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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

Held in the Centre William Rappard on 7 June 2011

Chairperson: Ambassador Federico A. González (Paraguay)

The present document contains the record of the discussion which took place during the Council for TRIPS meeting held on 7 June 2011.

Subjects discussed — Page nos.

A. NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

1. The Chairman said that, since the Council's meeting in March 2011, Saint Vincent and the Grenadines had notified its responses to the Checklist of Issues on Enforcement. These responses were being circulated in document IP/N/6/VCT/1.

2. Ukraine had notified its contact point under Article 69 for the exchange of information and cooperation on trade in infringing goods. The list of contact points under Article 69 on the transparency toolkit page of the WTO website had been updated accordingly.

3. He 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 in particular reminded those Members who had made any changes to their laws and/or regulations to implement the Decision on TRIPS and public health and who had not yet notified such changes to the Council to do so.

4. The Council took note of the information provided.

B. REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION

5. The Chairman said that, as regards the reviews of national implementing legislation that had been initiated at the Council's meetings since April 2001, there were three reviews that still remained on the Council's agenda. These reviews concern Cuba; Fiji; and Saint Kitts and Nevis. He urged the delegations concerned to provide the outstanding material as soon as possible, so as to allow the Council to complete the follow-up to these reviews.

6. The Council took note of the information provided.

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

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

E. PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

7. The Chairman suggested that the Council continue its past practice of addressing the three agenda items together on the basis of contributions by Members.

8. He recalled that, at the Council's meeting in March 2011, the Plurinational State of Bolivia had presented a paper further explaining its earlier proposal to amend the TRIPS Agreement to ban patents on life forms (document IP/C/W/554).

9. He also recalled that, at that meeting, Japan had made a presentation on the outcome of the tenth meeting of the Conference of the Parties (COP10) to the Convention on Biological Diversity (CBD) held in Nagoya in October 2010. India and a number of other Members had still wished to hear from the CBD Secretariat on the outcome, and had reiterated their suggestion that it be invited to provide a briefing on a one-time basis.

10. As requested by the Council, he said that he had consulted with a number of Members on that suggestion. Those Members that had been in favour of that suggestion explained that they had felt that the CBD Secretariat would be best placed to give further in-depth information on the interpretation and implementation of the Nagoya Protocol on Access to Genetic Resources and the

Fair and Equitable Sharing of Benefits Arising from their Utilization (the Nagoya Protocol). However, some others had felt that the countries that had negotiated the Nagoya Protocol would themselves be best placed to discuss any specific issues relating to it.

11. In his consultations, Members had explored the idea that the CBD Secretariat would organize a side event in the margins of the Council's meeting. Some Members had considered that as a good option, but some others had felt that, without a formal link to the Council's work, such an event would not add value. There had been a proposal that, if a side event were to be organized, it should then result in a formal report to the Council, and that the CBD Secretariat would then be invited to a subsequent meeting of the Council. However, some Members had felt that Members themselves would be best placed to bring any issues arising from such an event to the Council.

12. He had also discussed with Members the suggestion El Salvador had made at the last meeting that the WIPO Secretariat be invited to brief the Council on the work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic resources, Traditional Knowledge and Folklore (IGC). The reason for that suggestion was merely to provide the opportunity for all delegations present, particularly the smaller delegations that did not cover work at WIPO, to have an update on proceedings in the IGC. However, some Members had not found it necessary to have such a briefing at the Council's present meeting, but rather thought that such a briefing might be more useful at the meeting of October 2011. Accordingly, the Council might wish to consider at its October meeting whether to invite WIPO Secretariat to speak on that matter.

13. The representative of Plurinational State of Bolivia said that, at the TRIPS Council's meeting in March 2011, his delegation had submitted a second communication (IP/C/W/554) concerning the review of Article 27.3(b). The adoption of Article 27.3(b) of the TRIPS Agreement had been conducive to an extension of the patent system to life forms and their components and to manipulations based on them. Furthermore, laws allowing the patenting of life in all its diversity had become widespread and his delegation was witnessing the spread and multiplication of patents on forms of plant, animal or human life or on their components such as genes, cells, substances, proteins or tissues.

14. Figures showing the exact extent of such patents were scarce, but those that did exist gave some idea of the consequences of the adoption of Article 27.3(b). Already in 2000 there had been patents on 500,000 genes of living organisms, and 918 patents had been awarded in 1999 for seeds as essential as maize, rice, soya, sorghum or wheat. By 2005, 20 per cent of all human genes had been patented in the United States. It appeared that 660 animals had been patented by 2010 and patents awarded on animal tissues or cells had increased. And those figures represented only the tip of the iceberg. The tendency was undoubtedly even deeper and more widespread.

15. For Bolivia, the proliferation of patents on life forms was a source of concern, primarily for moral or ethical reasons, or in other words because of the way it conceived of life. Manipulated and patented life forms were labelled biotechnologies, but life did not stop being life because human beings discovered or developed it or because it met the requirements for patentability. A genetically modified microorganism, a gene for which a function had been discovered, or a patented seed, remained forms of life even if they were assigned names of biotechnology inventions.

16. Many peoples and cultures around the world saw life as the foundation and source of everything, as most precious possession, as something special which should on no account be treated as a thing or a commodity. To treat life as some kind of technology was unacceptable. Being so special and fundamental, life, whatever its form, should not fall within the scope of patentable material or be the subject of exclusive use rights or private monopolies.

17. He said that the current system under Article 27.3(b) was fundamentally unjust. For thousands of years, the peoples of Bolivia, like other peoples, had cared for life and safeguarded biodiversity, combining, crossing and developing new varieties and identifying their characteristics. Plants and animals had been identified, domesticated and developed for food, health or industry without a single claim to exclusive rights being made. Indeed, the knowledge and technologies acquired had been shared with the world. But today, the developed countries were claiming monopolies on resources from the very biodiversity that Bolivia had preserved, identified and developed.

18. Article 27.3(b) allowed a handful of transnational companies to appropriate and privatize our collective heritage, which was no more or less than the silent theft of centuries of knowledge, technologies and practices developed collectively by the peoples. Not only did the patenting of life raise issues of justice, or morality and ethics, it had serious consequences and adverse effects. It was said that the patenting of life was necessary to stimulate innovation and the development of biotechnologies, and that without patents there would be no one to work out solutions to humanity's major problems.

19. The fact was that the patenting of life encouraged only a certain type of innovation: the kind that enabled the large transnationals to strengthen their monopolies and create more dependency for peoples, the kind that suited large-scale investors and the owners of wealth. And when there were no potential markets for establishing monopolies, no solutions were worked out. The gains that monopolies obtained through patents were not put towards financing research and innovation, but ended up in the pockets of large-scale investors.

20. With the patenting of life, the future of the planet was put in the hands of a few transnationals whose sole aim was profit and not the common good of humanity. To prohibit the patenting of life would no doubt thwart their desire for gain, control and monopoly. But there had been and still were other models for innovation and research. Monopoly was not the only means of encouraging and funding innovation and research. Not all the players involved in research and innovation were driven by an unquenchable thirst for gain or by the profit motive alone. There were many who in fact already worked in a monopoly-free environment seeking solutions for the future of humanity and the good of peoples. The complaint heard increasingly among scientists now was that the patenting of life had adverse effects on innovation and limited the possibilities of research, particularly when such fundamental elements as genes were patented.

21. The adverse effects of that system far outweighed the benefits. It was a system that allowed patent owners to restrict access to innovations and fetter the freedom of those that use them. That had serious adverse consequences for peoples, particularly in terms of health and access to medicines and treatment, or in terms of agriculture and food and access to seeds. The patenting of seeds was without doubt one of the main threats since under the patent system royalties could be extracted from peoples and farmers thus limiting their freedoms and restricting their traditional and ancestral practices. Farmers the world over had lost the freedom to trade their seeds and soon they would have to pay royalties to use seeds that belong to them. Drugs were sold at exorbitant prices by companies that have sole rights to produce and use them. Indigenous peoples saw their traditional practices threatened and soon they would have to pay royalties to carry on using their traditional medicines.

22. A future worrying tendency that had been identified was the race to patent plants and plant components that had valuable traits for coping with climate change. Those resources, on which the future of humankind might well depend, were now in the hands of a few transnationals, the very companies that were largely responsible for climate change and to which peoples would end up paying royalties in order to use seeds that they developed using biodiversity. By 2008, it would appear that more than 500 patents had been registered on plant genes that were resistant to climate change.

23. The way forward was not for each one to privatize and patent biodiversity and knowledge, but rather to free the world of all monopolies and exclusive use rights over what people hold to be most fundamental in that world, namely life, biodiversity and their components.

24. In view of the foregoing, he reiterated Bolivia's proposal to review and amend Article 27.3(b) with a view to prohibiting the patenting of life forms and parts thereof.

25. The representative of the Bolivarian Republic of Venezuela supported Bolivia's proposal in view of the need, and the ministerial mandate, to conduct a review of Article 27.3(b) of the TRIPS Agreement. Domestic legislation, specifically Articles 124 and 127 of the Constitution of the Bolivarian Republic of Venezuela, prohibited the registration of patents for life forms. The West had imposed its view of life, its institutions and its rules on the rest of humankind and these had been adopted as they were, for better or worse, by the entire world. It was well established that morals were the foundation and source of rules and the law, since the law was there to respond to forms of life in society - in other words the law could not exist without some "moral" basis, the word "moral" coming from *morada*, meaning a dwelling, a place where one lived. Thus, international agreements, which were nothing if not laws, must be based on morals and on ethics. Those principles and the laws of Venezuela could not be invoked in attempting to patent life in many forms it took in nature and to convert it into a tradable commodity that could be assigned a price, particularly now that the ever-forgotten indigenous peoples of Venezuela were represented in National Assembly and there was an undertaking, now in the form of a law, to respect their way of life, their customs, their genetic resources and their traditional knowledge.

26. He said that what Bolivia sought in its paper was a review of Article 27.3(b), as provided for in the last sentence of Article 27.3(b), which stipulated that there shall be a review after four years, but none had ever been conducted. The content of that Article would appear not to have been so construed by one Member at the meeting of October 2010 who had said that the review had been intended not so much to revise content as to focus on implementation. He disagreed, because Article 71 of the TRIPS Agreement already made provision for a full review of TRIPS implementation at regular intervals, and in light of the general principle of law that he who could do most could do least, the express provision - which was restrictive, specific and time-bound -to review Article 27 would be meaningless, since any law must be interpreted as a coherent and structured whole.

27. It clearly emerged from a reading of Article 71 that periodic review of the entire TRIPS Agreement was fully warranted and necessary, not only because it needed to be adapted to the constantly arising changes of a globalized world with its fast-developing technologies, but also, and more importantly, because the issue of intellectual property was closely linked to human rights such as food security, education, health and the right to self-fulfilment, among others, which must be reviewed on an on-going basis so that they could be increasingly enjoyed by more and more people, in full conformity with the principles of the United Nations and the Millennium Goals, which were established in an attempt to make them more universal.

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

29. The representative of Brazil said that the TRIPS-CBD issue had been the object of extensive and detailed technical discussions at the WTO over the past years. The discussions had taken place not only in the TRIPS Council but also in the consultations conducted by Director-General Lamy. The Director-General's report of 21 April 2011 (document WT/GC/W/633) covered the three TRIPS-

related issues. The report clearly indicated that Members had covered many grounds and that the discussions had been useful for all parties involved.

30. The report indicated that "Members have consistently voiced support for the principles and objectives of the CBD, including the principle of prior informed consent and the principle of equitable sharing of benefits. They have agreed on the need to take steps to avoid erroneous patents, including through the use of databases, as appropriate, to avoid patents being granted on existing traditional knowledge or genetic resources subject-matter. None of the proposals discussed, namely disclosure requirements, databases, or the use of contracts, was proposed as a stand-alone response or complete solution to all problems outlined. Members continue to differ on whether the formulation and application of a specific, tailored disclosure mechanism relating in particular to genetic resources and associated TK would be useful and effective in ensuring that the patent system promoted CBD objectives, or whether other mechanisms should be preferred." The report was a concise and fair reflection of where Members stood at the moment.

31. He said that there was a broad convergence of views on the prevention of both misappropriation of genetic resources and the grant of erroneous patents, while differences persisted on how to pursue those objectives. Brazil remained hopeful that further debate in the Director-General's consultation process and in the TRIPS Council would help bridge the existing differences. He recalled that the group of countries including Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group and the African Group had tabled a new proposal on 15 April 2011 (document TN/C/W/59), which was intended to amend the TRIPS Agreement by inserting a new article entitled "Disclosure of Origin of Genetic Resources and/or Associated Traditional Knowledge".

32. TN/C/W/59 had been drafted as a legal text, which should be one of the bases for further discussion. Against the current background of uncertainty as to the way forward in the Doha Round, while Members continued to favour the parallel treatment of the three intellectual property issues in the Round, it did not mean that each issue could not be considered on its own merits. The protection of genetic resources and associated traditional knowledge against misappropriation had always been a priority for the developing countries.

33. He supported the proposal to invite the CBD Secretariat to make a briefing on the Nagoya Protocol in the TRIPS Council, and was open to the proposal to invite the WIPO Secretariat. He suggested that the Chair conduct consultations on that proposal. Given that there would be a key session of WIPO IGC in July 2011, he proposed that the TRIPS Council wait until October 2011 to invite WIPO to make such a briefing.

34. The representative of Peru said that the three agenda items were of the utmost importance in view of the current climate surrounding the Doha Round negotiations. Members were reflecting and consulting how to proceed over the next few months. That included the possibility of achieving some result for the Ministerial Conference in December 2011 as an early harvest that would ensure subsequent results in the other areas of the Single Undertaking. He said that any result in those negotiations must reflect the interests of the developing countries, particularly in the area of protection of genetic resources, traditional knowledge and folklore.

35. Peru supported an amendment to the TRIPS Agreement to bring it in line with the provisions of the CBD. A requirement for multilateral and mandatory disclosure would be the most efficient way to address the problem of misappropriation of genetic resources and traditional knowledge, as it would allow all countries to identify the supplying country by requiring patent applicants to disclose the country of origin as well as the evidence of compliance with prior informed consent and benefit sharing. That conviction, in addition to the need to improve the system to prevent biopiracy, had prompted Peru not only to co-sponsor, with some 110 Members, document TN/C/W/52, but also

document TN/C/W/59 which aimed at enhancing the relationship between the TRIPS Agreement and the CBD.

36. The co-sponsors of document TN/C/W/59 called for the inclusion of an Article 29*bis* in the TRIPS Agreement which would seek to establish a mutually supportive relationship between that Agreement and the CBD by incorporating the disclosure of origin requirement as well as evidence of prior informed consent and benefit sharing in patent applications involving the use of genetic resources and/or associated traditional knowledge. That requirement would facilitate the compliance with the provisions of the CBD, help to prevent biopiracy through the patent system, and ensure adequate compatibility between the TRIPS Agreement and the CBD.

