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**Council for Trade-Related Aspects of  
Intellectual Property Rights**

**MINUTES OF MEETING**

Held in the Centre William Rappard on 28-29 February 2012

*Chairperson: Ambassador Dacio Castillo (Honduras)*

The present document contains the record of the discussion which took place during the Council for TRIPS meeting held on 28-29 February 2012.

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A. ELECTION OF THE CHAIRPERSON

1. The representative of the Secretariat recalled that the Chairman of the TRIPS Council Ambassador Federico González had informed the General Council at its December 2011 meeting that he had relinquished the post because of his return to the capital to take up new responsibilities. The normal practice of the TRIPS Council was that the outgoing Chair held office until the end of the first meeting of each year. The new Chair was then normally elected at the end of that meeting. Since the Chair had already relinquished his post, the Council would this time need to start by electing a new Chair.

2. At its meeting of 24 February 2012, the General Council had noted the consensus on a slate of the names of chairpersons for WTO bodies. On the basis of the understanding reached, he proposed that the Council for TRIPS elect H.E. Mr. Dacio Castillo from Honduras as its Chairperson for the coming year by acclamation.

3. The Council so agreed.

*Adoption of the agenda*

4. In proposing the agenda for adoption, the Chairman said that item M on "Australia: Tobacco Plain Packaging Bill 2011 and Its Compatibility with the TRIPS Agreement" had been put on the proposed agenda at the written request of the delegation of the Dominican Republic. Item N on "IP Enforcement Trends" had been put on the agenda at the written request of the delegations of Australia, Canada, the European Union, Japan, Korea, Mexico, New Zealand, Singapore, Switzerland and the United States.

5. The representative of India said that he was surprised to see that an item on IP enforcement had again been proposed on the agenda. At its October 2011 meeting, the Council had had on its agenda a similar item at the behest of the Anti-Counterfeiting Trade Agreement (ACTA) participants. At that time, Members had said that the idea had been to circulate the ACTA text. The item had no place on the agenda of this meeting, since the Council was not a forum to discuss such an agreement. He therefore opposed the adoption of the proposed agenda.

6. The representative of China said that that her first concern was that there was an inconsistency between the proposed agenda item and the supporting documentation. While IP enforcement was a broad issue on which Members had various views, the document provided for the item was solely focused on ACTA. In her view, ACTA could not represent IP enforcement trends in general. She said that she did not understand the intention of the proponents and could not accept the proposed item as such.

7. Secondly, the Council had been instructed and mandated by Ministers at Doha and Hong Kong to focus its discussion on implementation-related issues. While those issues remained not fully resolved, it would not be appropriate for the Council to deviate from those instructed topics. Thirdly, the proposed item had already been on the agenda of the Council's last regular meeting and detailed presentations had been made on various parts of ACTA. A repetitive exercise would be redundant, except if there were further explanations. Finally, she emphasized that ACTA was not part of the TRIPS Agreement. It went beyond the enforcement requirements of the TRIPS Agreement and was a TRIPS-plus provision. It was concluded only between some Members of the WTO and therefore was neither a multilateral agreement among the whole WTO membership nor a plurilateral agreement as listed Annex 4 to the WTO Agreement. Therefore the content of ACTA should not be a topic for TRIPS Council meetings. If the proponents wished to share information on ACTA with other WTO Members, they could do so under item Q on "Other Business" or make a notification under Article 63 of the TRIPS Agreement.

8. The representative of Ecuador said that item N had already been dealt with at the Council's last meeting and should not become a permanent item of its agenda. ACTA was only one vision of IP trends, did not represent best practices and was not within the TRIPS framework. The item could be dealt with under "Other Business".

9. The representative of Egypt said that he did not accept item N on the agenda, although the matter could be dealt with under "Other business". The Council should not be a forum to promote TRIPS-plus issues and should stick to the mandate set up by Ministers.

10. The representative of the Plurinational State of Bolivia said that it was not appropriate to review ACTA as an item of the agenda. If the proponents wished to carry out a transparency exercise, that should be done under an appropriate agenda item. Furthermore, ACTA did not represent the best trends.

11. The representative of Cuba said that ACTA was not a relevant issue for the Council and did not agree that it be included on the agenda. Initiatives aiming at plurilateralism should not be analysed in the Council except under "Other business".

12. The representative of Brazil said that the discussion of enforcement at the WTO should be confined to matters related to the TRIPS Agreement and its implementation. There was no mandate to discuss TRIPS-plus measures in the Council.

13. The representative of the Bolivarian Republic of Venezuela said that he was against including item N on the agenda. ACTA went far beyond the TRIPS Agreement and therefore should not be raised in the Council. It was difficult to carry out a transparency exercise with something that had started without transparency. Most importantly, ACTA was not part of the multilateral context.

14. The representative of the United States said that, given that enforcement was the subject matter of Part III of the TRIPS Agreement, item N was perfectly consistent with the mandate of the Council. The delegations who had requested this agenda item had met all the procedural requirements for filing an item and consensus had been reached on the item title in October 2011 as well as on including the item on the agenda of the October Council meeting. If Members had questions regarding the subject-matter of the item, which was evident from the previous interventions, he would welcome the discussion.

15. As indicated in October, Members had raised questions in the past and there had been requests for additional information at the October meeting as well. Transparency lay at the foundation of the agenda item. Many Members, and not only proponents of the item, had explicitly supported the objective of promoting transparency at the Council's last meeting, and they had done so at the present meeting by suggesting that the item be discussed under "Other business". This was reflected in paragraphs 5 through 31 of the minutes of the October TRIPS Council meeting (document IP/C/M/67). To call for transparency and yet to oppose the proposed agenda item was curious and internally inconsistent. To deny a response from the ACTA participants to Members who had asked questions and sought additional information was difficult to reconcile.

16. He said that "Other business" was inappropriate since the proposed agenda item was not limited to an announcement, as was the purpose of "Other business". He also referred Members to Rule 25 of the Rules of Procedures, which confirmed this point. Instead, this item was a substantive item in nature and intended to promote a good exchange of views. With respect to the reference made to past ministerial statements, he recalled paragraph 3 of the statement of Ministers from the December 2011 Ministerial Conference (document WT/MIN(11)/W/2), where "Ministers underline the importance of the work of regular WTO bodies including their role in the oversight of implementing existing Agreements; dispute avoidance; transparency through monitoring and

reporting and as a forum for the consideration of trade-related issues raised by Members". In his view, the proposed agenda item was fully in line with the intent of Ministers. In contrast, it was difficult to understand how opposing this item fulfilled that intent.

17. The representative of Japan said that the proposed agenda item should be addressed in the Council because IP enforcement was a relevant issue for it. Furthermore, the Government of Japan had hosted a signing ceremony of ACTA in January 2012. He believed that the item was a useful opportunity to share on new developments since the Council's last meeting.

18. The representative of the European Union said that enforcement was an extremely important element of IP and of the TRIPS Agreement. It therefore made sense to have a discussion. He intended to talk about IP enforcement trends, *inter alia*, ACTA, and he looked forward to having that discussion at the present meeting under the relevant agenda item.

19. The representative of Canada said that she welcomed an informed discussion on enforcement issues in the Council, as counterfeiting and piracy posed serious threats to the global economy. Effective enforcement of IPRs was a fundamental aspect of the TRIPS Agreement and it should be addressed in the ambit of the Council. It was not only a matter of establishing procedures and remedies but also of improving cooperation, capacity building and communication among Members.

20. The representative of Australia said that his intention was to continue the discussion that had started at the Council's last meeting and had not been completed. It certainly would not be the first time that ACTA had been discussed in the Council. It had been raised a number of times previously.

21. The representative of New Zealand said that the proposed agenda item was appropriate and that it would provide an opportunity for a useful transparency exercise and to continue discussion on some questions remaining from the October meeting.

22. The representative of Switzerland said that the proponents of the agenda item had fully ensured compliance with the procedural requirements. Furthermore, the title had already been adopted in October 2011. ACTA was not the enforcement trend but obviously one development in the sphere of enforcement trends. The purpose of the discussion would be to give further explanations, as ACTA had been the subject of a fair amount of discussion on Internet blogs and the press, and there had also been misleading and wrong information about it. Accordingly, he felt that it was his obligation to correct and rectify that information and provide answers that Members had posed in earlier Council meetings.

23. The representative of Thailand said that that IP enforcement was a very important issue. However, if the Council were to discuss IP enforcement trends or any TRIPS-plus standard setting, it should move in very small steps. As agreed by many Members in the General Council meeting earlier that month, the Council should be pragmatic and avoid a dogmatic approach.

24. The representative of Mexico said that the proposed agenda item was important for transparency and he wished to continue in that direction with other delegations.

25. The representative of China said she could go along with Members who had said that the intention was to strengthen the regulative body of the WTO. At the Council's October meeting, the previous Chair had successfully facilitated a compromise among Members on this item. If the proponents would insist on the agenda to be adopted as proposed, the discussion under that agenda item should not be limited to ACTA, but Members should be entitled to raise other enforcement trends. In a spirit of collaboration and to avoid blocking the adoption of the agenda, she was ready to adopt the agenda with the proposed item with the understanding that it was a temporary item.

26. The representative of Korea said that the proposed agenda item fulfilled all the procedural requirements and fell within the Council's mandate. Moreover, several questions had been raised relating to the matter and not addressed at the Council's last meeting. She said that she could go along with China's constructive suggestion.

27. The representative of India said that, since there was no consensus regarding the inclusion of the proposed agenda item, it should be dealt with under "Other business".

28. The Chairman noted two points made by delegations, namely that the proposed agenda item should not become a standing item on the Council agenda, and that the request that the item be put on the proposed agenda did meet the procedural requirements for its inclusion. On that basis, he suggested that the Council take note of the statements made and adopt the proposed agenda.

29. The Council so agreed.

#### B. NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

30. The Chairman said that, since its meeting in October 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:

- Georgia had notified its laws on patents, copyright and neighbouring rights, trademarks, designs, appellations of origin and geographical indications of goods, topographies of integrated circuits, new breeds of animals and new varieties of plants, as well as a law on border measures relating to intellectual property and certain resolutions related to industrial property;
- Colombia had notified certain provisions of a law establishing the National Development Plan 2010-2014 that concerned the transfer of IPRs generated under services or employment contracts, or in research projects funded by the national budget;
- Japan had notified its Unfair Competition Prevention Act; and
- the United States had notified its Trademark Rules of Practice, and Trademark Technical and Conforming Amendments.

31. These notifications would be circulated in the IP/N/1-series of documents, which contained two types of documents. The base document for each notification contained the list of laws and regulations that a Member had notified and any explanations relating to them. The actual texts of the laws and regulations were circulated in a law series of documents. The base document provided a reference to each of these law series documents that contained the full texts of laws and regulations.

32. While the Secretariat would share under "Other business" information on the implementation of the recommendations for savings and more efficient use of resources made by the Budget Committee and adopted by the General Council and how this affected the TRIPS Council's work, he wished to already mention one element of the implementation of these recommendations. While the Secretariat was continuing to circulate base documents both in hard copy and electronic form, the actual texts of laws in the sub-series of documents would only be circulated in electronic form on the Documents Online database. This procedure also responded to the feedback from users that the routine circulation of hard copies of texts of laws and regulations did not, on the whole, facilitate access to these materials. To the contrary, feedback from users showed that, overwhelmingly, the first point of access was the on-line version of the document, not separate collections of hard copies.

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, since the Council's meeting in October, updates to contact points notified earlier have been received from Georgia and Ukraine. The information on the Members' transparency toolkit page had been updated accordingly.

34. The representative of Paraguay said that, since the entry into force of the TRIPS Agreement, Paraguay had made significant progress in the area of IP protection, not only with regard to the updating of legislation, but in work relating to the implementation of the Agreement. The following areas were those in which work had been carried out, activities organized, and measures taken.

35. In 2008, Paraguay had carried out a legislative reform whereby, pursuant to Law No. 3.440/2008 amending various provisions of the Criminal Code, the penalties for IP offences had been increased and custodial sentences of two to eight years had been introduced. The Office of the Public Prosecutor had also been reorganized into units, with the creation of a specialized unit for IP offences (*Unidad Especializada de Delitos Contra la Propiedad Intelectual*). This Unit's specific function was to combat the copying or plagiarism of copyright protected works. The prosecution department employed four prosecutors. In July 2010, the Unit's operations manual (*Manual de Funciones*) had been approved. This manual had helped to optimize the functioning of the area concerned by ensuring the appropriate distribution of tasks and proper coordination. In addition, training and updating activities were continuously being organized for the prosecutors involved. A prosecution department was also responsible for IP offences in Ciudad del Este, which was one of the most problematic areas in Paraguay.

36. In 2011, the Supreme Court of Justice ruled, by means of Decision (*Acordada*) No. 676, that a criminal court for economic offences (*Juzgado Penal de Garantías en Delitos Económicos*), responsible for addressing issues relating to economic crimes, would take charge of, *inter alia*, issues pertaining to the infringement of IPRs and in doing so speed up legal proceedings relating to such matters. The Supreme Court of Justice had also created an Intellectual Property Directorate within the judiciary with a view to supporting the work carried out in this area.

37. With a view to preventing piracy and counterfeiting and protecting copyright (Decree No. 603/2003), special measures had been taken to create the Register for Importers of Magnetic and Optical Media and Raw Materials Used in the Production thereof (*Registro de Importadores de Soportes Magnéticos y Ópticos y Materias Primas para su Producción*). In this respect, natural or legal persons that imported audiovisual recorded materials, videograms, films, musical and audiovisual compact discs and software, or the raw materials used to manufacture these products, required prior authorization from the Ministry of Industry and Trade.

38. In February 2010, the National Customs Directorate had created a trademark registration department (*Sección de Registro de Marcas*) to facilitate the identification of IPR infringing goods and to raise further awareness of the IPRs registered with the Directorate-General of Industrial Property at the Ministry of Industry and Trade. To this end, officials working in this department received on-going training and were brought up to date on procedures and techniques for identifying goods that infringe IPRs.

39. The national police force now had a department for economic and financial offences (*Departamento de Delitos Económicos y Financieros*) which was responsible for issues relating to IPR protection within its remit. A specialized technical unit (*Unidad Técnica Especializada - UTE*) was responsible for investigating and providing support in operations involving the seizure of goods related to alleged IPR offences.

40. The system for exchanging data between institutions involved in IP protection was currently undergoing a complete overhaul with a view to establishing a data and statistics centre (*Centro de*

*Datos y Estadísticas*). This centre would enable institutions, through their competent authority, to provide better information on procedures and seizures, and ensure accurate and timely information on IP-related issues. The Research and Data Centre would also improve coordination between institutions.

41. The Directorate-General of Intellectual Property at the Ministry of Industry and Trade was also working on the creation of a National Intellectual Property Directorate. The draft law establishing the National Intellectual Property Directorate (DINAPI) had been submitted to the Chamber of Deputies in December 2011 and was currently being examined by various committees within this legislative body. The purpose of establishing this National Directorate was to strengthen the body responsible for the administration and protection of IPRs and to raise awareness of these rights at the national level. In terms of infrastructure, the Office of the Public Prosecutor had been modernized and the Directorate-General of Intellectual Property was undergoing reform.

42. Another important aspect was the raising of awareness of legislation on trademark rights, copyright and patents through the publication of a compendium of key laws and decrees on intellectual property (*Leyes y Decretos Esenciales en Materia de Propiedad Intelectual*). This publication was distributed free of charge on a general basis to universities and legal professionals. Talks were also being given in colleges and universities throughout Paraguay with a view to introducing the subject of IPRs to around 10,000 young people. An agreement had also been signed by the Directorate-General of Intellectual Property and the Ministry of Education and Culture (MEC), under which a subject entitled "Intellectual Property" would be introduced into the school curriculum for final year students.

43. Combatting piracy was important to Paraguay, as was preventative action. The population was not fully aware of what IP was, which presented the Government with a considerable task, given the poor economic status of the country. Emphasis was being placed on the complex awareness-raising process in an attempt to prevent IP offences from increasing and getting worse.

44. Statistics had increased in recent years, in particular since 2005, which highlighted the considerable increase in the number of trademarks and patents registered nationally. This implied that the private sector had understood how important the intangible assets acquired by registering trademarks and products were for companies. Paraguay, as a developing country, considered it very important to highlight the intensive efforts that it had been making to introduce changes and move forward as regards IP, and to emphasize its firm commitment to continue making progress with its work in this area.

45. The representative of Colombia said that, on 13 January 2012, Colombia had deposited its instrument of accession to the World Intellectual Property Organization Trade Law Treaty and that this treaty would enter into force in Colombia on 13 April 2012. A notification would be made to the attention of all Members.

46. The Chairman thanked those Members who have notified new and revised laws and thus contributed to the goal, set by the General Council, of improving the timeliness and completeness of notifications across the Organization. This was an important practical reminder of the value of a comprehensive and up to date set of notifications. He therefore urged those Members whose initial notifications of laws and regulations remained incomplete to submit the outstanding material without delay. He also reminded other Members of their obligation under the TRIPS Agreement to notify any subsequent amendments of their laws and regulations without delay after their entry into force. He especially encouraged Members to notify changes made to their laws and/or regulations to implement the Decision on TRIPS and public health.

47. The Council took note of the statements made.

C. REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION

48. 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.

49. The representative of Cuba informed the Council of the recent enactment of Decree Laws Nos. 290, 291 and 292 relating to legislation on inventions and industrial designs, the protection of plant varieties, and layout-designs of integrated circuits. Once published, these Decree-Laws would be notified to the WTO. By the Council's next meeting in June, the Secretariat would also have received replies to the questions put forward by Members.

50. The Chairman recalled that, at its meeting in October 2011, the Council had agreed to review the national implementing legislation of Maldives at its next meeting scheduled for 5-6 June, and set the following target dates for the submission of questions and answers: questions should be submitted to Maldives, with a copy to the Secretariat, by 27 March at the latest; and responses to questions posed within that deadline should be submitted by 8 May at the latest.

51. The Council took note of the statements made.

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

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

F. PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

52. The Chairman suggested that the Council continue to discuss the three agenda items together on the basis of contributions by Members as had been the practice at past meetings. He recalled that, at its meeting in October 2011, the Council had requested the Chair to continue consulting on the suggestion that the CBD Secretariat be invited to brief the Council on the outcome of the Nagoya meeting. He said that he would be ready to continue his predecessor's consultations on that matter prior to the Council's meeting in June 2012.

53. The representative of Indonesia said that, as a proponent of document TN/C/W/52, her delegation remained of the view that all Members should take bold steps to address the issue so that the Council not only produced fruitful result but also contributed to substantive progress. Given the fact that the protection of genetic resources, traditional knowledge and folklore was crucial for developing countries, she reiterated the urgency of enhancing disclosure requirements. The implementation of the disclosure requirements would ensure the success of development, as the potential of genetic resources and associated traditional knowledge could become one of the key elements for economic welfare for people in developing countries, especially that of mega-diverse countries.

