably accused of being a vehicle for obstructing trade in legitimate generic drugs, but the Agreement would not address the cross-border transit of legitimate generic medicines. It would not affect the rules under which pharmaceutical companies filed applications for patent protection or extended patent terms. Importantly, the final text included a reference in the initial provisions to the objectives and principles of TRIPS, Articles 7 and 8 respectively to ensure that aspects of TRIPS were fully reflected under ACTA. Accordingly, ACTA would not affect a party's ability to use the Protocol amending the TRIPS Agreement to implement the Doha Declaration on TRIPS and Public Health. She strongly believed that all Members had the right to take measures necessary to protect public health. Finally, and as had already been mentioned by Japan and the United States, she emphasized that ACTA provided all WTO Members the opportunity to apply to join the Agreement.

481. The representative of Switzerland noted that his country was a negotiating Party of ACTA and, like the other 37 ACTA Parties, a WTO Member. ACTA dealt with measures to effectively enforce IPRs and more specifically to fight against counterfeiting and piracy. These issues were also dealt with in Part III of the TRIPS Agreement, and thus concerned the TRIPS Council.

482. For those reasons and for the sake of transparency, ACTA Parties wished to provide the Council with relevant information on ACTA and had circulated its text, now that it was final and had been signed by the first set of ACTA negotiating parties. Switzerland was finalizing its own internal procedures in light of the signature of ACTA.

483. At the national level, the Swiss Anti-Counterfeiting and Piracy platform, which was called STOP PIRACY, represented an instrument that allowed for enhanced coordination and cooperation among competent government agencies as well as between the public and private sector. Relevant information on that platform could be found in Switzerland's submission of 31 May 2007 (IP/C/W/492). Switzerland's participation in ACTA would reflect and reinforce those national efforts at the international level. Counterfeiting and piracy had transnational character, and he was convinced that successful efforts to combat those criminal activities effectively necessarily relied on closer international cooperation and coordination, which ACTA provided for.

484. The Agreement focused on commercially-oriented counterfeiting and piracy. It established an international framework for governments' efforts to more effectively combat the proliferation of counterfeiting and piracy, which continued to undermine legitimate trade and the sustainable development of the world economy.

485. In its Chapter II, building on the TRIPS Agreement, ACTA set out effective enforcement standards for existing IP rights. In Chapter III, the Agreement promoted important enforcement practices at the national level and Chapter IV provided for enhanced cooperation between the countries party to ACTA, among others, by facilitating the exchange of information, expertise and capacity building in the field of enforcement.

486. He said that concerns had been expressed by some Members that ACTA could negatively impact legitimate trade with and access to generic medicines in developing countries. ACTA negotiating Parties had strongly negated such claims and had publicly stated that ACTA would not, and had never been intended to, produce such effects.

487. The negotiating Parties had taken concerns that had been expressed regarding public health into account by introducing, for example, a specific reference to the Doha Declaration on the TRIPS Agreement and Public Health in the ACTA text. To preclude any doubts on potential effects of ACTA on the legitimate trade in generic medicines, the negotiating Parties had decided that patents would not fall within the scope of the ACTA provisions on border measures.

488. He reiterated that the focus of ACTA was on commercially-oriented counterfeiting and piracy and that the Agreement represented an important effort by a group of like-minded countries, both developing and developed, to cooperate and support each other in their efforts to more effectively combat these illegal and harmful activities. He encouraged other WTO Members to join ACTA participants in that effort and said that his delegation was ready to respond to any questions Members might have on ACTA, both at the current Council meeting and later meetings, as well as bilaterally.

489. The representative of Mexico said that, as it had made clear during its participation in the ACTA signing ceremony on 1 October 2011, her Government remained committed to the international protection of IPRs and, in particular, to ACTA and its scope and objectives.

490. Accordingly, Mexico had engaged in an intensive process of consultation and dialogue in an effort to raise awareness and provide information about the objectives, scope and benefits of ACTA. Her delegation was convinced of the need to pursue dialogue and would therefore exhaust all avenues of consultation and exchange with other sectors, such as the legislature and representatives of civil society, in furtherance of reaching its final decision on signing ACTA.

491. Mexico recognized the importance of signing the Agreement and the benefits that it would afford at national and international level, especially since ACTA took as its starting point the provisions of the TRIPS Agreement.

492. She noted that for her Government, ACTA offered the chance to be part of a valuable international effort to combat counterfeiting and piracy effectively. It was an opportunity to aim for full implementation of and compliance with WIPO treaties and the TRIPS Agreement, which would in turn enhance domestic and foreign investment flows, and boost the competitiveness of Mexican companies through innovation.