37. Peru was not seeking to prevent access to or use of its genetic resources, but to protect them against biopiracy in order to ensure that they were used sustainably to the benefit of all Peruvians, particularly indigenous communities. Inclusion of the disclosure of origin requirement would ensure the recognition of legitimate rights of peoples over their genetic resources, thereby adding to their development potential.

38. His delegation could not imagine a successful conclusion of the Round without any results in that area. Peru was fully convinced of the importance of intellectual property systems as a tool for the economic, social and cultural development of countries. Because of that conviction and the development mandate of the Doha Round, his delegation attached such importance to that issue as one of the outstanding implementation related issues mentioned in paragraph 12 of the Doha Declaration. An outcome on that issue would enable Members to establish a proper balance in the patent system and in the intellectual property system for the benefit of all, particularly the local and indigenous communities of developing countries.

39. Finally, he supported the proposal to invite the CBD Secretariat to provide a briefing on the Nagoya Protocol, saying that the relationship between the TRIPS Agreement and the CBD was obvious. He also said that it would be useful and appropriate for the WIPO Secretariat to provide Members with an update on the negotiating process taking place within the IGC.

40. The representative of India said that India was rich in biodiversity and associated traditional knowledge, which were both coded as it existed in ancient texts of Indian systems of medicines, and also non-coded, as it existed in oral undocumented traditions. India was one of the twelve mega-diverse countries. With only 2.4 per cent of the land area, India already accounted for seven to eight per cent of the recorded species of the world. That number was based on the survey of 65 to 70 per cent of the total geographical area of the country. Over 47,000 species of plants and 81,000 species of animals had been recorded by the Botanical Survey of India and the Zoological Survey of India respectively. It was anticipated that some of the remaining areas, e.g. the Himalayan region and the A&N Islands might be far richer in biological diversity than most of the areas already surveyed. India was also one of the twelve primary centres of origin of cultivated plants. India was equally rich in traditional and indigenous knowledge, both coded and informal.

41. Pursuant to ratification of the CBD, India had developed a comprehensive legislation on biodiversity. It had enacted a Biological Diversity Act in 2002 and notified Biological Diversity Rules in 2004. That Act gave effect to provisions of the CBD, including those relating to access and benefit sharing. In 2003 the National Biodiversity Authority had been set up. All matters relating to requests for access by foreign individuals, institutions or companies, and all matters relating to transfer of results of research to any foreigner were dealt with by the National Biodiversity Authority.

42. While India was undertaking a number of measures at the national level in order to prevent misappropriation of genetic resources and/or associated traditional knowledge, the problem had an obvious international dimension and needed an international solution in order to be addressed

effectively. In the past, there had been several instances of misappropriation of genetic resources and/or traditional knowledge. Studies undertaken in the year of 2000 by the Indian Council for Scientific and Industrial Research (CSIR) had estimated that about 2,000 wrong patents concerning Indian systems of medicine alone were being granted every year at the international level. India had been a major victim of biopiracy.

43. While India had pioneered the Traditional Knowledge Digital Library (TKDL) to overcome language and format barriers, the results could only be limited. Improving prior art searches through the TKDL was only one part of the solution. Further, the TKDL represented a subset of the universe of available traditional knowledge. The realm of traditional knowledge in areas other than herbal cures and genetic resources was not covered by the TKDL. The flip side of databases in general was that they might attract undesirable attention and might actually become a tool for misappropriation of genetic resources and traditional knowledge and further aggravate the problem if they were not handled carefully.

44. India and other developing countries had proposed viable solutions contained in document TN/C/W/59. A mandatory disclosure requirement in patent applications to include disclosure of origin and evidence of prior informed consent and access and benefit sharing, would, in addition to combating biopiracy, further strengthen the credibility of the patent system by facilitating assessment of the novelty and inventiveness criteria.

45. He reiterated that the TRIPS-CBD issue was one of the outstanding implementation issues and positive outcomes on outstanding implementation issues were one of the most important deliverables of the Doha Round for the developing countries. Exhaustive discussions alone in the last ten years on the TRIPS-CBD issue were not enough. Members needed constructive engagement which was sadly missing on part of some developed Members. The recent document TN/C/W/59 could be a good basis for future work and his delegation stood ready for discussions to move that process forward.

46. He noted that some Members could not agree to a presentation by the CBD Secretariat on the Nagoya Protocol. He said that the CBD had already made similar technical presentations in WIPO and the WHO and that it was ironical that the same Members who opposed a presentation by the CBD Secretariat in the WTO had had no problem in WIPO and the WHO. He reiterated his delegation's demand for a presentation by the CBD Secretariat on the Nagoya Protocol. In response to the suggestion that the CBD Secretariat be asked to make a presentation in an informal meeting, he said that Caterpillar, a private entity, could be invited to make a presentation in a NAMA meeting, but the CBD Secretariat, an intergovernmental organization with 193 members, was either not being allowed or was being asked to make a presentation in an informal setting.

47. Responding to the suggestion that the CBD Secretariat be invited to make a presentation in a side event, he said that, in order to move the process forward, his delegation could consider that suggestion only as an integrated package where the CBD Secretariat would make a presentation on the Nagoya protocol in a side event; with a report on the presentation to be considered in the TRIPS Council; and with an opportunity given to the CBD Secretariat to respond to Members' questions in the TRIPS Council.

48. In conclusion, he quoted paragraph 2 of the Doha Ministerial Declaration, reading "the majority of WTO Members are developing countries. We seek to place their needs and interests at the heart of the Work Programme adopted in this Declaration." He said that the TRIPS-CBD issue was one such issue which was important for developing countries and needed a speedy resolution.

49. The representative of Colombia said that genetic resources were of great interest to the biotechnology industry since they offered viable, high-potential alternatives for resolving problems in

areas such as health, food security, production, and protection of the environment. Such resources and associated traditional knowledge were a fundamental part of the wealth and culture of mega-diverse countries such as Colombia, and were thus inherent in their communities and strategic to their sustainable development.

50. Members had long shared and supported the following objectives: (i) to ensure authorized access to genetic resources, i.e. that prior informed consent is obtained; (ii) to achieve equitable sharing of benefits arising from the use of genetic resources and traditional knowledge; and (iii) to prevent the erroneous granting of patents. In that connection, the main issue that had been under discussion was the need to revise intellectual property systems and incorporate mechanisms that would help address the monitoring and follow-up difficulties highlighted by mega-diverse countries dealing with biopiracy.

51. The debate should be geared towards identifying points of convergence between the rules on intellectual property protection in the TRIPS Agreement and those relating to the conservation of biological diversity and the use of its components, including genetic resources, which were governed by the CBD. The goal was that the regime covering access to genetic resources and benefit sharing should be consistent with the objectives of both systems and that these should thus be mutually supportive, pursuant to Article 16.5 of the CBD and Article 4 of the Nagoya Protocol. That in turn would make it possible to address the mandate provided for in paragraph 19 of the Doha Declaration in a constructive manner.

52. The communication and proposal recently submitted by a group of Members in document TN/C/W/59 was in line with such objectives. The proposal sought to establish legality of access as a prerequisite for engaging in research for and the development of any invention in the biotechnology field and the use of biological or genetic resources or products derived therefrom, and the demonstration of such legality of access in a patent application for the product or process involved.

53. He acknowledged that the Director-General's consultations by the ministerial mandate had sought to lend structure to that debate. He nevertheless also noted that all those endeavours had failed to deliver concrete results. That debate concerned one of the implementation-related issues. By "implementation" he meant the problems encountered by developing countries in particular in implementing the current WTO Agreements, i.e. the Agreements arising from the Uruguay Round negotiations, including the TRIPS Agreement.

54. He said that the Ministers in Doha had handled the implementation-related issues in two ways. First, they had adopted around 50 decisions clarifying the obligations of developing country Members. As regards the other implementation-related issues, the Ministers had agreed in Doha on a future work programme. To the extent that the latter issues had remained unresolved, the system still owed an outstanding debt to developing countries. The relationship between the TRIPS Agreement and the CBD fell into that second category. He urged the membership and the Director-General to act with a sense of urgency so as to deliver an expeditious outcome satisfactory to all.

55. The representative of Indonesia highlighted the important relationship between the TRIPS Agreement and the CBD and the protection of traditional knowledge and folklore. As a proponent of documents TN/C/W/52 and TN/C/W/59, he believed that it was time to take bold steps to address that issue in the TRIPS Council in order to achieve progress. The problem of biopiracy and misappropriation of genetic resources and traditional knowledge had been taking place for such a long time. Many developing countries continued to lose economic benefits that had been acquired from genetic resources and traditional knowledge. Instead they were paying more for new inventions that were created by using those genetic resources and traditional knowledge.

56. The Nagoya Protocol was a major step to end that situation. It stipulated procedures concerning prior informed consent and benefit sharing for access to genetic resources and associated traditional knowledge. Paragraph 19 of the Doha Declaration gave a mandate to WTO Members to review Article 27.3(b) and examine the relationship between the TRIPS Agreement and the CBD and the protection of traditional knowledge and folklore. In accordance with that mandate, WTO Members should continue working to improve and strengthen the mutual supportiveness of the TRIPS Agreement and the CBD.

57. To that end, and taking into account the new development with the adoption of the Nagoya Protocol, Indonesia reiterated the importance of amending the TRIPS Agreement to include a disclosure requirement of origin of genetic resources and associated traditional knowledge in patent applications. As one of the co-sponsors of documents TN/C/W/52 and TN/C/W/59, Indonesia was of the view that the amendment of the TRIPS Agreement was one of the important development outcomes in the area of trade that Doha Development Agenda should deliver. The TRIPS-CBD issue together with the issues of GI register and GI extension should be discussed in parallel in the TRIPS Council as part of the Single Undertaking.

58. The representative of China said that WTO Members should take appropriate and effective measures to prevent misappropriation of genetic resources and avoid erroneous patents. The TRIPS Agreement, the CBD and the Nagoya Protocol should operate in a mutually supportive way. As one of the co-sponsors of documents TN/C/W/52 and TN/C/W/59, China believed that mandatory disclosure requirements would improve the transparency of the utilization of genetic resources and/or associated traditional knowledge, and help to achieve the shared objectives.

59. He appreciated the Director-General's consultations on the issues of TRIPS-CBD and GI extension as outstanding implementation-related issues in the Doha Round. Negotiations on those issues should be an integral part of the Work Programme, and the outcome of the negotiations should be treated as part of the Single Undertaking. The consultations should be continued based on a legal text.

60. He supported the proposal to invite the CBD Secretariat to make a presentation in the TRIPS Council, and was open to the proposal to invite the WIPO Secretariat to make a presentation, as those presentations would help improve Members' understanding of the Nagoya Protocol and the work of the WIPO IGC, which would contribute to the cooperation between the WTO and other international organizations.

61. The representative of Turkey said that negotiations on the three TRIPS issues were part of the Doha Round and the outcomes an integral part of the Work Programme and the Single Undertaking. She welcomed the Director-General's report on his consultations on the issues of GI extension and TRIPS-CBD, which had been circulated together with all other Doha Development Agenda documents.

62. She welcomed the submission of documents TN/C/W/59 and TN/C/W/60. With regard to the TRIPS-CBD issue, she supported the view that the TRIPS Agreement should be amended to introduce a mandatory disclosure requirement, but her delegation had an open mind on the introduction of prior informed consent and access and benefit-sharing requirements.

63. The representative of Ecuador supported the continuation of the debate based on Bolivia's submission. Members could take into account the discussion on the exclusion of patentability as provided in Article 27 of the TRIPS Agreement as an intermediate step to address some Members' concerns.

64. According to the mandate provided for in Article 27.3(b) of the TRIPS Agreement and paragraphs 12 and 19 of the Doha Ministerial Declaration, it was important for the TRIPS Council to find a multilateral solution on biopiracy and protection of traditional knowledge. Therefore, his delegation had co-sponsored the disclosure proposal contained in document TN/C/W/59. Given the lack of efficiency and effectiveness of regional and national laws to tackle the issue of biopiracy, the solution should be found at the international level. The Director-General's suggestion to put some of the outstanding implementation issues in the slow lane was not a viable solution, because they were matters of urgency.

65. Referring to India's proposal to invite the CBD Secretariat to make a report, he supported that proposal as it was vital for the TRIPS Council to understand the Nagoya Protocol in order to move its work forward.

66. The representative of Thailand said that the Director-General's consultations on the issues of TRIPS-CBD and GI extension that led to the submission of two text-based proposals, both of which had been co-sponsored by Thailand. He followed the negotiations on the three TRIPS issues in parallel as part of the Single Undertaking and looked forward to the next TNC meeting to clarify the way to move forward.

67. The representative of Japan said that the biopiracy issue could be divided into two issues: erroneously granted patents and the CBD compliance. Appropriate solutions should be sought respectively, bearing in mind that those solutions should not have adverse impacts on intellectual property systems. Regarding the CBD compliance, the Nagoya Protocol had provided solutions and Members should focus on how to implement these agreed solutions.

68. He said that the WIPO IGC had made meaningful progress on its work on the protection of genetic resources. The objectives and purposes identified through discussions provided a good basis for future work, since without well-defined objectives and purposes it was impossible to reach appropriate options. The TRIPS Council could learn a lot from the exercises in the IGC.

69. With regard to the Bolivian proposal, he reiterated the importance of patent systems as an incentive for technological development in the field of biotechnology.

70. The representative of Australia said that, as a mega-diverse country, Australia had a unique indigenous culture and a strong interest in a balance between holders and users of genetic resources and associated traditional knowledge. As a Party to the CBD, Australia shared relevant objectives in relation to genetic resources and associated traditional knowledge, including to facilitate access to genetic resources with prior informed consent and on mutually agreed terms, to take measures aimed at equitable sharing of the benefits of the utilization of genetic resources, and to respect, preserve and maintain traditional knowledge. In that regard, Australia's access and benefit sharing system provided for access and benefit sharing in relation to genetic resources and associated traditional knowledge consistent with their obligations under the CBD.

71. Australian national experience indicated that effective benefit-sharing regimes could be implemented without making changes to the patent system. Accordingly, the TRIPS Agreement and the CBD were consistent and could be implemented in a mutually supportive manner. Nevertheless, Australia was prepared to engage constructively in discussions on genetic resources in relevant international forums, including WIPO, the WTO, the CBD and the WHO.

72. Australia considered that disclosure requirements might merit further consideration in conjunction with other options such as databases. In that regard, the WIPO IGC was undertaking a detailed consideration of the relationship between intellectual property and genetic resources as well as traditional knowledge and folklore. The WIPO IGC had been requested to submit the text of an

international legal instrument or instruments on the protection of the three subject matters to the WIPO General Assembly in September 2011. The WIPO IGC had undertaken work in that area, and it was an appropriate forum to discuss in detail intellectual property issues relating to traditional knowledge and genetic resources.

73. Australia had participated actively in the Director-General's informal consultations on the TRIPS-CBD issue. However, significant divergences remained, and her delegation remained unconvinced that there was a need to amend the TRIPS Agreement as proposed in document TN/C/W/59.