54. As the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (Nagoya Protocol) had been adopted, she urged all Members, especially those who did not share her view, to seriously consider the importance of the issue and the matter at stake. It would be in Members' best interest to articulate through the TRIPS Agreement the aim to afford sufficient level of protection to genetic resources and to provide a fair practice for their use.

55. Referring to the 20<sup>th</sup> session of the WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), she said that her



delegation, together with the group of like-minded countries, had successfully come up with a draft text on the protection of genetic resources. That text was far from complete, since the negotiation on genetic resources, unlike that on traditional knowledge and traditional cultural expression, was not text-based, being still considered merely on the basis of draft objectives and principles. Against that background, she viewed the underlying importance of making a concrete connection between the discussions in the Council and in other forums, most notably within WIPO, to be crucial. She informed the Council that the Government of Indonesia would host an international symposium on defensive protection of genetic resources and traditional knowledge and folklore back-to-back with the meeting of the group of like-minded countries in Bali before the coming summer season.

56. The representative of the Plurinational State of Bolivia said that, in March 2011, Bolivia had submitted document IP/C/W/554, entitled "Article 27.3(b) and the Legalization of Biopiracy: Trends, Impacts and Why It Needs to be Amended", to contribute to the work programme of the Council and to continue the process of reviewing and amending one of the most controversial articles of the TRIPS Agreement. The document demonstrated how biopiracy had surged since the adoption of that article, turning what had previously been a number of isolated cases into a veritable race to patent genetic resources and their derivatives. The field of biotechnology could not be treated in a same manner as other areas of human knowledge. The patenting of life forms or parts thereof as genetic resources or their derivatives had serious implications for the livelihoods, beliefs and values of many populations and cultures in numerous parts of the world, and in particular those of the indigenous peoples of Bolivia.

57. The negative aspects of the TRIPS provision were not just limited to ethical questions. As stated in document IP/C/W/554, there was an adverse impact on various sectors of human activity at the global level, including agriculture, health and food, owing to the concentration of gene and technology patents in the hands of some ten multinational companies globally, which held a monopoly in that regard. If that was what Members were hoping to develop with the IP system, then they were heading for trouble. For the above reasons, he reiterated the imperative need to review the aforementioned Article as proposed in documents IP/C/W/554 of March 2011 and IP/C/W/545 of February 2010.

58. The representative of Brazil supported the introduction of a mandatory disclosure of origin requirement in the TRIPS Agreement. He said that this was an important step to make the IP system supportive of international provisions on that matter, such as the CBD and the Nagoya Protocol. A multilateral mandatory disclosure requirement would be the most efficient way to address the international problem of misappropriation of genetic resources and traditional knowledge as it would allow tracking down the country providing genetic resources and associated traditional knowledge through patent applications. The disclosure requirement would demand patent applicants to reveal the country providing genetic resources and associated traditional knowledge, as well as to provide evidence of compliance with the principles of prior informed consent and access and benefit sharing. Brazil supported the proposal to invite the CBD Secretariat to make a briefing on the Nagoya Protocol in the Council.

59. The representative of China said that, as patents were closely related to the utilization of genetic resources and/or associated traditional knowledge, WTO Members should take appropriate and effective measures in patent applications to prevent misappropriation of genetic resources and to avoid erroneous patents. The TRIPS Agreement, the CBD and the Nagoya Protocol should operate in a mutually supportive way. In the view of some Members, 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 disclosure requirement of prior informed consent and benefit sharing in patent applications was indispensable to achieve those objectives. In the view of China, contractual arrangements and the novelty requirement in patentability were not enough for the protection of genetic resources because contractual arrangement

depended on voluntary behavior and fulfillment of parties to contracts, and the novelty requirement played a secondary role in preventing erroneously granted patents. Databases and other information that patent examiners might have access to before granting a patent were limited compared to the large quantity of genetic resources existing in the world. As one genetic resource could generate several 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 requirements. 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 in the first place. As one of the co-sponsors of documents TN/C/W/52 and TN/C/W/59, China believed the mandatory disclosure requirement would improve the transparency of utilization of genetic resources and/or associated traditional knowledge, and would help to achieve the goals. 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.

60. She noted that the Eighth Ministerial Conference had agreed that "Ministers remain committed to work actively, in a transparent and inclusive manner, towards a successful multilateral conclusion of the Doha Development Agenda in accordance with its mandate" and that "Ministers maintain that, in their negotiations, they will continue their work based on the progress already made". The issues of TRIPS-CBD and GI extension were outstanding implementation-related issues in the Doha Round. Negotiations on those issues must be an integral part of the Work Programme, and the outcome of the negotiations must be treated as part of the Single Undertaking. She hoped that the Director-General would continue his consultations based on a legal text, in pace with the arrangements for other Doha negotiations. She supported the proposal to invite the CBD Secretariat to make presentations in the Council from a perspective different from CBD members. The presentation would help to improve Members' understanding of the Nagoya Protocol, and contribute to the cooperation between WTO and other international organizations.

61. The representative of Ecuador said that there were a number of reasons for preserving and protecting Ecuador's biological wealth and associated knowledge, one of them being the fact that Ecuador was one of the world's 12 mega-diverse countries. Despite being the smallest of the 12 countries, Ecuador was home to more species and plants than countries 30 times its size. In short, Ecuador had the highest density of species diversity in the world. In addition to environmental aspects and the spiritual and cultural value of preserving biodiversity and associated elements, economic assessments carried out in Ecuador had estimated that in the west of the country, the value of a square kilometer of land as a provider of potential new medicines could be US\$9,177. It would therefore seem, according to those studies, that that region was one of the most valuable for bio-prospecting in relation to 18 other world biodiversity hotspots. Furthermore, recent scientific studies showed that more than 35 per cent of the new medicines marketed in the last 20 years derived from natural products. Such scientific studies had determined, for example, that 74 per cent of the 135 species of microscopic fungi and bacteria living in the plants and tropical forests of the Amazon region shared by Ecuador and Peru were bioactive, i.e. of potential use to human beings. For example, fifteen years ago a new alkaloid called epibatidine had been extracted from the skin of tiny poisonous frogs (species *Epipedobates*) living in the tropical forests of Ecuador. That molecule was found to have painkilling properties 200 times more effective than morphine, despite being far less addictive. The same studies showed that more than 100 traces of alkaloids had been detected in frog skin extracts, the utility of which remained to be established.

62. All of those aspects made it clear why developing countries were so keen to promote sustainability and legitimate access to biodiversity and associated traditional knowledge by ensuring adequate protection at multilateral level in the field of IP. In that context, it was essential to bear in mind document TN/C/W/59 of 19 April 2011, which contained the minimum legal elements to be

incorporated into the TRIPS Agreement. It would ensure legal protection for legitimate and fair access to biodiversity resources and associated traditional knowledge, i.e. (i) disclosure of the source and country of origin in accordance with the CBD; (ii) presentation of a copy of an internationally recognized certificate of compliance of prior informed consent and fair and equitable benefit sharing, or, where that was not applicable in the providing country, provision of relevant information regarding compliance with prior informed consent and fair and equitable benefit sharing; (iii) adoption of appropriate, effective and proportionate measures so as to permit effective action against non-compliance with the obligations set out in points (i) and (ii); (iv) non-processing of patent applications that did not comply with the disclosure obligations listed above; (v) adoption of measures establishing administrative sanctions, criminal sanctions, fines and adequate compensation for damages in cases where non-compliance with points (i) and (ii) was discovered after the approval of a patent application; and (vi) adoption of measures which made it possible to determine other types of sanctions, including revocation of the patent due to non-compliance with points (i) and (ii).

63. In conclusion, he emphasized that while progress had been made in other multilateral negotiating forums, e.g. the Nagoya Protocol and the recently concluded 20<sup>th</sup> session of the IGC, which had resulted in the drafting of a document containing legal texts on that subject, part of the multilateral work was the contribution that WTO Members could make to ensuring adequate protection. It was therefore important for the Council to make progress in that respect.

64. The representative of Peru supported the statements made by Indonesia, Brazil and China on the three agenda items and the proposal to invite the CBD Secretariat. The international IP system as established in the TRIPS Agreement needed to be improved so as to ensure a fair and balanced regime for the protection of folklore and traditional knowledge and to avoid misappropriation and biopiracy. Since 2003, Peru, together with other WTO Members, had submitted 11 relevant working documents in the Council. Peru had also submitted four documents, which analyzed biopiracy cases and provided legal and practical arguments on the need for disclosure requirements in the patent system. The IP system could be adapted to the provisions of the CBD and the Nagoya Protocol through the amendment of the TRIPS Agreement. The disclosure requirements made it possible to identify the country of origin and to ensure that prior informed consent and benefit sharing were respected. In that context, a large number of WTO Members had submitted document TN/C/W/59, which proposed to include Article 29*bis* into the TRIPS Agreement with a view to establishing disclosure requirements. The proposal would not hamper the access to or use of genetic resources, but would protect genetic resources against biopiracy and ensuring their sustainable use. Unfortunately, the proposal had not been examined and discussed in the context of the Doha Round. He said that a successful conclusion of the negotiations in the WTO should include results in that area, and the interests of the developing countries should be reflected in the outcomes, in particular when it came to the protection of genetic resources, folklore and traditional knowledge. Only a solution that dealt with the problem of biopiracy would enable Members to establish a proper balance in the patent system and the IP system in general for the benefit of all, particularly the indigenous peoples of the developing countries.

65. The representative of the Bolivarian Republic of Venezuela supported Bolivia's proposal to review Article 27.3(b) of the TRIPS Agreement. Domestic legislation, especially Articles 124 and 127 of the Constitution of the Bolivarian Republic of Venezuela banned the registration of patents on all life forms. Review of Article 27.3(b), as provided for in the last sentence of Article 27.3(b) and as required by the Ministerial Conference, was part of the Doha mandate. Under Article 27.3(b), it was possible for Members to exclude from patentability plants and animals other than micro-organisms, and essentially biological process for the production of plants or animals other than non-biological and microbiological processes, which was against Venezuela's Constitution, and contradicted the principles related to food safety, values of the country, and the protection of indigenous peoples' knowledge and folklore, genetic resources and ancestral knowledge. Therefore, it was time for Members to modify or clarify Article 27.3(b). In addition to the constitutional and legal concerns over the patenting of life forms, there was also an ethical concern. While highlighting the sovereignty

of the State and indigenous peoples over their biological resources, he said that the authority to determine the access to the genetic resources lay with national governments and was subject to national legislation. In other words, genetic resources and traditional knowledge should not come within the IP framework as it was against the sovereignty of Venezuela.

66. The representative of New Zealand said that her country had a high degree of endemic flora and fauna, and therefore her 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. 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.

67. New Zealand's domestic policy was still evolving in the area, 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. The IGC was currently working on the text of an international instrument or instruments on the protection of the three subject matters. New Zealand considered that the IGC was an appropriate forum to discuss in detail the IP issues relating to traditional knowledge and genetic resources because it was able to look at those issues in a holistic and coordinated way. New Zealand was active and constructive in the IGC and was committed to the fulfillment of the IGC mandate. She noted that the IGC had met in February 2012 with the focus on genetic resources issues and had agreed to a single draft text. While the draft text contained a number of divergent policy objectives and policy options, it was nonetheless a positive step forward.

68. The representative of Turkey said that, due to its geographical location and climate, Turkey had rich animal and plant biodiversity. As a country having a high degree of unique endemic flora, Turkey had an interest in preserving its genetic resources, preventing the misappropriation of genetic resources and associated traditional knowledge, and preventing the grant of erroneous patents. She welcomed the progress made in the IGC, particularly the recent consolidated legal text on IP and genetic resources. She supported the introduction of a mandatory disclosure requirement, and was open to the introduction of the principles of prior informed consent, and access and benefit sharing.

69. The representative of Korea said that the review of Article 27.3(b) should be of a procedural nature and should not lead to a revision of the TRIPS Agreement. He did not subscribe to the idea of prohibiting the patenting of all life forms. Instead, he said that inventions in all fields of technology, including biotechnology, deserved to be incentivized through adequate patent protection. Given the huge potential benefits of biotechnology to all humankind, research and development in that field should be encouraged. His delegation did not support the proposal of introduction of a mandatory disclosure requirement, which would create legal uncertainties and would be too burdensome for patent applicants as well as for patent authorities. Further, it would not seem feasible to reach consensus among Members on a manageable definition of source and country of origin. Given the substantive progress made in the IGC, he said that the IGC was the right forum for further discussions. In addition, he was not convinced that the issues of TRIPS-CBD and GI should be discussed in parallel, as they were completely unrelated to each other and should not be linked in any form in the discussion.

70. The representative of India said that the issue of incorporating the CBD provisions into the framework of the TRIPS Agreement demanded much greater involvement of WTO Members, especially after the signing of the Nagoya Protocol by 193 countries. The first Conference of Parties

in the UN Decade on Biodiversity to be hosted by India in October 2012 would be the first milestone to assess the progress in the implementation of the Nagoya Protocol, and the work in the Council could significantly contribute to its success. The disclosure of origin had been successfully implemented in India and in many developing countries. It was indeed a workable solution which motivated developing countries to make submissions to the Council in order to have an international architecture that could protect their interests. The latest proposal contained in document TN/C/W/59 submitted in April 2011 was a major step forward from the proposal contained in document TN/C/W/52 and it incorporated the provisions of the Nagoya Protocol. The proposal was compatible with the TRIPS Agreement and did not diminish the rights of the patent holder as provided for in the TRIPS Agreement.

71. He said that the Indian Patent Law had incorporated the disclosure requirements within Section 10 specifying clear and complete disclosure requirements. While Section 10(4)(a) embodied the enablement and written description requirements, Section 10(4)(b) provided for the disclosure of the best mode of performing the invention. Further Section 25 of India's Patent Law provided for pre-grant and post-grant opposition that helped in avoidance or revocation of erroneous patents for failure of the patent applicant to meet the disclosure requirements. The prior approval of the National Biodiversity Authority was required for any invention based on research/information on biological resources. In addition, India's Traditional Knowledge Digital Library (TKDL) was an important contribution to prevent misappropriation of traditional knowledge at international patent offices. Today, the TKDL was capable of protecting about 2.5 lakh medicinal formulations similar to those of neem and turmeric. Access to the TKDL had been given to eight international patent offices as of now.

72. Challenging patents at international patent offices was a long drawn process and was very expensive. For example, Mexico had been able to get the patent on enola bean at the United States Patent and Trademark Office cancelled in July 2009 after more than 10 years of legal battle. Similarly, the Monsanto soybean patent was cancelled at the European Patent Office in July 2007 after 13 years of legal battle. India's limited initiative in the form of the TKDL could only prevent erroneous patents in the limited field of traditional Indian medicine. The TKDL enabled the cancellation/withdrawal of wrong patent applications at zero cost and in a time period of a few weeks. In sharp contrast, in the absence of the TKDL, it had taken 10 years (1995-2005) to get neem patent invalidated for antifungal properties at the European Patent Office. The TKDL's impact on biopiracy was already visible. The references to TKDL as prior art had led to significant outcomes towards achieving the goal of preventing misappropriation of Indian traditional knowledge. Beginning in July 2009, the TKDL team had submitted 571 prior art references, resulting so far in 88 patent applications of the pharmaceutical companies of the United States, the United Kingdom, Japan, Spain, Italy, China, etc. being set aside or withdrawn/cancelled or declared as dead patent applications. According to a recent study, there had been a sharp fall (44%) in patent applications filed at the EPO concerning Indian systems of medicines. While the disclosure obligation ensured that the applicant had provided accurate and adequate information on the source of the traditional knowledge, the TKDL enabled in identifying prior art and to ascertain the novelty in the claims. With the development of databases similar to the TKDL by other developing countries and their extensive use by the international patent offices, it was possible to avoid grant of erroneous patents in future in areas where the databases had been developed. Hence incorporating the disclosure provision was an appropriate measure that would bring in uniformity in the practice of patent offices in using such databases and coherence in ascertaining the validity of patent claims involving traditional knowledge and/or associated genetic resources.

73. In conclusion, he reiterated that the TRIPS-CBD issue was one of the outstanding implementation issues and the Council should take a serious note of the compliance issues under the Nagoya Protocol to deal with internalizing the relationship between access and benefit sharing and IP protection to become an important deliverable of the Round for developing countries. Exhaustive

discussions alone on the TRIPS-CBD issue over the last ten years were not enough if Members sought a positive outcome on the issue. Members needed constructive engagement in the Council, which was sadly missing on part of some developed country Members. He noted with considerable concern that some Members could not agree to a presentation by the CBD Secretariat on the Nagoya Protocol in spite of the fact that 193 countries had already adopted the Nagoya Protocol. It was unfortunate that the same Members who opposed a presentation by the CBD Secretariat in the WTO had no problems with the CBD being present in the WIPO or WHO.

74. The representative of Cuba endorsed the arguments put forward by Bolivia and the statements made by Ecuador and Venezuela on critical aspects of implementation. She reiterated Cuba's long held position on the need to amend Article 29 of the TRIPS Agreement so that Members had the right to request patent applicants to disclose the source and country of origin of inventions based on biological materials and to provide evidence of prior informed consent and benefit sharing among the parties receiving the consent to investigate and exploit genetic resources, as well as the publication of applications relating to biological material.

75. The representative of Colombia supported the statements made by some other co-sponsors of document TN/C/W/52. She said that the IP system was a mechanism for promoting innovation and investment. Patents should not have negative impacts on the protection of genetic resources and their derivatives. Not only the inventor but also the States providing the resources should receive the benefits arising from the use of the genetic resource. Members needed implementing tools for monitoring compliance with the provisions on access and benefit sharing. She supported the proposal to invite the CBD Secretariat to present the Nagoya Protocol to the Council.

76. The representative of Chile said that the three main requirements for patentability established under Article 27.1 of the TRIPS Agreement, i.e. novelty, inventive step and industrial applicability should be fully implemented by IP offices and, were that to happen, there should be no contradiction or conflict with the appropriation of naturally occurring life forms. It was vital for national and regional patent offices to have access to all the information available so as to avoid granting erroneous patents. Databases could be of great use in that regard. As Chile had endemic unique genetic resources, it was looking into the development of a system that would regulate those resources in compliance with its international commitments. In that context, Chile was analyzing the benefits of the disclosure requirement. He welcomed the work being carried out on that issue in other forums, in particular the IGC, and hoped an increase in the number of the meetings of the IGC in 2012 would allow for major progress in that regard.

77. The representative of South Africa said that there were three fundamental conflicts between the TRIPS Agreement and the CBD according to their respective spirit and the objectives. Firstly, Article 3 of the CBD provided that states had sovereign rights over their biological resources while the TRIPS Agreement overlooked states' sovereignty but recognized private IPRs over those resources. Secondly, the CBD provided states with an opportunity to demand sharing of the benefits arising from commercial use of biological resources while the TRIPS Agreement negated that legal authority. Thirdly, the CBD was aimed at reducing biopiracy by requiring prior informed consent whereas the TRIPS Agreement did not contain such a requirement, which meant that patent applications could be submitted over biological resources or knowledge of certain local communities in any other countries. The TRIPS Agreement recognized patent rights on the basis of novelty which did not take into account traditional knowledge and cultural practices. There was a need to avoid erroneous grant of patents for inventions that involved the use of genetic resources and related traditional knowledge. There was also a need to secure compliance with national access and benefit-sharing regimes in the relevant Member's jurisdiction. It was clear that the application of the TRIPS Agreement might threaten the preservation of biological resources and traditional knowledge.