493. The Agreement also had the praiseworthy objective of fostering international cooperation in the field of IP protection, an issue that was undoubtedly of relevance to the discussions in which Members were currently engaged. She concluded by stating that her delegation applauded the signatories of ACTA for the action that they had taken.

494. The representative of Singapore said that her delegation appreciated the opportunity to present ACTA to other WTO Members, provide transparency, and share its views on the enforcement of IPRs. With global economic activity increasingly driven by innovation, it was important to protect IPRs more effectively. A robust IPR regime with effective enforcement would strengthen economies and was essential to encouraging innovation, creativity and the growth of industry and commerce. That would give businesses and individuals the confidence that their propriety knowledge would be protected. It had contributed to helping Singapore's economy move up the value chain.

495. At the same time, the increasingly international character of commercial counterfeiting and piracy posed significant challenges to the effective protection of IPR. For instance, technological advances allowed the unauthorized replication, sale and distribution of copyrighted material and counterfeit goods across borders, which had had ramifications on her Government's efforts to develop viable and creative industries. That also had implications on public awareness and education programmes that were targeted at building respect for IP.

496. She also noted that with the need to strike a reasonable balance between private commercial rights and public policy interests, enforcement policy had to be considered in the context of national IP policy objectives and domestic circumstances.

497. It was in this context that Singapore had participated in and signed ACTA. International cooperation was essential for effective IPR enforcement and Chapter Four of ACTA contained a framework for international cooperation and sharing of information on enforcement practices. Enhanced international cooperation would improve efforts amongst ACTA parties to deal with flows of illicit goods without disrupting trade in legitimate goods. This was a positive step in wider international efforts combat IPR infringement more effectively, and in particular the proliferation of counterfeiting and piracy.

498. At the national level, ACTA encouraged the promotion and development of better domestic enforcement practices, captured in Chapter Three of the Agreement. For Singapore, this would mean a strengthening of existing multi-agency efforts to promote internal coordination in IPR enforcement and increasing public awareness of the importance of respecting IP.

499. As a small country with strong interests in international trade, Singapore placed great importance on the multilateral rules-based system. It remained a priority for her Government to ensure that bilateral and plurilateral agreements it signed were consistent with and strengthened existing international IP agreements, in particular TRIPS, and did not create new barriers to trade. Increased cooperation in IPR enforcement would strengthen the relevance and importance of TRIPS.

500. The representative of Canada said that ACTA represented an important initiative to more effectively combat the growing and internationally recognized problems of large-scale trademark counterfeiting and copyright piracy and achieve progress on enhancing IP enforcement. Increased global trade in counterfeit and pirated goods had negative impacts for knowledge-based economies and cost billions of dollars each year in lost revenues and trade. Canada, like many other countries, had suffered consequences which had negatively impacted its economic growth and the health and well-being of its citizens.

501. ACTA set new standards for the enforcement of existing IPRs, which were consistent with and complementary to those that had been provided in the TRIPS Agreement. In encouraging higher standards, there was no intention to exclude any country from joining efforts to combat counterfeiting and piracy. In fact, the Agreement had been negotiated with a view to be inclusive and attract accessions from other countries. It would foster mutually beneficial cooperation between partners by facilitating information exchange, such as statistical data or best practices, as well as capacity building and technical assistance, where appropriate.

502. ACTA was also consistent with the TRIPS Agreement and the Declaration on TRIPS and Public Health and would not hinder the cross-border transit of legitimate generic medicines. Canada would continue to work closely with other ACTA participants and other interested partners to halt once and for all the negative impacts of trade in counterfeit and pirated goods.

503. The representative of Australia said that Australia had signed ACTA in Tokyo on 1 October 2011, along with other ACTA negotiating parties. He associated his delegation with previous interventions, particularly the presentation by Japan as the ACTA depository. ACTA had been negotiated to ensure wide membership by including provisions that would allow any WTO Member to apply to join. The Agreement usefully complemented and built upon existing civil, criminal and border TRIPS enforcement standards and further reflected TRIPS-consistent measures that were already in place within WTO member countries. Although ACTA had been negotiated as a plurilateral agreement, his delegation looked forward to engaging other countries in the WTO and relevant multilateral fora in discussions on ACTA standards and the role they played in supporting

innovation and world trade in innovative products. His delegation encouraged WTO Members that were not part of ACTA negotiations to look closely at the final agreement and to consider ratification or accession to further enhance global standards.

504. In that context, it was important to stress that ACTA built upon the existing flexibilities of the TRIPS Agreement. He said that ACTA countries had been very careful to include language in ACTA that would ensure that the Agreement captured important elements of the balance struck in TRIPS between the use and protection of IP. Article 2 of ACTA stated that the objectives and principles in Part 1 of the TRIPS Agreement, in particular in Article 7 and 8, would apply as relevant to ACTA. Inclusion of that language reflected the balance that was required in WTO Member countries' laws. The preamble provided that the Agreement should operate in a manner that was mutually supportive of international enforcement work and cooperation that was conducted within relevant international organizations. ACTA was therefore an instrument which could complement the work on IP enforcement that was already being done in other multilateral organizations and was thus suitable for broad membership.