74. The representative of Nigeria said that, from document TN/C/W/474 to TN/C/W/59 via TN/C/W/52, the African Group, together with the large group of developing countries, had been advocating for the amendment of the TRIPS Agreement in order to introduce a mandatory disclosure requirement in patent applications. To achieve a mandatory requirement in the TRIPS Agreement, the proposal contained in TN/C/W/59 could be a basis for further work in addressing the problem of misappropriation of genetic resources and traditional knowledge. In that regard, the African Group welcomed the provisions contained in the Nagoya Protocol, in particular those regarding prior informed consent and access and benefit sharing. That issue being part of an outstanding implementation issue needed to be given high priority in consultations on the way forward in the DDA negotiations because an outcome on that issue was a step forward in assuring the developing countries that the Doha Round was a development round.

75. He fully concurred with the proposal made by India to invite the CBD Secretariat to make a presentation in a side event whereby the report of the side event would be considered in the TRIPS Council, and thereafter the CBD Secretariat would be invited to respond to questions raised by Members.

76. The representative of Switzerland said that his delegation attached great importance to ensuring food security, health and efficient action against climate change. In the view of Switzerland, new technology was key to address those challenges. It considered the patent system as an important tool to incentivize and disseminate such innovation. Therefore, it would not be appropriate to exclude biotechnology or any other technical field from patent protection.

77. Article 27.3(b) of the TRIPS Agreement provided sufficient flexibility to take the specific needs of developing countries and indigenous peoples into account. The way in which the patent system was implemented in Switzerland showed that different interests could be integrated and balanced. Switzerland shared the view of Bolivia that patents shall only be available for inventions, not for discoveries, as reflected in Article 27.1 of the TRIPS Agreement. Different tools could improve patent quality to ensure that patents were only granted to products or processes that were new, involved an inventive step and were capable of industrial application.

78. Databases helped avoiding patents on inventions which did not fulfil the novelty requirement. Switzerland had proposed the establishment of an international gateway for traditional knowledge (see documents IP/C/W/284, paragraphs 16-19, and IP/C/W/400/Rev.1, paragraphs 30-32). That gateway would electronically link existing databases and thus facilitate access to their contents by patent authorities.

79. Another tool to enhance transparency in patent application procedures was the disclosure requirement. In that regard, Switzerland had submitted proposals to WIPO and to the TRIPS Council respectively and also co-sponsored document TN/C/W/52, containing proposals for three TRIPS issues under negotiation in the Doha Round, and the proposal for a disclosure requirement in patent applications. At the national level, Switzerland had introduced a disclosure requirement for patent applications in relation to genetic resources and traditional knowledge.

80. As a transparency measure, the disclosure requirement could help to prevent the granting of bad patents. During the patent application, the examiner had to select databases for prior art searches. The patent examiner's awareness of the source of genetic resources or traditional knowledge on which the invention was based might help the examiner to decide which databases he had to include for prior art searches. Therefore, traditional knowledge databases and disclosure requirements were both efficient mechanisms to increase patent quality, to avoid patents on discoveries and ultimately to ensure a fair and equitable participation of all stakeholders in biotechnological inventions.

81. At the TRIPS Council's March 2011 meeting, several Members, including the United States, had expressed concerns vis-à-vis the disclosure requirement in patent applications. He said that the disclosure requirement should not hamper the patent system and should not be burdensome on patent applicants and patent offices. When designing international proposals and the provisions of the Swiss Patent Law, great care had been taken to avoid those pitfalls and to come up with a balanced approach. For those reasons, Switzerland had chosen the concept of "source".

82. Referring to the case study of "Velcro", he said that the hook-and-loop fastener had been invented in 1941 by a Swiss engineer, Georges de Mestral. The idea had come to him one day after returning from a hunting trip with his dog in the Alps. He had had a close look at the seeds of the thistle plant "burdock" that had kept on sticking to his clothes and his dog's fur. He had examined them under a microscope, and noted their hundreds of "hooks" that had caught on anything with a loop, such as clothing, animal fur, or hair. He had seen the possibility of binding two materials reversibly in a simple fashion. It had taken ten years to create a mechanized process to produce the hook-and-loop fastener. De Mestral had received patents for his invention in numerous countries in the mid-1950s.

83. In response to the question of whether the disclosure of source requirement in the Swiss Patent Law would apply to the Velcro case, he assumed a situation where de Mestral would have filed the patent application after the entry into force of the CBD and of the disclosure of source requirement in the Swiss Patent Law in 2008. The disclosure of source requirement in the Swiss Patent Law did apply – in addition to traditional knowledge – to "genetic resources." That term was defined in the CBD as genetic material, i.e. any material of plant, animal, microbial or other origin containing functional units of heredity that is of actual or potential value. As previously stated, the objective of the disclosure of source requirement in the Swiss Patent Law was to increase transparency in access and benefit sharing. Both Article 5 (fair and equitable benefit sharing) and Article 6 (access to genetic resources) of the Nagoya Protocol applied only as far as the utilization of genetic resources was involved. The recently adopted Nagoya Protocol defined "utilization of genetic resources" as conducting "research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology." Based on that definition, the Velcro case was not a case of utilization of genetic resources. The inventor of Velcro did not conduct R&D on the genetic or biochemical composition of the plant involved. Accordingly, the patent application submitted by de Mestral would not have had to disclose the source of the plant used in the development of the invention.

84. For the sake of the argument, if the disclosure of source requirement *would* apply to the Velcro case, de Mestral as the patent applicant would simply have to declare the source, i.e. the location where he had found the plant in question, i.e. the specific location and place, e.g. a forest, a moor, a mountain, a natural reserve, or others. That was information readily available to him. The Swiss legislation was an example of how a disclosure requirement could be implemented without burdening patent applicants. More detailed information on the concept of "source" was available in document IP/C/W/423, in particular paragraphs 14 to 23.

85. Regarding contractual and national approaches, he questioned how those purely national and contractual approaches could address problems arising from transboundary access and benefit sharing,

that is, where genetic resources and traditional knowledge were used outside the scope of application of national provisions; how the purely contractual approach could address cases where no contract on access and benefit sharing had been concluded between the provider and the user of genetic resources and/or traditional knowledge; how those approaches could resolve the need for transparency in access and benefit sharing; how those approaches would take into account the general long-term nature of research and development activities involving genetic resources; and how the purely contractual approach could ensure that the obligations arising from the contract would be fulfilled even if between the conclusion of the contract and the end of the research activities lay several years, and the parties originally involved might no longer be involved or exist. He also questioned what specific proposals beyond the establishment of databases those Members had that would increase transparency in access and benefit sharing.

86. He said that all those questions, as contained in document IP/C/W/446, were still pertinent, and replies to them from those delegations promoting the purely contractual approaches would be useful for discussions in the TRIPS Council.

87. The representative of New Zealand said that, while few patents originated from New Zealand in the global scheme, her delegation had a systemic interest in the stability of the patent system. It also had a significant indigenous interest in preventing misappropriation of New Zealand's genetic resources and traditional knowledge.

88. While New Zealand's domestic policy was still evolving, it was clear that its interests were much wider than erroneous patents and misappropriation of genetic resources. A narrow WTO response related to patent disclosure would detract from the broader issues associated with protection of traditional knowledge and biological resources. Many issues were not directly related to intellectual property, and could therefore not be resolved through intellectual property systems. For that reason, solutions should be developed within the WIPO IGC, which was able to look at all related issues in a holistic and coordinated way. New Zealand was active and constructive in the IGC and was putting all of its efforts into the fulfilment of the IGC mandate.

89. The representative of United States said that all Members agreed on the need to avoid erroneous patents and on ensuring that patent offices had available the information needed to make proper decisions on patent grants for inventions linked to genetic resources and traditional knowledge. His delegation was committed to meeting those needs, and also recognized the general principles of prior informed consent and equitable sharing of benefits and the importance of securing compliance with national benefit-sharing regimes.

90. As one of the top twenty mega-diverse countries, the United States recognized the value biodiversity contributed toward society. The US National Park Service required prior informed consent or permit which was publicly available, facilitating transparency, before genetic resources were taken from the parks, and reserved the right, in appropriate circumstances, to require benefit sharing.

91. Regarding the mechanisms to achieve common objectives, he said that the best approach would be to employ a contractual model within a national system in connection with the use of databases and third party prior art submissions, among others. For example, the contractual relationship between the biologists who conducted research in the US national parks and the National Park system could be enforced in court, and the United States had not encountered difficulties with that system. Issues of access and benefit sharing could be determined at their source rather than at some indeterminate point in the future, if any, such as the filing of a patent application.

92. One reason for the US positive experience was that universities and other entities generally followed "Ethical Codes of Conduct" which required prior informed consent before research was

begun, and a Material Transfer Agreement to show that the materials were legitimately in the possession of the researcher. Without that paperwork, universities and other entities would not release the research funds to allow the research to continue.

93. Likewise, work in WIPO had resulted in the sharing of best practices regarding databases, such as databases of traditional cultural expressions, traditional knowledge and genetic resources. India's TKDL, Japan's proposed one-click databases and the Swiss traditional knowledge gateway proposal were consistent with those best practices and that further such work could be undertaken.

94. While some Members had questioned the use of those mechanisms as ineffective to pursue the shared common objectives, his delegation looked forward to hearing more details regarding why such mechanisms were insufficient, exactly which national laws were alleged to have been violated, what kind of contractual obligations had been inadequate, and how databases could be improved to make them more informative.

95. Regarding amending the TRIPS Agreement to mandate a disclosure requirement, he said that it would not advance those objectives because of significant time delays, limited coverage, the problem of identifying origin, and negative impact on benefits. On timing, many years, if not decades, might pass between the sourcing of a genetic resource and the filing of a patent application, as Switzerland had confirmed. On coverage, only a tiny fraction of genetic resources found their way into patent applications. Origin could be impossible to determine, particularly when there might be multiple countries of origin. Additionally, many genetic resources were available on the open market legitimately and had been for decades.

96. Regarding the example of Velcro in Switzerland, if the disclosure requirement had applied to that example, he questioned how origin would have been determined with respect to de Mestral's hike in the Jura, when that range was in both France and Switzerland.

97. As patent disclosure requirements increased uncertainty and litigation exposure, research and investment in the innovation that ultimately provided the benefits would decrease, thereby frustrating rather than facilitating the fundamental objectives. Document TN/C/W/59 raised all of those concerns. Ultimately patent systems were designed to promote innovation and might lead to benefits to be shared. Patent systems were not, however, designed to enforce regulatory compliance. His delegation had strong reservations about a patent disclosure requirement and whether it would hinder rather than support the shared objectives.

98. In response to the suggestion to invite the WIPO Secretariat to make a presentation of its work, he said that it should not prejudge the negotiations of the WIPO IGC. Furthermore, it was premature to decide whether a presentation in October 2011 would be appropriate. He encouraged the Chair to continue to hold consultations on that issue.

99. As to the suggestion that the CBD Secretariat be invited to give a presentation, he said that it was the viewpoints of the CBD members rather than the CBD Secretariat that would give WTO Members a more complete picture of the Nagoya Protocol. He welcomed further consultations on that matter.

100. The representative of Chinese Taipei considered the TRIPS-CBD issue to be a crucial issue concerning a number of different stakeholders. For owners of genetic resources and traditional knowledge, a mechanism to ensure fairness and equitable benefit sharing was needed. For investors, it was needed to ensure that the incentive to invent and innovate was not reduced. For patent offices, the legal certainty of the patent system had to be preserved without placing undue burden on either patent examiners or applicants. Those principles were important criteria when delegations joined in discussions and consultations.

101. Referring to Bolivia's proposal, she said that the flexibilities provided for in Article 27.3(b) allowed Members to implement the relevant provisions appropriately at the domestic level and to take into account their own needs and interests. Members were able to take advantage of those flexibilities to suit their own particular and unique domestic conditions. She agreed that the review of Article 27.3(b) should not lead to any lowering of the level of patent protection for biotechnological inventions.

102. She reiterated that her delegation did not support any artificial parallelism in the three TRIPS issues and that the attempt to make a linkage between the three TRIPS issues and to include them jointly as part of the Single Undertaking was not helpful. Each issue should be discussed and considered on its own merits.

103. The representative of Korea said that her delegation was not convinced of the necessity to revise the provision of the TRIPS Agreement as Article 27 reflected a balance between the incentive mechanism of patent systems and the public interest. Revision of Article 27.3(b) to prohibit the patenting of all life forms was not desirable for the overall welfare of humanity, as biotechnology had greatly contributed to combating disease and relieving food shortage. The patent system was essential to make those innovations happen in the field of biotechnology.

104. There was no contradiction between the TRIPS Agreement and the CBD because those two agreements dealt with different subject matters and different objectives. Inserting a mandatory disclosure requirement in the TRIPS Agreement was not a solution to address the issue of access and benefit sharing of genetic resources and associated traditional knowledge. As indicated by the European Community in document IP/C/W/254, intellectual property rights did not aim to regulate the access and use of genetic resources or to regulate the terms and conditions for bio-prospecting or the commercialization of IPR-protected goods and services, and patents authorities were not there to act as an enforcement agency for the third party's legislation on access to genetic resources, but to examine whether inventions satisfied patentability criteria.

105. The mandatory disclosure requirement was an issue of burden sharing. The burden sharing under the current patent system was beneficial to researchers and developers. If the burden sharing was skewed at the expense of researchers, it would be disadvantageous to research and development.

106. Although Korea shared Article 17 of the Nagoya Protocol, it did not share the view presented in document TN/C/W/59. Her delegation was not convinced that inserting disclosure requirements and imposing sanctions on the violation of the requirements could help to achieve the objectives of the Nagoya Protocol and the CBD. The best solution was that each Member developed and implemented national access and benefit-sharing systems. In that regard, the proposals of searchable databases and post-grant opposition procedures could achieve the objective of preventing erroneously granted patents.

107. 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, as well as the suggestion that the WIPO Secretariat be invited to brief it on the work of the IGC.

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

F. NON-VIOLATION AND SITUATION COMPLAINTS

109. The Chairman recalled that, at the Seventh Session of the Ministerial Conference, Ministers had directed the TRIPS Council to continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of

GATT 1994 and make recommendations to their next Session. It was agreed that, in the meantime, Members would not initiate such complaints under the TRIPS Agreement. The eighth Ministerial Conference would be held in Geneva on 15-17 December 2011. At its meeting in March 2010, the TRIPS Council had agreed to keep the item of non-violation and situation complaints on the agenda as a regular item so as to allow Members who would have new thinking to share it, and also enable the Council to revert to the question of the further organization of its work in the light of any future suggestions.

110. He said that he had used the occasion of his consultations on a number of matters in preparation of this meeting to also remind delegations of this approaching deadline. While he did not have any new thinking to report on this matter, he reminded Members that the matter was to be addressed at the Ministerial Conference and that, apart from the present session of the Council, there would only be one regular session of the Council, in October, to reach any recommendation on this matter. He therefore urged delegations to turn their minds to this question with a view to reaching consensus at the next meeting in October.