78. The three conflicts were what Article 16.5 of the CBD advised against, which read that IPRs must not be in conflict with sustainable use of biodiversity. What could aid in reconciling the two agreements was a proper legal review of both agreements with the aim of making amendments where necessary to ensure mutually supportive application. Under the review of Article 27.3(b) of the TRIPS Agreement, amendments could be made to incorporate the CBD objectives into the TRIPS Agreements in order to preserve biodiversity, prevent biopiracy and include protection of local community rights in accordance with the spirits and purport of the CBD.

79. 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 CBD compliance. An appropriate solution should be considered in each case, bearing in mind that such solutions should accomplish each objective in a manner that would not have an adverse effect on the IP system. Japan had proposed the establishment of one-click databases to prevent erroneously granted patents. His delegation attached a great deal of importance to the Nagoya Protocol and expected that Members' efforts to implement it would have international effects. With regard to the Bolivian proposal, he reiterated that the patent system provided a critical incentive for technological development in all the fields, including biotechnology, which was crucial for the world at large.

80. 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. Australia had signed the Nagoya Protocol on 20 January 2012, and was currently undertaking internal processes to consider its ratification. Australia had already implemented an access and benefit-sharing system in relation to genetic resources and associated traditional knowledge, consistent with its obligations under the CBD. His delegation considered that the TRIPS Agreement and the CBD were consistent and could be and were implemented in a mutually supportive manner, but was willing to consider appropriate solutions to address misappropriation of genetic resources and erroneously granted patents. Australia had strong interest in the issue and welcomed the significant progress made at the 20<sup>th</sup> session of the IGC, which had focused on IP and genetic resources and had developed a single negotiating text in accordance with its mandate. Australia would continue its active and constructive engagement in the IGC, which was best placed to consider that complex IP issue.

81. The representative of Nigeria said that the TRIPS Agreement and the CBD should be implemented in a mutually supportive and consistent manner. Members should require patent applicants to disclose the source of the biological material that constituted input in an invention and the evidence of benefit sharing through their domestic laws. There was an emerging consensus among Members that the amendment of the TRIPS Agreement would ensure prior informed consent and sharing of the benefits arising from the use of the genetic resources and associated traditional knowledge and therefore avoid erroneously granted patents. The amendment would fulfill the objectives and principles provided in Articles 7 and 8 of the TRIPS Agreement, thereby establishing an adequate and effective coordination between the TRIPS Agreement and the CBD. The proposal contained in document TN/C/W/59 would enhance international action to ensure the mutual supportiveness between the TRIPS Agreement and the CBD. It would also help to avoid potential conflict in the application and practice of the two agreements. The African Group wished the Director-General to resume his consultations on that issue in line with paragraph 39 of the Hong Kong Ministerial Declaration.

82. The representative of Canada said that his delegation could not agree to negotiate an amendment to the TRIPS Agreement to establish stronger protection for genetic resources and/or associated traditional knowledge, including imposing a mandatory disclosure requirement for patent applications involving genetic resources and/or associated traditional knowledge. Canada was committed to work to secure compliance with legislative and regulatory obligations under national access and benefit-sharing policies for obtaining prior informed consent and negotiating mutually

agreed terms for access to genetic resources, as well as traditional knowledge associated with genetic resources. Canada was also committed to work to avoid the grant of erroneous patents and to ensure that patent offices have at their disposal the appropriate information required to make proper decisions on patent grant. She 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, e.g. India's TKDL, using mutually agreed terms in material transfer agreements, licensing, codes of conduct and contracts between users and providers. She said that the TRIPS Agreement and the CBD were mutually supportive and therefore there was no need to amend the TRIPS Agreement.

83. Canada continued to believe that WIPO remained the best forum for technical discussions of IP-related aspects of the protection of 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 instruments to ensure the effective protection of genetic resources, traditional knowledge and traditional cultural expressions. At the 20<sup>th</sup> session of the IGC, participants had prepared a consolidated document dedicated to genetic resources. Canada welcomed the progress made, notably that - in the spirit of the renewed mandate that called for accelerated work - members had a consolidated and structured text on genetic resources that was similar to the texts on traditional knowledge and traditional cultural expressions. While that text represented work in progress and was without prejudice to the positions of the participants, she was confident that the consolidated text would provide a sound basis for future work. Canada looked forward to participating in future IGC sessions.

84. She said that the review of Article 27.3(b) was meant to focus on Members' implementation issues rather than on revising the content of that article. Flexibility should be maintained in Article 27.3(b) to allow Members to implement it domestically as appropriate.

85. The representative of Chinese Taipei said that the flexibilities provided for in 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 those flexibilities to suit their particular unique domestic conditions. The review of Article 27.3(b) should not lead to any lowering of the level of patent protection for biotechnological inventions. She said that the TRIPS-CBD issue concerned a number of different stakeholders. On-going discussions and consultations should take those interests into consideration. The attempt to make a linkage between three TRIPS issues and to include them as part of the Single Undertaking was not helpful. Each issue should be discussed on its own merits.

86. The representative of Switzerland took note of the substantive and constructive discussion on IP and genetic resources in the IGC and said that the work in the WTO was of a complementary nature. Switzerland had submitted several proposals concerning the Patent Cooperation Treaty and Patent Law Treaty in the WIPO. Switzerland had also co-sponsored document TN/C/W/52 in the WTO, in which a large coalition representing more than two thirds of WTO membership had proposed modality wording for three outstanding implementation issues: the issues of TRIPS-CBD, GI extension and GI register. Switzerland associated itself with the statement by China on the need to continue the work on those three issues in the course of 2012. Switzerland was of the opinion that a non-burdensome disclosure requirement in patent applications relating to the source of genetic resources or traditional knowledge on which the invention was directly based could contribute to enhancing transparency in access and benefit-sharing regimes and could enhance legal certainty and patent examination standards. Genetic resources were particularly relevant in the context of biotechnological inventions. A disclosure requirement in the TRIPS Agreement could help to promote the understanding of the importance and benefit of biotechnology for mankind and the understanding of the role of patents in the fields of public health or food security. Switzerland was convinced of the importance of patents as a tool to incentivize and disseminate innovation, and



therefore patents should be available and enjoyable in the field of biotechnology. Article 27.3(b) of the TRIPS Agreement provided sufficient flexibilities, which allowed Members to take into account their specific needs.

87. The representative of the United States said that, as referred to by other Members, the IGC had held its 20<sup>th</sup> session in early February. As evidence of its constructive engagement at that session, the United States, together with Canada, Japan, Korea, and Norway, had made a proposal for a Joint Recommendation on Genetic Resources and Associated Traditional Knowledge (Joint Recommendation). Providing a few highlights of the Joint Recommendation, which incorporated Members' shared interest in addressing erroneously granted patents, he said that the objectives and principles of the Joint Recommendation were that "Member States, in protecting genetic resources and traditional knowledge associated with genetic resources, should aim to: (a) prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to genetic resources and traditional knowledge associated with genetic resources; (b) protect indigenous peoples and local communities from the limitations of the traditional use of genetic resources and their traditional knowledge associated with genetic resources that might result from the erroneous patenting thereof; (c) ensure that patent offices have the appropriate available information on genetic resources and traditional knowledge associated with genetic resources needed to make informed decisions in granting patents; and (d) maintain the incentives for innovation provided by the patent system."

88. He highlighted a number of important developments in the IGC, including the development of improved search tools and classification systems for patent examiners who examined patent applications, including applications that claimed genetic resources; the creation of a database of illustrative examples of mutually agreed terms concerning access and benefit sharing, which served as a capacity-building tool, and helped to inform the policy debate; and the drafting of guidelines on the IP aspects of equitable benefit-sharing arrangements.

89. In addition, mindful of the concerns being addressed at the IGC, the WIPO Patent Cooperation Treaty Working Group had established additional tools to improve the quality information available to patent examiners. Those tools included a supplemental international search mechanism and a mechanism for third parties to submit prior art to be considered during the international search and preliminary examination. The US Patent and Trademark Office had a similar mechanism in place.

90. Furthermore, the International Authorities under the Patent Cooperation Treaty had decided to expand the list of periodicals that were part of the PCT Minimum Documentation by adding the Korean Journal of Traditional Knowledge, the Indian Journal of Traditional Knowledge, and other periodicals. The PCT Minimum Documentation was the patent publications and non-patent literature that a patent examiner should search in conducting a search or preliminary examination of a PCT application. National authorities had created additional tools, such as patent prosecution highways and databases of information related to genetic resources and associated traditional knowledge.

91. He said that although the IGC had not yet finished its work, it had made significant contributions to addressing Members' shared concerns. He hoped that WIPO would adopt the Joint Recommendation and thereby demonstrate to the international community Members' commitment to prevent patents from being erroneously granted, including by creating and using relevant databases, and by encouraging compliance with relevant access and benefit-sharing and prior informed consent laws and regulations.

92. The representative of Egypt recalled the mandate given by Ministers to the Council, which had instructed the Council, in pursuing its work programme including under the review of Article 27.3(b), to examine, *inter alia*, the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore. The Council was therefore the best place to

conduct that work. He said that the disclosure requirement had been implemented by several developing and developed countries, where it worked very well in terms of contributing to innovation and not creating a burden on stakeholders. As highlighted by Switzerland, it was important to ensure legal certainty, confidence and credibility of the patent system. Regarding the IGC, he said that as long as databases did not lose the confidentiality, it could be supportive to the objective of avoidance of erroneous patents. He endorsed the request made by China and the African Group to invite the Director-General to continue his consultations on the TRIPS-CBD issue to ensure the mutual supportiveness between the TRIPS Agreement, the CBD and the Nagoya Protocol.

93. The Chairman suggested that the Council request the Chair to continue consulting on the suggestion that the CBD Secretariat be invited to brief the Council on the outcome of the Nagoya meeting.

94. The Council took note of the statements made under those three agenda items and so agreed.

#### G. NON-VIOLATION AND SITUATION COMPLAINTS

95. The Chairman recalled that, at its meeting on 17 November 2011, the Council had agreed to recommend that the Eighth Session of the Ministerial Conference to be held in December 2011 extend the moratorium on TRIPS non-violation and situation complaints. Pursuant to that recommendation, Ministers had directed the 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, which they had decided to hold in 2013. It was agreed that, in the meantime, Members would not initiate such complaints under the TRIPS Agreement. The Decision of the Eighth Session of the Ministerial Conference had been circulated in document WT/L/842.

96. The representative of Venezuela said that, in his view, it was not possible to apply subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 without the agreement of all Members established under Article 64(3) of the TRIPS Agreement. No such consensus had been reached in the Council. The lack of possible cases presented for the Council's assessment was clear proof that IP could not be dealt with as a good. The reasons for this were clearly set out in document IP/C/W/385 co-sponsored by Venezuela.

97. The representative of Cuba said that non-violation and situation complaints, as provided for in subparagraphs 1(b) and 1(c) of Article XXIII of the GATT 1994, were not applicable as grounds for dispute settlement within the framework of the TRIPS Agreement. All of the Agreement's flexibilities would be undermined if non-violation and situation complaints were to be applied to it, since countries could be exposed to complaints without having violated the Agreement in any way. An automatic extension of the doctrine and GATT concepts to the scope of the TRIPS Agreement would bring about legal uncertainty rather than providing security and predictability within the system.

98. The representative of Nigeria, speaking on behalf of the African Group, believed that non-violation complaints were inapplicable under the TRIPS Agreement. He recalled that the Council Chair had considered four options in May 2003 for a possible recommendation, namely (i) banning non-violation complaints in the TRIPS Agreement completely; (ii) allowing the complaints to be handled under the WTO's dispute settlement system as applied to goods and services cases; (iii) allowing non-violation complaints but subject to special modalities; and (iv) extending the moratorium. In response, most Members had favoured banning non-violation complaints completely or extending the moratorium. To date, no consensus had been reached, but the moratorium had fortunately been extended until the next Ministerial Conference in 2013. To avoid any legal uncertainty, the African Group therefore urged remaining Members to join the consensus that would

allow the Council to recommend banning non-violation complaints under the TRIPS Agreement. He requested the Chair to continue consultations with a view to exploring how to resolve the issue.

99. The representative of Ecuador supported the statements by Nigeria, Cuba and Venezuela, and reiterated Ecuador's view that non-violation and situation complaints did not fall under the TRIPS Agreement. The specific arguments contained in document IP/C/W/385 of October 2002 co-sponsored by Ecuador continued to be prevalent and remained unchanged. Even though the moratorium had again been extended, he believed that it was necessary to make a final decision that there was no legal basis for such complaints under the TRIPS Agreement.

100. The representative of Peru associated himself with the previous statements. In 2002, Peru had co-sponsored document IP/C/W/385, together with 14 other Members, outlining its position on the issue of non-violation and situation complaints. As set out in that document, Peru believed that non-violation complaints were unnecessary to protect the rights and obligations stemming from the TRIPS Agreement, because they were reflected in the main obligations and flexibilities of the Agreement. Furthermore, the Agreement explicitly provided that Members were not compelled to apply broader protection. He, therefore, believed that that non-violation and situation complaints were inapplicable to the TRIPS Agreement.

101. The representative of China welcomed the Ministerial Conference decision to extend the moratorium. The TRIPS Agreement differed from GATT 1994 both in nature and in structure. The application of non-violation and situation complaints under the TRIPS Agreement would be inappropriate and problematic. It would cause fundamental concerns and might also limit the use of flexibilities under the Agreement.

102. The representative of Brazil welcomed the extension by the Eighth Ministerial Conference of the moratorium for further two years. He considered that non-violation and situation complaints should be determined inapplicable to the provisions of the TRIPS Agreement. The TRIPS Agreement, unlike other WTO Agreements, was a *sui generis* agreement. It was not designed to protect market access or the balance of tariff concessions, but rather to establish minimum standards of IP protection. One of the consequences of the application of non-violation and situation complaints could be that developing countries might be prevented from successfully using the flexibilities contained in the Agreement, including those related to the protection of public health.

103. 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. He believed that the definition of Members' rights and obligations, based on the text of the Agreement, would become more difficult, leading to impacts on important public policies in the areas of public health, biodiversity protection and transfer of technology.

104. The representative of the United States said 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. He supported Nigeria's proposal for further consultations the issue.

105. The representative of India supported the statements by Brazil, China and other Members. Non-violation complaints had no place under the TRIPS Agreement as it would undermine the flexibilities provided by the Agreement.

106. The representative of Colombia said that the introduction of non-violation and situation complaints in the TRIPS Agreement was unnecessary and incompatible with the interests of Members. That belief was consistent with the positions already expressed by the various co-sponsors of document IP/C/W/385. Any advantage stemming from the Agreement could appropriately be

protected by applying the text of the Agreement in line with the principles of international law without introducing the uncertain notion of non-violation and other situation complaints. Non-violation complaints should therefore be determined inapplicable under the TRIPS Agreement.

107. The representative of the European Union said that non-violation and situation complaints were inapplicable under the TRIPS Agreement. Since the moratorium had been extended until the end of 2013, the Council had almost another two years to reflect on the matter. His delegation was open to having a debate and to listening to arguments by others that might come forward with convincing reasons and good examples on why non-violation complaints should be applicable to the TRIPS Agreement.

108. The representative of Switzerland said that, for reasons of consistency both from a systemic and legal point of view, he considered that non violation and situation complaints were applicable to the TRIPS Agreement, like to the two other pillars under the WTO Agreements. The fact that a moratorium had been agreed in the Uruguay Round for the purpose of examining the desirability of additional modalities for the application of such complaints in the TRIPS context spoke in favour of the principle that such complaints were actually applicable in the TRIPS context. He believed that the Dispute Settlement Understanding provided sufficient guidance. Switzerland had joined the consensus at the last Ministerial Conference to extend the moratorium once more in order to give those Members who believed that additional modalities in the TRIPS context were necessary the time and room to have a discussion and to come forward with proposals.

109. The representative of the Plurinational State of Bolivia considered that non-violation and situation complaints were inapplicable in the TRIPS context.

110. The Chairman suggested that he consult on how the Council should organize its continued examination of the scope and modalities for non-violation and situation complaints.

111. The Council so agreed.

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

112. No statements were made under this agenda item.

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

I. REVIEW OF THE APPLICATION OF THE PROVISIONS OF THE SECTION ON GEOGRAPHIC INDICATIONS UNDER ARTICLE 24.2

114. 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 TRIPS 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. 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. That exercise had already resulted in some useful and informative material.

115. As the question of GI protection remained a continuing interest, he urged those delegations that had not yet done so to provide responses to the Checklist of Questions. 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 considerable

benefit in having up-to-date, accurate and geographically more representative material available as the basis of the on-going review process.

116. In line with the Council's recommendation of March 2010, he also encouraged any Member that was party to any bilateral agreements related to the protection of GIs to share information on them with the Council if they had not yet done so.

117. The representative of the European Union referred to the additional information on EU technical co-operation activities in document IP/C/W/568, which he would introduce under item K of the agenda. At this stage, he shared some information in the document on technical assistance on GIs. This work had been carried out by TradeCom and the Business Climate facility (BizClim), which were joint initiatives of the European Commission and the ACP Group of States, with funding from the European Development Fund (EDF). The initiatives utilized consultancy companies and independent consultants, recruited in accordance with the 10<sup>th</sup> EDF rules and procedures. This assistance, like all assistance provide by the European Union, was demand-driven.

118. Some examples of the work in the last three years included the following: a Regional Workshop on the Development Benefits of Geographical Indications Protection for ACP States (June 2009, Trinidad and Tobago); a Regional Workshop on the Development Benefits of Geographical Indications (GIs) Protection for the ACP States (April 2010, Cameroun); a Regional Workshop on the Development Benefits of Geographical Indications Protection for the ACP States (May 2010, South Africa); a Regional Workshop on the Development Benefits of Geographical Indications and Traditional Knowledge Protection for the Pacific member countries of the ACP States (August 2010, Fiji); a Technical Workshop on GIs as a Tool for Enhancing Value to African Union Farmers in the Agri-Food Chain (November 2011, Uganda); and Technical Assistance to Saint-Lucia and the Organisation of Eastern Caribbean States Secretary on a GI Strategy (September 2011 – March 2012).

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

J. FOLLOW-UP TO THE NINTH ANNUAL REVIEW UNDER PARAGRAPH 2 OF THE DECISION ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT

120. The Chairman recalled that, at its meeting in October 2011, the Council had taken up its ninth annual review of developed country Members' reports on their implementation of Article 66.2 of the TRIPS Agreement. In concluding the item, the Chair had indicated that delegations would be provided an opportunity at the present meeting to make further comments on the information submitted for that meeting that they had not yet been able to study.