505. The representative of Korea stated that his Government was proud to have signed ACTA and believed that the enhanced cooperation of ACTA signatories would be an effective way of combating the proliferation of counterfeiting and piracy. It was a commonly known fact that counterfeiting and IPR piracy harmed fair competition in the market, shifted jobs from right holders to infringers, and funnelled money from where it rightfully belonged to underworld operators. All the harm caused, when added up, resulted in damage to the process of innovation, which was vital to economic growth and welfare. The perils of counterfeiting and IPR piracy were not limited by borders and thus global cooperation was necessary to address the epidemic.

506. He said that Korea was aware that some delegations had concerns about the possibility that ACTA would cause serious adverse impacts, including potential legal conflicts and unpredictability, possible distortions to legitimate trade, and incompatibility with TRIPS or other IPR agreements. However, his delegation believed that ACTA could usefully complement existing international IP efforts. Standards in ACTA had been largely built upon those that had been negotiated within the WTO, and reflected TRIPS-consistent measures that were already in place in many WTO member countries.

507. In addition, the preamble of ACTA made it clear that measures and procedures to enforce IPR should not become barriers to legitimate trade. ACTA was thus compatible with the TRIPS enforcement rules and went beyond the current regime to more efficiently counteract the adverse effects of increasing trade in counterfeiting goods and copyright piracy.

508. He reiterated the importance of higher IP enforcement standards, given the damaging effect that counterfeiting and piracy had in both developed and developing economies. ACTA would be implemented in a manner that would ensure legitimate trade and sustainable development of the world economy.

509. The representative of India said that, during past several TRIPS Council meetings, India along with other countries had been consistently highlighting the systemic implications of TRIPS-plus initiatives launched by a few Members. The ensuing discussions had demonstrated the concerns echoed by a vast majority of Members about how ACTA through its TRIPS-plus provisions could disturb the fine balance of rights and obligations that had been provided in the TRIPS Agreement and could negate decisions like the Doha Declaration on Public Health.

510. After years of negotiating in comparative secrecy, he appreciated that ACTA signatories had finally become transparent and had taken the initiative to brief the Council about ACTA under the

current agenda item. He thanked those Members for their constructive engagement in having changed the title of the agenda item and clarifying that it would not be a permanent agenda item.

511. He wished to highlight some important specific and systemic concerns that India had regarding ACTA. The scope of ACTA was broad and he felt that it would target generic medicines, which had served as a lifeline by providing access to medicines at an affordable cost in developing countries. The signatories to ACTA had said that the Agreement was intended to help them effectively combat the proliferation of counterfeiting and piracy and to protect consumers from potentially dangerous products like counterfeit medicines. However, ACTA did not limit itself to counterfeits, a category of products defined narrowly in the TRIPS Agreement as involving the deliberate or fraudulent use of trademark in order to deceive consumers. Instead ACTA targeted all forms of IP infringement under the guise of targeting counterfeits. ACTA civil enforcement measures applied broadly in connection with IP infringement, although the parties had the option of excluding patents and undisclosed information from the scope of civil enforcement. Goods that were suspected of infringing IP, broadly defined, might be seized by customs officials under ACTA. This was worrisome especially from a public health point of view as ACTA measures would target generic medicines.

512. He said that ACTA border measures, which were TRIPS-plus on several grounds, constituted a grave threat to trade in generics. The customs detention of legitimate Indian generics in the European Union on account of the EU border measures demonstrated the adverse impact that such border measures could have on public health on a global scale, including lifesaving medicines to treat HIV/AIDS, heart diseases etc. Under ACTA, such seizures would continue. The Agreement provided for the imposition of border measures following requests by right holders or as a result of ex officio action by customs officials. ACTA also provided for border measures for goods in transit through a signatory – even if they did not infringe any IP in the place of production or where they would be consumed. His apprehension was that ACTA would pose grave risks for international trade in generics and thereby adversely affect public health initiatives in developing countries.

513. Under ACTA, third parties supplying inputs or services in support of the manufacture or commercialization of allegedly IP infringing products could be subject to civil and criminal sanctions. The imposition of third party liability would dissuade suppliers from selling inputs and services to genuine generic manufacturers as well. In addition, ACTA also required that officials be authorized to grant injunctions, including against third parties allegedly contributing to IP infringement, in order to prevent the infringing goods from entering channels of commerce. ACTA language on aiding and abetting could affect providers of inputs including those that unknowingly supply labels, materials or services to IP infringers. That would have an adverse impact on the availability of affordable medicines globally.