111. The representative of India said that the application of non-violation and situation complaints to the TRIPS Agreement raised fundamental concerns. The TRIPS Agreement, unlike other WTO Agreements, was a *sui generis* agreement that was not designed to protect market access or the balance of tariff concessions, but rather to establish minimum standards of intellectual property protection. The Agreement explicitly stated that WTO Members were not obliged to implement more extensive protection. Non-violation complaints might have the effect of creating new, non-negotiated responsibilities in the TRIPS Agreement and also in other WTO agreements. Unlike tariff bindings, obligations under the TRIPS Agreement could not be revised as between individual parties. Consequently, the non-violation remedy might allow a Member claiming non-violation to express the impairing Member the threat of retaliatory reactions equivalent to those available in the case of a violation of the TRIPS Agreement, if the impairing measure was not withdrawn.

112. The creation of non-negotiated responsibilities was inconsistent with Article 3.2 of the Dispute Settlement Understanding (DSU), which provided that rulings of the Dispute Settlement Body (DSB) must not add or diminish the rights and obligations provided in the covered agreements. Non-violation complaints, currently inapplicable in TRIPS-related disputes, could potentially function as a tool to circumscribe developing country Members from effectively using flexibilities concerning public health in the TRIPS Agreement. The application of non-violation complaints might further unbalance the TRIPS Agreement by elevating private rights over the interests of the users of intellectual property, both within and between countries, and over public policy considerations. Non-violation complaints might be used to pressure developing countries not to fully explore their rights to use measures such as compulsory licensing to ensure access to essential medicines or to guarantee access to technology. Unilateral pressure based on non-violation complaints might also be applied to constrain the adoption of national measures under TRIPS Article 8 to protect public health and nutrition and to promote public interest in sectors of vital importance to the socio-economic and technological development.

113. He believed that extending the non-violation remedy to the TRIPS Agreement might also entail consequences for the predictability and security of the multilateral trading system. The uncertainty surrounding the remedy would make it harder for countries to rely on the text of the TRIPS Agreement to define their rights and obligations in the face of unilateral pressure by other more powerful WTO Members. A number of Members had noted with concern that non-violation complaints under the TRIPS Agreement might give rise to incoherence among the WTO agreements. The danger of incoherence had been raised in the Canadian paper (document IP/C/W/249), which had noted that otherwise WTO consistent measures, such as taxes or advertising requirements, could potentially be challenged under the TRIPS Agreement. It had noted that "it is highly questionable whether WTO Members would be in favour of leaving the option open for countries to file a

non-violation complaint under the TRIPS Agreement if the measure is found to be in full compliance with multilateral provision under GATT and its annexed agreements or the GATS". Such uncertainty was likely to further increase public concern over the impact of the TRIPS Agreement on important issues such as public health, bio-diversity protection and transfer of technology.

114. There had been substantial discussion on the scope and modalities of non-violation and situation complaints in the TRIPS Council since 1999. The discussions and submissions made by Members led him to believe that non-violation and situation complaints were not necessary to protect any balance of rights and obligations inherent in the TRIPS Agreement. Rights and obligations in the TRIPS Agreement were best performed through good faith application of its provisions in accordance with the established principles of international law recognized by the Appellate Body and did not require recourse to the legally imprecise notion of non-violation and situation complaints.

115. He proposed that the TRIPS Council recommend to the next Ministerial Conference that the violations of the type identified in subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 be determined inapplicable in the TRIPS Agreement, or at least imposing a moratorium for a substantial period such as 10 years before taking up the review.

116. The representative of Ecuador said that the issue was autonomous by nature and therefore could not be linked to issues in other areas of work of the WTO. Given the character and nature of the TRIPS Agreement, these kinds of complaints could not be encapsulated under it. Rather than laying out maximum levels of enforcement, the Agreement only set out a minimum standard of protection, and it did not touch upon tariff levels. Therefore, on the basis of the recommendations made to the TRIPS Council in May 2003 and given the understanding of the majority of the membership, he agreed with India's view that the Council should recommend to the next Ministerial Conference that Ministers also exclude the application of non-violation complaints in the TRIPS context.

117. The representative of the Bolivarian Republic of Venezuela said that, in his view, subparagraphs 1(b) and (c) of Article XXIII of GATT 1994 could not be applied to the TRIPS Agreement. If that assertion were to be wrong, such application would require the consensus of the entire membership, as stipulated in Article 64.3 of the TRIPS Agreement. Such application would be completely at odds with what many Members had stated in the Council's meetings, where ever increasing support was being expressed for a recommendation to the Ministerial Conference that the content of the above-mentioned GATT 1994 provisions be determined inapplicable to intellectual property. Moreover, the lack of any concrete cases for evaluation by the Council with a view to examining the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, as established in Article 64.3 of the TRIPS Agreement, was evidence that it was patently impossible to consider intellectual property as a good. The reasons for this were extensively set out in document IP/C/W/385, sponsored by Venezuela and a group of other countries and submitted in October 2002. This paper explained the factual and legal reasons that challenged the possibility of addressing the issue of intellectual property as a good.

118. The representative of Cuba endorsed the statements made by India, Ecuador and Venezuela.

119. The representative of China said that the TRIPS Agreement was quite different from GATT 1994 in its nature and structure. He believed that the application of non-violation and situation complaints under the TRIPS Agreement was not appropriate and would be problematic. It would cause fundamental concerns and might also limit the use of the flexibilities of the TRIPS Agreement.

120. He suggested that the eighth Ministerial Conference decide on an extension of the moratorium, if Members would not agree upon a permanent suspension.

121. The representative of Pakistan said that he shared the views expressed by India and other previous speakers. TRIPS had a very different nature. He recalled that he had been asking for quite a long time what was the nature of non-violation and situation complaints and this question was still to be addressed. Previous TRIPS dispute settlement cases had not clearly showed what TRIPS violations were. He therefore wondered how agreement could be achieved on the application of non-violation complaints. Non-violation and situation complaints would touch the enforcement area. One delegate had earlier pointed out that the "patent system is not designed to touch upon the regulatory systems or to take into account the regulatory systems". This statement could apply to all of the other IP systems and, therefore, non-violation and situation complaints should not be applicable in the TRIPS enforcement area.

122. He supported India's proposal that if an agreement on a permanent moratorium could not be reached, a long-term moratorium should be approved by Ministers. Since this issue had been on the agenda of previous Ministerial Conferences, there might be a benefit of discussing it in its entirety to see what were the possible scenarios, where non-violation could be applicable or where it could not.

123. The representative of the United States said that he continued to be of the view that it was entirely appropriate for non-violation and situation complaints to be applicable to the TRIPS Agreement. This was no less true now than when these complaints were included within the TRIPS Agreement. While Members had agreed to extend the moratorium on non-violation and situation complaints in the past, this concession was significant. The availability of these complaints would provide security and predictability to help ensure that Members' legitimate expectations with respect to the TRIPS Agreement were not frustrated.

124. He said that the moratorium was set to expire at the upcoming Ministerial Conference and that it should expire.

125. The representative of Colombia said that Colombia was one of the countries that had endorsed document IP/C/W/385 mentioned by Venezuela. The concerns spelled out in this document continued to be valid. He was willing to take part in any consultations that might take place on the matter before the Ministerial Conference.

126. The representative of the Bolivarian Republic of Venezuela said that nothing in Article 64 of the TRIPS Agreement envisaged the possibility of the expiry of the moratorium, since its paragraph 3 stipulated that decisions in this regard should be made by consensus by the membership, a consensus that clearly was not available.

127. The representative of Switzerland said that he had consistently made the point over the years that the TRIPS Agreement was one of the three main pillars of the WTO system. There was thus a systemic reason in favour of the application of the principle of non-violation also in the context of the TRIPS Agreement. Further, Switzerland also read Article 64.2 and 64.3 of the TRIPS Agreement as making clear and unambiguous reference to non-violation and situation complaints. The very fact of Article 64 providing for a moratorium for their application meant that, after its expiry, such complaints would become applicable under the TRIPS Agreement. Switzerland believed that with the DSU, there was sufficient guidance in case non-violation or situation complaints should occur in the TRIPS context. During the last two years of additional extension of the moratorium, those delegations who had in earlier years expressed concerns as to the exact scope and modalities of non-violation and situation complaints in the TRIPS context beyond those provided in the DSU had not come forward with submissions or proposals on how their concerns could be addressed through additional modalities.

128. Considering this and recalling that the moratorium had been extended four times already, he did not see any reason to recommend a further extension of the moratorium, which would expire at the next Ministerial Conference in December 2011, as it was the nature of moratoria.

129. The Chairman said that it was his intention to hold consultations in various formats on the matter prior to the Council's meeting scheduled for 25-26 October with a view to enabling the Council to agree on its recommendation to the Ministerial Conference at that meeting. He added that his door was open to all delegates who would like to share ideas and consider what kind of common position could be reached.

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

G. REVIEW OF THE IMPLEMENTATION OF THE AGREEMENT UNDER ARTICLE 71.1

131. No statements were made under this agenda item.

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

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

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

134. He recalled that, at its meeting in March 2010, the Council had agreed to encourage Members to share information on and notify bilateral agreements related to the protection of geographical indications, which they had entered into. This had already produced some useful and informative material. He therefore encouraged any Member that was party to any such bilateral agreement and had not yet shared such information with the Council to do so.

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

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

I. TECHNICAL COOPERATION AND CAPACITY-BUILDING

1. Arrangements for the annual review

137. The Chairman recalled that the Council had traditionally undertaken its annual review of technical cooperation each autumn. He therefore suggested that the Council hold its annual review at its next meeting scheduled for 25-26 October. Accordingly, he suggested that the Council invite developed country Members to supply information on their activities pursuant to Article 67 of the TRIPS Agreement. Other Members who also made available technical cooperation were encouraged

to share information on these activities if they so wished. He also suggested that the Council invite those intergovernmental organizations that had observer status in the Council for TRIPS to provide information on their activities of relevance and that the WTO Secretariat also be instructed to report on its activities. He proposed that the Council request that this information be made available by 30 September in order to allow its timely circulation before the meeting.

138. The Council so agreed.

2. Other matters

139. The Chairman recalled that, at its meeting in October 2010, the Council had held its previous annual review of technical cooperation. Since that meeting, the Council had received additional information from the European Union and individual member States and agencies, namely Austria, Belgium, Bulgaria, the Czech Republic, Finland, France, Germany, Hungary, Portugal, Romania, Spain, Sweden, and the United Kingdom, as well as the European Patent Office (IP/C/W/550/Add.7).

140. As regards LDC needs assessment, he recalled that paragraph 2 of the TRIPS Council's 2005 decision on the "Extension of the Transition Period under Article 66.1 for Least-Developed Country Members" provided that "with a view to facilitating targeted technical and financial cooperation programmes, all the least-developed country Members will provide to the Council for TRIPS, preferably by the 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". The Council had just received such information from Senegal (being circulated as IP/C/W/555). Such information had earlier been received from five other Members, namely Sierra Leone, Uganda, Bangladesh, Rwanda and Tanzania.

141. The representative of the Secretariat recalled that, at previous meetings of the Council, he had reported on a range of activities undertaken at the request of LDC Members to support this process. The Secretariat's work had been guided by the Council's 2005 decision, and in particular the three operational elements of that decision, the first element being that the LDCs were asked to provide the Council with as much information as possible on what was needed as a priority for technical and financial assistance. The second element was for developed countries that were asked to provide the technical and financial help required by the LDCs to address the identified needs effectively. The third element was of direct relevance to the Secretariat as it was a requirement to enhance cooperation with the World Intellectual Property Organization and with other relevant international organizations. The organizations concerned were indeed cooperating more closely in this area. In the case of WIPO in particular, this cooperation was required directly in response to the specific request of the Council, and was also based on the existing cooperation agreement as well as the joint initiative on technical cooperation for LDCs, which had been launched in 2001. Accordingly, this partnership remained a key element of this activity and perhaps it had become even more important with the elaboration of the WIPO Development Agenda and the programme established for LDCs in particular. Cooperation had also been enhanced with UNCTAD, which itself had contributed to the needs assessment process early on at the request of several of the countries which had since reported to the Council, and with other organizations dealing with specific subject areas, such as the stepped up cooperation with the World Health Organization on the public health dimension.

142. The Secretariat had been asked to undertake a series of activities by the LDC Group of Members in 2009, in particular a series of regional workshops, which had been planned to harvest the experience so far with the LDC needs assessment process, but also to lay the groundwork for improved coordination of the delivery of technical and financial assistance to meet the needs identified. The Secretariat had also been requested at that time to hold a final workshop in Geneva, at the end of the current year and at the culmination of the regional workshops, to draw together the wide range of experience that had been harvested and to reinforce coordination with the providers of

assistance and the concerned intergovernmental organizations. Accordingly, the regional workshops and the final Geneva workshop had been included in the biannual technical assistance and training plan for the current biennium 2010/11. The regional workshops had since then been undertaken in Uganda, Bangladesh and Senegal, and the contribution of the host governments was acknowledged with appreciation.

143. The planning for the Geneva workshop was still underway in consultation with the LDC Group and intergovernmental partners, in particular WIPO and UNCTAD. The current plan was for the event to be held back-to-back with the Council's October meeting so as to facilitate the participation of delegates and concerned officials. In practice, this would mean holding the workshop from 19-21 October as the most practical dates. Based on the past experience and the lessons learnt from the regional workshops, the important ingredients for the workshop would be, firstly, as far as possible, capital-based participation from those LDC Members who had a strong interest in this process in close coordination with the Geneva missions concerned and the LDC Group from whom the Secretariat would continue to take guidance. Secondly, the participation by a wide cross-section of national agencies and intergovernmental organizations with responsibility for coordinating and administering technical assistance programmes, the resources and the programmes that would respond to the needs identified. Thirdly, scope for some informal bilateral interaction as part of the workshop structure; this had been a well-received aspect of the regional workshops allowing for practical coordination at a very informal level between LDC Members who had communicated their individual priority needs and those who were responsible for technical assistance programmes and the other necessary resources to respond to the needs identified. There were ongoing resourcing and logistical issues for the workshop, but the Secretariat was working on a format that would make a concrete and tangible contribution to advancing all three aspects of the TRIPS Council decision and create a robust and practical basis for the next phase of the process of communicating and responding to individual priority needs of LDCs and focussing the resources on the needs identified, as well as resource mobilization through enhanced coordination. The Secretariat would continue taking the guidance of LDC Members as an immediate priority as this work would unfold through to the Geneva workshop and following through on any outcomes or recommendations from the workshop and the Council's October meeting.