121. No statements were made under this agenda item.

K. TECHNICAL COOPERATION AND CAPACITY BUILDING

122. The Chairman recalled that, at its meeting in October 2011, the Council had taken up its annual review of technical cooperation. Since then, the European Union had provided a communication entitled "Technical Cooperation Activities and Assistance for Least-Developed Countries" (IP/C/W/568), which complemented the information the European Union had provided in September 2011 for the Council's annual review (IP/C/W/560/Add.7). It contained further information regarding specific IP technical assistance that the European Union had provided to least developed countries, including in response to a number of priority needs identified by them.

123. He also recalled that paragraph 2 of the 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". To date, such information had been received from six Members, namely Sierra Leone, Uganda, Bangladesh, Rwanda, Tanzania and Senegal.

124. The Council's 2005 decision also provided that developed country Members were required to provide technical and financial cooperation in accordance with Article 67 in order to effectively address the needs identified by the least developed countries. 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.

125. At the Council's October 2011 meeting, Nigeria had made a suggestion that, if acceptable to it, the Secretariat would prepare a note aimed at indicating areas that had been implemented in those LDCs that had submitted their needs assessments, as well as the outstanding areas. Since another delegation had indicated that it needed further time for consideration, the Council had agreed to revert to that suggestion at the present meeting.

126. The representative of the European Union said that the Council October meeting had followed a symposium organized by the WTO Secretariat on LDC priority needs for technical and financial cooperation. His delegation had welcomed that opportunity to engage further with other Members and international organizations on how to assist the LDCs with TRIPS implementation.

127. Following its annual notifications of technical assistance under TRIPS Article 67, the European Union had undertaken to provide further and more detailed information on the technical assistance work it had recently carried out specifically in relation to LDCs in the area of IP. That information had now been set out in document IP/C/W/568. It provided an overview of recent specific projects, including those being undertaken in Bangladesh, Uganda and Zambia, as well as regional work being carried out in conjunction with COMESA, OAPI and ARIPO. It also provided information on the way the European Union delivers technical assistance and how its various bodies work together with recipient countries and other organizations.

128. The document provided information on EU funding of technical assistance, in particular in relation to the European Development Fund and the Development Cooperation Instrument. It also described how LDCs could obtain technical assistance, including an explanation of how Country and Regional Strategy papers functioned; these were three annual plans that framed the way technical assistance was provided.

129. Technical assistance was also available for developing countries, as well as for developed countries. In that regard, he referred to the latest annual notification under Article 67 (IP/C/W/560/Add.7), which contained numerous examples of those programmes.

130. The representative of the United States thanked the European Union for the paper it had presented. With respect to the proposal from the October 2011 Council meeting regarding a report to be produced by the Secretariat, his delegation was still in the process of considering that internally.

131. The representative of Nigeria thanked the US delegation and noted its request for more time to consider the proposal. The issue of LDC priority needs for technical and financial cooperation was being discussed in the Council and elsewhere, and it would be in the interest of all the LDCs, and especially the African Group which had 33 LDC members, if that factual information could be prepared by the Secretariat. It would also serve to give the Council a perspective on how to move forward.

132. The representative of Rwanda supported Nigeria's proposal that the Secretariat prepare a note indicating the areas implemented in LDCs based on their needs assessments. The objective should be to make an actual assessment of what was or was not being done, which would provide a basis for both LDCs and their development partners to continue working on pending issues.

133. The representative of China supported the suggestion to request the Secretariat to prepare a note under Article 66.2 to have a general review of the situation of technology being or having been transferred to LDCs. China believed that the questions posed by the LDC Group in document IP/C/W/562 were beneficial to improving the mechanisms for ensuring the monitoring and full implementation of Article 66.2. In addition to responding to those questions, she believed it would be highly beneficial if developed country Members could take the concerns of the LDC Members into account and improve these reports in the future.

134. The representative of the Secretariat provided a brief update to the Council on the work that the Secretariat was undertaking in relation to the needs communication, resource mobilization and coordination process focused on the individual priority needs of LDC Members. He said that the 2005 Council Decision concerning the implementation period for LDCs and the process for communication of individual priority needs and coordination on fulfilment of those needs included a requirement for the Secretariat to step up its coordination efforts. At the Council's October 2011 meeting, he had reported at length on the steps taken, under the guidance of the LDC Group of countries, to promote greater coordination of that process. Those steps had culminated in a workshop held in Geneva prior to that meeting.

135. The biennial technical assistance and training programme (document WT/COMTD/W/180/Rev.1 circulated on 3 February 2012) for the 2012-2013 biennium gave priority to the LDCs as a fundamental principle. Specific support was earmarked for needs assessments as such; and LDC needs assessments and trade policy reviews (TPRs) were integrated. reports for least developed and developing countries included a section on Aid for Trade which, *inter alia*, covered the country's TA needs and priorities, as identified during the review in cooperation with the Member concerned. That pointed to some of the on-going system-wide work that could be undertaken to support the specific needs-assessment process identified by the Council.

136. The TA plan included over the biennium two further Geneva Symposia scheduled for both 2012 and 2013 on LDC needs assessment concerning implementation of the TRIPS Agreement. The planning and consulting on these Symposia would be undertaken in close coordination and under the direction of the LDC Group of countries in particular, and Members in general. They offered a key opportunity to move towards a more focused, practical coordination of needs communicated and any updates of LDC needs. The TA programmes and resources of the WTO itself, other IGOs such as WIPO and UNCTAD, and bilateral programmes run by developed country Members and other providers of TA resources, many of which they knew from past consultations, were indeed already actively addressing the needs identified in that process. He underscored the benefit of such practical exchange of information and coordination that past workshops had focused on, and had been a particular feature of the October 2011 workshop.

137. In order to assist in the coordination process, the WTO webpage on the LDC needs assessment process already included practical information and resources on the process. It also included the full needs assessments themselves as submitted by LDC Members. There was also an additional section containing information from developed country Members on technical and financial cooperation provided to LDC Members, including in response to any priority needs identified by LDC Members. The recent submission by the European Union in document IP/C/W/568, as described by the EU delegation, was the first entry on that new section.

138. In addition, he noted that under the biennial TA programme, resources were earmarked for national activities under the general heading "assisting beneficiaries in conducting Needs Assessment". These resources might potentially be drawn upon by individual LDC Members to support the process, if they so required, in line with the general demand-driven approach to national TA activities.

139. In order to support LDCs, both in undertaking their needs assessments as required and in their coordination with providers of technical and financial resources to fulfil those needs, a guidebook was in the process of being curated through various phases of the work programme, including through regional workshops and Geneva-based workshops. He expected that resources would be available to support LDCs in undertaking that process in the course of the biennium exercise.

140. It was important to note, bearing in mind the direction from the Council towards greater and improved coordination in that area, that other international organizations had been active in supporting LDCs in identifying their priority development needs in relation to the IP system and the TRIPS Agreement in particular. Among international organizations, WIPO and UNCTAD were notable in that regard. It was also worth bearing in mind that existing needs assessments had been prepared with the support of such organizations, underscoring the necessity and the benefits of improved coordination between international organizations and other resource providers and programmes, in particular as that took on a more practical accent. He believed that such enhanced coordination would continue to be a focus of the WTO Secretariat's efforts and expressed his appreciation for the collegial and collaborative approach of colleagues, notably in WIPO, UNCTAD and, on health-related TA matters, the WHO. Additionally, a number of international experts and the ICTSD had also worked on the needs assessment process in a number of countries and the informal consultation and coordination network also included such active players.

141. He said that the Secretariat's work would continue to be guided by the directions given by Members and, in particular, those Members most concerned, i.e. the LDC Group and individual LDC Members. This also took a lead, as outlined earlier, from the Technical Assistance Plan approved by Members, which stressed the priority for support for LDCs and in particular for needs assessment activities.

142. The representative of Switzerland expressed his appreciation for the Secretariat's efforts to facilitate the process under Article 67 of the TRIPS Agreement and support for the LDC needs assessment process. Switzerland had participated in the regional workshop for Asian, Pacific and Caribbean Countries organized by the WTO in the second half of 2010 in Dakar, as one means of assisting and supporting the LDC needs assessment process. It had reported to the Council after that workshop that bilateral contacts between Bangladesh and Switzerland had taken place on the occasion of that workshop. As a result of those continuing contacts, a technical co-operation project had been agreed between the two countries, commencing with an inception mission the following week. This was intended to be a technical co-operation project based on the priority needs assessment submitted by Bangladesh to the Council. It was a project that would span two years and amounted to financial support of some CHF 1 million. Switzerland was looking forward to the implementation of the project in partnership with Bangladesh and looked forward to the support of its authorities. His delegation would update the Council with further details and relevant developments with regard to the progress of the project in future meetings.

143. The representative of the United States said that in a spirit of moving forward, his delegation would support consultations on that issue. His delegation was in the process of carrying out an extensive review of its programmes in support of needs assessments and it would be helpful to discuss the issue before the next meeting.



144. The Chairman urged all least developed country Members that had not yet provided information on their individual priority needs for technical and financial cooperation to do so. He said that the Council would revert to Nigeria's proposal on the work to be carried out by the Secretariat at its next meeting. In the meantime, he intended to discuss with delegations on how the Council could best proceed.

145. The Council took note of the statements made.

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

146. The Chairman recalled that, at its past few meetings the Council had had on its agenda a 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 at the October 2009 meeting a factual background note (IP/C/W/543) prepared at the Council's request, summarizing the relevant procedures and providing information on the use of those procedures. The document further contained suggestions for the Council's consideration on how to improve the transparency and user-friendliness of the notification system. At the subsequent meetings, the Secretariat had provided oral reports on further developments in that area. At its last meeting, the Council had agreed to revert to that agenda item at the present meeting, so as to provide Members with a further opportunity to share any comments and allow the Secretariat to inform the Council of any further enhancements to its services improving the transparency and user-friendliness of the notification system.

147. The representative of the Secretariat said that the work of the Secretariat on the process was very much guided by the directions in the letter from the Chairman of the General Council and the background note IP/C/W/543. The core objective of the work on timeliness and completeness of notifications and other information flows continued to be the goal of making that material available in a more user-friendly way, and thus to make it more straightforward for Members to prepare and submit their notifications, in short to reduce the burden on Members. This included both the documentary burden on Members to fulfil their notification obligations and making it easier to consult the information in a way that corresponded more directly with the actual needs of stakeholders. On a number of the substantive agenda items before the Council, the Secretariat continued to hold discussions with delegations very informally who expressed some uncertainty about how to obtain even some of the basic tools, i.e. some of the basic notifications. This underscored the continuing need for that work.

148. This was an area where the very considerable expense involved in processing those materials could be addressed, in response to the recommendations for savings and more efficient use of resources in the area of documentation recently made by the budget committee and adopted by the General Council. The focus was on a number of official documents. Some of the lengthy documents involved considerable effort, both in their preparation and in their handling, distribution and translation.

149. He stressed that the exercise was simply about practical document management. It was being undertaken entirely within the parameters already set by the Council's own decisions and the TRIPS Agreement and it continued to follow directly the outline set out in document IP/C/W/543. The work continued to review the body of existing notifications, a collection of over 15 years' worth of heterogeneous documents, of immense potential practical use, but at the same time presenting a major information management challenge. As it worked through the outline already reported to the Council, the increasing focus of the Secretariat was at present on examining ways of using appropriate information technology tools to improve the usability and the accessibility of those data to reduce wasteful and expensive paper-based approaches, where appropriate. In addition, improved

accessibility and usability of data would ensure that it could contribute to the broader effort across the Secretariat towards a more integrated holistic approach to managing notifications and other trade policy information. In this regard, he referred to the Integrated Trade Intelligence Portal (I-TIP), announced at the margins of the 2011 December Ministerial Conference.

150. An immediate need was to address the backlog of notified material that was not yet available in readily accessible text-searchable form. The Secretariat was currently working on a stocktake of all notification materials provided since the Council had commenced its work, so as to measure exactly the scale of the task of making that material more readily accessible and useable, in line with the directions set by the letter of the Chair of the General Council. The next step was to consider how to provide more user-friendly web tools for accessing and using the information contained in notifications, building on the pilot work already reported to the Council. Consideration should further be given to making use of such tools as the common portal established with WIPO for the submission of legislative texts and exploring further cooperation along those lines, given the overlapping responsibilities between the WTO and WIPO that were recognized in the TRIPS Agreement itself.

151. Other avenues that could be explored in the area of practical document management, rather than determining new notification approaches, might include (i) facilitating the submission of texts for regular notifications, other than legislative texts, through a notification tool; and (ii) a continued focus on suggested standard notification formats to facilitate both the preparation of notification materials and indeed their handling and dissemination. The Secretariat would seek to consult with delegates and other users of that information through informal workshops and technical assistance activities and aimed to develop appropriate tools that corresponded to the actual needs of actual stakeholders, particularly delegations. The work was very much at an early stage and further details would be reported to subsequent meetings of the Council as the preliminary work continued.

152. Notification materials were now routinely used to inform the Secretariat's technical cooperation activities, in response to the demand from Members for information at a very practical level and in a factual way about the approaches taken by Members in relation to various areas of IP law and policy. Further technical assistance activities would concentrate on more effective use of notification processes, so as to advance the objectives set out by the General Council concerning the timeliness and completeness of notifications under the TRIPS Agreement as well as user-friendly access to and use of those materials.

153. The Chairman suggested that the Council agree to revert to that agenda item at its next meeting so as to afford Members a further opportunity to make their comments on the subject and allow the Secretariat to inform the Council on any further improvements to its services aimed at enhancing transparency and use-friendliness of the notification system.

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

M. AUSTRALIA: TOBACCO PLAIN PACKAGING BILL 2011 AND ITS COMPATIBILITY WITH THE TRIPS AGREEMENT

155. The Chairman said that this item had been put on the agenda at the written request of the delegation of the Dominican Republic. Since its meeting in October, the Council has received two documents relating to this matter. At the request of the delegation of the Dominican Republic, the statement it made at the Council's meeting in October 2011 under item N on "Australia's Tobacco Plain Packaging Bill 2011" had been circulated in document IP/C/W/565. The Council had also received a communication from Moldova entitled "Australia's Tobacco Plain Packaging Bill 2011", which has been circulated in document IP/C/W/567.

156. The representative of the Dominican Republic said that his delegation wished to reiterate its serious concern at the plain packaging measures for tobacco products adopted by Australia. The Dominican Republic had already expressed its concern both to the Council and to the TBT Committee, and several other WTO Members had also questioned these unprecedented measures. He said that so far, Australia had not responded satisfactorily to these concerns but had only provided incomplete replies that failed to show the existence of any solid evidence used as a basis for these measures.

157. He said that Australia's plain packaging measures were a threat to many IPRs which were vital for international trade and should be a matter of concern to each and every Member. In particular, these measures were inconsistent with Australia's obligations under the TRIPS Agreement and the Paris Convention, which formed part of the TRIPS Agreement.

158. He said that, for any product that could be lawfully sold for consumption, registered trademarks, geographical indications and other elements that formed part of a product's packaging played an important role in providing information on products and producers, which was essential for consumers, as such information enabled consumers to differentiate and choose between competing products.

159. Australia's plain packaging measures would eliminate practically all the distinctive features of tobacco sector products by banning designs and trademarks, as well as by requiring packaging for different tobacco products to be virtually identical. These measures would, therefore, negate IPRs, preventing consumers from obtaining basic information on products they could lawfully purchase, thereby creating confusion in the market and lessening the opportunities for competition among imported tobacco products.

160. He said that, at the same time, these measures would not succeed in promoting public health goals. On the contrary, it was expected that they would have serious negative consequences. Tobacco consumption might increase, instead of decreasing, as prices fell because all tobacco products would look virtually the same. Furthermore, plain packaging would make it easier to counterfeit products and market them.

161. It was his delegations view that, instead of adopting such inappropriate and extreme measures to reach the objectives sought, Australia should focus on other available measures that would be effective in promoting public health. Such measures would not negate IPRs related to lawful products and would not undermine the benefits given to consumers by such rights.

162. The Dominican Republic believed that Australia's plain packaging measures for tobacco products would violate Articles 20, 22.2(b) and 24.3 of the TRIPS Agreement, as well as Article 10*bis* of the Paris Convention. According to Article 20 of the TRIPS Agreement, the "use" of registered trademarks relating to tobacco products would be "encumbered" by "special requirements" determined by Australia's plain packaging measures for tobacco products. Australia intended to prohibit the use of any design feature of the registered trademark, allowing only mention of the brand name and the variety in a predetermined location, in a predetermined font style and size on an identical background. These special requirements authorized the use of registered trademarks only in a "special form" that was "detrimental to [the trademark's] capability to distinguish the goods or services of one undertaking from those of other undertakings".

163. He said that Australia had contended on several occasions that the measures in question were justified by public health objectives, and had referred to a number of studies. His delegation wished to reiterate that in its understanding the factual and scientific evidence for these measures had been challenged in public documents that had been submitted to the Australian Government in a timely

manner. Australia had still not explained to Members how it justified the plain packaging measures in view of the lack of evidence.

164. Moreover, he said, Australia's 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". The plain packaging measures posed a serious risk of confusion among competing tobacco products because Australia would impose the use of virtually identical packaging for all such products. For similar reasons, the plain packaging measures would also violate Article 22.2(b) of the TRIPS Agreement - which referred back to Article 10*bis* of the Paris Convention - by creating confusion in relation to geographical indications.

165. He said that the Dominican Republic had also incorporated into its domestic legislation protection for geographical indications that was available under TRIPS, in order to provide competitive advantage to traditional products that were well known in domestic and international markets. His delegation had the pleasure of informing the Council that the Tobacco Institute (INTABACO), the Republic's cigar producers, together with the National Industrial Property Office (ONAPI), had developed the Dominican Republic's first geographical indication, "*Cigarros Dominicanos*", which was the fruit of two years of joint work. It was intended to identify and highlight the quality of Dominican cigars throughout the world. Against this background his delegation considered that Australia's plain packaging measures would also violate Article 24.3 of the TRIPS Agreement, which prohibited WTO Members from "[diminishing] the protection of geographical indications that existed in that Member immediately prior to the date of entry into force of the WTO Agreement [1 January 1995]". By eliminating the right to use geographical indications for the retail sale of tobacco products, Australia would violate this obligation as the plain packaging measures would be detrimental to this geographical indication in Australia.

166. He said that, for the foregoing reasons, the Dominican Republic urged Australia to honour its obligations under the TRIPS Agreement.

167. The representative of Australia said that her delegation welcomed the continued interest of other Members in its initiative to require the plain packaging of tobacco products. She thanked Members for their questions and the support Australia had received for these important measures and wished to provide an update on the status of the legislation and its implementation.

168. She said that Australia had addressed the various issues raised by Members in relation to its Tobacco Plain Packaging legislation at previous Council meetings and had comprehensively responded to all the claims made by the Dominican Republic and others. In order not to repeat those responses today, her delegation requested that Australia's previous interventions on its Tobacco Plain Packaging Bill, as recorded in previous minutes be included in the record.