514. ACTA rules provided that an infringer, who knowingly or unknowingly engaged in infringement, might be ordered to pay damages in order to compensate for injury to the right holder and introduce TRIPS-plus rules for calculating damages. The calculation method of using the lost profits on account of alleged infringement would act as a deterrent for involvement with a generic manufacturer, deterring generic producers from entering new markets.

515. As far as systemic concerns went, ACTA bypassed the multilateral processes of WTO or WIPO and went far beyond the enforcement levels laid down in the TRIPS Agreement. The MFN provisions of the TRIPS Agreement would mean that any TRIPS-plus protection secured by trading partners via an RTA or a plurilateral agreement, would be ipso facto applicable to all other WTO Members. Thus the Agreement would have direct bearing even on Members that were not involved in ACTA, but who would subsequently enter into RTAs with ACTA signatories. ACTA had thus inalterably changed the balance of rights and obligations of the parties to the TRIPS Agreement, without their having participated in the negotiation of ACTA.

516. It further caused concern when enforcement was seen as divorced from other obligations in the TRIPS Agreement. He recalled that Articles 7 and 8 of the TRIPS Agreement referred to transfer of technology, socio economic development, promotion of innovation and access to knowledge.

517. He drew the attention of Members to the Trans Pacific Partnership Agreement (TPP), which was still under negotiation. There had been unconfirmed reports in the media about the proposals that had been made by a developed country regarding the IPR chapters of the TPP Agreements. That agreement could also seriously hamper public health efforts in developing countries. That alleged stance of some parties at the TPP, if agreed upon, would result in creating monopolies for big pharmaceutical companies and would drive generic manufacturers out of the global market. According to these reports, there were proposals that could undermine the provisions and flexibilities in the TRIPS Agreement by requiring patentability of new uses and minor variations of older known drugs. That would result in the indefinite lengthening of patent life and would thus undermine the generics industry. There was also a proposal to lengthen the patent period by taking into account the time required for getting marketing approval, a measure that would introduce an element of subjectivity in determinacy of patent life and consequently delay the entry of generic drugs. There were also provisions against pre-grant opposition and compulsion to provide for patent linkage, indicating that even a spurious drug could act as a barrier due to the presence of patent linkage in the Agreement. Also of concern were the reports that pricing of drugs in the country would be dictated by large pharmaceutical companies, including essential medicines.

518. He concluded by expressing his deep concern regarding ACTA and other agreements like the TPP that were under negotiation and were aimed at enforcing TRIPS-plus measures against WTO Members, whether directly or indirectly. While India was committed to dealing with IPR enforcement issues in line with its TRIPS obligations, the introduction of intrusive IPR enforcement rules had set up extremely high non-tariff barriers in the multilateral trading system and his delegation could not remain oblivious to those developments. It was necessary to avoid exaggerating the issue of counterfeiting and piracy since there was no available empirical data and further work was needed in that area. Members needed to work collectively to maintain the sanctity of the international trading environment by respecting the multilaterally negotiated agreements like TRIPS.

519. The representative of Angola said that he agreed on the need to protect and respect IP and that he shared the concerns about counterfeiting, piracy, and transborder crime. He noted that even if an agreement were negotiated outside of the WTO, if a country correctly interpreted the Paris Convention, it might not apply. He did not want to exclude certain topics from discussion, and asked all delegations to have an open mind in relation to all topics. He sought clarification on a number of points: first, whether the member States of the European Union were included separately in the number of ACTA participants; second, what technical and financial cooperation was available in particular to build the necessary infrastructure for border enforcement; and third, what other international laws would be applicable with respect to customs enforcement. As to enforcement of IPRs in the digital environment, he asked whether ACTA contained any additional standards as compared to those already contained in the WIPO Copyright Treaty (WCT) and WIPO Performances and Phonograms Treaty (WPPT). He further raised questions on the practical evaluation standards for enforcement measures under Articles 14 and 18 of ACTA.

520. The representative of Ecuador stated that the questions raised by the delegation of Angola were both interesting and relevant. In its commitment to protecting IP, Ecuador had developed new mechanisms to directly combat piracy in addition to traditional enforcement mechanisms. That strategy included providing legal access by distributing free software via public institutions and libraries to replace the use of pirated software. In this manner, Ecuador had been able to ensure access while guaranteeing fair compensation for rights holders, thus ensuring effective enforcement.

521. Ecuador had also been working on fostering a culture of respect for creations by others, through the use of social networking sites for another campaign called "Ecuador Crea" (Ecuador Creates). In that campaign, faces or images of creators were shown and the public was invited to learn more about the creative processes, which thereby generated greater public awareness of what being a creator of a work or giving expression to an idea actually meant in practical terms.