144. The representative of Senegal introduced the document on Senegal's priority needs for technical and financial cooperation with a view to implementing the TRIPS Agreement (being circulated in IP/C/W/555). He recalled that the TRIPS Council's 2005 decision had extended until 1 July 2013 the transition period granted to LDC Members for the implementation of the TRIPS Agreement. LDCs were, in addition, free of the obligation, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016. Paragraph 2 of the 2005 decision called on LDC Members to 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 in taking steps necessary to implement the TRIPS Agreement.

145. In the context of the Biennial Technical Assistance Plan 2010-2011, Senegal had put WTO support and advice to good use in identifying its priority needs. It had also benefited from WIPO's technical assistance in drawing up its National Intellectual Property Development Plan (PNDPI). Senegal had a fairly substantial legal IP framework. It consisted of legal texts that dealt with the matter directly and others that addressed only certain aspects of IPRs. Senegal was also a party to several international, regional and multilateral agreements and treaties on IP currently in force.

146. This legal arsenal, however, needed a certain amount of adapting and updating, and the texts administered by bodies with remits that touched on IP issues (trade, customs) needed to be reviewed or supplemented. There were a number of obstacles in the path of IP development, one being that several bodies dealt with these matters and coordination between them was a problem for users of the

system (SME - SMI, CR&D and cultural players). The bodies involved were: the Ministries of Industry, Culture, the Interior, Scientific Research, Trade, Higher Education and Justice. Furthermore, the institutional framework had problems regarding the availability of material and financial resources, creating and building the capacities of players (staff and right holders), IP teaching in higher education, and the development of research.

147. In order to set up a framework for more effective enforcement of IPRs in Senegal, the main stakeholders had identified a number of priority needs for technical and financial cooperation: organization of awareness-raising campaigns; training for the staff of the bodies responsible for rights enforcement, including the police, customs, and the judiciary; provision of detection and testing equipment; development of IPR enforcement manuals for the main enforcement agencies; access to case law and research resources for the commercial courts, including through the establishment of a special IP section.

148. Senegal had the potential for innovation and creation. Unfortunately, it had not managed to set up a suitable IP regime. The public sector had a dominant role in research initiatives, while the private sector used the results without really participating. Yet, public sector R&D was unable to meet growing market demand. Most of the country's industries suffered from inadequate development, in particular because the necessary R&D facilities were lacking. Although the technologies used were for the most part imported, technology transfer was extremely limited. Virtually no patents were registered locally. Article 66.2 of the TRIPS Agreement required developed country Members to provide incentives to encourage technology transfer to LDCs for the purpose of capacity building, but its enforceability remained a problem.

149. He said that Senegal had just drawn up a National Intellectual Property Development Plan (PNDPI), which set out a strategy for IP development, the aim being to create a framework to protect and promote the IP system so that it could be used effectively in implementing the country's economic, social and cultural development policy. The PNDPI also focussed on the development of intellectual creation. It pursued four major objectives corresponding to priority areas of action, namely: (i) strengthening the legislative and regulatory framework; (ii) modernizing IP administration; (iii) promoting the use of IP by companies; and (iv) promoting IP in the education and research sector.

150. The main results expected from the PNDPI could be summarized as follows: (i) an improved legal framework aligned with the objectives, principles, rights, obligations and flexibilities set out in the TRIPS Agreement and with other commitments under international and regional IP standards; (ii) a modern, service-based, accessible and automated IPR administration, designed for enterprises, creators and inventors in Senegal; (iii) a strengthened institutional framework and improved IP coordination countrywide; (iv) an increased awareness and use of IP as a tool for economic development and integration; (v) a structured expansion of IP education, training and research institutions within a common national network; and (vi) increased capacities for effective and efficient enforcement and regulation of IPRs among bodies responsible for IPR administration such as the police, public prosecutors and the judiciary.

151. The representative of Senegal said that a memorandum for implementing the PNDPI had been recently signed with WIPO for an amount of CFA 8.5 billion (i.e. nearly 13 million Euros). The memorandum established a framework for cooperation with WIPO, which would enable Senegal to create an environment conducive to IP development. However, there had as yet been no real commitments to implementing the activities of the various programmes covered in the PNDPI and the needs expressed in the context of the PNDPI would in all likelihood expand, which would require additional funding. Hence the need to include the programmes already identified under the PNDPI among the priority needs that Senegal had expressed in view of the impending implementation of the TRIPS Agreement.

152. Senegal also planned to take account of the needs thus identified when updating its diagnostic trade integration study (DTIS) and action matrix, so that partial funding could be obtained through broader initiatives for LDC support, in particular the Aid-for-Trade initiative and the Enhanced Integrated Framework (IEF). Initiatives such as these afforded opportunities to strengthen and coordinate efforts made to meet the individual priority needs identified by LDCs in the area of TRIPS.

153. The PNDPI identified particular areas of action requiring technical and financial assistance. In this connection, Senegal was awaiting with interest such aid as the multilateral institutions and WTO Members might provide for its implementation.

154. The document that had been submitted had two annexes. Annex A highlighted the main priorities in terms of financial and technical elements allowing the necessary steps to be completed for the implementation of the TRIPS Agreement, taking as a basis the IP development strategy worked out from the responses and suggestions made in the course of consultations with the various stakeholders and in the context of talks held at national level. The needs evaluation covered IP policy and legal framework, administration, IPR observance and regulation, the promotion of innovation, technology transfer incentives and the use of IP as a tool for development. Annex B contained an indicative timeframe of a long-term national programme aimed at capacity building for IP development in keeping with Senegal's needs.

155. The representative of WIPO said that WIPO continued to provide support to LDCs in the use of the IP system to help meet their economic, social and cultural development goals. This included providing technical assistance and capacity building support in relation to the WTO LDC needs assessment exercise. WIPO looked to support all developing countries, in particular LDCs, in developing national IP and innovation strategies. These strategies aimed to provide a holistic framework for the delivery of WIPO's technical assistance and capacity building work.

156. WIPO had assisted Senegal in drafting and adopting the National IP Development Plan for the period 2011-2015. A memorandum of understanding relating to the Plan had been signed by the Minister of State, Minister of Mines, Industry, Agro-Industry and SMEs of Senegal, with the endorsement of the Minister of Culture, and also signed by the Director General of WIPO earlier in 2011. The IP Plan was a forward-looking document which set the vision of Senegal in using IP for its economic development endeavors. It made a diagnosis of the IP system of the country and all the stakeholder institutions and their potential contributions to an IP-led development process. It set out clear targets to be attained by 2015, including a revamping of the institutional framework of IP management in the country with the establishment of the *Conseil National de Coordination de la Propriété Intellectuelle* (CNCPI), in which the ministries in charge of IP and of Culture were represented.

157. The IP Plan emphasized the attainment of the goal set under the *Grande Offensive pour l'Agriculture, la Nourriture et l'Abondance* (GOANA), a flagship government programme for self-sufficiency in food production and transformation; capacity building and human resource development; access to and use of technology information through the strengthening of the network *Centre de Recherche Développement* (CRD). It also sought to involve SMEs in a more dynamic way.

158. WIPO had supported Senegal in the establishment of Technology Information Support Centres (TISC) in Dakar. Following the signing of a Service Level Agreement, training had taken place and would continue for the consolidation of the TISC network. TISCs were one of the seven deliverables of WIPO for LDCs, which would contribute to an increase in the building of a knowledge base in order to promote creativity, innovation and competitiveness of business, industry, enterprises, academics and researchers throughout Senegal.

159. WIPO was currently in the process of finalizing a WIPO commissioned study on Traditional Cultural Expressions of Senegal. WIPO had also organized a number of LDC High Level Forums aimed at supporting LDCs by providing a platform for Ministers and senior officials to discuss issues related to IP policies and implementation strategies. Senegal had participated at a senior Ministerial and senior officials level in all of those events.

160. The Ministerial Declaration on WIPO Deliverables for LDCs had been adopted by acclamation at the WIPO Ministerial Forum in Istanbul, which had taken place in parallel with the fourth UN LDC Ministerial Conference. Senegal was one of the countries that would benefit from its implementation. WIPO would continue to work closely with Senegal and with all LDCs as well as with the WTO Secretariat to support the WTO LDC needs assessment process.

161. The Council took note of the statements made.

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

162. The Chairman recalled that, at its past six meetings, the Council had had on its agenda the letter from the Chair of the General Council concerning ways to improve the timeliness and completeness of notifications and other information flows in the area of its responsibility. In order to facilitate the Council's consideration of this issue, the Secretariat had presented to the October 2009 meeting a factual background note IP/C/W/543 it had prepared at the Council's request that summarized the relevant procedures and provided information on the use of these procedures, as well as contained suggestions on how to improve the transparency and user-friendliness of the notification system. Furthermore, the Secretariat had orally reported on further developments in this area. Those delegations that had spoken on this issue had supported the suggestions contained in that note to improve the transparency of the system, and had encouraged the Secretariat to pursue this task.

163. The representative of the Secretariat said that the Secretariat had reported in great detail in previous sessions of the Council on this unfolding work and therefore would simply update the main elements that were relevant. Document IP/C/W/543 set out the state of play and described the various directions that the work could pursue. All of this work was undertaken strictly within the procedures and the decisions already established by the Council and simply amounted to ways of more efficiently using resources to manage this now immense wealth of information that had been notified.

164. The work that was under way included clarifying in a new useful way the best format for the input of notifications and the establishment, in cooperation with WIPO, of a joint portal to facilitate the submission of texts, where the two Organizations had joint competence. That had been reported on in the past, but it was now fully operational and the partnership with WIPO was a particular benefit of this arrangement. A transparency toolkit was now available on the WTO website to facilitate understanding of notification procedures, to facilitate the submission of up-to-date notifications and to provide better access to notified materials that were available online. The Secretariat had also incorporated both the notification procedures and the practical use of notified materials into a wide range of technical cooperation activities, putting these materials in the hands of beneficiaries to make them more useful tools. The Secretariat had implemented pilot projects to supplement the traditional paper-based circulation of such information as contact points through the creation of more accessible formats, in this case, a drop down list for greater ease of access. That pilot project paved the way for a more comprehensive approach to making the material available online. The future work and the ongoing work and its current directions would depend on available resources, especially the availability of necessary IT resources, because it was moving into a more IT-intensive phase. The envisaged work included improving online access to and searchability of the notified materials, including addressing the backlog of materials that currently remained in difficult to access formats, as well as developing possible links with other elements of the Secretariat IT infrastructure to provide a

more accessible, better integrated and user-friendly interface for access to and use of notified materials. The Secretariat was currently working on the groundwork of these next steps, coordinating in-house, because it was very much a cross-Secretariat programme. He therefore proposed to update the Council at the October meeting.

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

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

166. The Chairman recalled that this item had been put on the agenda at the written request by the delegation of the Dominican Republic.

167. The representative of the Dominican Republic said that, on 8 April 2011, Australia had notified to the Committee on Technical Barriers to Trade the "Tobacco Plain Packaging Bill 2011" ("the Bill") (G/TBT/N/AUS/67). That notification also referred to a "Plain Packaging of Tobacco Products Consultation Paper" ("the Consultation Paper") which described further provisions and other measures that Australia was considering for adoption for the purpose of implementing the Bill or regulating the packaging of tobacco products. She said that the Dominican Republic was seriously concerned about the impact of the measures proposed and their compatibility with the TRIPS Agreement and the TBT Agreement. Concentrating for the moment only on the issues that concern the TRIPS Agreement, her delegation was particularly worried about the impact the proposed measures could have on small economies that are largely dependent on the production and export of tobacco and tobacco products.

168. She said that the Bill would authorize the adoption of a series of regulations requiring "plain packaging for tobacco products", amounting to a ban on the use of registered trademarks, logos and other distinguishing features on tobacco packaging apart from the brand name, which would be subject to specified lettering and placement. The Consultation Paper laid down the steps proposed for implementation of the Bill as it concerned cigarette packaging. For other tobacco products, the Paper stated that the proposed design features for the plain packaging were still under development and that consultations would be held on them in the second half of 2011. According to the Consultation Paper, Australia would also require that all tobacco packets be coloured a shade of dark olive brown with matt finish and that cigarette packets display graphic health warnings that cover 75 per cent of the front of the packet in addition to the one already covering 90 per cent of the back, together with a further warning to cover one of the side panels. The other side panel was to display the manufacturer's details and a bar code. No details were given of changes in warning requirements for other tobacco products such as cigars. The Consultation Paper further stated that all cigarette packs had to be rectangular in shape with a flip-top opening, and that no branding, colours or design features other than those specified would be permitted. She said that these requirements would be in addition to Australia's existing laws and other provisions which prohibit the use of tobacco brand names on non-tobacco products and ban advertising campaigns that target consumers. Retail displays of tobacco products were also either banned already or to be banned throughout the country.

169. She said that these proposed measures would require all producers and importers of tobacco products to adopt highly standardized packaging which would in turn prevent sellers from asserting their intellectual property rights on packaging for cigarettes and other tobacco products, thereby depriving consumers of important information on the products they buy. The Dominican Republic was concerned as to the consistency of these measures with Australia's obligations as a WTO Member.

170. She said that, because the proposed measures had serious consequences, it was important to ensure that the policy objectives they underpinned were legitimate. According to Australia's notification to the TBT Committee, the measures were designed to "reduce the appeal of tobacco products to consumers; increase the effectiveness of health warnings on the packaging of tobacco products; and reduce the ability of the packaging of tobacco products to mislead consumers about the harmful effects of smoking". Apparently, each of these objectives formed part of a broader plan that sought to reduce the number of smokers in Australia. However, she said that it was unclear to her delegation as to how the proposed measures would contribute to meeting that goal.

171. She said that her delegation was also concerned that plain packaging might have unwanted effects that undermined the proposed health objectives. For example, if tobacco products were to be sold in standard packs thus making product differentiation difficult, sellers might feel compelled to compete solely on the basis of price, causing a drop in retail prices which might in turn produce an increase in the demand and consumption of tobacco products, including cigarettes and cigars. Furthermore, to sell tobacco products in plain packaging might make the production and sale of fake and counterfeit tobacco products easier, which would increase the sale and consumption of non-regulated products. In other words, the plain packaging measures proposed could actually run counter to the objectives sought.

172. She said that the Dominican Republic was also concerned over the compatibility of the proposed measures with the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property ("Paris Convention"). Article 20 of the TRIPS Agreement prohibited the imposition of unjustified barriers that affect trademarks. She said that a ban on the use of trademarks and a requirement for brand names to be displayed using a standard format and lettering would obviously "encumber" their use. Article 20 gave two instances of such encumbrance: (a) a requirement to "use [a trademark] in a special form"; and (b) a requirement for use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings.

173. She said that the proposed measures would require use of trademarks in a special form. Manufacturers of tobacco products would have to meet the following requirements for displaying the brand name: use a standard font style and size; use a dark olive brown background colour with a matt finish; use only the top and bottom of the packet and the bottom quarter of the front surface. Because of their design these restrictions would be "detrimental" to the capability of trademarks to distinguish the goods or services of one undertaking from those of other undertakings. With the packaging stripped of virtually all of the products' distinctive features and with a standardized brand name display, packets would look very much alike to consumers and retailers.