169. Since this Council last met in October 2011, the Tobacco Plain Packaging Act 2011 and the Trade Marks Amendment (Tobacco Plain Packaging) Act 2011 had been passed by the Australian Parliament and had received Royal Assent on 1 December 2011. The Tobacco Plain Packaging Bill 2011 had passed the Australian Parliament on 21 November 2011, which included amendments to (i) extend the implementation timeframes and provide an additional two weeks for retailers to sell through ('flush-through') any product in non-compliant packaging before the retail offences commence; and (ii) address a technical implementation issue identified by tobacco companies to permit rounded corners to be used on the inside lip of cigarette packs. The associated Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011 had passed the Parliament on 10 November 2011.

170. She said that all tobacco products manufactured or packaged in Australia would now be required to be in plain packaging by 1 October 2012 (previously 20 May 2012). All tobacco products

would now be required to be sold in plain packaging by 1 December 2012 (previously 1 July 2012). The final regulations as they related to cigarette products, which contained the specific details on how the plain packaging requirements were to be implemented, had been approved on 7 December 2011 and were publicly available. These regulations had been revised in response to comments from the industry on previous drafts.

171. She said that regarding non-cigarette tobacco products - including cigars, loose-leaf tobacco and bidis - the Government had issued a consultation paper on 30 September 2011 for public comment. Consultations had closed on 28 October 2011, with 33 submissions received. The Government had released draft regulations incorporating the specifications for plain packaging of non-cigarette tobacco products on 23 December 2011, for a public consultation period which ended on 20 January 2012.

172. The Government had revised the draft regulations in response to comments and was currently considering responses to the most recent consultation in finalising the Amendment Regulation, and planned to seek approval of the Amendment Regulation in the coming weeks.

173. She said that, as had been outlined at the previous meeting of the Council, her delegation was implementing this legislation in the interests of promoting public health. Her delegation was confident that, as part of a comprehensive package of tobacco reforms, it would make an effective contribution to reducing smoking, and thereby reduce the health impacts of smoking on Australian individuals and the community at large.

174. Australia was and would continue to be fully committed to its international obligations to protect IPRs, including the rights of trade mark owners. 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 consistent with that Agreement.

175. She said that plain packaging was a legitimate measure designed to achieve a fundamental objective – the protection of public health. It was based on a broad range of studies and reports, and was supported by leading Australian and international public health experts. Australia had been responsive to comments from trading partners and other stakeholders. Prior to the introduction into Parliament of the Bills, the Australian Government had consulted widely with trading partners, including through a series of outreach meetings to explain the proposed measures. These comments had been 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.

176. She said that amendments to the Tobacco Plain Packaging Bill had been proposed to ensure 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 and passed to allow the Government to strengthen those protections should any uncertainty arise.

177. Australia had also removed import offences for non-compliant tobacco products, in response to submissions received in public consultations. This change would allow tobacco products to be imported into Australia in non-compliant retail packaging, and then repackaged for retail sale in Australia. 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. Australia had further adjusted the measures to allow a greater timeframe for implementation and to address a technical concern raised by industry to avoid retooling of machinery.

178. In closing, her delegation wished to reiterate that Australia's Plain Packaging legislation was a legitimate and appropriate measure which would make a significant contribution to protecting the health of Australians.

179. As requested, the statement her delegation made at the Council's meeting in June 2011 is reproduced below<sup>1</sup>.

"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.

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.

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.

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.

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

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<sup>1</sup> Paragraphs 426-436 of IP/C/M/67.

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.

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.

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.

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.

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.

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.

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."

180. In addition, the representative of Australia requested that the statement made in the June 2011 meeting be included.<sup>2</sup>

"The representative of Australia said that her delegation welcomed the opportunity to discuss this extremely important public health issue in the TRIPS Council and to explain the health policy underpinnings of the Australian Government's proposal. In order to provide some context for Members, she said it was worth noting that some 3 million Australians continued to smoke daily, that smoking killed over 15,000 Australians per year and that the cost to Australia's society and economy was over \$31.5 billion per annum. This was the policy context in which the Australian Government approached this issue.

She said that, on 7 April 2011, the Australian Minister for Health and Ageing had released for public comment the Consultation Paper and draft legislation to mandate the plain packaging of tobacco products. The consultation period had closed on 6 June 2011. The comments lodged were currently being considered by the Australian Government. She said that Australia had been a global leader in tobacco control over the past 30 years and had implemented a comprehensive range of measures to reduce smoking rates. These included extensive and continuing public education campaigns on the dangers of smoking; age restrictions on tobacco purchase; comprehensive bans on tobacco advertising, promotion and sponsorship; bans on smoking in workplaces and enclosed public places; bans on smoking in cars with children and increasingly in open air public places where children may be exposed to second hand smoke; bans and restrictions on the retail display of tobacco products; pricing measures through excise and customs duties; and mandatory graphic health warnings on tobacco product packaging.

She said that tobacco packaging was one of the last remaining forms of tobacco advertising in Australia and the plain packaging legislation was the next logical step in Australia's tobacco control efforts. Guidelines agreed by the Conference of the Parties

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<sup>2</sup> Paragraphs 177-182 of IP/C/M/66.



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 legislation proposed by Australia was expected to commence on 1 January 2012, and would require all tobacco products offered for retail sale on or after 1 July 2012 to be compliant. The proposed legislation was part of a comprehensive package of new reforms to combat smoking announced by the Australian Government in April 2010. Other elements of the package were a 25 per cent increase in tobacco excise - Australia's tobacco excise and excise-equivalent duty was already high by international standards and now amounted to A\$8.40 on a packet of 25 cigarettes, and A\$10.09 on a packet of 30; increased investment in anti-smoking social marketing campaigns; and legislation to bring restrictions on tobacco advertising on the Internet into line with restrictions in other media and at retail points of sale.

She said that these measures had been recommended by Australia's leading public health experts on the National Preventative Health Taskforce, and accepted by the Australian Government. The Taskforce had considered that plain packaging would improve public health by reducing the attractiveness and appeal of tobacco products to consumers; reducing the ability of tobacco packaging to mislead consumers about the harmful effects of smoking; increasing the noticeability and effectiveness of mandated health warnings.

She said that her delegation had noted the comments from the Dominican Republic referring to an alleged lack of scientific evidence to indicate that a plain packaging requirement would work. She observed, however, that there was a body of peer-reviewed literature on the public record indicating that a plain packaging requirement would contribute to Australia's objectives. All of that literature was available on the preventative health website, the details of which she would be happy to furnish to Members. Australia did not consider that the plain packaging proposal would have a significant impact on the illicit trade in tobacco products since already branded products were quickly and readily counterfeited. Nevertheless, she said that anti-counterfeiting markings would be allowed to be used on the packaging provided those markings were not linked to tobacco marketing or promotions and did not interfere with graphic health warnings. She said that the Australian Government considered that the smoking of any tobacco products, whether licit or illicit, was fundamentally harmful to human health.

She said that Australia was, and would continue to be, fully committed to its international obligations to protect IPRs, including the rights of trademark owners. She assured all Members that, in framing its policy on plain packaging, Australia had paid full regard to the TRIPS Agreement and would ensure that the new policy was implemented in a manner that was consistent with that Agreement."

181. The representative of Cuba said that the Australian bill had created tension between the right of governments to protect human health, and the commercial interests associated with tobacco consumption. She said that the requirement of standard packaging with no distinguishing trademark features would have an impact on advertising and consumption, which would in turn affect commercial interests. This was not the first time that tensions between commercial interests and the right to health had appeared.

182. She said that Cuba was recognized internationally as a staunch defender of the right to life and health, which it viewed as a supreme human right, and had maintained a consistent and proactive position with respect to this principle. Scientific and technological developments had provided

irrefutable proof that tobacco consumption affects not only human health but life expectancy, and her delegation recognized that governments were responsible for protecting the health of their citizens. The Cuban Government was also adopting measures in this regard, thus applying the principle set forth in Article 8.1 of the TRIPS Agreement whereby Members had the right to adopt measures to protect public health, provided that such measures were consistent with the provisions of the Agreement.

183. Nevertheless, she said, Cuba shared the concerns expressed by other countries regarding the measure's impact on trademark law and, in particular, the legislation's impact on the capacity of registered trademarks to distinguish one company's goods and services from those of another. If registered trademarks could not be used and displayed because of this legislation's plain packaging requirements, this did not bode well for the future as it undoubtedly generated some expectation for legislation on distinctive signs in business activities.

184. As Australia had affirmed that the legislation's measures had been properly examined to ensure consistency with the TRIPS Agreement, her delegation would be interested to know how Australia had assessed not only the problem of using a trademark in a form that differs from the design of the registered trademark, but also the issue of potential trademark infringements, where such trademarks, regardless of their registered design, appeared on plain packaging merely as words. The question was whether, under the plain packaging, it was possible to display the trademark as it had been registered, which was after all a trademark's function in the market.

185. In her delegation's view it would be appropriate for Australia to explain why it believed that these measures were the best way of meeting the proposed objective. Australia should also share with Members its analysis regarding these measures' consistency with the provisions of the TRIPS Agreement, as well as the measures available to right owners to minimize the risks of counterfeiting and unfair competition, given that plain packaging involving the brand name in standard size and font was so easy to reproduce.

186. She said that Cuban cigars had been the target of counterfeiting for many years and in many markets, forcing the industry to adopt various measures to minimize this problem. These measures were not advertising measures but measures to highlight the origin and authenticity of the products. Plain packaging defeated all those measures. For example, it would no longer be possible to use the "*Habanos*" designation of origin seal or the national guarantee of origin seal used by the Republic of Cuba on all its cigars since almost 100 years. Nor would it be possible to use the ring on the upper part of each cigar bearing the brand name and place of origin, La Habana, Cuba.

187. The representative of El Salvador said that his delegation wished to reiterate a number of systemic observations on Australia's Tobacco Plain Packaging Bill 2011 and its compatibility with the TRIPS Agreement. In line with the objectives set forth in Article 7 of the TRIPS Agreement, El Salvador believed that IP belonged to a set of trade policy tools designed to promote the development of the economy. It allowed Members, *inter alia*, to add value to goods and services in a way that ensured their distinctiveness and afforded them due protection in transactions on both the El Salvadorian and destination markets.

188. In his view, the IPRs system constituted a balance between guaranteed rights for IPR holders and exceptions to allow states to safeguard their legitimate public policy objectives, such as the protection of health, education, safety and market competition. In this context, El Salvador had concerns about how Australia's measure might unduly affect trade and create non-tariff barriers. His delegation was also concerned that this type of measure could set a precedent for other goods and services. Against this background, his delegation wished to ask Australia a few questions.

189. With regard to Article 8 of the TRIPS Agreement, could Australia please provide the basic information that it used to determine that the measure was necessary to protect public health and explain how it is consistent with the provisions of this Agreement? With reference to Article 20 of the TRIPS Agreement, to what extent did Australia view its measure as detrimental, or otherwise, to the capability of trademarks to distinguish the goods - in this case tobacco - of one undertaking from those of other undertakings? With regard to this same Article, if Australia was undermining the distinctive capacity of trademarks, would it please identify its specific justifications for restricting trademark use in relation to the goods covered by the measure? In light of Article 22.2 of the TRIPS Agreement, what was Australia doing to ensure that owners of geographical indications could prevent the measure from potentially undermining their right to use this category of IPR to render their goods distinctive - as in the aforementioned cases? Finally, when applying the measure, did Australia consider alternatives in order to avoid potential contradictions with WTO law and a possible impact on private rights? If so, his delegation would like to know what those alternatives were.

190. He said that El Salvador would continue to monitor Australia's measure, including within the framework of the WTO Committee on Technical Barriers to Trade.

191. The representative of Norway thanked the Australian delegation for the update on the status of the tobacco plain packaging legislation and its implementation. Norway had expressed its support for the Australian measures at previous meetings of the Council and wished to reiterate its view that the TRIPS Agreement provided Members the flexibility to adopt measures necessary to protect public health. Following the information provided by the Australian delegation in this matter, Norway remained confident that the measures described would be implemented in a manner consistent with Australia's WTO obligations.

192. The representative of Honduras said that her delegation shared the concerns raised by the Dominican Republic and others regarding the plain tobacco packaging measures adopted by Australia in the Tobacco Plain Packaging Act 2011 No. 148 and the law on trademarks No. 149 of 2011. The regulations on plain tobacco packaging for cigarettes and cigarette packaging had been adopted on 7 December 2011 as the public consultations on cigar regulations and the regulations for other tobacco products had now ended.

193. She said Honduras was concerned by the lack of comprehensive responses from Australia to the concerns expressed by Members, and the lack of evidence that supported the measure, as well as the effective prohibition of the use of trademarks as regards logos, designs, colours and brands on the packaging of all tobacco products, both cigars and cigarettes. Her delegation feared that under these measures, producers and importers of related tobacco products would be obliged to adopt standardized packaging and would at the same time be prevented from using their legitimate IPRs on the packaging, preventing consumers from having access to important information on the product that they were buying.

194. Honduras believed that this requirement would violate Article 20 of the TRIPS Agreement, which clearly established that the use of a trademark could not be unjustifiably encumbered in trade operations by specific requirements such as the use with another trademark, the use in a special form, or use in a manner which could undermine the ability for the brand to distinguish the goods or services of one company from those of other companies. It was her delegation's view that plain packaging represented a special requirement of the type listed in Article 20 and was therefore by definition an unjustified encumbrance of the use of a trademark. Although Australia's intention in adopting this type of measure was understandable, her delegation believed that the end could not justify the means. Such measures had to be based on proof and had to meet the requirements and objectives of public interest. In this case, she said, there was not sufficient proof to guarantee that this plain packaging was really effective in discouraging consumption.

195. Her delegation believed, on the contrary, that plain packaging measures created a serious risk of confusion between competing tobacco products. These measures would also violate Article 22.2(b) of the TRIPS Agreement which referenced Article 10*bis* of the Paris Convention, because it generated confusion with respect to geographical indications. Lastly, Article 10*bis* of the Paris Convention itself would be violated, as this Article prohibited any act that could create confusion through whatever means regarding this establishment, the products, or the industrial trade activity of a competitor.

196. The representative of Ukraine said that his delegation had expressed serious concerns regarding Australia's proposed Tobacco Plain Packaging Bill 2011 at the Council's previous meetings in June and October 2011. Ukraine and others had noted that, if the proposed legislation were enacted into law as drafted, the plain packaging requirements set forth in the legislation would violate a number of Australia's WTO obligations, including obligations under the TRIPS Agreement, as well as provisions of the Paris Convention for the Protection of Industrial Property that had been incorporated into the TRIPS Agreement.

197. He said that, at the time of the Council's meeting in October 2011 when the Bill had passed Australia's House of Representatives and was pending before its Senate, Ukraine had expressed its hope that Australia's Senate would amend the bill to bring it into compliance with Australia's obligations under the TRIPS Agreement. Since the Council's last meeting, there had been a number of important and highly troubling developments in Australia with regard to the Tobacco Plain Packaging Bill 2011. The legislation had passed Australia's Senate on 10 November 2011 without substantive amendments and received Royal Assent on 1 December 2011, thus becoming Australian law as the Tobacco Plain Packaging Act 2011.

198. He said that Australia had also implemented the final Tobacco Plain Packaging Regulations 2011 relating to cigarettes on 7 December 2011, and had proposed amendments to these regulations concerning non-cigarette tobacco products, including cigars and other products. It was his delegation's understanding that Australia intended to implement these regulations in the course of the coming month.

199. He said that Ukraine wished to reiterate its strong concern that the Tobacco Plain Packaging Act 2011 and its implementing regulations violate several provisions of the TRIPS Agreement, such as Article 20, Articles 15 and 16 and Article 8.1, as well as provisions of the Paris Convention as incorporated into the TRIPS Agreement. Serious concerns about the lack of consistency of the Act and its regulations with fundamental international rules on the protection of IP had been echoed by a number of other Members and leading international IP and business organizations throughout the world, as referenced in detail at the Council's last meeting.

200. He said that the delegation of Ukraine appreciated Australia's intention to develop and implement policies for the health of its citizens. Ukraine strongly supported the implementation of rational, effective, evidence-based measures to achieve health-related goals. It was merely requested of Australia, like of all other Members, to formulate health policies in a manner consistent with international obligations, including those under the TRIPS Agreement. Article 8.1 of the TRIPS Agreement expressed the very same principle in no unclear language: Members may of course impose measures that are necessary to protect health, provided that they are consistent with the obligations under the TRIPS Agreement. Unfortunately, Australia's measure appeared to be neither necessary to protect health, nor consistent with the provisions of the TRIPS Agreement. His delegation was deeply disappointed to have received no responsive information from Australia regarding these critical points.

201. He said that Ukraine would continue to follow in the most serious manner the further implementation of this measure and reiterated its request that Australia reconsider the Plain Packaging

Act 2011 and revise the measure as needed to ensure the conformity with Australia's international treaty obligations, including those under the TRIPS Agreement.

202. 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. It was within a Member's right to implement necessary measures in order to protect public health. Her delegation noted the clear assurances by Australia that it had paid close attention to and respected its WTO obligations in developing its plain packaging proposal. She further noted the numerous scientific studies which demonstrated that plain packaging of tobacco products could lead to positive public health outcomes by reducing the attractiveness and desirability of smoking and by increasing the prominence of public health warnings. It was her delegation's view that plain packaging, as part of a comprehensive suite of tobacco control measures, could contribute to efforts to reduce smoking rates.

203. The representative of Uruguay said that his delegation's position regarding the law on plain packaging was well known. In summary, his delegation believed that Australia had acted in accordance with the TRIPS Agreement and its objective of public health protection, and Uruguay therefore respected the legislative initiative by Australia.

204. The representative of Chile said that, in the three meetings in which this issue had been on the agenda of the TRIPS Council, Chile had highlighted the systemic importance of this discussion, particularly in relation to the legitimate use of flexibilities in the area of public health, and regarding the protection of IPRs and the legal certainty necessary in international trade. His delegation wished to reiterate that the right of WTO Members to regulate and protect public health, which was made abundantly clear in Article 8 of the TRIPS Agreement and the Doha Declaration, was not in dispute. The discussion did therefore not concern the legitimacy of measures to protect public health, nor should it be seen as a dispute opposing those for and against the protection of public health.

205. Nevertheless, it was clear that any measure taken by Members to protect public health had to be consistent with the relevant international trade agreements. In this case, they had to be consistent with provisions and recognized rights in the area of IP. They also had to comply with TBT provisions, in particular with Article 2.2 of the TBT Agreement, which stipulated that technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective.

206. He said that Members did not dispute that tobacco had a harmful effect on health. However, was there no other measure to reduce cigarette consumption less onerous than prohibiting the use of trademarks, thereby undermining their capability to distinguish the goods and services of one undertaking from those of other undertakings? The provisions of the TRIPS Agreement were clear in this respect, in particular Article 20, which specifically stated that the use of a trademark shall not be unjustifiably encumbered by special requirements, such as use in a special form. If the plain packaging measure were deemed consistent with the TRIPS Agreement, did this then mean that every time a product was considered harmful to health, trademark owners could be stripped of their right to use their registered trademark, or that they might be obliged to use their trademark in such a way that it loses its distinctive character, and consequently its value?