522. The fight against infringements of IPRs demanded considerable efforts from developing countries, especially if there were no legal alternatives for accessing culture, education and technology. Given that not many developing countries were considered to be attractive markets for investment, the only option they had in terms of access was to take the illegal path. It was important to build consensus so that right holders understood the efforts that all Members had to make to fight piracy, and to seek legal alternatives that, thanks to information and communications technology, were currently feasible and economically viable.

523. He believed that it was the responsibility of all Members to also explore new ways to promote IPRs that produced better results in combating infringement of those rights by developing means of legal access and fair compensation.

524. Additionally, he requested clarification from one of the Members that were taking part in the Trans-Pacific Partnership negotiations to inform the Council as to the extent IP matters that were being negotiated in that forum were more restrictive than the provisions that were set out in ACTA and in the free trade agreements that the participants in that process had agreed to amongst themselves. In particular, he sought clarification in relation to Article X, paragraph 2 of that Agreement, which was being negotiated but had not yet been confirmed, and whether it could limit the implementation of the Doha Declaration on Public Health.

525. The representative of Brazil said that the present agenda item had been put on the proposed agenda as "Enforcement of Intellectual Property Rights (Paragraph III of the TRIPS Agreement)", but the discussion had not been about the TRIPS Agreement or enforcement overall. Instead, ACTA participants had presented that agreement and encouraged other Members to sign it. The WTO was a multilateral forum, and ACTA was a plurilateral agreement that had been deliberately negotiated outside the WTO. He voiced his delegation's concern regarding plurilateral agreements being advocated in a multilateral forum such as the WTO and shifting focus away from its multilateral nature.

526. The representative of China said that his delegation had expressed its concerns regarding ACTA in the past at the TRIPS Council. The legal system to protect IPRs should be comprehensive and well balanced; it needed to protect rights holders as well as the public interest. There had been controversies even in those countries that had participated in ACTA negotiations, including concerns about transparency and inconsistencies with domestic legislation. ACTA should be implemented in a way consistent with WTO rules and the TRIPS Agreement. It was important that protection and enforcement did not contravene the provisions of TRIPS; indeed, Members were required to ensure that matters and procedures to enforce IPRs did not themselves become barriers to legitimate trade, or create distortive effects on legitimate international trade. The additional protection under ACTA could not inappropriately restrict the inbuilt flexibilities and exceptions in the TRIPS Agreement.

527. The representative of Chile said that he recognized the importance of IPRs and upheld them accordingly. Intellectual property and its enforcement were crucial tools in promoting research and development, and were subject to growing demands and challenges. However, IP enforcement, including civil penalties, possible criminal penalties, border measures and so forth, could not be considered in isolation but had to be coherent and consistent with each country's situation. Enforcement tools had to, for example, be in keeping with the financial resources available for other areas of primary public necessity, particularly given that IPRs were, after all, private rights.

528. Likewise, enforcement measures had to be consistent with the legal system and could not constitute a barrier to the population's legitimate access to protected works and essential goods such as cultural goods and medicines. In that regard, any provision on enforcement included in bilateral or plurilateral agreements needed to respect and be consistent with the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement. Those provisions had to, in particular, be consistent with ensuring that the enforcement of IPRs furthered technology transfer that was beneficial to producers and users alike. That had been Chile's focus in all negotiations on IP enforcement.

529. Although ACTA negotiating parties had stated in previous interventions that the Agreement was open to any WTO Member to join, Article 43.2 of the Agreement, which concerned accession, stated that Committee members, the original parties to ACTA, could define the terms of accession for each new applicant. He sought clarification on whether this referred simply to procedural matters such as time limits for entry into force, or whether Parties deciding on a new Party's accession could request compliance with substantive measures that would be more stringent than those that had been incumbent on the original Parties to the Agreement.

530. The representative of the Bolivarian Republic of Venezuela, supporting the statement by Brazil, said that his delegation preferred multilateralism and transparency. It was his understanding that ACTA would raise IP standards to a higher level and that it was a TRIPS-plus measure. Recognizing the information that was made available, he regretted that the process of negotiations had not been transparent.

531. The representative of Zimbabwe was concerned that ACTA was a plurilateral agreement that did not embrace all WTO Members. He sought clarification with respect to the clear lacunae in the TRIPS Agreement that ACTA participants claimed ACTA sought to address.

532. The representative of the United States, responding to the questions raised by Angola, said Article 35 of ACTA did provide for capacity building and technical assistance for Members and prospective Members. As to Article 14.2 of ACTA, on small consignments and personal luggage, he noted that Article 14.2 had been taken from Article 60 of the TRIPS Agreement. As to other treaties such as the WIPO WCT and WPPT, ACTA implemented key provisions of those treaties.