174. She said that it would be most helpful to her delegation if Australia could explain how these measures could be justified and specify the evidence it used as a basis for showing that the plain packaging requirement would meet the objectives set out in the notification and, more generally, how tobacco consumption would be reduced. It would also be useful to know whether Australia had explored the kind of effects that the plain packaging requirement would have on low budget generic type tobacco products and on unregulated trade in tobacco products, such as illegally imported counterfeit or fake products.

175. With respect to the obligation of Members to comply with 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", she said that, in the view of the Dominican Republic, there was a serious risk that the proposed generic packaging requirements might lead sellers to use packets that create confusion. Indeed, one of the plain packaging requirements seemed to have been designed to prevent consumers from distinguishing between different tobacco products. Pursuant to the plain packaging requirement, all

distinctive features that currently appeared on a cigarette packet would have to be removed. As observed earlier, although the brand name would appear, this information would have to be conveyed in a standard font style and font size and displayed on a dark olive brown background with a matt finish, and could only be placed on the top and bottom of the packet and on the bottom quarter of the front surface. This meant that the appearance of competitors' tobacco products would be almost identical and there was a genuine risk that consumers in a retail market context would be unable to adequately distinguish between them.

176. In view of the above, the Dominican Republic requested that Australia take account of these concerns and review the Bill accordingly.

177. 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.

178. 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.

179. 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 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.

180. 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.

181. 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.

182. She said that Australia was, and would continue to be, fully committed to its international obligations to protect intellectual property rights, 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.

183. The representative of Honduras said that her delegation endorsed the concerns expressed by the Dominican Republic regarding the Australian Bill, the purpose of which was to attempt to protect human health. Australia's measure caused systemic concerns because, according to her delegation's view, its implementation would be detrimental to trademark owners. The obligation to apply or fit in with specific forms for display on tobacco packaging would require certain adjustments to their trademarks in order to satisfy Australia's "health warning" requirements. This special requirement to create novel "plain packaging" for this product would make it difficult for a trademark to distinguish a product from that of a competitor. This was contrary to Article 20 of the TRIPS Agreement and failed to take account of the legitimate interests of trademark owners, as stipulated in Article 17 of the Agreement.

184. She said that, as a Member of the WTO whose objective was to oversee trade law, Honduras was committed to fulfilling the undertakings made under the trade agreements. This did not preclude Members from adopting certain sanitary measures for the protection of human health, as was the case here, which may also have trade implications. Honduras was of the view that Australia's proposed measure could only be valid if it were revised to achieve the pursued public health objectives in a manner consistent with the commitments and obligations under the WTO framework, in particular the provisions of the TRIPS Agreement. Australia could rectify the measure by reducing the space designed for displaying the health warning on both sides of the packet, front and back, to use up only 50 per cent or less of the surface for messages and pictograms of its choice. This would allow the trademark owner more freedom to use the remaining space to differentiate its own product, in recognition of its legitimate right to do so.

185. She said that Honduras had had a similar experience in this regard when its Special Law on Tobacco Control was enacted through Decree No. 92-2010. While the original requirement had been that health warnings should take up 80 per cent of the package surface, this requirement was subsequently amended, and the space for health warnings reduced to 50 per cent on the front and back of the package, precisely because of the aforementioned considerations.

186. The representative of Nicaragua said that her delegation shared the concerns regarding the Australian plain packaging bill 2011 presented by Australia. If the plain packaging of tobacco products were to be implemented as outlined in the Consultation Paper, this would go against the TRIPS Agreement and would also be in contravention of other international trade agreements. With respect to the TRIPS Agreement, she said that Article 20 very clearly laid down that the use of a

trademark in the course of trade should not be unjustifiably encumbered by special requirements, by use of a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from that of the competition. The Australian bill on plain packaging did violate that provision because it would lay down a particular requirement for the trademark and would therefore hinder trade.

187. She said that Article 15 of the TRIPS Agreement and Articles 6 and 7 of the Paris Convention provided that countries had to accept trademarks registered in other countries and that they may not discriminate against those trademarks. These agreements implicitly required that parties to these agreements provide a positive right to the trademark holders in question to use the trademark for the goods that they are selling. The right to use a trademark must be put into practice, because having a theoretical right without having the practical use of trademark would not be fair. The TRIPS Agreement stipulated that any measure to deal with public health issues should be in keeping with the TRIPS principles and this would not be the case with respect to the Australian measure.

188. With respect to the WHO Framework Convention on Tobacco Control, she said that this only contained recommendations on plain packaging and that there was no obligation on parties to the framework convention to use plain packaging. As a tobacco producer, Nicaragua considered that the adoption of the law in question by Australia would undermine the rights of tobacco producers in Nicaragua and would therefore have a direct effect on their ability to generate revenue. Her delegation would therefore like to request Australia to consider amending the Bill, so that its right as a sovereign state to protect public health would not actually go against the rights that others enjoy under the TRIPS Agreement.

189. She said that her delegation further believed that the adoption of this measure in Australia would not be in keeping with Article 2.2 of the TBT Agreement and that it might raise the TBT-related issues in another forum. Her delegation believed that plain packaging would not affect consumer behaviour, and that the measure would therefore not actually fulfil the goals laid down by Australia, rather it would simply mean economic difficulties for those having to comply with the legislation. The Bill also violated Article 12.3 of the TBT Agreement as well as the Paris Convention on the Protection of Intellectual Property. She invited Australia to take these concerns on board and refrain from adopting the measures as outlined.

190. The representative of Cuba thanked the Dominican Republic for having included this matter on the Council agenda. He believed that the Bill could well have an effect on trademark use and it was therefore appropriate to have the TRIPS Council consider the proposed legislation. This was a complex issue with two facets: on one hand, there was the objective of protecting human health which motivated the measure, and on the other hand there were the potential implications for trade in tobacco products from the point of view of intellectual property rights. The Bill's stated objectives were to improve public health by discouraging people from taking up smoking, discouraging people who have given up smoking from relapsing, and reducing people's exposure to smoke from tobacco products. He said that Cuba considered these to be legitimate objectives that were essential to high-level public health care, a human right that should be defended and given priority by all States.

191. He said that, nevertheless, for many of the small and under-developed economies, tobacco products were an exportable staple on which thousands of families in the rural areas depended. Moreover, as for any other legal products - that is any products whose trade had not been forbidden - trade in tobacco products was governed by the rules of the WTO and as a result, there were a number of legitimate questions and concerns regarding the impact of these regulations on trade.

192. His delegation was concerned about how to protect the rights of owners under Article 16 of the TRIPS Agreement and to prevent counterfeiting or unfair competition. Plain packaging, he said, eliminated the distinctive elements of a brand and the appearance of the packaging became uniform

for all marks, making it difficult for consumers to identify and differentiate tobacco products on the basis of brand preference. At the same time, the lack of distinctive elements would make the packaging easier to reproduce and could lead to an increase in illicit trade in counterfeit products which would threaten the rights of owners. In view of these foreseeable implications of the Australian bill, his delegation would be grateful if Australia could share with all Members the scientific evidence at its disposal concerning the direct link between the measure and the health protection objectives it was seeking to achieve, in the light of Article 8 of the TRIPS Agreement. It would also be useful to know whether Australia had considered other measures, less restrictive of intellectual property rights, that would achieve the same health objectives and, if so, whether it could provide Members with the results of the analysis conducted. His delegation would be grateful if Australia could provide information on these issues at the next regular session of the TRIPS Council.

193. The representative of Ukraine said that her delegation would like to echo the concerns expressed by other countries regarding Australia's notification G/TBT/N/AUS/67 on its Tobacco Plain Packaging Bill of 2011. Ukraine considered that the adoption of this legislation and the introduction of the plain packaging requirements and the proposed terms would violate the provisions of the TRIPS Agreement, in particular Articles 8.1, certain provisions of Articles 6 and 7 of the Paris Convention as incorporated into the TRIPS Agreement, Article 17, and Article 20 of the TRIPS Agreement. On 2 June 2011, Ukraine had sent its comments and questions to the Australian government department of Foreign Affairs and Trade, and urged the Australian Government to consider the revision of the proposed draft in order to make it WTO consistent. Her delegation was confident that the Australian Government would carefully consider the concerns of Members about the proposed legislation and ensure its compatibility with the requirements of the TRIPS Agreement.

194. The representative of Brazil said that his delegation had listened to the Dominican Republic's reasons for having brought this issue to the attention of the Council as well as Australia's explanations of the rationale for introducing its plain packaging legislation for cigarettes. He said that this was yet another example of the extremely diversified and complex interplay between public health on one hand, and intellectual property rights on the other. Brazil recognized the importance of the matter under discussion, and accordingly reserved its rights to revert to this issue in the future for more detailed comments.

195. The representative of India said that the matter raised important questions on the interplay between the TRIPS Agreement and the right of a Member to protect public health. There had been a number of experimental studies on plain packaging. A study by Wakefield, Germain and Durkin had shown that as brand design information was progressively removed from cigarettes, they were seen as less appealing and the cigarettes in the packs were considered to be less satisfying and of lower quality. A major Canadian study had concluded that "plain and generic packaging of tobacco products, all other things being equal, through its impact on image formation and retention, recall and recognition, knowledge and consumer attitudes and perceived utility, would likely depress the incidents of smoking uptake by non-smoking teens and increase the incidence of smoking cessation by teens and adult smokers".

196. He said that the WHO Framework Convention on Tobacco Control stated that parties should consider adopting measures to restrict or prohibit the use of logos, colours, brand images, or promotional information on packaging other than brand names and product names displayed in a standard colour, and font type. This could increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others.

197. While refraining from comments on the specific elements of the Australian measure under discussion, he said his delegation wished to make observations on the larger systemic issue of protection of public health and the TRIPS Agreement. The Appellate Body in *EC - Asbestos* had held

that it is "undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation". The panel in *EC - Trademarks and Geographical Indications* had explained that the TRIPS Agreement generally provided negative rather than positive rights. The panel had stated that "the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures do attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement". Any interpretation of the TRIPS Agreement had to be done keeping in view the objectives and the principles of this Agreement.

198. He said that Article 8 of the TRIPS Agreement provided enough flexibility for Members to adopt measures necessary to protect public health and nutrition and to promote public interest in sectors of vital importance to the socio-economic and technological developments. The Doha Declaration on the TRIPS Agreement and Public Health also made it clear that the TRIPS Agreement did not, and should not prevent Members from taking measures to protect public health and that the TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health. His delegation believed it was implicit in the TRIPS Agreement, and especially in Article 20, that a high degree of domestic regulatory autonomy had to be afforded to a Member to enact measures to protect and promote public health.

199. The representative of New Zealand said that her delegation welcomed the Australian legislation for the plain packaging of tobacco products. The disastrous effects of smoking could not be overstated. Smoking was one of the leading preventable causes of early deaths and caused around 85 per cent of lung cancers and was linked to many other types of cancers. It was also a major cause of heart attacks, strokes, serious respiratory diseases such as emphysema, bronchitis and asthma, and a range of other conditions including blindness and infertility. Numerous scientific studies showed that plain packaging of tobacco products would lead to positive public health outcomes by reducing the attractiveness and desirability of smoking and increasing the prominence of public health warnings.

200. She said that, as a comprehensive suite of tobacco control measures, plain packaging would contribute to efforts to reduce smoking rates. New Zealand applauded Australia's commitment to taking the next step to reduce smoking rates through the introduction of plain packaging of tobacco products. She also noted that the guidelines agreed by the Conference of Parties to the World Health Organization Framework Convention (FCTC) on tobacco control in 2008 for the implementation of Articles 11 and 13 of the FCTC recommended that parties consider the introduction of plain packaging. New Zealand also appreciated to hear that Australia had paid close attention to its WTO obligations in developing its plain packaging proposal. Members should recall that the Doha Declaration on the TRIPS Agreement and Public Health had confirmed that the TRIPS Agreement did not and should not prevent Members from taking measures to protect public health. The TRIPS Agreement could and should be interpreted and implemented in a manner supportive of Members' rights to protect public health, and to use to the full the provisions in the TRIPS Agreement which provided flexibility for this purpose.

201. The representative of Uruguay said that his delegation was concerned about the inclusion of this item in the agenda of the Council for TRIPS. Uruguay considered it a general principle that the protection of public health fell within the sovereign authority of states and that every country was therefore entitled to legislate in the public interest, as had recently been recognized in the Punta del Este Declaration on the implementation of the WHO Framework Convention on Tobacco Control. In that Declaration, the 172 countries parties to the Convention had reaffirmed their commitment to prioritize the implementation of health measures designed to control tobacco consumption, and had reasserted the right of states to define and implement national public health policies to protect their people. In Uruguay's case, the implementation of tobacco control policies had led to notable

improvements, including a 24 per cent drop in the prevalence of daily smokers, air pollution in closed public spaces had fallen by over 90 per cent and, more significantly, hospitalization for myocardial infarction has declined by 17 per cent.

202. He said that Article 20 of the TRIPS Agreement provided that the use of a trademark should not be *unjustifiably* encumbered by special requirements. Recently, states had shown the clear tendency to prioritize the implementation of measures designed to control tobacco consumption in their territories because of its devastating health, social, economic and environmental consequences. Uruguay was therefore of the view that the measure proposed by Australia should raise no objections since it was consistent with the provisions of the WTO Agreements.

203. The representative of the Philippines said that his delegation shared the concerns expressed by other delegations on how the Bill violated Article 20 of the TRIPS Agreement. The Philippines were still in the process of evaluating the proposal and therefore reserved the right to revert to this issue at later meetings of the Council.

204. The representative of Chile said that this was a complex issue on which his delegation did not yet have all the elements needed to form a final opinion. On a preliminary basis, he nevertheless wished to raise two systemic aspects. The first concerned use of flexibilities afforded by the TRIPS Agreement on public health grounds. Numerous discussions had taken place in the Council on the importance of the flexibilities contained in the TRIPS Agreement for public health reasons, as well as the flexibilities on grounds of public interest, and of those applied to prevent abuse of intellectual property rights under Article 8 of the TRIPS Agreement. He said that the case before the Council further strengthened the legitimacy and importance of flexibilities, particularly in the public health sphere. This case highlighted that the flexibilities in question had been established not only for the benefit of developing countries, as people usually tended to think, but also because their use might be necessary in developed countries such as Australia.

205. The second issue concerned the proper balance between use of a flexibility afforded by the TRIPS Agreement - since this was a legitimate tool provided for by the system - and the provisions governing the protection of intellectual property rights, in this instance trademarks. It was without question that the flexibilities needed to be applied in a manner that was fully consistent with the protection provided for in the TRIPS Agreement, and that their use could not unjustifiably undermine intellectual property rights recognized in the Agreement, including the relevant provisions of the Paris Convention. He emphasized that Chile entirely shared Australia's concern regarding public health protection. Nonetheless, the present case raised questions which called for careful and in-depth analysis. Chile would closely follow implementation of the legislation in Australia because of the potential repercussions of the issue in systemic terms.