207. Chile believed that this issue related neither to tobacco nor to public health, but rather to the regulation of international trade in accordance with the WTO Agreements. His delegation did not dispute the legitimacy of the objective sought by the Australian authorities, nor Australia's right to take measures to protect public health. However, his delegation had serious doubts that imposing plain packaging for cigarettes was the least trade restrictive measure and that it was consistent with certain provisions of the TRIPS Agreement, in particular Article 20.

208. The representative of Canada said that her delegation followed with interest the on-going international developments regarding the plain packaging of tobacco products, and how such a measure interacted with both IP and public health. She said that Canada had adopted and implemented the WHO Framework Convention on Tobacco Control (FCTC) and encouraged other Members to consider doing so. Canada had been a pioneer in packaging requirements for tobacco products and her delegation recognized how challenging it was to introduce tobacco control measures that had never been implemented before. Canada had been in a similar situation a decade ago when it had introduced pictorial health warnings on tobacco packages. This measure had been put in place after extensive research had suggested that it was effective at increasing public awareness of health effects and hazards. It was her understanding that Australia had also conducted serious research to support the introduction of their new measure.

209. She said that the information Australia had provided, and its experience with plain packaging, would help WTO Members gain a better understanding of the complex issues at stake. She thanked Australia for updating the Council on the implementation of its plain packaging initiative, and its various implications, and was confident that Australia, in the elaboration of its Bill, had taken into account the importance of respecting international obligations.

210. The representative of Zimbabwe said that her delegation shared the concerns expressed by the Dominican Republic and other delegations as regards the likely consequences for consumers and producers of tobacco products of the plain packaging measures being put in place by Australia. It was her delegation's view that Australia, like any other Member, was obliged to protect and advance the public health of its citizens within the limits of its undertakings and commitments under the WTO TRIPS Agreement.

211. The representative of Mexico said that her delegation was sensitive to the legitimate objectives sought by Australia, which served as a basis for its plain packaging bill. At the same time, Mexico shared the concerns regarding potential commercial implications, and particularly the possible negative systemic implications of such a measure as expressed in the statement by Chile. The discussion on this measure did not just concern public health and tobacco, it was a more systemic issue and Mexico would continue to follow the developments in the implementation of this bill very closely and analyse its consistency with both the TRIPS and the TBT Agreement.

212. The representative of China said that her delegation noted that the Draft Bill of Australia had the legitimate objective to protect human health by introducing the requirement of plain packaging on tobacco products, with the aim to reduce their appeal to consumers and increase the effectiveness of health warnings. With regard to the utilization of trademarks, Sections 20 and 22 of Tobacco Plain Packaging Act 2011 provided a general prohibition on marks appearing on retail packaging of tobacco products and on the wrapper. Section 21 of the Act set out requirements for the appearance of brand, business, company and variant names on cigarette packs and cigarette cartons, including the surfaces on which the names may appear and where the names may appear on those surfaces. Division 2.4 of Tobacco Plain Packaging Regulations 2011 added to those requirements, and specified the typeface, font size, colour and capitalization of the brand, business, company and variant names. The Regulation prohibited any permitted trademarks or marks obscuring relevant legislative requirements, or constituting or providing access to tobacco advertising and promotion.

213. She said that without touching the legal nature of these provisions, her delegation believed that these public health measures were also related to IPR protection. Members of WTO needed to be cautious and strike a balance between the protection of IP right holders and the public interest in general. Her delegation believed that such measures should not contravene international obligations under TRIPS Agreement.

214. The representative of Brazil said that his delegation's position on the matter was well known. It believed that the existing international rules on IP should be supportive of public policy measures designed to protect public health within Members. For Brazil, a balance had to be found with a view to guaranteeing the legitimate interests of right holders and, at the same time, ensuring that public health policies could be duly implemented in our countries. Article 8 of the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health should guide the interpretation of the applicable provisions on trademarks of the Agreement.

215. The representative of Switzerland said that his delegation was supportive of public health measures in the area of anti-smoking as long as such measures were implemented in a manner consistent with the TRIPS Agreement and also the Paris Convention. This meant that such measures needed to be both effective and proportionate, taking into account the various interests at stake in a balanced manner. It was against this background that Switzerland had posed a question to Australia at the last meeting. It referred to the consultation paper on the plain packaging amendment the Australian Government had submitted to interested stakeholders for comments in spring 2011. This paper mentioned a caveat to the full ban of using the trademark, meaning that under certain circumstances the 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 ask whether Australia could clarify to the Council what the final version of the Tobacco Plain Packaging Bill Act and implementing regulations, as they had now been approved, provided in that respect.

216. The representative of Ecuador said that his delegation understood the concerns expressed by Members regarding the possible commercial and social effects of the plain packaging bill. This concerned especially the local farming communities as such a measure would seem to constitute an obstacle to a product exported by developing countries.

217. With respect to the WHO taking the floor, the Dominican Republic said that his delegation had no objection a statement to be made by the WHO Secretariat, as long as the statement focused on the health aspect and did not touch on aspects which fell under the responsibility of the WTO. He wished to repeat that the Dominican Republic did not deny the harm tobacco caused to health, but what was of concern to his delegation was that a Pandora's box could be opened which would have an impact on any products which countries considered harmful to health.

218. The representative of the World Health Organization (WHO) said that tobacco use was one of the greatest threats to public health the world had ever faced, and the single most preventable cause of death in the world today. Globally, tobacco consumption 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 reside in low- and middle-income countries. Tobacco also 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, currently accounted for 63 per cent of all deaths worldwide. These diseases killed an astounding 36 million people each year, with nearly 80 per cent of deaths occurring in low- and middle-income countries.

219. He said that, as necessary tobacco control measures continued to be implemented in developed countries, the tobacco industry, through aggressive marketing and interference practices, had shifted its focus to new markets in the developing world some time ago. 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. He said that, given that smoking caused 30 per cent of all cancers, including greater than 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 effort to curb the tobacco epidemic for the introduction of necessary public health interventions under the WHO Framework Convention on Tobacco Control (FCTC), like the measure under consideration in this Council.

220. He said that the economic costs of tobacco use were equally as devastating as the public health costs. Though the tobacco industry routinely cited the economic contribution of tobacco, the reality was that tobacco use put 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, 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 total annual health expenditures in low- and middle-income countries.

221. He said that the economic burden of NCDs, with tobacco representing the largest risk factor, was also staggering. 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, representing 48% 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, were relevant in addressing both health and economic concerns.

222. He said that the WHO wished to draw the attention of delegations to the fact that the impact of tobacco and NCDs on both public health and country economies had been highlighted at the recent United Nations High-Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases, held in September 2011 in New York. There, the UN General Assembly, comprised of Heads of State, had adopted a Political Declaration which recognized the fundamental conflict of interest between the tobacco industry and public health, and wherein Member States unanimously committed to advancing the implementation of multi-sectoral, cost-effective, population-wide interventions in order to reduce the impact of NCD risk factors.

223. He said that the WHO was of the view that the implementation of plain tobacco product packaging, representing 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 FCTC.

224. Another representative of the WHO said that the FCTC consisted of a series of obligations to undertake tobacco control measures and that the parties to the WHO FCTC largely overlapped with WTO membership. She said Members could refer to the comments WHO had made at the two previous Council meetings but she wished to draw the attention of the Council to an upcoming event that the FCTC Secretariat was planning at the WHO headquarters. This event stemmed from a decision by the Conference of the Parties, the supreme governing body of the FCTC, to collaborate with and cooperate with the WTO Secretariat in terms of information sharing and exploration of trade-related tobacco control measures and issues arising therefrom.

225. The FCTC Secretariat was hosting on 15-16 March a workshop at the WHO headquarters in order to promote the sharing of knowledge and information amongst representatives of countries that are parties to the FCTC and also Members of the WTO. The primary goal was to invite health attachés and trade attachés of Permanent Missions in Geneva to this workshop so as to examine the issues of intersection between tobacco control measures and trade-related issues. She said that the FCTC Secretariat would very much welcome the participation by Members of the TRIPS Council and other WTO bodies.

226. The representative of South Africa said that, although there had been an opportunity to speak before the WHO took the floor, his delegation preferred to reserve its comments. This was an issue that South Africa had previously taken the floor on, and would continue to do so. He said that the



discussion Members were having in the Council was a very sensitive discussion that involved a tension between public health and a legitimate right to trademark protection. His delegation recognised the sensitivity of the issue even if it did not have a view one way or the other. His delegation did, however, believe that the remit of the TRIPS Council went beyond the issues that the representatives of the WHO had correctly raised and which were substantively the same as had been heard before.

227. South Africa had no difficulty as a delegation with what it had heard. He did, however, consider it worth recalling that Members' responsibility was both to the questions of public health, and to the trade and commercial aspects of the issue. Therefore, although his delegation appreciated the WHO's angle, it considered it worthwhile recalling the presentation from Chile, which he believed had been very balanced and had brought forward precisely the responsibilities that Members had in the Council. His delegation wished therefore to urge the WHO, in going forward, to also appreciate that Members' mandate in this body was broader than the issues WHO had to consider. He said that his delegation had expressed this particular concern at the Council's last meeting, and would continue to do so, also in stronger terms if necessary, as it was important that this Council be allowed to have an in-depth debate on this issue that was within the framework of its mandate.

228. The representative of the Dominican Republic said that what the WHO had requested would amount to allowing it to hold debates on the functions of this organization. He said that the WHO event could be helpful, given that the WHO had extended invitations to a series of seminars including on tobacco consumption as well as on alcohol consumption, both of which were harmful to health and had a high cost burden throughout the world.

229. The Council took note of the statements made.

#### N. IP ENFORCEMENT TRENDS

230. The Chairman said that this had been put on the agenda at the written request of the delegations of Australia, Canada, the European Union, Japan, Korea, Mexico, New Zealand, Singapore, Switzerland and the United States. They had also requested that the text of the Anti-Counterfeiting Trade Agreement (ACTA) be circulated to Members. He recalled that the text had already been circulated in advance of the Council's October 2011 meeting in document IP/C/W/563 entitled "Enforcement of Intellectual Property Rights".

231. The representative of Japan reported on developments on ACTA since the Council's last meeting. On 26 January 2012, the European Union and 22 of its member States had signed the agreement in Tokyo. It was hoped that other participants to the agreement who had not yet signed it would soon be able to do so. No instrument of ratification, acceptance or approval had been deposited so far with the Government of Japan in its capacity as the agreement's Depositary.

232. ACTA represented a modest but important step forward in order to deal with infringement of IPRs, in particular given the proliferation of counterfeiting and piracy in the current technological environment, as well as the diversification and refinement of IP infringing activities. This had led to a substantive expansion of counterfeiting and piracy at the global level since the entry into force of the TRIPS Agreement. The purpose of circulating the text of ACTA was to clarify what was provided for and what was not covered by the agreement, as well as to give an overview of the many optional provisions included therein. Some Members might thus realize that they had already legislative measures in place that were similar to those provided under ACTA. To address certain concerns expressed about the potential impact of ACTA, he underlined that the agreement explicitly provided for its implementation to be done in a manner that avoided the creation of new barriers to legitimate trade.

233. The representative of the United States welcomed the opportunity to discuss enforcement of IPRs, which could serve to dispel some misperceptions about IP enforcement in general and ACTA in particular. In his delegation's view, the effective enforcement of IPRs was critical to sustaining economic growth across all industries and globally. The proliferation of counterfeit and pirated goods, as well as of services that distributed infringing material, undermined legitimate trade and sustainable development of the world economy, caused significant financial losses for right holders and for legitimate businesses, and, in some cases, provided a source of revenue for organized crime and otherwise posed risks to the public. Effective IPR enforcement benefited from enhanced international cooperation and more effective international enforcement. He said that principles regarding effective IPR enforcement thus formed part of the bedrock of ACTA.

234. To help promote a dialogue among Members, his delegation wanted to address some of the issues that had been raised at the Council's last meeting in October 2011. In response to the question asked by the delegation of Zimbabwe about the "lacunae" in the TRIPS Agreement which ACTA sought to address, he provided a few examples. First, ACTA provided a forum for its participants to work cooperatively together to protect and enforce IP. The ACTA cooperation provisions were more extensive than those in the TRIPS Agreement, but as with the rest of ACTA, they were fully TRIPS-consistent. ACTA further provided that Parties to the Agreement had to authorize their border enforcement authorities to act on their own initiative against trademark counterfeit and copyright pirated goods. This addressed a gap in existing standards under which customs officials were sometimes powerless to take action against fake and pirated goods. Application of this stronger standard would help protect consumers. Finally, ACTA included new commitments on the seizure and destruction of fake goods, on the seizure of the equipment and materials used in their manufacture, and on the seizure of the criminal proceeds from piracy and counterfeiting offenses. This ensured that police and prosecutors would be able to take away both ill-gotten gains and the tools of illicit trade.

235. When the TRIPS Agreement had been negotiated almost 20 years ago, the type of complex distribution webs encountered today had not existed. ACTA was intended to ensure that enforcement authorities had the legal tools to address the new sophisticated ways by which illegal, and often deadly, products were distributed. The examples provided to the delegation of Zimbabwe reflected an effort to provide appropriate tools. Governments had to modernize their approaches to adapt to evolving illegal activities, especially to keep up with criminals.

236. Turning to concerns expressed about the impact of ACTA on generic medicines, the representative of the United States clarified that ACTA did not target such medicines. Among others, ACTA did not require border enforcement of patents. On the other hand, border enforcement of trademarks constituted an important element of protecting the public. In the United States, authorities had, for example, recently uncovered a significant problem of fake cancer drugs in the domestic supply chain. Among other things, such fake drugs sometimes bore counterfeit trademarks. Empowering border authorities to act in regard to such fake trademarks could have real health benefits.

237. As noted by the delegation of Japan, Article 13 of ACTA provided, similarly to the TRIPS Agreement, that barriers to legitimate trade should be avoided. Furthermore, ACTA also protected against abuse. Like the TRIPS Agreement, it stipulated that IP enforcement procedures "shall be applied in such a manner so as ... to provide for safeguards against their abuse."

238. With respect to questions regarding transparency which were raised at the Council's last meeting, he said that ACTA was not secret. A draft had been released in April 2010, while negotiations had still been ongoing. A near-final text had been published in October 2010, as well as the final text in December 2010. In May 2011, French and Spanish translations had been published. The final English text had thus been public for more than a year.

239. The representative of Switzerland said that a fair amount of misleading, if not wrong, information was circulating about ACTA. His delegation was therefore pleased to seize this opportunity to clarify a number of points and, in particular, to address the objectives of ACTA, including the benefits which ACTA Parties hoped to derive from the agreement.

240. He emphasized that ACTA dealt with measures to effectively enforce IPRs and more specifically to combat counterfeiting and piracy. ACTA was thus not ratcheting up higher levels of IP protection, but rather aimed at enforcing more effectively existing standards of protection. It focused on large scale, commercially-oriented counterfeiting and piracy. Those activities, which were constantly growing, had a significant negative impact on the world economy, on legitimate business and on the public's health and safety.

241. ACTA had not been negotiated by 38 like-minded Parties to bypass multilateral institutions. On the contrary, his delegation, like the other ACTA Parties, would have preferred to address the growing problem of counterfeiting and piracy, including ways and means how best to counter that trend, in multilateral fora like the WTO or WIPO. There had been numerous attempts to do so in the past, during which it had been clarified that the purpose of such a discussion was not about finger pointing but to take up a challenge that all Members faced jointly and which should therefore be addressed jointly. However, there had been strong opposition from a number of countries to even raise or discuss the subject in these fora.

242. Counterfeiting and piracy was a challenge of transnational character to which efforts at national level could not provide an effective solution. ACTA Parties had therefore opted for the second best alternative, i.e. to take a step forward among a group of like-minded countries. Since countries depended on each other in order to address the issue of counterfeiting and piracy, cooperation was in their mutual interest. This responded to a challenge which not only created enormous economic damage, but also represented in many instances serious safety and health risks for their citizens.

243. Switzerland had adopted a range of measures to combat counterfeiting and piracy at the national level. The Swiss anti-counterfeiting and piracy platform, called STOP PIRACY, represented such an instrument. It allowed for enhanced coordination and cooperation among competent government agencies as well as between the public and private sector.

244. Enhanced cooperation between the ACTA Parties, as provided for in Chapter IV of the agreement, could reinforce such national efforts by adding the international dimension. It thus contributed to efforts to address the growing proliferation of counterfeiting and piracy in a more effective manner than could be done at the national level. ACTA represented an effort by a group of like-minded countries, both developing and developed, to cooperate with a view to supporting each other in their efforts to more effectively combat counterfeiting and piracy.

245. The representative of Singapore welcomed the opportunity to discuss IP enforcement trends, particularly to provide clarifications on issues related to ACTA. It was important to base discussions on ACTA on the actual provisions in the final text, rather than on proposed language which had been deleted or on provisions which were misattributed to ACTA, or extrapolations of ACTA provisions.

246. In reaction to concerns that ACTA could reduce the freedom of access to the Internet and impede cross-border trade, in particular as regards the movement of generic medicines across borders, she said that ACTA would not interfere with a signatory's ability to ensure that citizens continued to enjoy ease of legitimate access to the Internet. Similarly, ACTA did not limit the ability of signatories to exercise flexibilities that existed within the TRIPS Agreement, nor did it prevent signatories from protecting or enforcing IPRs in a manner conducive to social and economic welfare. Nothing in ACTA imposed a requirement on signatories to introduce a specific measure, such as a graduated

response (three strikes) or site-blocking policy, against copyright infringement. ACTA also did not compel Internet service providers to monitor Internet users' traffic.

247. As a small country with a strong interest in international trade, Singapore placed great importance on a multilateral rules-based system. A key priority had therefore been to ensure that the enforcement measures in ACTA were consistent with existing international IP agreements and did not create new barriers to trade. Nothing in ACTA derogated from the TRIPS Agreement, which established *minimum* standards for IP protection. ACTA was built on existing TRIPS flexibilities. Nothing in ACTA obliged border authorities to search travelers' baggage or their personal electronic devices for infringing materials. As regards more specifically access to medicines, there were no provisions in ACTA which hindered the cross-border transit of legitimate generic medicines. Patents were not covered in the section on border measures. ACTA was consistent with the TRIPS Agreement and respected the Declaration on TRIPS and Public Health.

248. The representative of Canada said that the ACTA partners had been committed to transparency throughout the negotiations. Since August 2008, they had issued joint public statements after each round or meeting. Her delegation, like other ACTA negotiating partners, had undertaken consultations with stakeholders throughout the negotiations. As agreed during the sixth round of negotiations that had taken place in Seoul in November 2009, the participants to ACTA negotiations had published the agenda for each round in advance of the meeting. They had published a summary of elements under discussion in the ACTA negotiations in April 2009. A fact sheet prepared by the participants to the negotiations had been made available to the public in April 2010. Following the round of negotiations in New Zealand, they had regularly released a revised negotiating text to the public with a view to increasing transparency and to providing accurate information to the public about the negotiations. She also stressed that, in encouraging higher standards, there was no intention to exclude any country from joining efforts to combat counterfeiting and piracy. The agreement had been negotiated with a view to being inclusive and attracting accessions from other countries.