533. He said that the concerns raised regarding "TRIPS-plus" provisions were somewhat confusing. The TRIPS Agreement was a minimum standards agreement, and its Article 1 provided that Members “may…implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.” Many Members had chosen to do so, many of which were not ACTA participants. In fact, several WTO Members that were not ACTA participants had already adopted ACTA provisions in their domestic law. It was curious that Members opposed ACTA because it was TRIPS-plus on one hand, but implemented ACTA provisions in their law on the other.

534. Regarding *ex officio* authority**,** for example, Article 16(1)(a) of ACTA required border enforcement authorities to be empowered to act on their own initiative against both imports and exports of counterfeit and trademark goods. He pointed out that, for instance, the India Customs Department would *ex officio* suspend the clearance of alleged counterfeit goods if the department had prima facie evidence or reasonable grounds to believe the goods to be counterfeit, which had been provided for in Notification No. 47/2007 – Cus. (N.T.) of 2007. As the delegation of China had confirmed in the discussion under item C of the agenda, Chinese Law, specifically Article 16 of the Regulation on the Customs Protection of Intellectual Property Rights, also provided for *ex officio* action at the border, as long as the right holder registered its IP with customs and followed certain procedures.

535. Likewise, WTO Members had already implemented provisions on damages and statutory damages that closely followed those in ACTA. China's law, for instance, was similar to ACTA Article 9 on determining the amount of damage that had been suffered by the right holder. He further noted that Article 65 of China's Patent Law, Article 56 of China's Trademark Law and Article 49 of China's Copyright law aligned closely with ACTA Article 9. The same provisions of Chinese law also had provisions on pre-established and statutory damages like those that were contained in ACTA Article 9.3

536. The representative of the European Union said that the many interesting comments made and questions raised showed that that this was a useful debate to have. Although it was impossible to reply to all of them, he might be able to do so at a future occasion. As to the alleged secrecy of the negotiations, he said that draft versions of the ACTA text had been made available publicly and that all ACTA participant countries had conducted stakeholder consultations. The European Union had done so at least once a year during the three years when the Agreement was under discussion, and hundreds of persons from the civil society, various sectors of the industry, press etc. had participated. Activists and NGOs had participated in several of the negotiating rounds and had discussed the issues with the negotiating parties. He further noted that it was understandable that in negotiating bilateral free trade agreements, for example, there would be some level of discretion involved. Despite this, the misconception regarding secrecy had unfortunately lasted a long time.

537. The European Union was not requesting the topic to be a permanent agenda item, but it was not waiving its right to request the item to again be put on the agenda of a future meeting.

538. With respect to the concern that with ACTA the detention of Indian goods would continue, he said that the incidents in 2007 and 2008 had been isolated, and very serious measures had been taken to prevent them from being repeated. Regrettably, he could not say that they would never again be repeated, since a human error could take place.

539. On the point that Brazil had raised, that ACTA had deliberately been negotiated outside the WTO, he recalled that there had been great difficulties in discussing enforcement at the TRIPS Council, so at some stage, Members had thought that it might be necessary to discuss the issue among interested parties and work to improve enforcement mechanisms.

540. In response to China's intervention, he reiterated that ACTA parties remained committed to the provisions of the TRIPS Agreement and did not seek to contravene them.

541. With respect to the question on accessions under Article 43.2 raised by Chile, he said that while many internal rules still needed to be discussed, there was no intention to hold new Members to a higher standard than the one that had been laid out in ACTA.

542. The representative of Japan thanked all the Members that had taken the floor, and noted that the numerous interventions had indicated a high level of interest and a need for on-going dialogue on ACTA issue.

543. The Council took note of the statements made.

P. INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

544. The Chairman recalled that, under this agenda item, information had usually been provided in relation to new accessions to the WTO and developments in the area of dispute settlement, as well as about acceptances of the recent TRIPS amendment. However, information on acceptances of the TRIPS amendment had been provided under item G, and on this occasion he had no other new developments to report in these areas.

Q. OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

545. The Chairman said that the Secretariat had circulated the list of 15 pending requests for observer status in the TRIPS Council by other intergovernmental organizations in document IP/C/W/52/Rev.12. At its meeting in June 2011, the Council had requested the Secretariat to contact the international intergovernmental organizations whose requests for observer status were pending to request up-to-date information, including on the nature of their work and the reasons for their interest in being accorded observer status. So far, the Secretariat had received updated information from the European Free Trade Association (EFTA), faxed to all Members on 7 October, and from the South Centre and the Conférence des Ministres de l'Agriculture de l'Afrique de l'Ouest et du Centre (CMA/AOC), faxed to all Members on 17 October, and from the Cooperation Council of the Arab States of the Gulf (GCC). Given that this information had been shared with Members only recently and that more information from other IGOs could be expected, he suggested that he consult with Members on the requests for observer status with a view to seeing if any decisions could be taken at the next meeting.