206. The representative of Zambia said noted Australia's statement that it was committed to fulfil its international obligations, including those under TRIPS Agreement. In light of this, her delegation would like to know how plain packaging conformed to Australia's obligation under Article 20 of the TRIPS Agreement. Her delegation would also be grateful to receive information on any impact assessments undertaken by Australia to arrive at the conclusion that plain packaging would reduce the appeal of tobacco products to consumers, particularly the young people.

207. Marking and labelling provided consumers an important basis for making informed choices on the products in question. As other delegations that had spoken before her, she would be interested to hear how Australia would ensure that consumers were not subject to more harmful, high-toxin tobacco products through plain packaging. It was her delegation's view that the Bill - if implemented - would not only be counter to obligations under Article 20 of the TRIPS Agreement but would also have lasting negative effects for small and medium size enterprises, without any guarantee that the measure would lead to reduced appeal of tobacco products to consumers.

208. The representative of Switzerland said that his delegation was supportive of public health measures in the area of anti-smoking. At the same time, it was clear that such measures had to comply with TRIPS obligations and had to be implemented in a TRIPS-consistent manner. In particular, such measures had to be appropriate to achieve the goal and the public interest for which they were being implemented, and they had to be supported by relevant evidence that they could actually achieve the stipulated goal. Furthermore, such measures could not be more restrictive than necessary to achieve the public health objective, as compared to other measures which could equally achieve that same objective through less restrictive measures.

209. Therefore, he said, while fully sharing Australia's concerns with regard to the damaging effects of smoking for individual and public health, the right balance had to be struck between such public health measures and the safeguards of property rights, including intellectual property rights, and in the case at hand, the rights of trademark owners. His delegation appreciated the assurances given by the delegation of Australia and trusted that, in the further elaboration of its draft legislation and its later implementation, the Australian legislator would take into account the legitimate interests of trademark owners in a manner compatible with its international obligations, and in particular with Articles 17 and 20 of the TRIPS Agreement.

210. The representative of Ecuador said that his delegation had listened with sympathy to the concerns raised by the Dominican Republic and others that the Bill could affect these countries' exports and how it complied with the provisions of the TRIPS Agreement, particularly as tobacco products were generally exported by developing countries. Given the complexity and all the concerns connected with the issue, however, his delegation believed that Members needed to go deeper into the debate on the relationship between TRIPS, intellectual property rights, trademarks and protection of public health, and that further debate and study was required on this issue.

211. The representative of Norway said that it was within a Member's right to implement necessary measures in order to protect public health. Her delegation trusted that the Australian measures would be implemented in a manner that was consistent with the TRIPS Agreement. She said that Norway had also implemented a number of measures to combat smoking, and she would follow developments regarding the plain packaging issue with great interest.

212. The representative of Mexico said that, while recognizing Australia's efforts to protect public health and ensure full protection of its citizens, her delegation would nevertheless like to reiterate the high level of concern on the draft bill. Even measures taken to protect public health had to comply with the TRIPS Agreement, in particular Articles 8 and 20 which had been repeated various times in interventions made by others. It was clear that this proposal could go beyond these protection requirements and could actually be counter-productive and have undesired results, for example by increasing consumption through a reduction in price. Her delegation believed that the Australian proposal went beyond the scope of international instruments in this area.

213. The representative of China said that the Australian draft bill had the legitimate objective to protect human health by introducing legislation on plain packaging on tobacco products, with the aim to reduce their appeal to consumers and increase the effectiveness of health warnings. Although Articles 15 and 16 of the Bill provided some assurances for the effect of a trademark or an industrial design, Article 14 stipulated that a trademark and industrial design could be prevented from use on tobacco products, or the conditions of their use could be specified, which had led to some debate on its compatibility with the TRIPS Agreement. Noting that the measure was currently only a draft bill for comment, he said that China would keep a close watch on its development.

214. The representative of the Dominican Republic thanked Australia for its explanations and said that the Dominican Republic had no intention to question the right of countries to enact legitimate policies to protect public health, which was the sovereign right of each state which the Dominican

Republic supported. But her delegation wanted to make sure that Members who take such steps also abide by their commitments in the WTO and other international fora, and take into the account the possible effects on trade flows of small and vulnerable economies in developing countries. Her delegation hoped that Australia had taken this message on board, and was looking forward to further collaboration on this issue in the future.

215. The representative of Australia thanked delegations for the discussion and said that, while emphasising again the very clear public health policy underpinning of the proposed legislation and Australia's absolute determination to reduce smoking rates, her delegation would also like to reassure Members of its continued commitment to framing legislation and policies in line with Australia's international obligations.

216. The representative of the World Health Organization (WHO) said that the WHO viewed tobacco use as one of the greatest threats to public health the world has ever faced. Tobacco consumption currently killed nearly six million people a year through direct use and the deadly effects of second-hand smoke, and an average of one person every six seconds and one in ten adults succumbed to tobacco use. Tobacco was indeed the single most preventable cause of death in the world today. It was the only legal consumer product that killed up to half of those who used it as intended and recommended by the manufacturer. Moreover, tobacco was a prominent risk factor for six of the eight leading causes of death in the world. The economic costs of tobacco use were equally as devastating as the public health costs, killing people at the height of their productivity. Yet these disastrous consequences continued in large part due to aggressive and widespread marketing and practices by multinational tobacco companies, including through the use of targeted and precisely designed tobacco product packaging aiming to initiate and maintain addiction among consumers.

217. He said that a strong and irrefutable body of evidence had demonstrated that product packaging traditionally served as one of the tobacco industry's central vehicles in initiating and maintaining addiction to their lethal products among consumers. For example, detailed analyses of tobacco industry documents had illustrated that tobacco companies viewed product packaging as a critical marketing strategy in promoting brand image in order to increase their market share, and target vulnerable segments of the population, including women and children. Peer-reviewed research indicated that plain packaging on tobacco products would increase the impact of health warnings, reduce false and misleading messages that deceive customers into believing that some tobacco products are safer than others, and reduce the attractiveness of products to segments of the population specifically targeted by tobacco companies. Given that the majority of smokers began a lifetime of addiction before the age of 18, plain packaging would severely restrict the industry's capacity to appeal to young people. In the context of the tactics employed by the tobacco industry to use tobacco packaging to mislead consumers with respect to the level of risk to which consumers are exposed, he said plain packaging also circumvented and avoided communication of disparate levels of harm.

218. He said that the tobacco industry would vehemently lobby in opposition to the introduction of plain packaging legislation, even in the face of overwhelming evidence. Fundamentally, the introduction of plain packaging would represent the inability of tobacco companies to appeal to consumers in ways to which they are accustomed, and, in this way, could affect the tobacco industry's economic interests. It was important to note that this nature of opposition to effective tobacco control policies was a traditional tactic employed by the tobacco industry as tobacco companies had operated for decades with the sole purpose of compromising public health policies in order to expand market share. WHO was of the view that a discussion in this forum of these legitimate tobacco control measures would have a substantial impact on tobacco consumption and, in turn, on the national burden of disease attributed to non-communicable diseases, which represented 60 per cent of all deaths worldwide.

219. Another representative of the WHO said that the WHO Framework Convention on Tobacco Control (FCTC) was the first international treaty negotiated under the auspices of the World Health Organization. The Convention had been developed in response to the globalization of the tobacco epidemic and was an evidence-based treaty that reaffirmed the right of all people to the highest standard of health. It had been adopted by the World Health Assembly on 21 May 2003 and had entered into force on 27 February 2005. It had since become one of the most rapidly and widely embraced treaties in the United Nations history. The Convention currently had 173 Parties and she noted that, of the 153 WTO Members, 138 were party to the FCTC, and thus subject to the obligations it contained.

220. She said that the WHO FCTC contained a number of provisions relevant to the issue of plain packaging of tobacco products. Article 3 of the WHO FCTC set out the collective objectives of the parties in negotiating the FCTC in the following terms: "to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke."

221. The general obligations of the parties to the WHO FCTC were set out in Article 5 of the FCTC, and included the development and implementation of comprehensive multi-sectoral national tobacco control strategies, plans and programs in keeping with the convention and any future protocols. In addition, Article 5 made it clear in paragraph 2 (b) that each party to the WHO FCTC had committed itself to adopting, implementing and periodically updating and reviewing effective legislative, executive, administrative and/or other measures aimed at inter alia preventing and reducing tobacco consumption.

222. She said that in addition to these general obligations, the parties to the WHO FCTC had committed themselves to certain specific obligations, including in respect of measures relating to the reduction of demand for tobacco products. Among these agreed measures were non-price measures to reduce demand for tobacco products, including the obligation on parties to adopt and implement effective legislative, executive, administrative or other measures necessary to fulfill their obligations under Articles 8 to 13 of the FCTC. Importantly, Article 7 also included the obligation, through the Conference of the Parties, to propose appropriate guidelines for the implementation of Articles 8 to 13. In terms of specific obligations, Article 11 of the Convention required Parties to adopt and implement effective measures in respect of the packaging and labelling of tobacco products, including health warnings and other appropriate messages.

223. She said that Article 13 of the WHO FCTC had to be read in light of the broad definition of "tobacco advertising and promotion" contained in Article 1(c) of the FCTC as follows: "'tobacco advertising and promotion' means any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly." Article 13 of the FCTC required parties to undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship.

224. As already noted, Article 7 of the WHO FCTC required the Conference of the Parties - the FCTC's governing body, which comprised all 173 parties to the FCTC - to adopt guidelines for the implementation of certain of the obligations undertaken by the parties, including those in Articles 11 and 13. With respect to the preparation of guidelines under the FCTC, she said that this was an intergovernmental process in which the parties to the Convention created working groups in which the text of the guidelines was elaborated by representatives nominated by the parties before being sent to the Conference of the Parties for consideration for adoption. Members should note that the

Conference of the Parties had adopted *all* guidelines by consensus. Resources and references used in the development of the guidelines for implementation were made available to the public on the WHO FCTC website.

225. She said that Members had already referred to the guidelines for the implementation of Articles 11 and 13 which specifically referred to taking measures in respect of plain packaging of tobacco products as a means of implementing party obligations to undertake a comprehensive ban of all tobacco advertising.

226. She said that it might also be of interest to Members of the TRIPS Council to note two recent decisions of the Conference of the Parties of the FCTC, the governing body of the Convention which met every two years, most recently in November 2010 in Punta del Este, Uruguay. The first decision of interest was the Punta del Este Declaration (FCTC/COP4(5)) regarding public health policy, international trade and the activities of the tobacco industry, which specifically references Articles of the TRIPS Agreement as well as the Doha Declaration on the TRIPS Agreement and Public Health. The second COP Decision of interest in this context (FCTC/COP4(18)) requested, inter alia, the FCTC Secretariat to cooperate with the WTO Secretariat with the aim of sharing information on trade-related tobacco control issues. She said that all decisions were available on the WHO FCTC website - http://www.who.int/fctc/en/.

227. She informed the Council that a draft protocol to eliminate illicit trade in tobacco products was currently under negotiation. The protocol would deal with certain matters, including counterfeit products, illicit trade and the like. The final session of the Intergovernmental Negotiating Body, open to all parties to the FCTC, was expected to take place in March 2012.

228. The Council took note of the statements made.

L. INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

229. The Chairman updated the Council on the status of acceptances of the Protocol Amending the TRIPS Agreement. He said that, since the Council's previous meeting, Bangladesh had deposited its instrument of acceptance on 15 March (document WT/Let/758). He encouraged Members that had not yet notified their acceptance of the Protocol to ensure that necessary measures were being taken in their capitals to allow the consideration of the acceptances in a timely fashion.

230. Recalling some of the information on the procedural requirements for acceptance that the Legal Affairs Division of the WTO Secretariat provided to the Council at the previous annual review of the Paragraph 6 System, he said that, by accepting the Protocol, a Member signalled its consent that all Members were entitled to make use of the additional flexibilities that the amendment provided. Since the acceptance of the Protocol and the adoption of domestic implementing legislation were two distinct processes, there was no need to have in place any domestic implementing legislation at the time of acceptance of the Protocol.

231. He also recalled that the Secretariat had made this information, together with a model instrument of acceptance, available in writing in order to further assist Members in drawing up their own instruments of acceptance. This information was available on a webpage on "How to Accept the Protocol Amending the TRIPS Agreement"[1], which could be accessed through the dedicated gateway page on "TRIPS and Public Health".[2]

[1] http://www.wto.org/english/tratop_e/trips_e/accept_e.htm
[2] http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

M. OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

232. The Chairman said that the list of 15 pending requests for observer status in the TRIPS Council by other intergovernmental organizations was contained in document IP/C/W/52/Rev.12. Although the Council had recently made some progress on two requests, it had not been able to reach consensus on the others.

233. At its last meeting, the Council had requested him to continue his consultations on the matter. These consultations had focussed on the two issues that Members had specifically discussed at the last meeting, namely the suggestion that the CBD Secretariat be invited to the Council's meetings on an ad hoc, meeting-by-meeting basis, and the suggestion that the ad hoc, meeting-by-meeting invitations to the Secretariats of the African Regional Intellectual Property Organization (ARIPO) and the African Intellectual Property Organization (OAPI) be converted into a permanent observer status. He said that, unfortunately, he was not in a position to report any new thinking with respect to these issues.

234. He added that some delegations had also referred to the other 14 pending requests. Given that most of them had been pending for some time, some delegations had felt that the Council's consideration of these requests would be facilitated if these organizations could provide up-to-date information, including on the nature of their work and the reasons for their interest in being accorded observer status. The Chairman suggested that the Council request the Secretariat to contact the organizations whose requests were pending to request such updated information.

235. The representative of Kenya, speaking on behalf of the African Group, thanked the Council for its decision, at its meeting in June 2009, to grant ARIPO and OAPI ad-hoc observer status on a meeting-by-meeting basis. The two organizations undertook substantial examinations of patents, trademarks and the industrial design applications, and were also responsible for the grants, administration and harmonization of laws relating to these fields of intellectual property in African countries. Given the functions performed by these two bodies, it was apparent that they had a direct bearing on the work of the TRIPS Council. Predictability of the relationship between the two Organizations and the WTO could be helpful in assisting African countries to implement the TRIPS Agreement. He therefore requested the TRIPS Council to grant ARIPO and OAPI permanent observers status.

236. The representative of Nigeria endorsed the statement made by representative of Kenya. He also supported the CBD Secretariat's admission as an observer on a meeting-by-meeting basis, since the Council's work had a significant nexus with that of the CBD Secretariat.

237. The representative of Egypt recalled his delegation's position that there remained a systematic issue that had not been resolved. Accordingly, having heard the statements by Kenya and Nigeria, he felt that the best way forward was to welcome the continued participation of OAPI and ARIPO as ad-hoc observers on a meeting-by-meeting basis. Furthermore, he said that all pending requests should be dealt with equally.