249. The representative of New Zealand said that questions had been raised for some time about the challenge of enforcing IPRs in the digital environment. In recent months, there had been many misleading statements about possible negative impacts of ACTA. For example, ACTA had been unfairly accused of posing a threat to freedom of expression on the Internet, stifling innovation, and negatively affecting individuals' abilities to access and use the Internet. Freedom of speech, fair process and privacy were core values for her delegation. These values applied in both the physical world and on the Internet. Freedom of speech did not mean, however, that a person had a right to engage in unauthorized reproduction, distribution and sale of copyright-protected works over the Internet.

250. All WTO Members were required to provide copyright protection as set out in Articles 9 to 14 of the TRIPS Agreement. Pursuant to Article 41, procedures for enforcement of IPRs, including copyright, had to be effective and remedies to infringement had to constitute a deterrent to further infringements. The TRIPS Agreement did not allow its Members to turn a blind eye to copyright piracy that was increasingly occurring over the Internet. Accordingly, Article 27 of ACTA obliged each Party to ensure that enforcement provisions were available under their laws so as to permit effective action against copyright infringements in the digital environment.

251. She noted that a common fiction perpetuated about ACTA by critics was an unsubstantiated allegation that ACTA interfered with civil rights and in particular freedom of expression. Article 27 contained clear and unequivocal language that a Party was not required to interfere with either civil rights or freedom of expression. It stated that "procedures shall be implemented in a manner that avoids the creation of barriers to legitimate activity, including electronic commerce, and, consistent with that Party's law, preserves fundamental principles such as freedom of expression, fair process, and privacy".

252. Another common fiction perpetuated about ACTA was that it required the blocking of Internet access as a result of copyright infringement. She clarified that the ACTA text did not contain a requirement to block access to the Internet, nor did it require the criminalization of illegal downloading. In her delegation's view, ACTA struck an appropriate balance between the rights and interests of rights holders, Internet service providers and users of online content, while also explicitly preserving fundamental principles such as freedom of expression, fair process, and privacy.

253. The representative of Australia said that ACTA was an important initiative to address growing international trade in counterfeit trademark and pirated copyright goods. Concerns raised during previous discussions in the Council and elsewhere that the enforcement provisions in ACTA could undermine the balance in the TRIPS Agreement were unwarranted. Participants to ACTA negotiations had worked hard to achieve a balanced agreement. The final text struck a balance between *use* and *protection* of IP and affirmed, and built on, the balance and flexibilities in the TRIPS Agreement.

254. In particular, all TRIPS flexibilities were preserved because ACTA made specific reference, in Article 1, to not derogating from any obligation of a Party, with respect to any other Party, under existing agreements, including under the TRIPS Agreement. Furthermore, Article 2(3) of ACTA explicitly stated that the objectives and principles in Part 1 of the TRIPS Agreement, in particular its Articles 7 and 8, were applicable to ACTA. Article 7 addressed the balance in IP systems, i.e. the rights and obligations of producers and users, and Article 8 provided flexibilities for Members in formulating and amending legislation and regulations in the public interest. In addition, Article 6 of ACTA incorporated the standards in TRIPS Article 41 dealing with "enforcement obligations" and those in Article 46 dealing with "other remedies". Amongst other things, ACTA Article 6 required that (i) enforcement procedures be applied "in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse", (ii) procedures implementing the provisions of the chapter be "fair and equitable", (iii) Parties provide "for the rights of all participations subject to such procedures be appropriately protected", and (iv) Parties "take into account the need for proportionality between the seriousness of the infringement, the interests of third parties and the applicable measures, remedies and penalties". Therefore, the ACTA text explicitly preserved and affirmed the important balance and flexibilities contained in the TRIPS Agreement.

255. The representative of the European Union said that businesses based on creativity required the protection and enforcement of IPRs. The most conservative estimates put the size of the global counterfeiting and piracy industry at €200 billion a year. But that estimate excluded all Internet piracy, as well as any act of counterfeiting and piracy where the product was sold in the country of production. The EU had a comprehensive system to protect and enforce IPRs which had been implemented in its 27 member States together with national enforcement authorities. When elaborating its IPR regime, the rights of citizens to free speech, data protection and access to information had been safeguarded, as well as the rights of Internet service providers and other intermediaries who dealt with protected goods. These two goals were compatible and even mutually supportive.

256. IPR enforcement in the EU was evolving to become increasingly effective. The EU customs enforcement legislation, which had already resulted in annual detentions of more than one hundred million fake objects, was currently being reviewed. There were also plans to revisit the civil enforcement legislation. Furthermore, a European Observatory on the protection of IPRs had been established. Its primary goal was to obtain factual and accurate information that was needed to better substantiate new policy measures and to optimize resources.

257. In addition to the work in the area of enforcement, the European Commission was also preparing initiatives to make digital content more accessible to citizens. For instance, a pan-European licence for music, easier licensing for "orphan works", and the creation of online digital libraries were

under consideration. Such initiatives sought to give consumers and users better access to cultural content while allowing for new business models to thrive.

258. He said that ACTA was another important tool to ensure more effective IP enforcement at the international level. It was an enforcement treaty which dealt with civil, criminal and border enforcement. It also set out some basic principles for Internet enforcement and encouraged international cooperation between 38 countries. While not covering the details of what was legal and what was illegal, ACTA addressed procedures for ensuring that what was illegal could be redressed. ACTA thus simply meant that companies and individuals who wished to protect their ideas so as to defend their livelihoods would find it easier to do so in the 38 countries that had participated in the negotiations.

259. His delegation would have preferred that ACTA be negotiated at a global level, but this had not been possible. Thus, ACTA constituted a significant first step by a nucleus of countries that were committed to the highest standards of IPR enforcement. This nucleus was expected to grow. Countries joining the agreement would see the benefits of effective enforcement measures in terms of increased investment and innovation, as well as more generally economic growth and the creation of quality jobs. For example, the OECD had found that an increase of 1 per cent in the strength of patent rights led to an increase of 1.7 per cent in foreign direct investment flows in developing countries.

260. The representative of the European Union gave examples of misconceptions about ACTA. As regards access to medicines, there were no provisions in ACTA that could directly or indirectly affect the legitimate trade in generic medicines or, more broadly, global public health. On the contrary, ACTA contained unequivocal language safeguarding access to medicines and expressly referred to the Doha Declaration on the TRIPS Agreement and Public Health. ACTA also excluded patents from criminal and border measures.

261. As regards concerns expressed about the transparency of the negotiating process, he said that ACTA had not been negotiated in secret. The text of ACTA had been made publicly available since April 2010. It had already been made public during the negotiations. His delegation had organized four stakeholder conferences on ACTA, which had been open to all stakeholders, including citizens, industry, NGOs and press. Negotiators had also met and extensively debriefed NGOs, academia and representatives from political parties in public debates held as side events in the margins of the last four rounds of negotiations.

262. The representative of Mexico said that her Government recognized that piracy and counterfeiting had had a very significant impact worldwide, calling for solutions that required effective international coordination, including the establishment of higher standards for the enforcement of IPRs through agreements such as ACTA. With a view to the implementation of more effective measures to combat IPR violations, her delegation was convinced that active involvement in the development of mechanisms for cooperation among countries would make it possible to ensure better protection of IPRs.

263. The representative of Korea addressed the relationship of ACTA with the TRIPS Agreement. In her view, ACTA was a legal framework for countries to more effectively combat counterfeiting and piracy, which built on the TRIPS Agreement but did not supplant nor undermine it. It thus complemented the TRIPS Agreement in terms of IPR enforcement and was fully consistent with it. The TRIPS Agreement set minimum standards for IPR protection, which granted its Members flexibilities to choose effective measures and procedures to implement its objectives.

264. As regards concerns about a possible conflict between ACTA and basic human rights, including freedom of speech and privacy, namely by changing the role of Internet service provider, she emphasized that ACTA struck a fair balance between the need to protect innovation on the one

hand and the rights of consumers and public interests on the other hand. It had all the necessary safeguards to shield freedom of speech, piracy and data protection. This was expressly stipulated in Article 27. In addition, ACTA only focused on IPR infringement on a commercial scale, not on private, non-commercial activities of individuals. It did not affect the free flow of non-pirated information, nor did it require Internet service providers to monitor individuals.

265. While ACTA sought to strengthen the level of IPR protection in general, it provided its Parties with enough discretion on the measures to be taken domestically. The reason was that each country had different legal system and the balance to be struck between the protection of right holders and public interests varied from one country to another. Such flexibilities in ACTA could enable more countries to join the agreement in the future. In her view, ACTA provided for a well-balanced and flexible legal framework for Members to better achieve the objectives of IPR protection, as stipulated in the TRIPS Agreement, through combating counterfeiting and piracy. ACTA could thus contribute to a sounder multilateral trading system. She hoped to work closely with all Members in the Council on how to best protect IPRs in an effective and balanced manner.

266. The representative of Malaysia said that Members' views differed on whether the current level of IP enforcement under the TRIPS Agreement was sufficient or whether additional measures needed to be taken. This underlined the need for and importance of preserving flexibilities in determining the appropriate level of enforcement obligation. The TRIPS Agreement provided such flexibility, as it imposed minimum standards, while recognizing Members' right to adopt higher standards. This flexibility should not be restricted, neither by raising the floor on what had to be done, nor by imposing a ceiling on what could be done.

267. The representative of India recalled that, at the Council's meeting in October, his delegation had pointed out that TRIPS-plus provisions in plurilateral agreements like ACTA and TPP could undermine the flexibilities and disturb the delicate balance provided by the TRIPS Agreement, thus adversely affecting access to health in the developing countries. This issue equally affected developing and developed countries. The unprecedented economic and financial crisis in the developed world and the austerity measures that had been taken by many countries, had adversely affected their health budgets. In such a situation, it was essential that access to affordable medicines did not get circumscribed by agreements like ACTA and TPP, which were motivated by the interests of pharmaceutical companies.

268. For instance, reports on the situation in Greece had highlighted how its extensive public health care system, under which care had been taken of every need of its people, had been pushed hard for dramatic cost savings in order to cut back on the deficits. These measures were taking a brutal toll on the system and on the country's growing number of poor and unemployed, who could neither afford high health insurance premiums nor high cost of drugs applied by the pharmaceutical companies. Similar austerity measures in other parts of Europe were beginning to affect access to medicines for patients.

269. He said that the post-TRIPS era had seen a reduction in the policy space required for designing IP policy. It had witnessed an enormous increase in cost of essential medicines and the countries that lacked manufacturing capacity were in a further difficult situation. For the last few years, barriers had been created, even to import generic medicines, through their seizure during their transshipment at European ports. Attempts were also made through bilateral, regional and plurilateral agreements to stifle the manufacturers of generic medicines that were a life line for billions of poor in the developing countries. In his delegation's view, the Council would be better advised to deliberate on how the TRIPS Agreement could promote access to health for the billions of needy people rather than discuss the IP agenda of a few countries.

270. Despite the statements made by ACTA signatories and their reassurance that ACTA would not affect access to medicines in developing countries, his delegation was nevertheless afraid that, once ACTA comes into force, the ACTA border measures, which were currently limited to some parts of Europe, could be extended to the territories of other ACTA signatories. This would further stifle the supply of generic medicines to the needy countries. The very need of ACTA remained unclear in the absence of reliable estimates of the extent of counterfeiting and piracy and the exact impact of such activities on domestic industry. Various industry estimates had been criticized for being based on downright incorrect data and at best dubious methodology to the extent that some estimates relied on failure to meet targeted sales as evidence of piracy and counterfeiting.

271. He referred to several ACTA provisions which might be worrisome for developing countries despite the ostensible removal of "patents" from the ambit of border measures. First, ACTA was not limited to 'counterfeiting', as defined in the TRIPS Agreement. Even while admitting that the term 'counterfeit' applied to trademarks only, the agreement had extended it to all forms of IPRs as covered under the TRIPS Agreement, including data, copyrights, patents, etc. Stating that patents were not the subject matter of the Agreement would be inappropriate. For example, while patents (and undisclosed information) were kept outside the scope of border measures, the application of civil enforcement measures was preserved on an optional basis in the agreement. This represented a marked increase over the TRIPS Agreement which limited itself to counterfeit trademark and pirated copyright goods only. In addition, by criminalizing wilful use of trade labels or packaging without authorization by the right holder, Article 23.2 of ACTA clearly militated against parallel importation even though the relevant domestic law might not expressly forbid it.

272. As regards border measures, ACTA initially went much beyond TRIPS Article 51 and included all forms of IPRs. However, in response to criticism voiced during the secret negotiations of ACTA, as well as in the light of several incidents of generic drugs in transit seized at European ports, the ACTA signatories had finally decided to exempt patents and undisclosed test data from border measures. While this move had to be welcomed, the mandatory application of border measures to other forms of IPRs could still affect the trade in goods transiting through ACTA countries.

273. The representative of India recalled that in past Council meetings, his delegation and other Member had highlighted their concerns over the seizure of generic medicines in transit at European ports when there had been no IP infringement. Some consignments had been detained not for patent violation but had been suspected of trademark violation. Based on ACTA's expansion of border measures far beyond "counterfeit trademark or pirated copyright goods", seizures of suspected "confusingly similar" trademarks could be authorized. Taking a decision on cases of ordinary trademark infringement required a comprehensive legal analysis, which was much less straightforward than determining whether goods were counterfeit. Such an assessment was typically performed by courts or trademark offices, which had the necessary legal expertise, case law, and experience to rely upon. Imposing this task on customs officers was likely to result in a considerable increase in seizures and temporary detentions based on right holder allegations that transiting products were confusingly similar.

274. Article 16 of ACTA extended the requirements with respect to border measures while reducing safeguards. Under ACTA, ex officio seizures were mandatory, as well as the application of border measures to exports. No reference was made to a prima facie evidence requirement or limited duration of the suspension pending a determination on the merits. This went much beyond TRIPS Article 58 that imposed restrictions on the ability of customs officials to take ex officio action to stop goods at the border without any complaint from a right holder. Further, right holders could also use this customs authority to launch harassing actions against legitimate competitors.

275. Finally, the delicate balance established by Article 57 of the TRIPS Agreement with respect to the right of inspection and information was upset by Article 22 of ACTA which favoured right



holders vis-a-vis the importer of goods. This provision could be used by right holders to discover details on distribution chains of generic companies on the basis of alleged infringement rather than proven infringement. These companies could then mount aggressive and expensive litigation against suppliers and intermediaries to deter generic entry into key markets.

276. His delegation was also concerned about new benchmarks for international standards on IP enforcement being established by ACTA. These standards were likely to become the bedrock of future negotiations between developed and developing countries in various RTA negotiations currently under way. As the lure of immediate market access was a potent one, many of the developing countries might end up accepting these standards as their own. This would severely inhibit South-South trade since it would impose obligations on the importing countries to follow the new standards of enforcement.

277. Another matter of concern was the impact of ACTA on digital goods and Internet freedom. In this regard, ACTA obligations with respect to the enforcement of copyright were not only of particular interest, but also problematic. Those included digital rights management and technology protection measures, which were coupled with new norms for damages for infringement, such as the suggested retail price of goods being the determinant factor for the injury. This could have a severe impact on the efforts towards literacy and access to knowledge and information that had been at the core of the aspirations of the developing world to convert themselves into information societies and knowledge economies. In these areas, consumers in the US and the EU were rightfully concerned, because ACTA was fundamentally hostile to consumers, by systematically excluding consumer interests from having meaningful roles in the ACTA negotiations. This practice was expected to be continued by the ACTA Committee, which was under no obligation to operate in a transparent, open and inclusive manner.

278. He concluded by reiterating his delegation's concern that the adverse effect of TRIPS-plus enforcement provisions contained in ACTA and other plurilateral agreements could affect developing countries and developed countries likewise. It was therefore essential that collective efforts be made to protect the policy space needed not only to ensure access to affordable medicines but also to provide freedom to mankind.

279. The representative of Ecuador said that, in his view ACTA was an agreement that sought to create a form of basic general framework which went beyond the TRIPS Agreement in terms of levels of enforcement in the multilateral sphere. It also seemed to be more targeted at developing countries. The main participants in the ACTA negotiations were developed countries which most probably already had similar legal enforcement standards in place while many developing countries did not have such standards in their domestic legislation for reasons relating to internal sovereign decisions and economic and social development. In his view, ACTA violated the basic principles of the United Nations Declaration on the Right to Development insofar as the Declaration clearly established the primacy of self-determination and the principle of inclusive participation in multilateral decision-making processes affecting people's economic and social development.

280. More specifically, the measures introduced in Article 9 of ACTA on damages might make natural and legal persons more cautious in their legitimate activities because of the risk of not meeting these very high legal standards, without really achieving the objective of preventing undesirable illicit activities. In the area of copyright, in particular, effective solutions to extensive infringements, which occurred both in developing and developed countries, would be better based on improved access through content that was legitimately licensed at reasonable prices. His was concerned about ACTA's new and much more aggressive rules on damages which would severely weaken the legitimate TRIPS flexibilities provided for in Article 44.1 and 44.2 on injunctions. Its rules on civil liability would not only be much harder to implement, but would actually be inconsistent with the current national legal systems of most WTO Members.

281. He said that the increase in civil liability requirements in ACTA in relation to possible infringements could create a bias in favour of IP right holders, to the detriment of the rights of consumers and users. By granting special rights to right holders, including specific rights authorizing such holders to elaborate extensive theories before courts on damages, hitherto unheard of in legal systems and case law, ACTA appeared to attempt to increase the level of risk involved in any activity where there was the slightest possibility of committing an offence. For this reason, ACTA was most probably inconsistent with the objectives of Article 7 and the principles of Article 8 of the TRIPS Agreement which guaranteed: (i) a balance of rights and obligations between producers and consumers of IP; (ii) the promotion of the public interest in sectors of importance for countries; and (iii) the prevention of the abuse of IPRs by right holders.

282. The representative of Egypt said that the TRIPS Council should not be a forum to promote TRIPS-plus standards. ACTA had created a heated controversy in many countries that had signed the agreement. In some cases, this had led countries to freeze the verification process, driven by fears that ACTA might be constraining access to information, knowledge and health. Such trends in IP enforcement could accentuate the tension between IP and public policies and should therefore be dealt with very carefully. He said that the Council's discussion on IP enforcement trends should be informed by development considerations and imperatives, instead of looking into the narrow scope of police, customs and judicial measures. Issues related to affordability and availability, even of protected subject-matters, needed to be considered so as to ensure effective enforcement of the IP standards contained in the TRIPS Agreement. IPR enforcement had to be addressed in the context of broader interests, taking into account development-oriented concerns, as stipulated by the TRIPS Agreement according to which "the protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

283. The representative of Bangladesh drew Members' attention to the fact that LDC countries were entitled to TRIPS flexibilities in order to create a level playing field for their infant industries and also to give them time to develop necessary infrastructure of enforcement. If higher standards than those set by the TRIPS Agreement were put in place, LDCs would find it difficult to exert. Besides the possible impact of ACTA on LDCs regarding vital issues such as access to generic medicines, various issues regarding access to content on the Internet remained unclear. This would put additional burden on LDC enforcement agencies. Among others, consideration of the role of right holders by the judicial authorities in determining compensation or damages might lead to undue advantage. While taking note of statements by some delegations according to which ACTA did not target generic medicines, he said that mechanisms to differentiate between generic and counterfeit medicines had to be established in order to avoid unnecessary harassment. Furthermore, ACTA did not seem to take development components of enforcement measures adequately into account.