546. The representative of Nigeria, speaking on behalf of the African Group, recalled that the African Regional Intellectual Property Organization (ARIPO) and the African Intellectual Property Organization (OAPI) had already been granted an *ad hoc* observer status on a meeting by meeting basis in the TRIPS Council. Given that the functions performed by these two bodies had a bearing on the work of the Council (in this regard, he referred to the enumeration of the functions of the two organizations made at the last Council meeting by the representative of Kenya, speaking on behalf of the African Group), it would be pertinent that they be granted a permanent rather than *ad hoc* observer status.

547. The representative of Angola, speaking on behalf of the LDC Group, said that the activities of OAPI and ARIPO, both of which undertook substantive examinations of patents and trademarks and were also responsible for the grants, had a bearing on the work of the TRIPS Council. Therefore, it was time to try to grant them observer status on a permanent basis. It would also be pertinent to give observer status to other international organizations, such as the South Centre and the Convention on Biological Diversity.

548. The representative of Egypt supported the Chair's proposal regarding conducting consultations. He also said that granting observer status to international organizations was a systemic issue. Clear procedures, criteria and rules were needed to be dealt with and addressed in a holistic approach, not on a case-by-case basis. In the past, there had been no generally applicable precise and objective conditions regarding the granting of observer status for international organizations.

549. The representative of Cameroon supported the views expressed by Nigeria and Angola. He said that OAPI had its headquarters in Yaoundé and his delegation had a moral responsibility to support the request of this organization. If Egypt was objecting granting a permanent observer status to OAPI, he wondered what would justify such a position. It was good to mention systemic issues, but it was also pertinent to state why granting permanent observer status would pose a systemic problem. He also supported the request made by ARIPO. Both sister organizations worked in Africa to serve the continent. Granting observer status on a meeting-by-meeting basis did not enable the Council to address the issue calmly and in a credible way.

550. The representative of the United States supported the proposal by Nigeria, Angola, Cameroon and others to include OAPI and ARIPO as permanent observers.

551. The representative of Brazil supported the statement by Nigeria to grant ARIPO and OAPI permanent observer status.

552. The representative of India reiterated that the request by the CBD Secretariat had a direct relevance to the issues being discussed in the Council. The CBD Secretariat fulfilled all the criteria for observership at WTO. It was an intergovernmental body, and it had more Members than even the WTO. The overwhelming majority of the WTO Members were also party to the CBD. He urged again the Council to positively and expeditiously consider the request of the CBD and until then *ad hoc* invitations should be extended on a meeting-by-meeting basis.

553. The representative of Zimbabwe said that he supported Nigeria with respect to granting ARIPO and OAPI permanent observer status. He referred to the master's degree in IP that was being offered at the Africa University in Mutare, Zimbabwe, with the support of WIPO and ARIPO, and thought it would be prudent to give these sister organizations a permanent observer status. He also said that, at the last meeting, Egypt had been ambivalent on this issue. A clarification would therefore be necessary. However, given what had already been said by Brazil, the United States, Nigeria, Cameroon and Angola, he believed that it would be right to give ARIPO and OAPI permanent observer status.

554. The representative of the European Union supported that ARIPO and OAPI, two respectable IP organizations with whom the European Union had close cooperation links, become permanent observers of the TRIPS Council.

555. The representative of China supported India's proposal and said that the CBD Secretariat should be granted observer status as TRIPS/CBD was an important issue at the TRIPS Council. He also supported the proposal by Nigeria to grant OAPI and ARIPO permanent observer status.

556. The representative of South Africa supported the proposal by Nigeria, Angola and Cameroon. He also agreed with the proposal to grant permanent observer status to the CBD Secretariat.

557. The representative of Ecuador supported India's position with respect to recognition of observer status for the CBD on an *ad hoc* basis. His delegation was willing to continue contributing to the Chair's consultations on this matter, given the lengthy list of organizations to be evaluated. He also said that the South Centre would as well be a valuable contribution as observer.

558. The representative of Egypt said that he was not opposing any specific organization to be granted observer status. He had only mentioned the systemic issue and the need to address it in a holistic approach. The requests from various international organizations, including the CBD, should be examined in an overall manner. He also confirmed that he supported further consultation on this issue.

559. The representative of Indonesia supported the suggestion to invite the CBD Secretariat as an observer to the Council's meetings and said that the adoption of the Nagoya Protocol had made it more relevant for Members to discuss the relationship between the TRIPS Agreement and the CBD. He believed that observer status for the CBD Secretariat was necessary to enrich and deepen the discussion.