238. The representative of South Africa and Zambia supported the proposal by Kenya.

239. The representative of India said that, while he was open to the made at the previous informal meeting to consider all pending requests for observer status, the request from the CBD Secretariat presented a special case due to its direct relevance to three regular agenda items discussed in the Council. The CBD was doing useful work on ABS regimes, technology transfer and cooperation, and traditional knowledge. The presence of the CBD Secretariat in the Council's meetings would help with the coherence of WTO's mandate. The CBD Secretariat fulfilled all the required parameters for observership at the WTO. It was an intergovernmental body, with more members than the WTO. Further, the overwhelming majority of WTO Members were also parties to the CBD. He did not

understand the opposition to granting observer status to it. The Members opposing the proposal had not provided any reason to deny such status to the CBD. He urged the Council to positively and expeditiously consider the request of CBD Secretariat. He proposed that until permanent observer status was granted, ad hoc invitations should be extended to it on a meeting-by-meeting basis.

240. The representative of Ecuador supported the granting observer status to the CBD Secretariat. He said that the CBD was an intergovernmental organization that had 192 members. It dealt with specific substantive issues that were relevant to the Council's debates. Further, given that the 14 pending requests for observer status were not really opposed, he suggested that the Council recognize the CBD Secretariat as a permanent observer, or at least to invite it to participate in Council sessions on an ad hoc basis.

241. The representative of China said that the TRIPS/CBD issue was an important one for the TRIPS Council meetings. It was regrettable that the CBD Secretariat was still not an observer. China continued to support the proposal for granting observer status to the CBD Secretariat, at least on an ad hoc basis.

242. The representatives of Brazil and Colombia supported granting observer status to the CBD Secretariat.

243. The representative of Peru said that all the requests for observer status were equally important. It would be useful to have observers in the TRIPS Council because of the contribution they could make due to their experience with intellectual property. The CBD Secretariat's request was particularly relevant. This issue had come up when the Council had discussed agenda items C, D and E. The relationship between TRIPS and the CBD was clear, and he saw no reason why the CBD Secretariat should not be able to participate on an ad hoc basis in the Council's work. He would welcome any first-hand information that the CBD Secretariat could provide to the Council on the systems it had. Therefore, Peru supported granting permanent observer status to the CBD Secretariat, or at least inviting it on an ad hoc basis.

244. The representative of the United States joined Kenya, Nigeria, South Africa and Zambia in support of granting ARIPO and OAPI permanent observer status. However, he was not in a position to join those Members seeking to include the CBD as an observer, either on a permanent or ad hoc basis.

245. The Chairman suggested that the Council request the Secretariat to contact the international intergovernmental organizations whose requests for observer status were pending to request updated information, including on the nature of their work and their reasons for their interest in being accorded observer status. This would enable the Council to review these applications on a case-by-case basis at a later date.

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

N. OTHER BUSINESS

(i) Invitation to ARIPO and OAPI

247. 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 and the African Intellectual Property Organization. He suggested that the Council again invite ARIPO and OAPI to attend the Council's next formal meeting on an ad hoc basis.

248. The Council so agreed.

(ii) Annual review of the functioning of the Paragraph 6 System

249. The Chairman recalled that, at its last meeting, the Council had requested him to hold consultations on any further follow up to the annual review of the functioning of the Paragraph 6 System held in October 2010, and the preparations for the forthcoming annual review to be held in October 2011. During his consultations with a number of delegations, all of them had shared the view that the last annual review conducted on the dedicated day in October 2010 and the follow-up discussion in March had been very useful and constructive. All delegations had also shared the importance they attach to this matter.

250. Some delegations had said that they still had not heard the views of the civil society and industry, and had reiterated their suggestion concerning a workshop open to all stakeholders that should be organized so that it could feed into the 2011 review. Some other delegations had emphasized that this was first of all a process between Members and regretted that they had still heard very little from potential importers and beneficiaries of the System concerning any problems they might have faced. Therefore, these delegations had felt that such a workshop would be premature. It had also been said that there could be, at some point, a stakeholder meeting in the broader context of access to medicines, which should not be focused exclusively on the Paragraph 6 System, but should also include other issues such as pricing, procurement and customs tariffs. It had also been said that, if such a workshop were to be organized, it should not be in lieu of a workshop dedicated to the Paragraph 6 System.

251. Regarding the preparations for the next annual review, all delegations had shared the desire to make it as productive and constructive as possible. Some delegations had said that the focus should be on receiving more information from beneficiaries. It had been said that the October 2010 questions and the March 2011 follow-up questions were a good starting point for the preparations. In addition, there had been a suggestion that the Council work towards timely acceptances of the Protocol.

252. The Chairman said that it was his intention to pursue further consultations after the June meeting on the preparations of the Council's next annual review and the issue of a possible workshop. He suggested that the Council should work on the assumption that the annual review would at least follow a similar approach to that which had been widely welcomed by delegations in October 2010, noting that consultations would continue on further ways of improving and preparing for the review.

253. The representative of India reiterated his delegation's request for an open-ended workshop on the implementation of the Paragraph 6 System. There was a need to move beyond the mere annual ritualistic review of the working of the System. To date, its use had been sub-optimal. Since the issue was of fundamental importance and interest to most WTO Members, it was important to hold a dedicated workshop, which would provide an opportunity for substantive and serious discussion on the relevant issues and involve all relevant stakeholders. There was no a priori assumption that the Paragraph 6 System was unworkable or that it needed to be amended. However, a fact-based discussion eight years after its adoption was essential for understanding its functioning and improving its operationalization.

254. Although the previous discussion on this subject had been useful, it had not depicted the full picture. The scope of discussion had to be expanded in order to involve other stakeholders. There was a need to understand why Doctors Without Borders (MSF) had argued that the System was neither expeditious nor a solution to the problem, why Apotex, a Canadian pharmaceutical company, had said that the System was unworkable, and why the System had only been used once. He asserted that the answer to many of these questions could be found if the Council agreed to a dedicated workshop. He was puzzled by some Members' opposition towards this proposal because many of them were supportive of enlarging the debate in the DSU negotiations. In that forum, they had suggested that

allowing unsolicited and amicus curiae briefs in panel and Appellate Body proceedings would enrich the debate and would lead to better quality panel reports that would add to the credibility of the WTO. However, with respect to the Paragraph 6 System, which so many Members wanted to better understand, some delegations insisted on limiting the discussion to Members only. He hoped that constructive engagement would clear the road blocks to an early organization of an open-ended workshop on the Paragraph 6 System.

255. The representative of the Bolivarian Republic of Venezuela said that considerable efforts had been taken to reach consensus on holding an open-ended workshop to help Members better understand why the System had not worked in all these years. When he had asked the Chair at the beginning of the meeting why this issue had not been put on the agenda, the Chair had replied that he would provide Members with information on his consultations under "Other Business". The representative of Venezuela said that he had thought that agreement had been reached in those consultations to place the matter on the Council's agenda. As established by the rules of procedure, substantive discussions could not be held under "Other Business" and the issue should therefore not have been placed under that item without the agreement by India and other sponsors of its proposal, including Venezuela. Sponsors alone could withdraw a proposal before agreement is reached. He said that if no opportunity were provided to learn the full reasons that had prevented the System from being used, his delegation would request that there be no further extensions of the period of acceptance of the Protocol Amending the TRIPS Agreement.

256. The Chairman said that delegations could ask for items to be included on the Council's proposed agenda up to ten working days prior to the date set for its meeting. In the absence of such a request, he had taken up this matter under "Other Business" so that he could inform the Council about his consultations. As he had already indicated at the beginning of the discussion, it was his intention to pursue further consultations after the meeting on the preparations of the Council's next annual review and the issue of a possible workshop with a view to reaching consensus on the matter.

257. The representative of Ecuador said that there had been no consensus on the workshop. The request had been made in the interest of deepening the debate among Members on the Paragraph 6 System that his delegation was hoping to expedite. The Council had held useful discussions on the matter, but needed to take them further. In support of the statements made by India and Venezuela, he highlighted the need to fully understand how the System worked, what its most effective aspects were and how its effectiveness could be guaranteed. To do so, he urged Members to reach consensus on an open-ended workshop that would include industry, academia, and civil society, so that everyone could work together to clarify the situation.

258. The representative of Canada said that his delegation's particular interest in issues related to the Paragraph 6 System and welcomed the Chair's consultations on this matter, as well as Bangladesh' acceptance of the Protocol Amending the TRIPS Agreement. He appreciated the Secretariat's work in providing further information and guidance with a view to facilitating the task of Members which still had to accept the Protocol and encouraged those Members to proceed. This would concretize one of the more significant developments in the Doha Development Round. It would constitute welcome news for the Ministerial Conference in December, if additional Members accepted the Protocol in time so that the derogations could then become a permanent part of the TRIPS Agreement.

259. He thanked the Secretariat for distributing the report on the trilateral symposium held by the WTO, WIPO and WHO in February 2011, concerning various issues affecting access to essential medicines. Both this and the previous symposium had been good opportunities to delve into a complex subject matter. Information provided could serve Members' respective constituencies. The trilateral symposia also confirmed the positive collaboration between the three international organizations. He encouraged similar activities to be organized in the future.

260. His delegation was pleased with the high level of activity regarding the review of the System. The last review had provided an opportunity for delegations to provide additional information with respect to their experience. Unfortunately, the kind of feedback his delegation was hoping for from some of the potential beneficiaries of the System had not been received, including any potential concerns that they may have had with it. This was directly related to the suggestion that an open-ended workshop be held. As noted in the past, his delegation was, in principle, not opposed to the idea. However, it would seem premature to go ahead with it before a full scale exchange of experiences among Members was completed.

261. While interested stakeholders could sometimes provide additional perspectives that could be helpful for Members, the key in this case was to focus on decision makers, i.e. the Members themselves. He noted that it was them who decided whether to use the System, and not MSF, Apotex, or other stakeholders that had been mentioned. Therefore, if the Council were to have a valuable engagement with other parties, first and foremost, it had to do its homework within the membership. It was important to have answers to a number of outstanding questions that had been asked by his delegation and by others with respect to some Members' experiences. He therefore encouraged Members who had been unable to share their experiences in the previous annual review, to do so at the forthcoming review.

262. The representative of Zambia said that her delegation had an interest in ensuring that the Paragraph 6 System was effectively implemented. Since the Council was mandated to review the System annually, the preparations for these reviews were important. She was surprised that the issue was being discussed under the agenda item "Other Business", given that there were so many issues that related to the System, including the information on the status of acceptances of the Protocol. She believed that it should have come under a substantive agenda item. She said that her delegation wanted to ensure that, whatever mechanism were to be used, the work would highlight how the System could be used in order to maximize its benefits.

263. The representative of Nigeria said that he was concerned about Venezuela's statement on further extensions of the period of acceptance of the Protocol. Members of the African Group were making efforts in order to proceed with its acceptance. In any case, the 2003 waiver decision continued to apply. Any calls for not extending the period for acceptance had far-reaching implications for the African Group, which was the major beneficiary of the System. It had been the demandeur for discussions on matters related to TRIPS and public health and the debate itself had helped bringing down prices of medicines, irrespective of whether the System had been used or not.

264. The representatives of Cuba and China supported the proposal on a dedicated open-ended workshop on the implementation of the Paragraph 6 System. The representative of China added that such a workshop would help Members to gather first-hand information and suggestions from industry and would usefully assist them in their discussions in the Council.

265. The Council took note of the statements made.

(iii) Ninth annual review under paragraph 2 of the decision on the "Implementation of Article 66.2 of the TRIPS Agreement"

266. The Chairman said that, since its meeting in March 2011, the Council had received additional reports relating to its eighth review from the European Union and individual member States, namely Austria, Belgium, Finland, France, Germany, the Slovak Republic, Spain, Sweden, and the United Kingdom (document IP/C/W/551/Add.7).

267. Turning to the arrangements for the Council's ninth review under the decision on the "Implementation of Article 66.2 of the TRIPS Agreement", he recalled that paragraph 1 of the

Decision provided that developed country Members shall submit annually reports on actions taken or planned in pursuance of their commitments under Article 66.2. To this end, they were to provide new detailed reports every third year and, in the intervening years, provide updates to their most recent reports. These reports were to be submitted prior to the last Council meeting scheduled for the year in question. Paragraph 3 of the decision determined the information that had to be provided in these reports.

268. The first, second and third sets of detailed annual reports under the Decision were presented to the Council's end-of-year meetings in 2003, 2006 and 2009, and updates to the Council's meetings in the intervening years. Therefore, this year developed country Members should submit the second set of updates to the new detailed reports they provided in 2009 on actions taken or planned in pursuance of their commitments under Article 66.2 prior to the Council's end of year meeting scheduled for 25-26 October. As provided in paragraph 2 of the Decision, the Council shall review these updates at that meeting.

269. Accordingly, he suggested that developed country Members be requested to provide updates to their reports on actions they had taken or planned in pursuance of their commitments under Article 66.2 by 30 September, i.e. about three weeks before the meeting, in order to allow their timely circulation and review at the Council's meeting in October.

270. The Council so agreed.

271. The representative of the Secretariat said that the 2003 Decision followed through on the decision of Ministers at Doha to establish a mechanism for ensuring the monitoring and full implementation of Article 66.2 obligations. On top of earlier reports on Article 66.2 implementation, this monitoring system had yielded a significant body of material on reported incentives and programmes related to technology transfer, approaching 100 reports in all, some extending to over 100 pages. This sheer volume of information clearly created a challenge for delegations to obtain a general overview of the reported material.

272. In recent years, workshops had been held to help delegations prepare for the annual review that was required to take place at the final Council meeting for the year. This enabled those delegations that had made reports to explain the details of their submissions, and then for an informal dialogue to take place between LDC representatives and the reporting countries, to deepen understanding of the information needs of LDC representatives and of the content of the submissions. This discussion had also turned to questions of how the reporting format and content could be enhanced and focussed so as to improve the utility and consistency of the reports on implementation of Article 66.2.

273. Since the feedback had been positive from these recent events, the Secretariat had scheduled a similar event for the afternoon of October 24, immediately preceding the Council's next meeting. The Secretariat intended to coordinate with LDC Members to ensure that the workshop continued to provide a useful service for those Members in particular, in providing an informal supplement to the Council's formal review of the submissions and in helping to promote understanding and accessibility of the information reported. As noted at the Council meeting in October 2012, this would again be guided by the interests and the priorities of the delegations concerned and the LDC Group in particular.

274. The representative of Zambia thanked the Secretariat for its report on the work it had undertaken in relation to Article 66.2. She also thanked those delegations that had made submissions, which her delegation was still studying in light of the discussions delegations had had in the past, especially the constructive discussions in October 2010.

275. The Council took note of the statements made.

(iv) Other reviews

276. The Chairman said that, as had already been discussed under a previous agenda item, the Council would take up at its October 2011 meeting its annual review of technical cooperation under Article 67. Furthermore, the Council would have on its agenda the final transitional review under Section 18 of the Protocol of the Accession of the People's Republic of China.