284. The representative of Brazil said that IPRs had been negotiated during the Uruguay Round as part of a broader package, which included agriculture, NAMA, services and other areas. There was no mandate to discuss TRIPS-plus enforcement measures in the Council. The discussion of ACTA could therefore only be of an informative nature.

285. IP infringement was a global phenomenon, which affected developing and developed countries, albeit in different ways. Given the complexities involved, "one size fits all" solutions were not the best approach. Each country required specific solutions. Only a broad discussion at the multilateral level could therefore reflect the different political and social variables.

286. He drew Members' attention to TRIPS Article 1.1, which allowed Members to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. In addition, Article 41.5 stated that there was no "obligation to put in place a judicial

system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general (...)".

287. ACTA was a plurilateral agreement negotiated with selective participation, which did not follow the standards of inclusiveness and transparency of multilateral negotiations. A superficial approach risked, among others, that (i) IPRs be abused; (ii) obstacles to legitimate commerce be erected, which had already led to serious consequences in the area of public health, with the apprehension of medicines in transit; and (iii) due process of law be disregarded and civil rights not be respected.

288. A number of analyses questioned the compatibility of ACTA with the TRIPS Agreement, regarding its provisions on border measures, civil and administrative procedures and remedies, as well as provisional measures. ACTA only provided repression as the remedy to counterfeiting and piracy. There was, however, a growing perception that, in order to face IP infringement, a comprehensive policy was necessary, combining repressive measures, educational efforts and public policies to foster the creation of formal jobs.

289. The agreement claimed to strike a balance between IP enforcement and the rights to freedom of expression and privacy, in particular due to the existence of some safeguards in the text. However, substantive provisions raised concerns that it was biased in favour of IP right holders. There was no guarantee that the implementation of its substantive provisions would not affect fundamental civil rights, such as the right to privacy, presumption of innocence, due process of law, proportionality between offenses and sentences, protection of third party interests, participation in the information society, etc. For instance, ACTA allowed for the identification of internet subscribers in case of alleged infringement, upon request by the right holder. It also stated that such personal data was to be disclosed by an online service provider. In the absence of a precise definition of "online service provider", it could be understood in a very broad way, ranging from access providers to sites which hosted contents, including social networks.

290. He noted that ACTA had been the object of deep concern of civil society organizations around the world, including in the countries that had signed the agreement. Recently, the EU trade Commissioner had announced the European Commission's decision to ask the European Court of Justice for a legal opinion regarding the conformity of ACTA with European legislation. This was an indication of the need of promoting a true public debate on the merits of such an agreement.

291. The representative of Chile recognized the importance of enforcing IPRs. At the same time, it was important to ensure that the system was balanced and consistent with the requirements and priorities of all countries and their various legal systems. Given that his delegation's position had not changed since earlier discussions of the issue, he requested that the following statement made at the Council's October 2011 meeting be reproduced:<sup>3</sup>

"The representative of Chile said that he recognized the importance of IPRs and upheld them accordingly. IP 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.

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<sup>3</sup> Paragraphs 527-529 of IP/C/M/67.

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.

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."

292. The representative of Thailand urged Members to take note of the differences in the level of development, the availability of resources as well as the IP infringement situation in different countries. He concurred with the delegation of Brazil which had stated that there was no "one-size-fits-all" approach to IPR enforcement. His delegation would like to preserve the flexibilities under the TRIPS Agreement.

293. The representative of China referred to her intervention at the beginning of the meeting, reiterating that information on ACTA could better be provided under another item of the agenda. She also recalled that the Chairman had said at the adoption of the agenda that this was not a permanent item on the Council's agenda. Given that ACTA did not form part of the WTO legal framework, it was not appropriate for the Council to discuss it.

294. Her delegation recognized that the legal system to protect IPRs should be comprehensive and well balanced. Next to protecting the rights of IPR holders, it also had to protect the public and social interests. Although the TRIPS Agreement was setting minimum standards, enforcement levels could not be raised to the extent that they would contravene the TRIPS Agreement, in particular the flexibilities enshrined in it, nor should the fine balance of rights and obligations in the TRIPS Agreement be disturbed.

295. ACTA broadened the scope of piracy and counterfeiting, enhanced the standards of protection through criminal, border and civil enforcement measures, and set up special disciplines for the digital environment. Most of those measures went beyond the TRIPS Agreement. Even in countries which had participated in the ACTA negotiations, there were a lot of controversies over the agreement, including concerns on the transparency of negotiations, inconsistency with domestic legislation, and its impact on free communication on the Internet and human rights.

296. She said that, for example, ACTA provisions on criminal procedures went beyond TRIPS Article 61, as they applied at lower thresholds and included higher penalties. The first sentence of Article 61 provided that "Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale". The Panel in *China — Measures Affecting the Protection and Enforcement of IPRs* (DS362) had found that, in quantitative terms, the benchmark for an activity to qualify as being carried out on a commercial scale was "the magnitude or extent of typical or usual commercial activity". Accordingly, what constituted counterfeiting or piracy of a particular product in a particular market on a commercial scale would depend on the magnitude or extent that was typical or usual with respect to

such a product in such a market. According to the Panel, the negotiators had chosen the word "scale" in order to refer to size. This showed that the limitations in Part III, Section 5 of the TRIPS Agreement on criminal procedures reflected an effort to address only the more blatant and egregious infringements. On the other hand, the second sentence of Article 23.1 of ACTA provided that "acts carried out on a commercial scale include at least those carried out as commercial activities for direct or indirect economic or commercial advantage". This provision read the word "scale" out of the context of "commercial scale". It meant that any profit-making activity which was not carried out on a typical or usual scale would also be subject to criminal procedures. This would lower the threshold of criminal procedures and might increase Members' obligation to impose criminal penalties.

297. She noted that Article 23.3 of ACTA also provided that a party "may provide criminal procedures for the unauthorized copying of cinematographic works from a performance in a motion picture exhibition facility generally open to the public". However, the text did not clarify whether the activity had to be "wilful" and "on a commercial scale", as required by the TRIPS Agreement. According to the second sentence of Article 61 of the TRIPS Agreement, the legal remedies available in criminal procedures had to include imprisonment "and/or" monetary fines. It was therefore left to Members' discretion to provide the appropriate remedies. On the other hand, Article 24 of ACTA used the words "as well as", instead of "and/or", between the words "imprisonment" and "monetary fines". This would limit the flexibility available under the TRIPS Agreement since all ACTA Parties had to provide both imprisonment and monetary fines.

298. With respect to seizure and forfeiture, ACTA provided that the competent authorities shall have the authority to order the forfeiture or destruction of the assets derived from, or obtained directly or indirectly through, the infringing activity, and may have the authority to order the seizure and forfeiture of assets the value of which corresponds to that of the assets derived from, or obtained directly or indirectly through, the infringing activity. This meant that not only the assets related to the infringing activity, but also other assets irrelevant to the infringing activity could be subject to forfeiture. In contrast, the TRIPS Agreement only requested that "the infringing goods and any materials and implements the predominant use of which has been in the commission of the offence" be seized, forfeited and destroyed.

299. The representative of China referred to Article 26 of ACTA according to which "each Party shall provide that, in appropriate cases, its competent authorities may act upon their own initiative to initiate investigation or legal action with respect to the criminal offences." Recognizing that IPRs are private rights, the TRIPS Agreement did not oblige the competent authorities to initiate criminal investigation or act upon their own initiative.

300. It appeared that ACTA strengthened IP enforcement and raised the level of IP protection. ACTA Parties had to allocate more resources to IP enforcement, and this despite TRIPS Article 41.5 which provided that Part 3 of the TRIPS Agreement on enforcement of IPRs "does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of IPRs and the enforcement of law in general".

301. The implementation of ACTA would influence the interests of Members and limit their capacity to use the flexibilities provided by the TRIPS Agreement. She noted that protests against ACTA had been held in more than 200 European cities on 11 February 2012. This was a useful reminder that IP protection and enforcement should recognize and accomplish the underlying public policy objectives, including developmental and technological objectives. Her delegation cautioned against the protection and enforcement of IPRs which would contravene the provisions of the TRIPS Agreement. Enforcement procedures should neither become a barrier to legitimate trade, nor create distortive effects on legitimate international trade.

302. The representative of Cuba said that her delegation shared many of the concerns that had been raised by other Members. The Council was not the appropriate forum to discuss ACTA, which reduced the flexibilities provided for under the TRIPS Agreement. It was contradictory that the United States did not comply with its obligations under the TRIPS Agreement and nevertheless advocated TRIPS-plus standards. Ten years ago, the Dispute Settlement Body had ruled that Section 211 of the US Omnibus Appropriations Act was inconsistent with the TRIPS Agreement and the Paris Convention because it undermined the rights of the owners of Cuban trademarks by enabling Bacardi to engage in the fraudulent sale of products under the Havana Club trademark, despite these products not being of Cuban origin. This situation not only had a negative impact on Cuba, but also affected the commercial interests of businesses in other Members, such as those of the French company Pernod Ricard.

303. In response to references made to some incidents that had taken place in the European Union in 2007 and 2008 regarding the detention of pharmaceuticals in transit, the representative of the European Union said that considerable efforts had been made to ensure that such incidents would not occur again. Instead of constantly recalling those cases in the past, it would be worthwhile looking at the equally worrying situation of counterfeit medicines in the pharmaceutical sector. According to figures published by the EU, 3,200,000 fake pharmaceuticals had been detained by EU customs in 2010, of which 93.6 per cent had come from India. This was of concern to consumers and citizens and needed to be discussed too.

304. In response to a point made by the delegation of India with respect to confusingly similar trademarks, the representative of the United States said that providing for the availability of border enforcement against confusingly similar marks was a best practice reflected in the laws of many WTO Members, including the United States. This would, for example, allow border authorities to take action when fake goods bore trademarks that were only slightly modified but still confusing. In his view, the determination that, for example, "Sialis" with an "S" was confusing with "Cialis" with a "C" was not a matter of such profound legal complexity as to be beyond the abilities of the same border enforcement officials entrusted with safeguarding citizens from all sorts of potential threats. When there were hard cases, the laws of his own country and those of other countries provided appropriate legal means to resolve those issues.

305. Remarks on "TRIPS-plus" requirements remained somewhat mystifying. Many WTO Members that were not ACTA participants had implemented ACTA-type provisions. For several examples, he referred Members to the minutes of the Council's last meeting (paragraphs 534 and 535, document IP/C/M/67). He asked why those provisions were acceptable in countries' domestic law, but not in ACTA. For example, there was a paradox between the analysis of the criminal provisions of ACTA provided by the delegation of China and its own domestic law providing for criminal procedures to enforce IPRs.

306. With respect to the concerns raised by the delegation of India regarding Article 22 of ACTA, he noted that paragraph 9 of the "Notification No. 47/2007 – Customs (N.T.)" of the Government of India called for the provision of similar information by customs authorities to right holders upon request. The same Notification appeared to implement numerous ACTA provisions, including Article 16(1)(a) of ACTA on ex officio authority for customs officials, which was mirrored by Article 7(1)(b) of the Notification. Likewise, the equivalent of Article 15 of ACTA on the provision of information from rights holders to customs officials could be found in Article 7(5) of the Notification. Furthermore, the Notification covered copyright, trademark, designs and patents.

307. The representative of the Bolivarian Republic of Venezuela reiterated his delegation's concern about the inclusion of the item on the agenda, as well as its opposition against ACTA. He requested that the following statement made at the Council's October 2011 meeting be reproduced:<sup>4</sup>

"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."

308. The representative of Japan said that his delegation had been one of the advocates of the initiative which had resulted in the conclusion of ACTA. As early as 2005, the Prime Minister of Japan had promoted the idea. This did not merely respond to the interests of a particular industry, but affected a wide range of sectors. 25 per cent of Japanese companies reported that they were suffering from counterfeiting and piracy.

309. As regards the balance between the interests of right holders and those of users, he said that ACTA contained the necessary provisions to prevent the abuse of enforcement measures by the right holder, for example as regards the initiation of border measures. Under Article 18 of ACTA, right holders requesting customs authorities to take action had to provide a security or equivalent assurance, depending on Parties' respective national legislations.

310. The Council took note of the statements made.

#### O. INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

311. The Chairman recalled that, at its meeting in October 2011, the TRIPS Council had agreed to forward to the General Council a proposal for a decision to extend the period of acceptance by Members of the Protocol Amending the TRIPS Agreement until 31 December 2013 (document IP/C/58). Pursuant to this proposal, the General Council had decided, at its meeting of 30 November 2011, to further extend the period for acceptances of the Protocol until 31 December 2013 or such later date as may be decided by the Ministerial Conference (document WT/L/829).

312. As regards the status of acceptances of the Protocol Amending the TRIPS Agreement, since the Council's meeting in October, the following Members had deposited their instruments of acceptance: Cambodia, Panama, Costa Rica, Rwanda and Honduras (documents WT/Let/833, 837, 838, 839 and 843, respectively). To date, 42 instruments of acceptance had been deposited, including the one from the European Union and its member States. The Secretariat had circulated an update to the note on the status of acceptances of the Protocol Amending the TRIPS Agreement in document IP/C/W/490/Rev.9.

313. He urged those Members that had not yet notified their acceptance of the Protocol to ensure that necessary measures are being taken in capitals to allow the consideration of the acceptance in a timely fashion.

314. As regards the issue of transition period for LDCs, he recalled that, at its meeting on 17 November 2011, the TRIPS Council had agreed to submit a text concerning that matter to the General Council with the recommendation that it be forwarded to the Eighth Session of the Ministerial Conference for its consideration (paragraphs 3-4 of IP/C/59/Add.2).

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<sup>4</sup> Paragraph 530 of IP/C/M/67.

315. Pursuant to this, Ministers had invited the Council to give full consideration to a duly motivated request from least developed country Members for an extension of their transition period under Article 66.1 of the TRIPS Agreement, and report thereon to the WTO Ninth Ministerial Conference. This decision of the Eighth Session of the Ministerial Conference had been circulated in document WT/L/845.

316. Noting that no such request had yet been received, he said that he would naturally be available to facilitate work on any such request that might be submitted.

317. As regards accessions to the WTO, he said that the General Council had approved the accession package of Vanuatu on 26 October 2011. The Eighth Ministerial Conference held on 15-17 December 2011 had adopted the packages of accession of the Russian Federation, Samoa and Montenegro. The relevant decisions could be found in documents WT/L/823, 839, 840 and 841, respectively. In keeping with WTO provisions, Vanuatu, the Russian Federation, Samoa and Montenegro would become Members 30 days following the dates of their ratification of their respective protocols of accession.

318. The Council took note of the information provided.

#### P. OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

319. The Chairman said that the list of 15 pending requests for observer status in the Council by other intergovernmental organizations was contained in document IP/C/W/52/Rev.12. He recalled that, 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.

320. Since the Council's meeting in October, the Secretariat had received updated information from the United Nations Environment Programme (UNEP), faxed to all Members on 3 November. Before the October meeting, such information had been received from the European Free Trade Association (EFTA), the South Centre and the Conférence des Ministres de l'Agriculture de l'Afrique de l'Ouest et du Centre (CMA/AOC), and the Cooperation Council of the Arab States of the Gulf (GCC). This information was also available for Members on the Members' website.

321. At its October meeting, the Council had agreed that the Chair should continue his consultations on the issue of observer status, in particular in the light of this updated information received from a number of IGOs. In the absence of a regular Chair, it had not been possible to hold such consultations. He suggested that he continue consultations on the requests for observer status with a view to seeing if the Council could take any decisions at its next meeting.

322. The Council so agreed.

#### Q. OTHER BUSINESS

##### (i) *Improvements in the documentation, scheduling and management of meetings*

323. The representative of the Secretariat said that, at the meeting of the General Council on 14 February 2012, the Director-General had shared, under "Other Business", information on the implementation of the recommendations for savings and more efficient use of resources made by the Budget Committee (WT/BFA/128) and adopted by the General Council. In providing an update on the Secretariat's work in implementing these decisions, he had sought Members' support and cooperation in carrying the work further.



324. The WTO's 2012-13 Budget, approved by the General Council in November 2011, provided for zero nominal growth in 2012. In December, the General Council had approved a number of recommendations for savings and more efficient use of resources made by the Committee on Budget, Finance and Administration, including the specific recommendations contained in paragraphs 29-31 of the Budget Committee's report circulated in document WT/BFA/128.

325. Highlighting just a few actions that immediately affect the Council's work, the representative of the Secretariat said that the decision provided for the discontinuance of the distribution of official documents, previously circulated in meeting rooms and at the document centre, as of the beginning of 2012. While all Members had already been informed about the implementation of this change, the Secretariat had sent a fax on 24 February reminding TRIPS delegates about this change. Otherwise the daily distribution of documents on paper and electronically on the Documents Online database would continue as before. Documents for this and future Council meetings could also be easily accessed through the "Documents for Meetings" module on the Members' site. The fax contained further information on this facility.

326. The recommendations also called for the reduction in the use of paper in particular as regards notifications. The Chair had already mentioned under item A one element of the implementation of these recommendations. While the Secretariat was continuing the circulation of base documents containing lists of notified laws and regulations and related explanations both in hard copy and electronic form, the actual texts of laws in the sub-series of documents would now only be circulated in an electronic form on the Documents Online database.

327. He suggested, in addition, that more consistent formats and submission methods for other lengthy reporting requirements - such as on technical cooperation and Article 66.2, which represented a major portion of the Council's formal documentation and thus its use of resources - could not only reduce costs significantly, but would also make the material thus reported more accessible and useful for its intended readership. The Secretariat would look into the technical aspects, with a view to advising Members subsequently on practical possibilities.

328. The decisions also called for the Chair to explore ways to further reduce the use of paper and to take steps to move towards the online submission and distribution of notifications. He said that the report that the Secretariat had provided for Members under item L went into more detail about proposed ways of developing its services, so as to make this material more easily accessible and thus more useful. The process was not only about cutting costs for the sake of it, although an important element as a component of maintaining zero growth nominal budget, but it also represented an opportunity to more effectively respond to the practical needs of the users of the system, principally WTO Members, and to find ways of servicing their needs more directly, efficiently and in line with the ways that they would choose to access and make use of that material as well as to prepare and submit it. Hence under the guidance of the Chair and in consultations with Members, the Secretariat would actively be looking to improve ways of making that material available. He encouraged interested delegations to consult with the Secretariat on how they preferred to work with those materials.

329. The Chairman thanked the Secretariat for the updated information and said that, as called for in the decision, he intended to informally explore with delegations further ways to make the Council's work increasingly cost effective.

330. The Council took note of the statements made.

(ii) *Invitations to ARIPO and OAPI*

331. 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.

332. The Council so agreed.

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