560. The representative of Japan supported the permanent observer status for ARIPO and OAPI which were relevant to the TRIPS Council.

561. The representative of Mauritius, speaking on behalf of the ACP Group, supported the proposal of Nigeria. From what Egypt had just said, an implicit consensus had emerged concerning granting permanent observer status to ARIPO and OAPI. He therefore recommended that the Council decide accordingly. Although Members would need more time to consider other requests, he expressed his support to the admission of the South Centre and the CBD Secretariat.

562. The representative of the United States said that he maintained his position, and that he was not in a position to join other Members seeking to include the CBD as an observer. He looked forward to continued consultations.

563. The representative of Angola, speaking on behalf of the LDC Group, noted that Egypt had a systemic concern it had expressed on behalf of the Arab Group. This had to be addressed in a positive way. He recalled that the status of ARIPO and OAPI had been under consideration for nearly one year. Time had been given for things to ripen and so he was ready to have consultations with respect to other organizations, for example, with the ACP Group, the South Centre and the GCC. A global approach was necessary to establish parameters to discuss this. However, a fixed approach did not seem to be appropriate. Positions might change, and there was, therefore, a need to be open, as it was important in multilateralism to have an open mind.

564. The representative of Egypt said that, regarding ARIPO and OAPI, *ad hoc* observer status had been granted, and he was not against consensus. He just asked for further consultations about the other organizations.

565. The representative of Nigeria, speaking on behalf of the African Group, thanked the delegations that had supported his request for permanent observer status for ARIPO and OAPI. Referring also to the master's degree offered by the Africa University, WIPO and ARIPO, he said that it was an African institution that was trying to educate Africans on IP issues. The bearing was similar with the TRIPS Council. Since there was no consensus, he welcomed the Chair's consultations and hoped that he would come up with a positive conclusion, at least before the eighth Ministerial Conference.

566. The representatives of Zimbabwe and Angola requested that Egypt clarify whether it agreed to grant ARIPO and OAPI permanent observer status or whether the requests from these organizations should be considered together with other pending requests in further consultations.

567. The representative of Egypt said that he supported ARIPO and OAPI having *ad hoc* observer status in the TRIPS Council, and affirmed the need for further consultations regarding all pending requests, including from ARIPO and OAPI. He said that he did not have a rigid position. While he had talked about the systemic issue, he was not opposing any specific organization to be granted observer status in the TRIPS Council.

568. The Chairman suggested that he continue his consultations on the issue of observer status for international intergovernmental organizations and that the Council revert to the matter at its next meeting.

569. The Council took note of the statements made and agreed to proceed as suggested by the Chair.

R. ANNUAL REPORT

570. The Chairman said that the draft Annual Report of the Council to the General Council had been circulated in document JOB/IP/5. It still needed to be updated so as to reflect the discussions at the present meeting. He suggested that the Secretariat be requested to update the draft to reflect the discussions at the present meeting. This draft would be faxed to Members, who would have one week to comment on the updated parts of the draft report once it had been circulated by the Secretariat.

571. The Council so agreed.[11]

572. At its reconvened meeting of 17 November, the Chairman suggested that the Council adopt an update to the Report covering the reconvened meeting, which the Secretariat had prepared at the request of the Council and made available at the reconvened meeting.

573. The Council so agreed.[12]

S. OTHER BUSINESS

(i) Dates of the Council's meetings in 2012

574. The Chairman suggested that the Council agree on the following dates for its meetings in 2012: Tuesday and Wednesday, 28 and 29 February; Tuesday and Wednesday, 5 and 6 June; and Tuesday and Wednesday, 6 and 7 November.

575. The Council so agreed.

(ii) Invitations to ARIPO and OAPI

576. The Chairman recalled that, at its meeting in June 2010, the Council had agreed to grant an *ad hoc* observer status on a meeting-to-meeting basis to the African Regional Intellectual Property Organization (ARIPO) and the African Intellectual Property Organization (OAPI). He suggested that the Council again invite ARIPO and OAPI to attend the Council's next formal meeting on an *ad hoc* basis.

577. The Council so agreed.

578. The representative of Ecuador informed the Council that Ecuador was analysing the presentation of a document on technology transfer and climate change. The purpose of the document that was being drafted was to facilitate combatting the harmful effects of climate change on the part of developing countries who did not have the necessary technologies to do so. His delegation would be carrying out consultations before the next Council session, and would circulate the document in a timely fashion to Members so that they could assess it.

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[11] The Annual Report (2011) of the Council for TRIPS was subsequently circulated as document IP/C/59.

[12] An addendum to the Annual Report (2011) of the Council for TRIPS was subsequently circulated as document IP/C/59/Add.1.